STATE OF NEBRASKA SERVICE CONTRACT AMENDMENT

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

Telephone: (402) 471-6500
Fax: (402) 471-2089

PAGE	ORDER DATE
1 of 2	02/23/26
BUSINESS UNIT	BUYER
25530001	BROOK TAYLOR (AS)

CONTRACT NUMBER
81109 O4

VENDOR NUMBER: 1300096

VENDOR ADDRESS:

REVVITY OMICS INC
250 INDUSTRY DR STE 400
PITTSBURGH PA 15275-1017

THE CONTRACT PERIOD IS:

JULY 01, 2022 THROUGH JUNE 30, 2028

THIS SERVICE CONTRACT HAS BEEN AMENDED PER THE FOLLOWING INFORMATION:

THIS CONTRACT IS NOT AN EXCLUSIVE CONTRACT TO FURNISH THE SERVICES SHOWN BELOW, AND DOES NOT PRECLUDE THE PURCHASE OF SIMILAR SERVICES FROM OTHER SOURCES.

THE STATE RESERVES THE RIGHT TO EXTEND THE PERIOD OF THIS CONTRACT BEYOND THE TERMINATION DATE WHEN MUTUALLY AGREEABLE TO THE VENDOR/CONTRACTOR AND THE STATE OF NEBRASKA.

Original/Bid Document 5710 Z1

Contract to supply and deliver Newborn Screening Laboratory Testing Services to the State of Nebraska.

This is the fourth renewal of the contract as amended.

Vendor Point of Contact:

Name: Peter J. Borandi
Phone: 412-220-2300 Ext. 154
Fax: 412-722-7863
E-Mail: PJ.Borandi@revvity.com

Amendment One (1) as Attached. (mel 02/26/20)
Amendment Two (2) as Attached. (mel 10/29/20)
Amendment Three (3) as Attached. (BT 01/16/24)
Amendment Four (4) as Attached. (MSH 06/19/24)
Amendment Five (5) as Attached. (BT 10/20/25)
Amendment Six (6) as Attached. (BT 02/23/26)

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
1	NEWBORN SCREENING LAB AT NO COST TO THE STATE INITIAL AWARD - YEARS 1 AND 2	1.0000	$	0.0000	0.00
2	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 1 - YEARS 3 AND 4	1.0000	$	0.0000	0.00

DS

Signed by: Brook Taylor 3/4/2026
9D9E6EDF47644FB...
BUYER

Signed by: 3/5/2026
CDD60DEA36BD496...
MATERIEL ADMINISTRATOR

STATE OF NEBRASKA SERVICE CONTRACT AMENDMENT

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PAGE	ORDER DATE
2 of 2	02/23/26
BUSINESS UNIT	BUYER
25530001	BROOK TAYLOR (AS)

VENDOR NUMBER: 1300096

CONTRACT NUMBER
81109 O4

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
3	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 2 - YEARS 5 AND 6	1.0000	$	0.0000	0.00
4	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 3 - YEARS 7 AND 8	1.0000	$	0.0000	0.00
5	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 4 - YEARS 9 AND 10	1.0000	$	0.0000	0.00
	Total Order				**0.00**

Initial
BT
BUYER INITIALS

Amendment Six
Contract Number 81109 O4

Newborn Screening Laboratory Testing Services

Between
The State of Nebraska
And
Revvity Omics Inc.

THIS AMENDMENT is entered into by and between the State of Nebraska ("State/Entity") and Revvity Omics Inc. ("Vendor").

WHEREAS, the State of Nebraska has a contract with Vendor identified as 81109 O4 for use by state agencies and other entities.

WHEREAS, the terms of the contract specifically state that the contract may be amended when mutually agreeable to the Vendor and the State of Nebraska.

WHEREAS, This Amendment and any attachments hereto will become part of the Contract. Except as set forth in this Amendment, the Contract is unaffected and shall continue in full force and effect in accordance with its terms. If there is conflict between this Amendment and the Contract or any earlier amendment, the terms of this Amendment will prevail.

NOW, THEREFORE, it is agreed by the parties to amend the contract as follows:

1. Effective March 1, 2026, Section VII.A is hereby amended to read:

   Specimen testing cost for the screening panel as described in this RFP including Pompe, MPS-I, X-ALD, and SMA: **$69.34**+ $20/infant screened fee = Total amount per infant billed upon completion of initial specimen testing: **$89.34**. All requested repeat specimens shall be tested without billing to the submitter.

   The State reserves the right to review all aspects of cost for reasonableness and to request clarification of any proposals where the cost component shows significant and unsupported deviation from industry standards or in areas where detailed pricing is required.

IN WITNESS WHEREOF, the parties have executed this amendment as of the date of execution by both parties below.

State of Nebraska

By: Signed by: D5D6C0E236ED496...

Name: Michelle Potts

Title: Materiel Administrator

Date: 3/5/2026

Revvity Omics Inc.

By: DocuSigned by: PJ Borandi A1E4E3EAA04E49F...

Name: PJ Borandi

Title: Senior Director

Date: 3/3/2026

STATE OF NEBRASKA SERVICE CONTRACT AMENDMENT

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

Telephone: (402) 471-6500
Fax: (402) 471-2089

PAGE	ORDER DATE
1 of 2	11/13/25
BUSINESS UNIT	BUYER
25530001	BROOK TAYLOR (AS)

CONTRACT NUMBER
81109 O4

VENDOR NUMBER: 1300096

VENDOR ADDRESS:

REVVITY OMICS INC
250 INDUSTRY DR STE 400
PITTSBURGH PA 15275-1017

THE CONTRACT PERIOD IS:

JULY 01, 2022 THROUGH JUNE 30, 2028

THIS SERVICE CONTRACT HAS BEEN AMENDED PER THE FOLLOWING INFORMATION:

THIS CONTRACT IS NOT AN EXCLUSIVE CONTRACT TO FURNISH THE SERVICES SHOWN BELOW, AND DOES NOT PRECLUDE THE PURCHASE OF SIMILAR SERVICES FROM OTHER SOURCES.

THE STATE RESERVES THE RIGHT TO EXTEND THE PERIOD OF THIS CONTRACT BEYOND THE TERMINATION DATE WHEN MUTUALLY AGREEABLE TO THE VENDOR/CONTRACTOR AND THE STATE OF NEBRASKA.

Original/Bid Document 5710 Z1

Contract to supply and deliver Newborn Screening Laboratory Testing Services to the State of Nebraska.

This is the fourth renewal of the contract as amended.

Vendor Point of Contact:

Name: Peter J. Borandi
Phone: 412-220-2300 Ext. 154
Fax: 412-722-7863
E-Mail: PJ.Borandi@revvity.com

Amendment One (1) as Attached. (mel 02/26/20)
Amendment Two (2) as Attached. (mel 10/29/20)
Amendment Three (3) as Attached. (BT 01/16/24)
Amendment Four (4) as Attached. (MSH 06/19/24)
Amendment Five (5) as Attached. (CMP 11/13/25)

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
1	NEWBORN SCREENING LAB AT NO COST TO THE STATE INITIAL AWARD - YEARS 1 AND 2	1.0000	$	0.0000	0.00
2	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 1 - YEARS 3 AND 4	1.0000	$	0.0000	0.00
3	NEWBORN SCREENING LAB	1.0000	$	0.0000	0.00

DS

DocuSigned by:
Craig Palik
122DB31782AB47E...
11/20/2025
BUYER

Signed by:
D5D6C0E236ED496...
11/21/2025
MATERIEL ADMINISTRATOR

STATE OF NEBRASKA SERVICE CONTRACT AMENDMENT

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

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PAGE	ORDER DATE
2 of 2	11/13/25
BUSINESS UNIT	BUYER
25530001	BROOK TAYLOR (AS)

VENDOR NUMBER: 1300096

CONTRACT NUMBER
81109 O4

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
	AT NO COST TO THE STATE RENEWAL 2 - YEARS 5 AND 6				
4	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 3 - YEARS 7 AND 8	1.0000	$	0.0000	0.00
5	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 4 - YEARS 9 AND 10	1.0000	$	0.0000	0.00
	Total Order				**0.00**

DS
cp
BUYER INITIALS

Amendment Five
Contract Number 81109 O4

Newborn Screening Laboratory Testing Services

Between
The State of Nebraska
And
Revvity Omics Inc.

THIS AMENDMENT is entered into by and between the State of Nebraska ("State/Entity") and Revvity Omics Inc. ("Vendor").

WHEREAS, the State of Nebraska has a contract with Vendor identified as 81109 O4 for use by state agencies and other entities.

WHEREAS, the terms of the contract specifically state that the contract may be amended when mutually agreeable to the Vendor and the State of Nebraska.

WHEREAS, This Amendment and any attachments hereto will become part of the Contract. Except as set forth in this Amendment, the Contract is unaffected and shall continue in full force and effect in accordance with its terms. If there is conflict between this Amendment and the Contract or any earlier amendment, the terms of this Amendment will prevail.

NOW, THEREFORE, it is agreed by the parties to amend the contract as follows:

1. The third renewal of the above-named contract to the State of Nebraska expires June 30, 2026.

2. The State of Nebraska wishes to execute the fourth renewal to the contract for an additional two (2) year period.

3. The contract end date, wherever such reference appears in the contract, shall be changed from June 30, 2026 to June 30, 2028.

4. The previous subject to funding/funding out clause language is hereby deleted and replaced with the following:

SUBJECT TO FUNDING / FUNDING OUT CLAUSE FOR LOSS OF APPROPRIATIONS
The State's obligation to pay amounts due on the Contract is contingent upon legislative appropriation and executive distribution of funds. Should said funds not be appropriated and delivered, the State may terminate the contract with respect to those payments for the periods of time for which such funds are not appropriated and distributed. In the event of such funds unavailability, the State will give the Vendor prompt written notice of the effective date of termination. All obligations of the State to make payments after the termination date will cease. The Vendor shall be entitled to receive just and equitable compensation for any authorized work which has been satisfactorily completed as of the termination date. In no event shall the Vendor be paid for a loss of anticipated profit.

IN WITNESS WHEREOF, the parties have executed this amendment as of the date of execution by both parties below.

State of Nebraska

By: Signed by: D5D6C0E236ED496...

Name: Michelle Potts

Title: Materiel Administrator

Date: 11/21/2025

Vendor: Revvity Omics Inc.

By DocuSigned by: PJ Borandi A1E4E3EAA04E49F...

Name: PJ Borandi

Title: Senior Director

Date: 11/20/2025

STATE OF NEBRASKA SERVICE CONTRACT AMENDMENT

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

Telephone: (402) 471-6500
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PAGE	ORDER DATE
1 of 2	06/19/24
BUSINESS UNIT	BUYER
25530001	MATTHEW HANSEN (AS)

CONTRACT NUMBER
81109 O4

VENDOR NUMBER: 1300096

VENDOR ADDRESS:

REVVITY OMICS INC
250 INDUSTRY DR STE 400
PITTSBURGH PA 15275-1017

THE CONTRACT PERIOD IS:

JULY 01, 2022 THROUGH JUNE 30, 2026

THIS SERVICE CONTRACT HAS BEEN AMENDED PER THE FOLLOWING INFORMATION:

THIS CONTRACT IS NOT AN EXCLUSIVE CONTRACT TO FURNISH THE SERVICES SHOWN BELOW, AND DOES NOT PRECLUDE THE PURCHASE OF SIMILAR SERVICES FROM OTHER SOURCES.

THE STATE RESERVES THE RIGHT TO EXTEND THE PERIOD OF THIS CONTRACT BEYOND THE TERMINATION DATE WHEN MUTUALLY AGREEABLE TO THE VENDOR/CONTRACTOR AND THE STATE OF NEBRASKA.

Original/Bid Document 5710 Z1

Contract to supply and deliver Newborn Screening Laboratory Testing Services to the State of Nebraska.

This is the third renewal of the contract as amended.

The contract may be renewed for one (1) additional two (2) year period when mutually agreeable to the vendor and the State of Nebraska.

Vendor Point of Contact:

Name: Peter J. Borandi
Phone: 412-220-2300 Ext. 154
Fax: 412-722-7863
E-Mail: PJ.Borandi@revvity.com

Amendment One (1) as Attached. (mel 02/26/20)
Amendment Two (2) as Attached. (mel 10/29/20)
Amendment Three (3) as Attached. (BT 01/16/24)
Amendment Four (4) as Attached. (MSH 06/19/24)

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
1	NEWBORN SCREENING LAB AT NO COST TO THE STATE INITIAL AWARD - YEARS 1 AND 2	1.0000	$	0.0000	0.00
2	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 1 - YEARS 3 AND 4	1.0000	$	0.0000	0.00

DocuSigned by: Charity Menefee 112DC07AECBA4F1... 7/17/2024
DHHS DIVISION DIRECTOR

DocuSigned by: Matthew Hansen D09C6E7ACB6340E... 7/17/2024
BUYER

DocuSigned by: D5D6C0E236ED496... 7/19/2024
MATERIEL ADMINISTRATOR

STATE OF NEBRASKA SERVICE CONTRACT AMENDMENT

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PAGE	ORDER DATE
2 of 2	06/19/24
BUSINESS UNIT	BUYER
25530001	MATTHEW HANSEN (AS)

VENDOR NUMBER: 1300096

CONTRACT NUMBER
81109 O4

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
3	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 2 - YEARS 5 AND 6	1.0000	$	0.0000	0.00
4	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 3 - YEARS 7 AND 8	1.0000	$	0.0000	0.00
5	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 4 - YEARS 9 AND 10	1.0000	$	0.0000	0.00
	Total Order				**0.00**

DS

BUYER INITIALS

Amendment Four
Contract Number 81109 O4

Newborn Screening Laboratory Testing Services

Between
The State of Nebraska
And
Revvity Omics Inc.

THIS AMENDMENT is entered into by and between the State of Nebraska ("State/Entity") and Revvity Omics Inc. ("Vendor").

WHEREAS, the State of Nebraska has a contract with Vendor identified as 81109 O4 for use by state agencies and other entities.

WHEREAS, the terms of the contract specifically state that the contract may be amended when mutually agreeable to the Vendor and the State of Nebraska.

WHEREAS, This Amendment and any attachments hereto will become part of the Contract. Except as set forth in this Amendment, the Contract is unaffected and shall continue in full force and effect in accordance with its terms. If there is conflict between this Amendment and the Contract or any earlier amendment, the terms of this Amendment will prevail.

NOW, THEREFORE, it is agreed by the parties to amend the contract as follows:

1. The second renewal of the above-named contract to the State of Nebraska expires June 30, 2024.

2. The State of Nebraska wishes to execute the third renewal to the contract for an additional two (2) year period.

3. The contract end date, wherever such reference appears in the contract, shall be changed from June 30, 2024 to June 30, 2026.

4. Effective July 1, 2024, Section VII.A is hereby amended to read:

   Specimen testing cost for the screening panel as described in this RFP including Pompe, MPS-I, X-ALD, and SMA: **$67.65** + $20/infant screened fee = Total amount per infant billed upon completion of initial specimen testing: **$87.65**. All requested repeat specimens shall be tested without billing to the submitter.

   The State reserves the right to review all aspects of cost for reasonableness and to request clarification of any proposals where the cost component shows significant and unsupported deviation from industry standards or in areas where detailed pricing is required.

IN WITNESS WHEREOF, the parties have executed this amendment as of the date of execution by both parties below.

State of Nebraska

By: DocuSigned by: Adam Kauffman F92FFF73F7F3467...

Name: Adam Kauffman

Title: Materiel Administrator

Date: 6/21/2024

Vendor: Revvity Omics Inc.

By: DocuSigned by: Peter J. Borandi A1E4E3EAA04E49F...

Name: Peter J. Borandi

Title: Senior Director

Date: 6/20/2024

Department of Health and Human Services

By: DocuSigned by: Charity Menefee 112DC07AECBA4F1...

Name: Charity Menefee

Title: Director Division of Public Health

Date: 6/20/2024

STATE OF NEBRASKA SERVICE CONTRACT AMENDMENT

State Purchasing Bureau
1526 K Street, Suite 130
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PAGE	ORDER DATE
1 of 2	01/16/24
BUSINESS UNIT	BUYER
25530001	MATTHEW HANSEN (AS)

CONTRACT NUMBER
81109 O4

VENDOR NUMBER: 1300096

VENDOR ADDRESS:

REVVITY OMICS INC
250 INDUSTRY DR STE 400
PITTSBURGH PA 15275-1017

THE CONTRACT PERIOD IS:

JULY 01, 2022 THROUGH JUNE 30, 2024

THIS SERVICE CONTRACT HAS BEEN AMENDED PER THE FOLLOWING INFORMATION:

THIS CONTRACT IS NOT AN EXCLUSIVE CONTRACT TO FURNISH THE SERVICES SHOWN BELOW, AND DOES NOT PRECLUDE THE PURCHASE OF SIMILAR SERVICES FROM OTHER SOURCES.

THE STATE RESERVES THE RIGHT TO EXTEND THE PERIOD OF THIS CONTRACT BEYOND THE TERMINATION DATE WHEN MUTUALLY AGREEABLE TO THE VENDOR/CONTRACTOR AND THE STATE OF NEBRASKA.

Original/Bid Document 5710 Z1

Contract to supply and deliver Newborn Screening Laboratory Testing Services to the State of Nebraska as per the attached specifications for the period July 1, 2022 through June 30, 2024. The contract may be renewed for two (2) additional two (2) year periods when mutually agreeable to the vendor and the State of Nebraska.

Vendor Contact: Peter J. Borandi
Phone: 412-220-2300 Ext. 154
Fax: 412-722-7863
E-Mail: PJ.Borandi@revvity.com

THIS IS THE SECOND RENEWAL OF THE CONTRACT AS AMENDED. (6/13/22 sc)
AMENDMENT THREE (3) AS ATTACHED. (01/16/24 BT)

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
1	NEWBORN SCREENING LAB AT NO COST TO THE STATE INITIAL AWARD - YEARS 1 AND 2	1.0000	$	0.0000	0.00
2	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 1 - YEARS 3 AND 4	1.0000	$	0.0000	0.00
3	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 2 - YEARS 5 AND 6	1.0000	$	0.0000	0.00
4	NEWBORN SCREENING LAB	1.0000	$	0.0000	0.00

DocuSigned by: Charity Menefee 1/26/2024
112DC07AECBA4F1...
DHHS DIVISION DIRECTOR

DocuSigned by: Matthew Hansen 1/26/2024
D09C6E7ACB6340E...
BUYER

DS RT

DocuSigned by: Amara Block 2/2/2024
4CFF2711162A4A2...
MATERIEL ADMINISTRATOR

STATE OF NEBRASKA SERVICE CONTRACT AMENDMENT

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

Telephone: (402) 471-6500
Fax: (402) 471-2089

PAGE	ORDER DATE
2 of 2	01/16/24
BUSINESS UNIT	BUYER
25530001	MATTHEW HANSEN (AS)

VENDOR NUMBER: 1300096

CONTRACT NUMBER
81109 O4

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
	AT NO COST TO THE STATE RENEWAL 3 - YEARS 7 AND 8				
5	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 4 - YEARS 9 AND 10	1.0000	$	0.0000	0.00
	Total Order				**0.00**

DS

BUYER INITIALS

AMENDMENT THREE
Contract 81109 O4
Newborn Screening Laboratory Testing Services for the State of Nebraska
Between
The State of Nebraska and Revvity Omics, Inc.

This Amendment (the "Amendment") is made by the State of Nebraska and Revvity Omics, Inc. (the "Contractor") parties to Contract 81109 O4 (the "Contract") and upon mutual agreement and other valuable consideration, the parties agree to and hereby amend the contract upon execution as follows:

1. Contractor Address Book # is updated as follows:

   AB# 1300096
   Revvity Omics, Inc.
   250 Industry Dr. Ste 400
   Pittsburgh, PA 15275-1017

2. Contractor Contact Information:

   Vendor Contact: Peter J. Borandi
   Phone: 412-220-2300
   Fax: 412-220-0784
   E-Mail: PJ.Borandi@revvity.com

This Amendment and any attachments hereto will become part of the Contract. Except as set forth in this Amendment, the Contract is unaffected and shall continue in full force and effect in accordance with its terms. If there is conflict between this Amendment and the Contract or any earlier amendment, the terms of this Amendment will prevail.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date of execution by both parties below.

State of Nebraska

By: DocuSigned by: Amara Block 4CFF2711162A4A2...

Name: Amara Block

Title: Materiel Administrator

Date: 2/2/2024

Contractor: Revvity Omics, Inc.

By: DocuSigned by: Peter J. Borandi 1AD3F5894A4A4FD...

Name: Peter J. Borandi

Title: Senior Director

Date: 1/18/2024

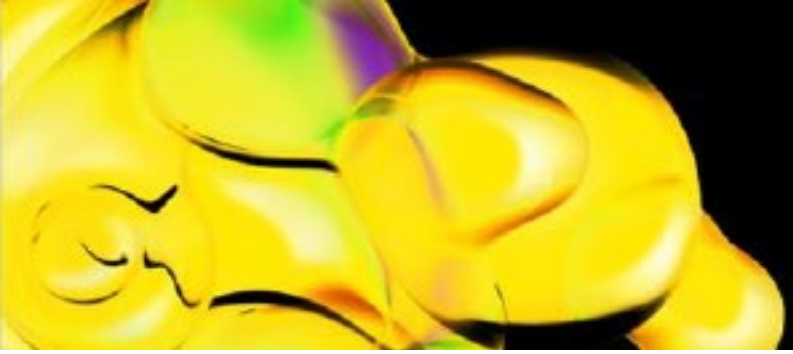
Department of Health and Human Services

By: DocuSigned by: Charity Menefee 112DC07AECBA4F1...

Name: Charity Menefee

Title: Director

Date: 1/26/2024



PerkinElmer Genomics is becoming Revvity Omics

June 26, 2023

Dear Valued Partner,

We are excited to share with you that PerkinElmer Genetics, Inc., d/b/a PerkinElmer Genomics, is becoming Revvity Omics, Inc., while maintaining the standard of excellence in newborn screening services. This change is being made in conjunction with our parent company PerkinElmer, Inc.'s recent rebranding as Revvity, Inc.*

This will be a legal name change only, and will take effect on or about July 17, 2023. Revvity Omics, Inc. will maintain the same address(es), license, permit and other accreditation numbers (*e.g.*, CAP, CLIA), banking information (except our name), and NPI and Tax ID number(s).

While we do not need you to take any action at this stage, we are providing this notice so you have time to prepare any necessary changes from your standpoint.

You may continue to use filter paper cards, documents, and other items at your location that include PerkinElmer Genomics (or PerkinElmer Genetics, Inc.) markings or branding. There is no need to replace or dispose of these items for branding purposes.

With respect to vendor setup and invoice processing, to the extent that you may need to update your systems to accommodate our name change once it takes effect, please let us know whether you will need any updated documentation using the contact information below.

Should you have any questions, please contact us at
PerkinElmerGenetics.Information@PerkinElmer.com

Your Revvity Team

*Checkout our press release on the Revvity website (www.revvity.com) under our news updates.

STATE OF NEBRASKA SERVICE CONTRACT AWARD

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

Telephone: (402) 471-6500
Fax: (402) 471-2089

PAGE	ORDER DATE
1 of 2	06/13/22
BUSINESS UNIT	BUYER
25530001	VACANT (AS)

VENDOR NUMBER: 1300096

VENDOR ADDRESS:

PERKINELMER GENETICS INC
90 EMERSON LN STE 1403
BRIDGEVILLE PA 15017-3473

CONTRACT NUMBER
81109 O4

AN AWARD HAS BEEN MADE TO THE VENDOR/CONTRACTOR NAMED ABOVE FOR THE SERVICES AS LISTED BELOW FOR THE PERIOD:

JULY 01, 2022 THROUGH JUNE 30, 2024

THIS CONTRACT IS NOT AN EXCLUSIVE CONTRACT TO FURNISH THE SERVICES SHOWN BELOW, AND DOES NOT PRECLUDE THE PURCHASE OF SIMILAR SERVICES FROM OTHER SOURCES.

THE STATE RESERVES THE RIGHT TO EXTEND THE PERIOD OF THIS CONTRACT BEYOND THE TERMINATION DATE WHEN MUTUALLY AGREEABLE TO THE VENDOR/CONTRACTOR AND THE STATE OF NEBRASKA.

Original/Bid Document 5710 Z1

Contract to supply and deliver Newborn Screening Laboratory Testing Services to the State of Nebraska as per the attached specifications for the period July 1, 2022 through June 30, 2024. The contract may be renewed for two (2) additional two (2) year periods when mutually agreeable to the vendor and the State of Nebraska.

Vendor Contact: Peter J. Borandi
Phone: 412-220-2300 Ext. 154
Fax: 412-722-7863
E-Mail: PJ.Borandi@perkinelmer.com

THIS IS THE SECOND RENEWAL OF THE CONTRACT AS AMENDED. (6/13/22 sc)

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
1	NEWBORN SCREENING LAB AT NO COST TO THE STATE INITIAL AWARD - YEARS 1 AND 2	1.0000	$	0.0000	0.00
2	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 1 - YEARS 3 AND 4	1.0000	$	0.0000	0.00
3	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 2 - YEARS 5 AND 6	1.0000	$	0.0000	0.00

DocuSigned by: Charity Menefee 0AB2A41B6ABB4C3...
DHHS Division Director

DocuSigned by: Connie Heinrichs 5E58C9A2CCD947A...
BUYER

DS PK

DocuSigned by: Amara Block 4CFF2711162A4A2...
MATERIEL ADMINISTRATOR

STATE OF NEBRASKA SERVICE CONTRACT AWARD

State Purchasing Bureau
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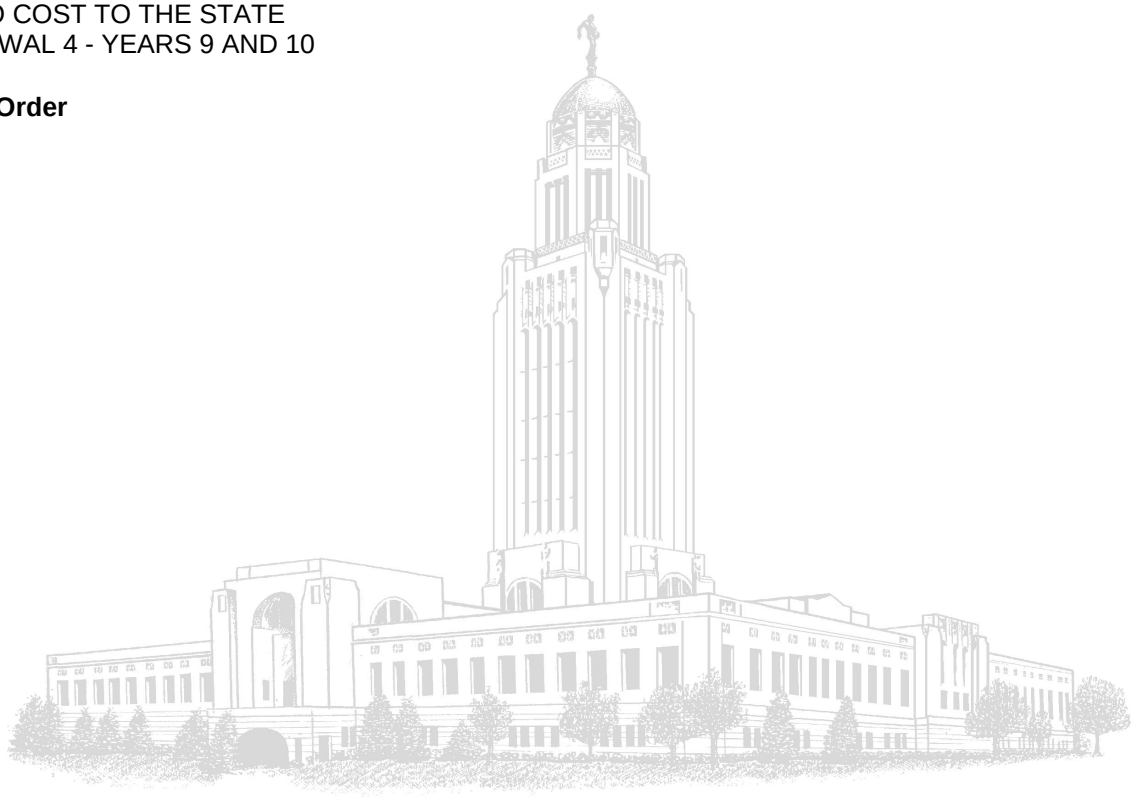
PAGE	ORDER DATE
2 of 2	06/13/22
BUSINESS UNIT	BUYER
25530001	VACANT (AS)

VENDOR NUMBER: 1300096

CONTRACT NUMBER
81109 O4

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
4	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 3 - YEARS 7 AND 8	1.0000	$	0.0000	0.00
5	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 4 - YEARS 9 AND 10	1.0000	$	0.0000	0.00
	Total Order				**0.00**



DS

BUYER INITIALS

NEBRASKA
Good Life. Great Service.
DEPT. OF ADMINISTRATIVE SERVICES

Pete Ricketts, Governor

CONTRACT RENEWAL

March 25, 2021

Mr. Peter J. Borandi
PerkinElmer Genetics Inc.
250 Industry Drive
Pittsburgh, PA 15275

RE: Contract Number 81109 O4, Newborn Screening Laboratory Testing Services

Dear Mr. Borandi:

The above named contract for providing Newborn Screening Laboratory Testing Services to the State of Nebraska, Department of Health and Human Services expires June 30, 2022.

The State of Nebraska is currently interested in renewing the Contract for an additional two (2) year period, i.e. July 1, 2022 through June 30, 2024. If PerkinElmer Genetics Inc. wishes to renew the Contract as stated, please DocuSign and return this as soon as possible, keeping one copy for your files.

The State will consider your signature as an agreement to be bound to the renewal, but the renewal will not be agreed to and accepted by the State until award signature page is executed by the Materiel Administrator.

If no response is received within 30 calendar days, the State of Nebraska will assume that the contractor does not intend to renew the contract and thus may begin the formal solicitation process.

Sincerely,

DocuSigned by:
Julie Schiltz
5CDDEE19EB984B4...

Julie Schiltz, Buyer
State Purchasing Bureau

PerkinElmer Genetics Inc. is agreeable to the renewal of 81109 O4 for Newborn Screening Laboratory Testing Services July 1, 2022 through June 30, 2024.

Signature DocuSigned by: Peter J. Borandi
430E95C69E6E4B5...

Title General Manager

Date 3/25/2021

Doug Carlson, Materiel Administrator
Department of Administrative Services | MATERIEL DIVISION
1526 K Street, Ste. 130
Lincoln, Nebraska 68508
OFFICE 402-471-6500
FAX 402-471-2089
das.nebraska.org

STATE OF NEBRASKA SERVICE CONTRACT AMENDMENT

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

Telephone: (402) 471-6500
Fax: (402) 471-2089

PAGE	ORDER DATE
1 of 1	10/29/20
BUSINESS UNIT	BUYER
25530001	JULIE SCHILTZ (AS)

CONTRACT NUMBER
81109 O4

VENDOR NUMBER: 1300096

VENDOR ADDRESS:

PERKINELMER GENETICS INC
90 EMERSON LN STE 1403
BRIDGEVILLE PA 15017-3473

THE CONTRACT PERIOD IS:

JULY 01, 2020 THROUGH JUNE 30, 2022

THIS SERVICE CONTRACT HAS BEEN AMENDED PER THE FOLLOWING INFORMATION:

THIS CONTRACT IS NOT AN EXCLUSIVE CONTRACT TO FURNISH THE SERVICES SHOWN BELOW, AND DOES NOT PRECLUDE THE PURCHASE OF SIMILAR SERVICES FROM OTHER SOURCES.

THE STATE RESERVES THE RIGHT TO EXTEND THE PERIOD OF THIS CONTRACT BEYOND THE TERMINATION DATE WHEN MUTUALLY AGREEABLE TO THE VENDOR/CONTRACTOR AND THE STATE OF NEBRASKA.

Original/Bid Document 5710 Z1

Contract to supply and deliver Newborn Screening Laboratory Testing Services to the State of Nebraska as per the attached specifications for the period July 1, 2020 through June 30, 2022. The contract may be renewed for three (3) additional two (2) year periods when mutually agreeable to the vendor and the State of Nebraska.

Vendor Contact: Peter J. Borandi
Phone: 412-220-2300 Ext. 154
Fax: 412-722-7863
E-Mail: PJ.Borandi@perkinelmer.com

This is the first renewal of the contract as amended (mel 4/20/20)

Amendment two (2) as attached. (mel 10/29/20)

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
1	NEWBORN SCREENING LAB AT NO COST TO THE STATE INITIAL AWARD - YEARS 1 AND 2	1.0000	$	0.0000	0.00
2	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 1 - YEARS 3 AND 4	1.0000	$	0.0000	0.00
3	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 2 - YEARS 5 AND 6	1.0000	$	0.0000	0.00
4	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 3 - YEARS 7 AND 8	1.0000	$	0.0000	0.00
5	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 4 - YEARS 9 AND 10	1.0000	$	0.0000	0.00
	Total Order				**0.00**

DocuSigned by:
Dr. Gary Anthone
C09BC9B303CC41D...
DHHS DIVISION DIRECTOR

DocuSigned by:
Julie Schiltz 11/12/2020
BUYER

DS
PK 11/12/2020

DocuSigned by:
11/12/2020
6F1A26D8C1D24BC...
MATERIEL ADMINISTRATOR

AMENDMENT TWO
Contract 81109 O4
Newborn Screening Laboratory Testing Services
Between
The State of Nebraska and PerkinElmer Genetics, Inc.

The following Terms and Conditions of Contract 81109 O4 have been reviewed and agreed upon between PerkinElmer Genetics, Inc. "Contractor" and the State of Nebraska "State". This amendment will become part of the contract for Newborn Screening Laboratory Testing Services.

The following terms related to the testing for SMA will become effective on November 14, 2020:

ACRONYMS is hereby amended to add:

SMA: Spinal Muscular Atrophy

Appendix F is amended to add the following row:

Condition Screened	Instrumentation	Method	Screening Algorithm	Cutoffs	Flow Chart attached?	Narrative Description of Algorithm	Back up Methodology and Instrumentation used in the event of equipment failure by the primary method.
SMA	V.C.33	V.C.33	V.C.33	V.C.33	V.C.33	V.C.33	V.C.37

Section V.C.44 is hereby added to read:

Spinal Muscular Atrophy (SMA): To be screened using PCR as the primary screen to detect homozygous deletion of the SMN1 gene, and when homozygous deletion of SMN1 is identified, the specimen will reflex to a secondary test to detect the copy number of the SMN2 gene.

Section V.F is hereby amended to read:

The contractor will report all results to the NNSP according to these technical requirements. The laboratory reports newborn screening results needing follow-up via telephone to the NNSP, the newborn's physician or designee, and the submitter (facility submitting the specimen) as soon as the results are available including afterhours weekdays, weekends and holidays. Exceptions to after normal business hours reporting include specimens collected at less than 24 hours of age, unsatisfactory specimens, transfused specimens, specimens with multiple amino acid elevations indicating likely hyperalimentation, non-clinically significant hemoglobinopathy abnormalities, positive and inconclusive Cystic Fibrosis results and inconclusive biotinidase (likely partial or carrier) deficiency results. Weekend after-hours reporting is also not conducted for SCID, Pompe, X-ALD, MPS-I and SMA. Weekday and Sunday after hours reporting is not conducted for

positive CPH results. The laboratory also faxes all reports that are phoned, during weekday working hours, to the physician, submitter & NNSP.

All initial repeat and confirmatory test results must be reported to the NNSP and submitters or made available electronically within 24 hours of test completion.

The laboratory test results report format and explanatory comments will be determined, as mutually agreed upon by the laboratory and the NNSP. The laboratory test results report format will include identification for each disorder screened by tandem mass spectrometry (MS/MS) and any other multiplex method; the name of the condition screened, the analyte or test name, the numerical value when available for quantitative or semi-quantitative assays, the unit of measure, other values such as the alpha description for hemoglobinopathies, a relative interpretation (WNL for within normal limits), and identify the cut-off or reference range (expected normal) for each analyte. Comments must be agreed to by the NNSP, and should identify for which condition the screening test abnormality is “inconclusive” or “preliminary positive” or “positive” and recommended next steps (e.g. repeat dried blood spot filter paper specimen or confirmatory testing, and or referral to pediatric sub specialist). Laboratory report comments relative to specimens drawn early, unsatisfactory specimens, transfused specimens, and specimens collected post-hyperalimentation must also be developed in collaboration with and agreed to by the NNSP.

For conditions screened by MS/MS the laboratory report will list a result for the acylcarnitine profile and the amino acid profile as WNL, abnormal or positive, and “see comment”. Comments for MS/MS will describe which analytes are abnormal, the degree to which they are abnormal, provide the numerical value of the screening result and expected (normal) reference value or range, using the same unit of measure, as well as any ratios applied by the laboratory. It will provide an interpretation that at a minimum distinguishes between results which urgently require confirmatory testing and/or referral to a pediatric sub specialist, vs. those which require repeat testing via dried blood spot filter paper specimens. A list of conditions screened by MS/MS at the laboratory will also be listed separately on the laboratory report.

Any proposed changes to laboratory report format, content or language must be mutually agreed upon in writing between the laboratory and the NNSP before such changes are implemented.

Complete MS/MS screening profile results including specific analyte values and ratios will be provided by the laboratory to the NNSP upon request for all babies that are confirmed positive.

The contractor will report every “positive” and/or abnormal screening result immediately via phone and in writing to the Nebraska Newborn Screening Program (NNSP), the submitter and the physician identified on the filter paper collection device (and alternate physician when discovered that the physician on the filter paper collection device is no longer seeing the baby). This notification is expected whenever the results become available on a 24 hour, seven day a week basis regardless of time. The written notification (fax) may be sent the following business day when the results are first available and reported on the weekend or after hours. After normal business hours reporting exceptions are positive, abnormal or inconclusive results for BIO, CF, Hgb’s, SCID, PD, MPS-I, SMA

and X-ALD which are only required to be phoned to the NNSP, submitter and physician via phone, and in writing, during normal business hours.

The contractor will report immediately via phone and in writing to the NNSP, the submitter and the physician every abnormal screening result that is "inconclusive" or in need of a repeat dried blood spot specimen only, on a 24 hour, seven day a week basis. These following exceptions need only be reported within twenty-four (24) hours and during normal business hours Monday through Friday: results indicating possible hyperalimentation (multiple amino acids elevated), specimens collected post transfusion, specimens collected too early at < 24 hours of age, unsatisfactory specimens, abnormal hemoglobinopathy results not expected to be clinically significant to the newborn; specimens that are considered abnormal (AF) or unreliable because of transfusion, and any abnormal results for BIO, CF, MPS-I, PD, SMA and X-ALD. Specimens with substantially abnormal or clinically significant results on a post transfusion result still require notification after normal working hours and on weekends. Positive results for CPH will be reported out only during normal business hours Monday through Friday, and on Saturdays. Depending on the screening algorithm proposed by the laboratory other abnormalities may be included in the "Monday through Friday" only expected reporting period, if mutually agreed upon by the NNSP. Unsatisfactory specimens must be reported by phone to the submitter and physician within 24 hours of when they are determined to be unsatisfactory, and in writing to the NNSP and submitter within 24 hours of this determination.

The contractor will document communication with submitters and physicians regarding unsatisfactory specimens, drawn early specimens, presumptive positive, inconclusive or abnormal, initial or repeat specimen screening results, confirmatory test results conducted by the laboratory, and reporting of laboratory errors. Laboratory (testing and reporting) errors shall be reported to the NNSP, physician and submitter within 24 hours of discovery of each error.

Section V.V is hereby amended to read:

This is an exclusive contract to provide newborn screening testing services for all newborns born in the State of Nebraska and is not purchased by the State of Nebraska. Invoices for testing services are to be provided to specimen submitters.

The per-infant screened fee money (currently $20.00) shall be submitted monthly by the bidder awarded this contract, to the NNSP within 45 days following the end of each calendar month for which billing was submitted. (For example fees for specimens tested in January, billed and collected, shall be submitted to the NNSP by March 17.)

Section VII.A is hereby amended to read:

Specimen testing cost for the screening panel as described in this RFP including Pompe, MPS-I, X-ALD, and SMA: **$66.00** + $20/infant screened fee = Total amount per infant billed upon completion of initial specimen testing: **$86.00**. All requested repeat specimens shall be tested without billing to the submitter.

The State reserves the right to review all aspects of cost for reasonableness and to request clarification of any proposals where the cost component shows significant and

unsupported deviation from industry standards or in areas where detailed pricing is required.

This Amendment and any attachments hereto will become part of the Contract. Except as set forth in this Amendment, the Contract is unaffected and shall continue in full force and effect in accordance with its terms. If there is conflict between this Amendment and the Contract or any earlier Amendment, the terms of this Amendment will prevail.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date of execution by both parties below.

State of Nebraska

By: DocuSigned by: 6F1A26D8C1D24BC...

Name: Doug Carlson

Title: Materiel Administrator

Date: 11/12/2020

Contractor: PerkinElmer Genetics, Inc.

By: DocuSigned by: Peter J. Borandi 430E95C69E6E4B5...

Name: Peter J. Borandi

Title: General Manager

Date: 11/2/2020

State of Nebraska Department of Health and Human Services

By: DocuSigned by: Dr. Gary Anthone C09BC9B303CC41D...

Name: Dr. Gary Anthone

Title: CMO/Director of Public Health

Date: 11/12/2020

STATE OF NEBRASKA SERVICE CONTRACT AWARD

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

Telephone: (402) 471-6500
Fax: (402) 471-2089

PAGE	ORDER DATE
1 of 1	04/20/20
BUSINESS UNIT	BUYER
25530001	JULIE SCHILTZ (AS)

VENDOR NUMBER: 1300096

VENDOR ADDRESS:

PERKINELMER GENETICS INC
90 EMERSON LN STE 1403
BRIDGEVILLE PA 15017-3473

CONTRACT NUMBER
81109 O4

AN AWARD HAS BEEN MADE TO THE VENDOR/CONTRACTOR NAMED ABOVE FOR THE SERVICES AS LISTED BELOW FOR THE PERIOD:

JULY 01, 2020 THROUGH JUNE 30, 2022

THIS CONTRACT IS NOT AN EXCLUSIVE CONTRACT TO FURNISH THE SERVICES SHOWN BELOW, AND DOES NOT PRECLUDE THE PURCHASE OF SIMILAR SERVICES FROM OTHER SOURCES.

THE STATE RESERVES THE RIGHT TO EXTEND THE PERIOD OF THIS CONTRACT BEYOND THE TERMINATION DATE WHEN MUTUALLY AGREEABLE TO THE VENDOR/CONTRACTOR AND THE STATE OF NEBRASKA.

Original/Bid Document 5710 Z1

Contract to supply and deliver Newborn Screening Laboratory Testing Services to the State of Nebraska as per the attached specifications for the period July 1, 2020 through June 30, 2022. The contract may be renewed for three (3) additional two (2) year periods when mutually agreeable to the vendor and the State of Nebraska.

Vendor Contact: Peter J. Borandi
Phone: 412-220-2300 Ext. 154
Fax: 412-722-7863
E-Mail: PJ.Borandi@perkinelmer.com

This is the first renewal of the contract as amended (mel 4/20/20)

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
1	NEWBORN SCREENING LAB AT NO COST TO THE STATE INITIAL AWARD - YEARS 1 AND 2	1.0000	$	0.0000	0.00
2	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 1 - YEARS 3 AND 4	1.0000	$	0.0000	0.00
3	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 2 - YEARS 5 AND 6	1.0000	$	0.0000	0.00
4	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 3 - YEARS 7 AND 8	1.0000	$	0.0000	0.00
5	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 4 - YEARS 9 AND 10	1.0000	$	0.0000	0.00
	Total Order				**0.00**

DHHS DIVISION DIRECTOR

BUYER

4/20/2020

MATERIEL ADMINISTRATOR

NEBRASKA

Good Life. Great Service.

DEPT. OF ADMINISTRATIVE SERVICES

CONTRACT RENEWAL

July 17, 2019

Mr. Peter Borandi
PerkinElmer Genetics Inc.
90 Emerson Ln Ste 1403
Bridgeville, PA 15017-3473

RE: Contract Number 81109 (O4), Newborn Screening Laboratory Testing Services

Dear Mr. Borandi:

The above named contract for providing Newborn Screening Laboratory Testing Services to the State of Nebraska, Department of Health and Human Services expires June 30, 2020.

It carries a provision for renewal when mutually agreeable to the Vendor and the State of Nebraska. The State of Nebraska wishes to renew this contract for an additional two (2) year period, i.e. July 01, 2020 through June 30, 2022.

If this is agreeable with PerkinElmer Genetics Inc., please sign and return as soon as possible, keeping one (1) copy for your files.

If no response is received within thirty (30) calendar days, the State of Nebraska will assume that PerkinElmer Genetics Inc. does not intend to renew contract number 81109 (O4) and thus may begin the formal solicitation process to obtain Newborn Screening Laboratory Testing Services.

Sincerely,

Julie Schiltz, Buyer
State Purchasing Bureau
DATE: 7/17/19

PerkinElmer Genetics Inc. is agreeable to the renewal of 81109 O4 for Newborn Screening Laboratory Testing Services July 01, 2020 through June 30, 2022.

SIGNATURE: _____

TITLE: SITE LEADER
DATE: 7/17/2019

Department of Administrative Services | MATERIEL DIVISION
1526 K Street, Ste. 130
Lincoln, Nebraska 68508
OFFICE 402-471-6500
FAX 402-471-2089
das.nebraska.org

STATE OF NEBRASKA SERVICE CONTRACT AMENDMENT

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

Telephone: (402) 471-6500
Fax: (402) 471-2089

PAGE	ORDER DATE
1 of 2	02/26/20
BUSINESS UNIT	BUYER
25530001	JULIE SCHILTZ (AS)

CONTRACT NUMBER
81109 O4

VENDOR NUMBER: 1300096

VENDOR ADDRESS:

PERKINELMER GENETICS INC
90 EMERSON LN STE 1403
BRIDGEVILLE PA 15017-3473

THE CONTRACT PERIOD IS:

JULY 01, 2018 THROUGH JUNE 30, 2020

THIS SERVICE CONTRACT HAS BEEN AMENDED PER THE FOLLOWING INFORMATION:

THIS CONTRACT IS NOT AN EXCLUSIVE CONTRACT TO FURNISH THE SERVICES SHOWN BELOW, AND DOES NOT PRECLUDE THE PURCHASE OF SIMILAR SERVICES FROM OTHER SOURCES.

THE STATE RESERVES THE RIGHT TO EXTEND THE PERIOD OF THIS CONTRACT BEYOND THE TERMINATION DATE WHEN MUTUALLY AGREEABLE TO THE VENDOR/CONTRACTOR AND THE STATE OF NEBRASKA.

Original/Bid Document 5710 Z1

Contract to supply and deliver Newborn Screening Laboratory Testing Services to the State of Nebraska as per the attached specifications for the period July 1, 2018 through June 30, 2020. The contract may be renewed for four (4) additional two (2) year periods when mutually agreeable to the vendor and the State of Nebraska.

Vendor Contact: Peter J. Borandi
Phone: 412-220-2300 Ext. 154
Fax: 412-722-7863
E-Mail: PJ.Borandi@perkinelmer.com

(3/29/18 sc)

Amendment one (1) as attached. (mel 02/26/20)

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
1	NEWBORN SCREENING LAB AT NO COST TO THE STATE INITIAL AWARD - YEARS 1 AND 2	1.0000	$	0.0000	0.00
2	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 1 - YEARS 3 AND 4	1.0000	$	0.0000	0.00
3	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 2 - YEARS 5 AND 6	1.0000	$	0.0000	0.00
4	NEWBORN SCREENING LAB AT NO COST TO THE STATE	1.0000	$	0.0000	0.00

3/4/20 3-4-20
BUYER

3/4/2020
MATERIEL ADMINISTRATOR

DHHS DIVISION DIRECTOR

STATE OF NEBRASKA SERVICE CONTRACT AMENDMENT

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

Telephone: (402) 471-6500
Fax: (402) 471-2089

PAGE	ORDER DATE
2 of 2	02/26/20
BUSINESS UNIT	BUYER
25530001	JULIE SCHILTZ (AS)

VENDOR NUMBER: 1300096

CONTRACT NUMBER
81109 O4

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
	RENEWAL 3 - YEARS 7 AND 8				
5	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 4 - YEARS 9 AND 10	1.0000	$	0.0000	0.00
	Total Order				**0.00**

BUYER INITIALS

AMENDMENT ONE
Contract 81109 O4
Newborn Screening Laboratory Testing Services
Between
The State of Nebraska and PerkinElmer Genetics, Inc.

The following Terms and Conditions of Contract 81109 O4 have been reviewed and agreed upon between PerkinElmer Genetics, Inc. "Contractor" and the State of Nebraska "State". This amendment will become part of the contract for Newborn Screening Laboratory Testing Services.

The following amendment to Section V.C.22 will become effective upon the execution of this Amendment One by the parties. Section V.C.22 is hereby amended to read:

> *Pompe Disease (PD): Primary screen may be MS/MS or Digital Microfluidics. Screens that are out of range, reflex to sequencing of DNA. *** To be added effective July 1, 2018.**

This Amendment and any attachments hereto will become part of the Contract. Except as set forth in this Amendment, the Contract is unaffected and shall continue in full force and effect in accordance with its terms. If there is conflict between this Amendment and the Contract or any earlier Amendment, the terms of this Amendment will prevail.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date of execution by both parties below.

State of Nebraska

By: _____

Name: Douglas D Carlson

Title: Materiel Administrator

Date: 3/4/2020

Contractor: PerkinElmer Genetics, Inc.

By: _____

Name: PETER J. BORAARDI

Title: SITE LEADER

Date: 2/26/2020

State of Nebraska Department of Health and Human Services

By: Gary Anthone, MD

Name: Gary Anthone, MD

Title: CMO / Director of Public Health

Date: 3-3-20

STATE OF NEBRASKA SERVICE CONTRACT AWARD

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

Telephone: (402) 471-6500
Fax: (402) 471-2089

PAGE	ORDER DATE
1 of 2	03/29/18
BUSINESS UNIT	BUYER
25530001	ANNETTE WALTON (AS)

VENDOR NUMBER: 1300096

VENDOR ADDRESS:

PERKINELMER GENETICS INC
90 EMERSON LN STE 1403
BRIDGEVILLE PA 15017-3473

CONTRACT NUMBER
81109 O4

AN AWARD HAS BEEN MADE TO THE VENDOR/CONTRACTOR NAMED ABOVE FOR THE SERVICES AS LISTED BELOW FOR THE PERIOD:

JULY 01, 2018 THROUGH JUNE 30, 2020

THIS CONTRACT IS NOT AN EXCLUSIVE CONTRACT TO FURNISH THE SERVICES SHOWN BELOW, AND DOES NOT PRECLUDE THE PURCHASE OF SIMILAR SERVICES FROM OTHER SOURCES.

THE STATE RESERVES THE RIGHT TO EXTEND THE PERIOD OF THIS CONTRACT BEYOND THE TERMINATION DATE WHEN MUTUALLY AGREEABLE TO THE VENDOR/CONTRACTOR AND THE STATE OF NEBRASKA.

Original/Bid Document 5710 Z1

Contract to supply and deliver Newborn Screening Laboratory Testing Services to the State of Nebraska as per the attached specifications for the period July 1, 2018 through June 30, 2020. The contract may be renewed for four (4) additional two (2) year periods when mutually agreeable to the vendor and the State of Nebraska.

Vendor Contact: Peter J. Borandi
Phone: 412-220-2300 Ext. 154
Fax: 412-722-7863
Mail: PJ.Borandi@perkinelmer.com

(3/29/18 sc)

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
1	NEWBORN SCREENING LAB AT NO COST TO THE STATE INITIAL AWARD - YEARS 1 AND 2	1.0000	$	0.0000	0.00
2	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 1 - YEARS 3 AND 4	1.0000	$	0.0000	0.00
3	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 2 - YEARS 5 AND 6	1.0000	$	0.0000	0.00
4	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 3 - YEARS 7 AND 8	1.0000	$	0.0000	0.00
5	NEWBORN SCREENING LAB AT NO COST TO THE STATE RENEWAL 4 - YEARS 9 AND 10	1.0000	$	0.0000	0.00

DHHS Division Director

5/4/18 Annette Dickerson 5/1/18
BUYER

5/9/18
MATERIEL ADMINISTRATOR

R43300|NISK0002|NISK0002 20150901

STATE OF NEBRASKA SERVICE CONTRACT AWARD

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

Telephone: (402) 471-6500
Fax: (402) 471-2089

PAGE	ORDER DATE
2 of 2	03/29/18
BUSINESS UNIT	BUYER
25530001	ANNETTE WALTON (AS)

VENDOR NUMBER: 1300096

CONTRACT NUMBER
81109 O4

Line	Description	Quantity	Unit of Measure	Unit Price	Extended Price
	Total Order				**0.00**

BUYER INITIALS

For public information purposes only; not part of contract.

Request for Proposal Number 5710 Z1
Contract Number 81109 O4
Proposal Opening: January 8, 2018

In accordance with Nebraska Revised Statutes §84.712.05(3), the following material(s) has not been included due to it being marked proprietary.

PerkinElmer Genetics, Inc.

1. Flow Chart – Biotinidase
2. Flow Chart – CAH
3. Flow Chart – CF
4. Flow Chart – Hemoglobinopathies
5. Flow Chart – CPH
6. Flow chart - Galactosemia

PerkinElmer Genetics, Inc.

Response to

Request for Proposal (RFP) #5710Z1

Newborn Screening Laboratory Testing Services

ORIGINAL - TECHNICAL PROPOSAL

ORIGINAL
Form A
Bidder Contact Sheet
Request for Proposal Number 5710Z1

Form A should be completed and submitted with each response to this RFP. This is intended to provide the State with information on the bidder's name and address, and the specific person(s) who are responsible for preparation of the bidder's response.

Preparation of Response Contact Information	
Bidder Name:	PerkinElmer Genetics, Inc.
Bidder Address:	90 Emerson Lane Suite 1403 Bridgeville, PA 15017
Contact Person & Title:	Peter J. Borandi, Site Leader
E-mail Address:	PJ.Borandi@perkinelmer.com
Telephone Number (Office):	412-220-2300 Ext. 154
Telephone Number (Cellular):	412-722-7863
Fax Number:	412-220-0784

Each bidder should also designate a specific contact person who will be responsible for responding to the State if any clarifications of the bidder's response should become necessary. This will also be the person who the State contacts to set up a presentation/demonstration, if required.

Communication with the State Contact Information	
Bidder Name:	PerkinElmer Genetics, Inc.
Bidder Address:	90 Emerson Lane Suite 1403 Bridgeville, PA 152017
Contact Person & Title:	Peter J. Borandi, Site Leader
E-mail Address:	PJ.Borandi@perkinelmer.com
Telephone Number (Office):	412-220-2300 Ext. 154
Telephone Number (Cellular):	412-722-7863
Fax Number:	412-220-0784

Response to Request for Proposal (RFP) #5710Z1
RFP Title: Newborn Screening Laboratory Testing Services

Technical Proposal

From:

PerkinElmer Genetics, Inc.
90 Emerson Lane, Suite 1403
Bridgeville, Pennsylvania 15017

For:

State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, Nebraska 68508

Attention: Michelle Thompson / Annette Walton

Due Date and Time:

January 8, 2018 2:00 P.M. Central Time

Respectfully submitted:

Peter J. Borandi
Site Leader
PerkinElmer Genetics, Inc.
90 Emerson Lane, Suite 1403
Bridgeville, Pennsylvania 15017
Phone: (412) 220-2300 Ext. 154
Email: PJ.Borandi@PerkinElmer.com

Table of Contents

1. Request for Proposal for Contractual Services Form

BIDDER MUST COMPLETE THE FOLLOWING

By signing this Request for Proposal for Contractual Services form, the bidder guarantees compliance with the procedures stated in this Request for Proposal, and agrees to the terms and conditions unless otherwise indicated in writing and certifies that bidder maintains a drug free work place.

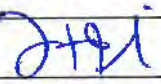
Per Nebraska's Transparency in Government Procurement Act, Neb. Rev Stat § 73-603 DAS is required to collect statistical information regarding the number of contracts awarded to Nebraska Contractors. This information is for statistical purposes only and will not be considered for contract award purposes.

_____ NEBRASKA CONTRACTOR AFFIDAVIT: Bidder hereby attests that bidder is a Nebraska Contractor. "Nebraska Contractor" shall mean any bidder who has maintained a bona fide place of business and at least one employee within this state for at least the six (6) months immediately preceding the posting date of this RFP.

_____I hereby certify that I am a Resident disabled veteran or business located in a designated enterprise zone in accordance with Neb. Rev. Stat. § 73-107 and wish to have preference, if applicable, considered in the award of this contract.

_____ I hereby certify that I am a blind person licensed by the Commission for the Blind & Visually Impaired in accordance with Neb. Rev. Stat. §71-8611 and wish to have preference considered in the award of this contract.

FORM MUST BE SIGNED USING AN INDELIBLE METHOD (NOT ELECTRONICALLY)

FIRM:	**PerkinElmer Genetics, Inc.**
COMPLETE ADDRESS:	**90 Emerson Lane, Suite 1403, Pittsburgh, PA 15017**
TELEPHONE NUMBER:	**412-220-2300 Ext. 154**
FAX NUMBER:	**412-220-0784**
DATE:	**January 2, 2018**
SIGNATURE:	
TYPED NAME & TITLE OF SIGNER:	**Peter J. Borandi, Site Leader**

2. Corporate Overview

a. Bidder Identification and Information

PerkinElmer Genetics Incorporated is a wholly owned subsidiary of PerkinElmer Incorporated.

PerkinElmer Genetics (formerly Pediatrix Screening) was founded/incorporated in 1994 as NeoGen Screening in Pennsylvania.

Physical address of the lab:

PerkinElmer Genetics, Inc.
90 Emerson Lane, Suite 1403
Bridgeville, Pennsylvania 15017
Federal Employer ID: 25-1645804

Corporate headquarters:

PerkinElmer, Inc.
940 Winter Street
Waltham, Massachusetts 02451

b. Financial Statements

PerkinElmer's most recent financial statements are included with this document. An electronic version of the most recent copy can be viewed at http://ir.perkinelmer.com/annuals-proxies.cfm

c. Change of Ownership

No change of ownership or control of the company is anticipated during the twelve (12) months following the proposal due date.

d. Office Location

PerkinElmer Genetics, Inc. address is:

90 Emerson Lane, Suite 1403
Bridgeville, PA 15017

The laboratory location is expected to change sometime in 2018. PerkinElmer Genetics will notify the state when the relocation will occur. The new address is:

250 Industry Drive
Pittsburgh, PA 15275

e. Relationships with the State

Nebraska Current Contract 56060 O4 – Newborn Screening Services

Primary Contact:	Julie Luedtke Program Manager Nebraska Health & Human Services 301 Centennial Mall South Lincoln, NE 68508-5026 Phone: 402-471-6733 Fax: 402-471-1863 Email: Julie.Luedtke@nebraska.gov
Service Date:	2003 to Present
Scope of Service:	Newborn Screening for: Biotinidase Deficiency, Congenital Hypothyroidism, Hemoglobinopathies, Galactosemia, Congenital Adrenal Hyperplasia, Cystic Fibrosis, Amino Acid Disorders, Fatty Acid Disorders, Organic Acid Disorders and Severe Combined Immunodeficiency (SCID)

f. Bidder's Employee Relations to State

PerkinElmer Genetics, Inc. declares that no relationship exists or previously existed.

g. Contract Performance

No PerkinElmer Genetics contracts have been terminated in the last 5 years.

h. Summary of Bidder's Corporate Experience

i. Narrative Descriptions

Time Period of Project	Scheduled & Actual Completion Dates	Contractor's Responsibilities	Customer Contact Information	Project Description
2003 to present	Scheduled Completion of Current Agreement in 2018	Newborn Screening Service of mandatory first sample with additional samples on a request basis. Annual Volume – 30,875 samples from 65 different submitters	Julie Luedtke, Program Manager Nebraska Health & Human Services 301 Centennial Mall South Lincoln, NE 68508-5026 Telephone: 402-471-6733 FAX: 402-471-1863 Email: Julie.Luedtke@nebraska.gov	Work performed as the Prime Contractor. Newborn Screening: Biotinidase Deficiency, Congenital Hypothyroidism, Congenital Adrenal Hyperplasia, Hemoglobinopathies, Galactosemia, Cystic Fibrosis, Amino Acid Disorders, Fatty Acid Disorders, Organic Acid Disorders and Severe Combined Immunodeficiency (SCID) Abnormal results notified by Genetic Counselors.
2003 to present	Scheduled Completion of Current Agreement in 2019	Newborn Screening Service of mandatory first sample with additional samples on a request basis. Annual Volume – 39,584 samples from 135 different submitters.	Beryl Polk, PhD, Director of Genetic Services Mississippi State Department of Health P.O. Box 1700 Jackson, MS 39215-1700 Telephone: 601-576-7619 FAX: 601-576-7598 Email: Beryl.Polk@msdh.state.ms.us	Work performed as the Prime Contractor. Newborn Screening : Pompe, Biotinidase Deficiency, Congenital Hypothyroidism, Congenital Adrenal Hyperplasia, Hemoglobinopathies, Galactosemia, Cystic Fibrosis, Amino Acid Disorders, Fatty Acid Disorders, Organic Acid Disorders and Severe Combined Immunodeficiency (SCID) Abnormal results notified by Genetic Counselors.
1999 to present	Scheduled Completion of Current Agreement in 2018	Newborn Screening Service of mandatory first sample with additional samples on a request basis. Annual Volume – 141,748 samples from 174 different submitters including several midwives.	Kelly Holland, Division Director Pennsylvania Department of Health, Bureau of Family Health 625 Forster Street Harrisburg, PA 17120 Telephone: 717-783-8143 FAX: 717-724-0323 Email: kholland@pa.gov	Work performed as the Prime Contractor. Newborn Screening: X-ALD, MPS-I, Pompe, Biotinidase Deficiency, Congenital Hypothyroidism, Congenital Adrenal Hyperplasia, Cystic Fibrosis, Hemoglobinopathies, Galactosemia, Amino Acid Disorders, Fatty Acid Disorders, Organic Acid Disorders, G6PD Deficiency and Severe Combined Immunodeficiency (SCID). Abnormal results notified by Genetic Counselors.

ii. No work was performed by a Subcontractor.

iii. No work was performed by a Subcontractor.

Summary of Previous Work

i. Overall ability to perform the newborn screening.

PerkinElmer Genetics, Inc. (formerly Pediatrix Screening) was founded/incorporated in 1994 as NeoGen Screening and has over 23 years of dedicated Newborn Screening experience screening more than 6,900,000 babies using advanced technologies: Biochemical, Molecular Genetic (DNA), patented Tandem Mass Spectrometry (MS/MS) and Next Generation Sequencing. PerkinElmer Genetics is located in Pennsylvania. No facility expansion is required to handle the Nebraska Department of Health newborn screening service as PerkinElmer Genetics has been screening babies in Nebraska for over 14 years.

The laboratory has always been focused on bringing modern technologies into clinical laboratory practice for newborn screening. Numerous innovations resulting from the efforts of the laboratory's dedicated professionals include: the advent of tandem mass spectrometry; the use of DNA technologies as both primary and secondary means of disease detection; the advent of unique testing algorithms to improve the accuracy of newborn screening; and the development and implementation of screening assays for Severe Combined Immunodeficiency (SCID), Lysosomal Storage Disorders (LSD), and X-linked adrenoleukodystrophy (X-ALD).

These innovations are well documented in a series of publications and in our ongoing laboratory practice today. PerkinElmer Genetics team members impact the lives of over 1,000,000 newborns per year through its metabolic screening programs and relationships. The laboratory provides state mandated services for numerous states within the United States, both under direct contract and through health care provider choice in states where that is an available option. Distribution of quality newborn screening services is made available to municipal and state governments, hospitals, physician practices, and individual parents.

From the beginning, the laboratory had been innovating new approaches to newborn metabolic screening that incorporated modern laboratory technologies including most recently Next Generation Sequencing. These pioneering efforts provided improved sensitivity and specificity to existing assays traditionally used in newborn metabolic screening, and allowed for substantial, cost-effective expansion in the scope of disorders detected in screening programs. Numerous peer reviewed publications have been generated as the result of these efforts. Many of these initiatives were the result of federally funded research programs.

Noteworthy contributions to the field of newborn screening laboratory science are the following:

- Developed the application of electron spray MS/MS for newborn screening. Subsequent work further characterized operationally important features, and resulted in patented technology.[1,2,3,4,5,6]

- Actively developed quality assurance standards for the use of tandem mass spectrometry for newborn screening and clinical chemistry in general.[7,8,9]

- Demonstrated the importance and significance of multiplex analyte profiling in disease identification using tandem mass spectrometry.[10,11,12]

- Introduced DNA second tier analysis to improve characterization of hemoglobinopathies.[13,14] Work resulted in patented technology.[15]

- Developed first tier DNA assay to characterize glucose-6-phosphate dehydrogenase deficiency and hemoglobinopathies.[16,17]

- Participated in national discussions of newborn screening for cystic fibrosis.[18]

- Described importance of environmental factors on the assessment of enzyme markers from filter paper analysis.[19]

PerkinElmer Genetics metabolic screening laboratory is focused on continuous process improvement. PerkinElmer Genetics operates under the principles of LEAN and Six Sigma, and provides an intact program of metrics driven continuous improvement. Using the principles of continuous improvement we are able to work internally and with clients to improve the performance of newborn screening programs. This improves the efficiency of newborn screening allowing for more efficient resource allocation to other key client-driven program initiatives (e.g., follow-up and case management).

As a subsidiary of PerkinElmer, Inc., PerkinElmer Genetics collaborates with corporate affiliates that provide unique access to the latest technologies in newborn screening, a sharp focus and dedication to improving the lives of newborns worldwide, and the financial strength and stability of the world leader in supplying neonatal screening systems to laboratories. Through its neonatal screening technology utilized in laboratories worldwide for more than 20 years, PerkinElmer has helped to identify many infants at risk for potentially life-threatening diseases.

All of the approximately four million babies that are screened in the U.S. each year have their blood sample processed through a PerkinElmer system or PerkinElmer Genetics service.

The approximately 1,000,000 newborn samples screened annually by PerkinElmer Genetics support not only several State mandated programs in Pennsylvania, Mississippi, Nebraska, District of Columbia, and Louisiana, but also includes Hospital Supplemental programs nationwide along with the recently introduced

concept of lab-in-a-lab (LiL). The LiL concept is currently used for MS/MS screening in Minnesota, SCID screening in Florida and XALD screening in California.

The average approximate turn-around-times:

Facility Shipment to Receipt – <1.5 days*
Lab Receipt to Report – 1.7 days
Birth to Report – <5.5 days*
*Facility must ensure proper collection and shipping practices are followed.

The laboratory presently has a capacity of greater than 500,000 specimens per year. PerkinElmer Genetics will be relocating in 2018 to a larger facility that will expand the capacity. This new location will allow for expansion of equipment and personnel when necessary.

PerkinElmer Genetics receives samples 6 days a week – Monday through Saturday. The Genetic Counselors are available 24 hours per day, 7 days per week to facilitate short-term follow-up, communication and education to health care providers worldwide regarding the newborn screening program. Educational support is provided as well through on-line education and on-site training and feedback as required.

Our Information Systems Department has a proven track record of data management and support. The PerkinElmer Genetics information management system will fulfill all the requirements specified in the RFP. The Information Systems Department will provide system support to ensure user needs are addressed promptly. As in the past, the Information Systems team will work closely with the newborn screening staff to make enhancements to the existing software. The staff at PerkinElmer with the help of the Nebraska Newborn Screening Program (NNSP) created a web based platform currently used by the NNSP to support their daily screening activities.

ii. A listing of laboratory instrumentation, methods, backup capabilities (Describe the methodology used to test for each disorder)

Note: Additional information can be found in Appendix F.

Methods Used

17α-Hydroxyprogesterone - Congenital Adrenal Hyperplasia (CAH)
Time-resolved fluoroimmunoassay AutoDELFIA®;
PerkinElmer®, Waltham, MA
Interferences: EDTA and citrate anticoagulants
Minimum Detectable Level: 1.3 ng/mL

Biotinidase Deficiency
Colorimetric; Astoria-Pacific, Inc., Clackamas, OR
Interferences: sulfonamide drugs, heat denaturation
Minimum Detectable Level: 2 ERU

Galactose-1-Phosphate Uridyl Transferase (GALT, UT) - Galactosemia
Fluorometric; Astoria-Pacific, Inc., Clackamas, OR
Interference: UDP Galactose, heat denaturation
Minimum Detectable Level: 5 µM

Galactose - Galactosemia
Fluorometric; Astoria-Pacific, Inc., Clackamas, OR
Interferences: galactose contamination, NADH
Linearity up to 50 mg/dL
Minimum Detectable Level: ~ 2 mg/dL (sensitivity 0.3 mg/dL)

Hemoglobinopathy
Iso-electric Focusing; PerkinElmer®, Waltham, MA
Interference: Contaminated specimens

Immunoreactive Trypsinogen (IRT) - Cystic Fibrosis
Time-resolved fluoroimmunoassay AutoDELFIA®;
PerkinElmer®, Waltham, MA
Interferences: EDTA and citrate anticoagulants
Minimum Detectable Level: 4 ng/mL

Thyroxine (T4) - Congenital Primary Hypothyroidism
Time-resolved fluoroimmunoassay AutoDELFIA®;
PerkinElmer®, Waltham, MA
Interferences: EDTA and citrate anticoagulants
Minimum Detectable Level: 1.5 µg/dL

Thyroid Stimulating Hormone (hTSH) - Congenital Primary Hypothyroidism
Time-resolved fluoroimmunoassay AutoDELFIA®;
PerkinElmer®, Waltham, MA
Interferences: EDTA and citrate anticoagulants
Minimum Detectable Level: 2.2 µIU/mL

Amino Acids, Organic Acids, Acylcarnitines
Tandem Mass Spectrometry (MS/MS); laboratory developed test
Interference: EDTA anticoagulant
Minimum Detectable Level: Varies with the analyte ~ 0.0071-17.5742 µM

Lysosomal Storage Disorders (LSD)
Enzymatic with Tandem Mass Spectrometry (MS/MS) detection; laboratory developed test
Interference: Heat denaturation
Mimimum Detectable Level: Varies with the analyte

X-linked Adrenoleukodystrophy (X-ALD)
Tandem Mass Spectrometry (MS/MS) and Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS); laboratory developed test
Interfcrence: Unknown
Minimum Detectable Level: 0.01 µM

DNA Mutation Testing

A. PCR and allele specific hybridization; laboratory developed test
Interference: Contaminated specimens, specimens exposed to strong oxidizers such as bleach, heparin anticoagulant

B. xTAG® Cystic Fibrosis Kit; Luminex Corporation, Austin, TX
PCR, Allele Specific Primer Extension (ASPE), flow cytometry
Interference: Contaminated specimens, specimens exposed to strong oxidizers such as bleach, heparin anticoagulant

T-cell receptor excision circles (TRECs) for
Severe Combined Immunodeficiency (SCID)
Real-time Quantitative PCR; laboratory developed test
Interference: Contaminated specimens, specimens exposed to strong oxidizers such as bleach, heparin anticoagulant
Minimum Detectable Level: 5 copies/µL

Biochemistry Instrumentation

Instrumentation	Disorders	# of Instruments	Average Age	Average Samples/Day/Instrument
PerkinElmer AutoDELFIA	Thyroid [CH], 17-α- hydroxy progesterone [CAH], IRT [cystic fibrosis]	6	10 Years	167
Astoria-Pacific Continuous Flow Analyzers	Total Galactose, Galactose-1-Phosphate Uridyl Transferase, Biotinidase	8	14 Years	125
Isoelectric Focusing Chambers	Hemoglobinopathies	12	15 Years	83
Wallac DBS Puncher	All	12	16 Ears	>500
Panthera Puncher	All	1	2 Years	>500

Molecular Instrumentation

Instrumentation	Disorders	# of Instruments	Average Age	Average Samples/Day/Instrument
Roche LightCycler	TRECs [SCID], second tier testing	4	10 Years	250
Roche LC480 II	TRECs [SCID], second tier testing	5	5 Years	200
Luminex	Cystic Fibrosis Panel	2	5 Years	250

Mass Spectrometry Instrumentation

Instrumentation	Disorders	# of Instruments	Average Age	Average Samples/Day/Instrument
Sciex API 3000 Mass Spectrometer	Amino Acids, Acylcarnitines, Organic Acids, LSD, XALD	3	16 Years	333
Sciex API 3200 Mass Spectrometer	Amino Acids, Acylcarnitines, Organic Acids, LSD, XALD	5	4 Years	200
Waters Quattro-Micro Mass Spectrometer	LSD	1	6 Years	200

The backup for the equipment is redundancy. Currently, PerkinElmer Genetics has at least 50% reserve capacity with the present collection of instrumentation.

iii. List all analytical instruments available for this project, their age and support agreements (including repair histories and average time for repair), current workload with these instruments, and backup capabilities.

The above instruments are regularly maintained with scheduled factory engineer service. These maintenance records are available for onsite examination.

iv. Experience with all newborn screening tests, technology and methodologies proposed to be utilized including Tandem Mass Spectrometry and molecular testing. Describe specific experience (amount and type) with this methodology and other methodologies associated with population based newborn screening for each relevant key staff person. (Years of experience in performing each type of screening test and estimated volume).

Note: Additional information is contained in section v. below.

Support Personnel Description	# of Personnel	Notes
Administrative	6	Billing/Collections/Project Management
Client Services	6	The supervisor of the Client Services section has 4 years of experience as a medical technologist and over 13 years of experience pathology support services
Data Entry	5	The lead in the Data Entry section has over 15 years of experience at this laboratory.
Genetic Counselors	2	The Master's Degree licensed Genetics Counselors each have over 10 years of experience with one having over 20 years of experience.
Information Technology	2	Both IT staff members have been with PerkinElmer over 5 years. Additional IT support is available from the corporate office.
Specimen Processing	3	The section supervisor has over 15 years of experience in this laboratory in the specimen processing department.
Total	24	

Lab Personnel Description	# of Personnel	Notes
Lab Directors	2	Laboratory Director and Assistant Director (both are board certified with a PhD). CLIA Laboratory director has over 30 years of experience as a clinical laboratory director and holds licenses in California, Georgia, Nevada, New Jersey, and New York.
Biochemistry	14	13 Technologists 3 ASCP 4 General Supervisor qualified 6 Technical Supervisor qualified 1 Technician The Section Supervisor has over 20 years of experience as a general laboratory technologist.
Molecular	10	10 Technologists (2 with Master's degree) 1 ASCP 2 General Supervisor qualified 4 Technical Supervisor qualified The Section Supervisor has over 18 years of experience working with molecular techniques.
Mass Spectrometry	13	13 Technologists (1 with PhD, 1 with Master's degree) 3 General Supervisor qualified 4 Technical Supervisor qualified The Section Supervisor has over 25 years of experience working with tandem mass spectrometers.
Total	39	

v. Number of tests currently performed each year for each disorder listed above in section V.C.

		Test Volume 2016		Test Volume 2017*	
Disorder	**Year Testing Started**	**PerkinElmer**	**Nebraska**	**PerkinElmer**	**Nebraska**
Argininosuccinic Acidemia	1994	332,158	30,780	303,239	28,510
Beta-Ketothiolase Deficiency	1994	333,954	30,780	304,783	28,510
Biotinidase Deficiency	1999	326,185	27,633	297,279	25,368
Carnitine Uptake Defect	1994	332,158	30,780	303,239	28,510
Citrullinemia	1994	332,158	30,780	303,239	28,510
Congenital Adrenal Hyperplasia	1999	330,294	28,040	299,011	25,812
Congenital Primary Hypothyroidism	2003	343,272	32,044	313,341	29,297
Cystic Fibrosis	1999	322,856	28,063	294,067	25,851
Galactosemia	1999	321,774	27,607	293,370	25,359
Glutaric Acidemia Type 1	1994	333,954	30,780	304,783	28,510
Hemoglobinopathies	1999	322,711	30,742	294,248	28,444
Homocystinuria	1994	332,158	30,780	303,239	28,510
Isovaleric Acidemia	1994	333,954	30,780	304,783	28,510
Long-Chain Hydroxyacyl-CoA Dehydrogenase Deficiency	1994	333,954	30,780	304,783	28,510
Maple Syrup Urine Disease	1994	332,158	30,780	303,239	28,510
Medium Chain Acyl Co-A Dehydrogenase Deficiency	1994	333,954	30,780	304,783	28,510
Methylmalonic Acidemia (Mutase Deficiency)	1994	333,954	30,780	304,783	28,510
Methylmalonic Acidemia (Cbl. A, B)	1994	333,954	30,780	304,783	28,510
Muccopolysaccharidosis Type I	2011	18,012	-	144,204	-

		Test Volume 2016		Test Volume 2017*	
Disorder	**Year Testing Started**	**PerkinElmer**	**Nebraska**	**PerkinElmer**	**Nebraska**
Multiple Carboxylase Deficiency	1994	333,954	30,780	304,783	28,510
Phenylketonuria	1994	332,158	30,780	303,239	28,510
Pompe Disease	2011	167,816	-	191,125	-
Propionic Acidemia	1994	333,954	30,780	304,783	28,510
Severe Combined Immune Deficiency	2010	227,363	27,583	227,193	25,329
Tri-Functional Protein Deficiency	1994	333,954	30,780	304,783	28,510
Tyrosinemia	1994	332,158	30,780	303,239	28,510
Very Long Chain Acyl-CoA Dehydrogenase Deficiency	1994	333,954	30,780	304,783	28,510
X-linked Adrenoleukodystophy	2016	7	-	103,585	-
3-Hydroxy 3-Methyl Glutaric Aciduria	1994	333,954	30,780	304,783	28,510
3-Methylcrotonyl-CoA Carboxylase Deficiency	1994	333,954	30,780	304,783	28,510

* January 2017 through November 2017

vi. Describe the organization's current licensures, accreditations and certifications. (Provide copies of relevant paperwork)

PerkinElmer Genetics is accredited by CLIA and the College of American Pathologists (CAP).

A copy of the most recent CLIA and CAP certificates are provided below. Additional certificates may be viewed at http://www.perkinelmer.com/genetics/about/lab-accreditations.html

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
PERKINELMER GENETICS INC
90 EMERSON LANE SUITE 1403
PO BOX 219
BRIDGEVILLE, PA 15017

CLIA ID NUMBER
39D0673919

EFFECTIVE DATE
02/02/2015

LABORATORY DIRECTOR
JOSEPH M QUASHNOCK PHD DIR

EXPIRATION DATE
02/01/2018

Pursuant to Section 353 of the Public Health Service Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments of 1988, the above named laboratory located at the address shown hereon is certified to perform laboratory examinations or procedures.

This certificate shall be valid until the expiration date shown, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS

Karen W. Tritz, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties, subspecialties you are certified to perform and their effective date.

LAB CERTIFICATION CODE	EFFECTIVE DATE	LAB CERTIFICATION CODE	EFFECTIVE DATE
BACTERIOLOGY (110)	02/10/2014		
VIROLOGY (140)	06/15/2010		
ROUTINE CHEMISTRY (310)	01/23/2004		
ENDOCRINOLOGY (330)	04/16/2008		
CYTOGENETICS (500)	07/16/2010		

FOR MORE INFORMATION ABOUT CLIA VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE

COLLEGE of AMERICAN PATHOLOGISTS

The College of American Pathologists
certifies that the laboratory named below

PerkinElmer Genetics Inc
Laboratory
Bridgeville, Pennsylvania
Joseph M. Quashnock, PhD,HCLD(ABB),CC(ABB

CAP Number: 1286403
AU-ID: 1178174
CLIA Number: 39D0673919

has met all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to June 15, 2018 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Chair, Commission on Laboratory Accreditation

President, College of American Pathologists

vii. Availability of qualified and experience personnel, facilities, general environment and resources for the proposed services.

As described throughout the previous sections, PerkinElmer Genetics has the availability of qualified and experienced personnel, facilities, general environment and resources for the proposed services. This is evident in that PerkinElmer Genetics is currently providing newborn screening for the State of Nebraska.

viii. Familiarity and experience consulting with the medical community relative to conditions included in the core newborn screening panel.

Since its inception over 20 years ago, PerkinElmer Genetics has consulted with the medical community in various capacities. These interactions include abnormal results notifications to departments of health, healthcare providers and specialists. In addition, PerkinElmer Genetics' personnel participate in various industry symposiums and technical advisory boards. PerkinElmer Genetics routinely attends in person the Nebraska Newborn Screening Advisory quarterly meetings.

ix. Information management systems

PerkinElmer Genetics has collaborated with the Nebraska Newborn Screening Program to create a web based system that helps to manage the day to day activities of the department. The system has been in place for 14 years and continues to evolve to keep pace with the NNSP's needs.

For example, if awarded the contract, PerkinElmer Genetics will work with the NNSP to add an enhancement that enables attaching and saving as part of individual patient records, electronic documents of follow-up activities (letters, faxes, reports in scanned or other Microsoft Office readable format). In addition, a mechanism will be developed for "closing" follow-up action on patient records to enable the pending action to be dropped from the active worksheet reports, while retaining the record in open status for any other pending/needed follow-up actions.

The current system has the ability to capture all demographic information required on the NNSP collection and reporting form filter paper collection device and is entered into an electronic database the day the forms are received. The database system has unlimited availability during each 24 hour period for data transmission and data access, with the exception for routine technical maintenance of the database system. The electronic data system ensures standard SSL (Secure Sockets Layer) 128-bit encryption necessary for transmission of data.

Test result information is entered within 24 hours of completion of the tests. The system allows secure remote access for tracking of all Nebraska newborn's specimens. It is used by the NNSP to generate reports and letters. All newborn laboratory test and result data shall are kept in the computerized record system accessible to the laboratory performing the services for a period no less than 25 years

from the date of the test, and to the NNSP for a period no less than 29 years from the date of the test.

Timely and accurate data entry is required to facilitate the NNSP follow-up component which will contact the primary care physician with recommendations on all abnormal screening results, unsatisfactory, drawn early, and post-transfusion specimens and which will maintain follow-up until adequate specimens are submitted, diagnosis is ruled out, or diagnosis of the infant is confirmed and the infant is in treatment or according to NNSP written procedures that the infant is determined lost to follow-up.

Data entry errors will be reported by phone to the NNSP within 24 hours of discovery of such error.

PerkinElmer Genetics electronically transmits or allows electronic access to test results and other data via a secure connection. All electronic transmissions of data must meet all State and Federal security requirements including those in the Bureau of Information Services Security Manual and Health Information Portability and Accountability Act (HIPAA) and regulations and be compatible with provisions of the Health Information Technology for Economic and Clinical Health (HITECH Act). The laboratory IT personnel will provide training to the Nebraska Newborn Screening Program Manager and follow-up personnel on how to use the applications. PerkinElmer Genetics currently supports a comprehensive data export in comma delimited format for an upload to an SQL server maintained by the Department of Administrative Services Office of the Chief Information Officer. The data is uploaded weekly and includes all data including comments-field content.

PerkinElmer Genetics has the capacity to export comma delimited text files compliant with Health Level Seven (HL7) standards to the Nebraska Department of Health and Human Services so that the data can be integrated into tables in the Nebraska Vital Records electronic registration system or other database system. The export files will maintain the referential integrity of the data and be exported to a Nebraska FTP (file transfer protocol) site.

A computerized system is maintained and updated to allow remote access by or transmission to the NNSP to the database containing all the information from the Nebraska Newborn Screening Program Collection and Reporting form on Nebraska specimens including: the date and time each sample was collected, date each sample was received from the specimen submitter, the date the laboratory tests were completed; the date results of the laboratory analyses were reported to or made available for access by the NNSP; the status of laboratory analysis (e.g. in progress, completed, or not done and reason why), results and other actions. This system allows the NNSP to search for information, and report results of laboratory analysis on individual specimens to hospitals, and to the physician of record upon request. PerkinElmer Genetics provides reports of all test results to the submitter. When applicable, written reports to the submitter are in electronic format for incorporation

into each hospital/submitter's electronic medical records. The electronic data system is HL7 compliant and capable of interfacing with hospital laboratory information systems or other health information exchanges in Nebraska to facilitate adoption of electronic medical records by providers. PerkinElmer Genetics has over 10 years of experience with HL7 messaging for newborn screening. Approximately 60,000 HL7 orders are received each year along with over 100,000 HL7 results being sent per year. Specifically in Nebraska, PerkinElmer Genetics has implemented HL7 messaging for over 60% of the samples collected on Nebraska babies. PerkinElmer Genetics will continue to work with other facilities that desire an interface.

The data system currently has the ability to produce reports of tests missing, unsatisfactory specimens, drawn early, transfused specimens, inconclusive cystic fibrosis, newborns with meconium ileus or other bowel obstruction, out of hospital births, presumptive positives and confirmed positives that are necessary for follow-up and tracking. The data system currently has the ability to produce reports of low T4s with low TSH's for information purposes only (not for required physician reporting). All reports listed in Appendix D of the RFP with the exception of the ones expected in 2018 are currently available in the data system used by the NNSP.

Currently, the data system can produce quality assurance reports necessary for monitoring of turnaround times, missing demographic information from the filter paper cards, statistical averages including mean, median, quarterly percentiles of all lab results producing a quantitative value, age at collection, and hospital QA reports comparing hospital numbers with State averages and percentiles of performance on multiple measures. The NNSP currently has the ability to access a database of scanned images of dried blood spot filter paper devices received at the laboratory. PerkinElmer Genetics currently performs daily monitoring using a UPS electronic tracking report to identify any specimen shipments not received by 4 days from shipment. The laboratory follows up with the submitter and if necessary the shipper, the day an exception is identified. Exceptions are reported to the NNSP program manager, and a weekly report is routinely submitted.

All initial, repeat and confirmatory test results are reported to the NNSP or made available electronically within 24 hours of test completion. A mechanism is available for the NNSP to enter/edit data or have data entered on confirmatory test results obtained from other laboratories or physicians/health care providers. Confirmatory tests used to aid in diagnosis may be done at various laboratories within and outside of Nebraska and may or may not be completed at the laboratory. When these are not done at the screening laboratory the NNSP follow-up program in the Department of Health and Human Services will track and monitor and has the capacity to enter these results into the Nebraska data.

The electronic data system currently has the capacity to produce template letters populated with patient and health care practitioner demographic information, and test results for all abnormal screen results, as well as second request letters and

letters for specimens collected too early, unsatisfactory specimens, transfused specimens and any other results requiring follow-up.

A procedure has been implemented to identify and merge/eliminate duplicate records. Specifically, when multiple (two or more) records on the same infant are identified when the infant has more than one specimen, there must be a mechanism to merge these into one record. The laboratory must be notified for the merging to occur.

The data system has the capacity to close a record when confirmed negative, confirmed positive or determined lost to follow-up so these records do not remain on a "pending" report. The data system has the capacity to remove inconclusive abnormal results from reports as closed.

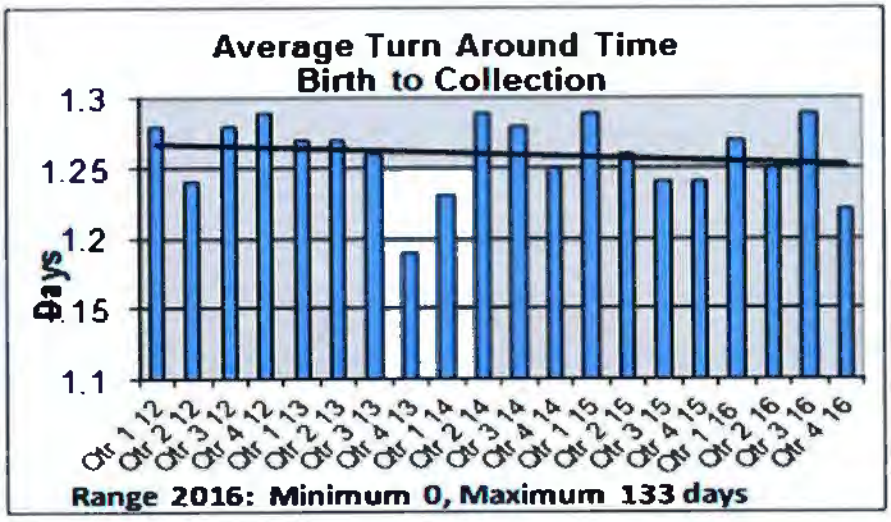
The data system has the ability to generate ad-hoc reports for quality assurance on variable date ranges and variable data elements.

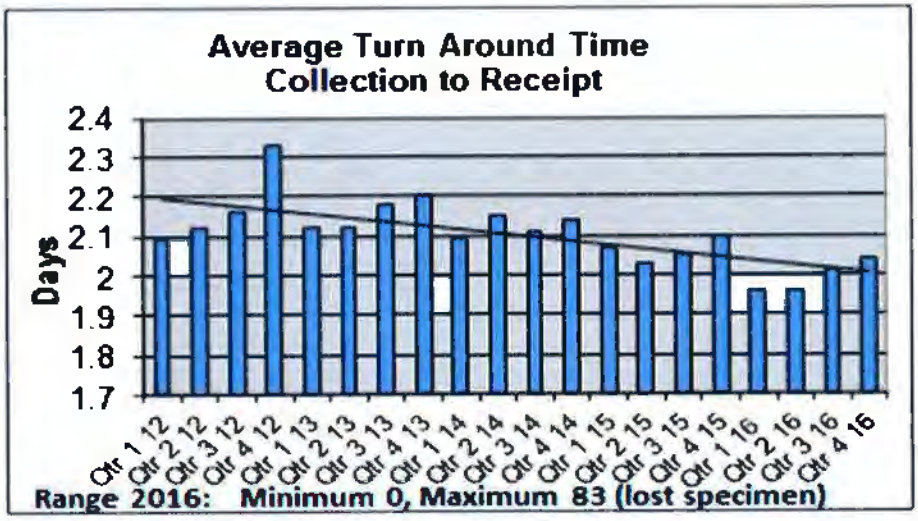
PerkinElmer Genetics has and will continue to work with the NNSP to create the reports required to support and manage the program including ones related to new disorders.

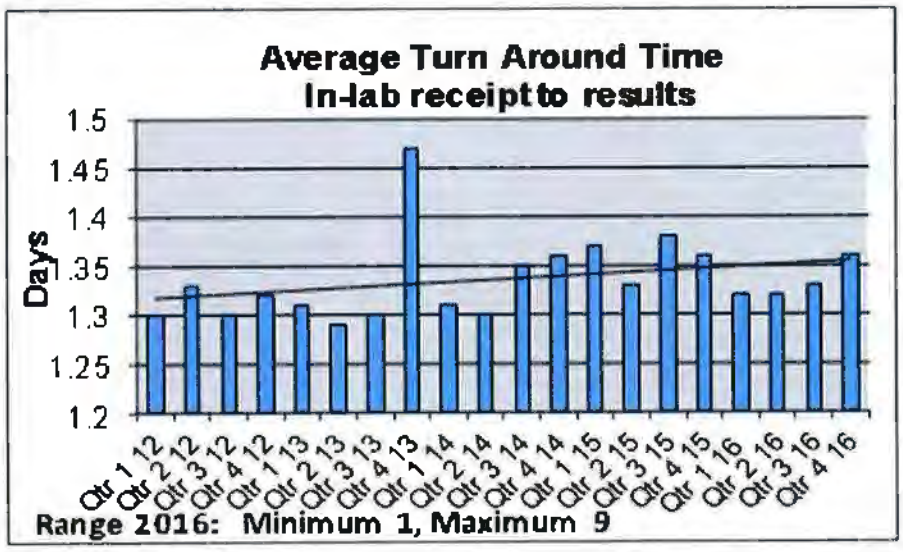
x. Current analytical workload, turnaround time (in-lab and collection to completion), and capacity to add Nebraska's specimens to existing workload

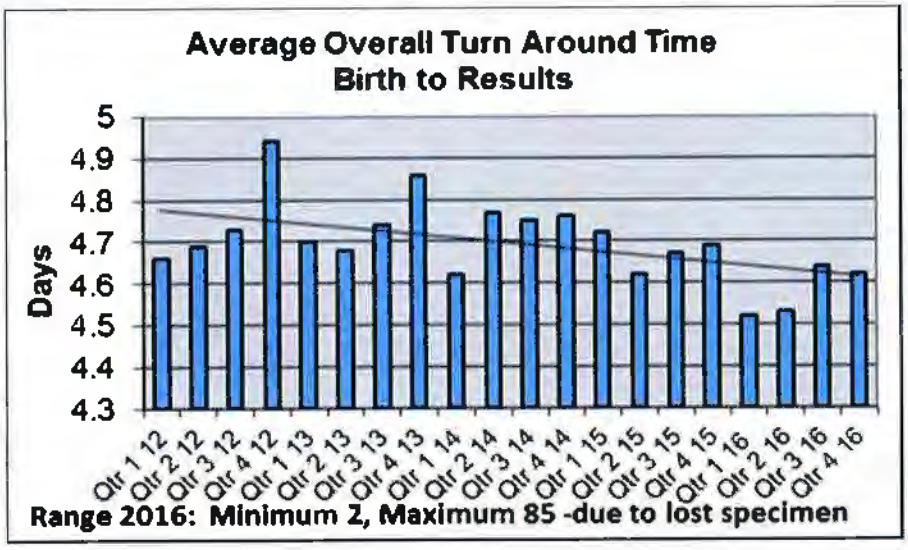
PerkinElmer Genetics currently screens more than 330,000 samples per year which includes the samples from Nebraska. The laboratory has excess capacity of approximately 50%.

The average turnaround times in Nebraska for the last 5 full years are included in the graphs below. These charts were created by the NNSP and presented during the January 2017 Nebraska newborn screening advisory committee meeting.






Average Turn Around Time
In-lab receipt to results
Days
1.5
1.45
1.4
1.35
1.3
1.25
1.2
Qtr 1 12
Qtr 2 12
Qtr 3 12
Qtr 4 12
Qtr 1 13
Qtr 2 13
Qtr 3 13
Qtr 4 13
Qtr 1 14
Qtr 2 14
Qtr 3 14
Qtr 4 14
Qtr 1 15
Qtr 2 15
Qtr 3 15
Qtr 4 15
Qtr 1 16
Qtr 2 16
Qtr 3 16
Qtr 4 16
Range 2016: Minimum 1, Maximum 9


Average Overall Turn Around Time
Birth to Results
Days
5
4.9
4.8
4.7
4.6
4.5
4.4
4.3
Qtr 1 12
Qtr 2 12
Qtr 3 12
Qtr 4 12
Qtr 1 13
Qtr 2 13
Qtr 3 13
Qtr 4 13
Qtr 1 14
Qtr 2 14
Qtr 3 14
Qtr 4 14
Qtr 1 15
Qtr 2 15
Qtr 3 15
Qtr 4 15
Qtr 1 16
Qtr 2 16
Qtr 3 16
Qtr 4 16
Range 2016: Minimum 2, Maximum 85 -due to lost specimen

xi. Clinical consultation experience for metabolic, endocrine, hemoglobin, pulmonologic and immunologic, lysosomal and peroxisomal disorders.

The Genetic Counselors at PerkinElmer Genetics communicate with healthcare providers on a routine basis. They provide consultation including results notification and education about newborn screening disorders. In addition, the laboratory directors and certain consultants provide consultation on an as needed basis. Disorders covered include hemoglobin, pulmonologic and immunologic, lysosomal and peroxisomal.

xii. If sub-specialists are under contract to provide such consultation for the laboratory identify the scope of the contract, and availability/accessibility of consultants to the NNSP.

PerkinElmer Genetics and PerkinElmer, Inc. have several contracts with individuals who provide clinical consultation to the newborn screening laboratory and clients. These specialists can be made available to clients on an as needed basis with advanced notice. It is anticipated that additional specialists will be contracted in the coming year as necessary.

xiii.

Outline a transition plan that, if awarded the contract, would be implemented to ensure a smooth transition by July 1, 2018. Plan should include communication paths with NNSP staff and DHHS information technology staff, and methods.

Implementation – Work Plan

The primary tasks required for implementation would be related to the addition of the new conditions. All other critical assays, workflows and computer systems are already in place.

Based on an estimated contract award date of March 26, 2018:

Deliverable	Responsible Party	Due Date
Contract Negotiations	PerkinElmer/NNSP	April 2, 2018
Create Algorithms for New Conditions	PerkinElmer/NNSP	April 20, 2018
Approval of New Algorithms	NNSP	April 27, 2017
Notify Submitters of New Conditions/Algorithms	PerkinElmer/NNSP	April 30, 2018
Software Modifications	PerkinElmer/NNSP	May 18, 2018
HL7 Interface Updates	PerkinElmer/Submitters	June 15, 2018
Go Live	All	July 1, 2018

Note: Some tasks will be addressed in parallel

xiv. **Ability to offer full service to Nebraska by July 1, 2018**

No transition is required since PerkinElmer Genetics is currently offering Nebraska all services requested with the exception of the new disorders. PerkinElmer Genetics has validated assays for the new disorders requested in the RFP and is already performing this testing for other state contracts. In addition, PerkinElmer has existing electronic interfaces with submitting Nebraska facilities. These items in addition to the plan above allow for a seamless addition of the new disorders by July 1, 2018.

xv.

Adequacy of plans for the administration of the program.

Describe the number and qualifications of professional and technical staff in each area: specimen processing/accessioning, biochemistry, MS/MS, DNA testing, data entry, data/information systems management and all management staff, Specify for all key professional staff their roles and responsibilities. Identify numbers and qualifications of staff maintained for laboratory operations by area, e.g. specimen accessioning/processing, data entry, testing (by area), reporting, initial notifications, filter paper management, etc.)

Support Personnel Description	# of Personnel	Notes
Administrative	6	Billing/Collections/Project Management
Client Services	6	The supervisor of the Client Services section has 4 years of experience as a medical technologist and over 13 years of experience pathology support services
Data Entry	5	The lead in the Data Entry section has over 15 years of experience at this laboratory.
Genetic Counselors	2	The Master's Degree licensed Genetics Counselors each have over 10 years of experience with one having over 20 years of experience.
Information Technology	2	Both IT staff members have been with PerkinElmer over 5 years. Additional IT support is available from the corporate office.
Specimen Processing	3	The section supervisor has over 15 years of experience in this laboratory in the specimen processing department.
Total	24	

Lab Personnel Description	# of Personnel	Notes
Lab Directors	2	Laboratory Director and Assistant Director (both are board certified with a PhD). CLIA Laboratory director has over 30 years of experience as a clinical laboratory director and holds licenses in California, Georgia, Nevada, New Jersey, and New York.
Biochemistry	14	13 Technologists 3 ASCP 4 General Supervisor qualified 6 Technical Supervisor qualified 1 Technician The Section Supervisor has over 20 years of experience as a general laboratory technologist.
Molecular	10	2 with Master's degree 10 Technologists 1 ASCP 2 General Supervisor qualified 4 Technical Supervisor qualified The Section Supervisor has over 18 years of experience working with molecular techniques.
Mass Spectrometry	13	13 Technologists (1 with PhD, 1 with Master's degree) 3 General Supervisor qualified 4 Technical Supervisor qualified The Section Supervisor has over 25 years of experience working with tandem mass spectrometers.
Total	39	

i. Summary of Bidder's Proposed Personnel/Management Approach

Management of Project
The following are brief resumes for key laboratory personnel that are currently working and will work on the Nebraska project if awarded the contract. Additional staff resumes are available upon request.

Dr. Madhuri Hegde, VP of Lab Services and Chief Scientific Officer for PerkinElmer Global Genomics Lab Services. Dr. Hegde previously held the position of Adjunct Professor, Human Genetics and Pediatrics at the Emory University School of Medicine Department of Human Genetics. Dr. Hegde is a world-renowned medical geneticist with over 20 years of experience in clinical genetic testing. She has served on national committees including: CAP, AMP, ACMG, and the FDA. Her areas of specialty and interest are muscular dystrophy, neonatal genomics, and novel high throughput methodologies to detect and interpret sequence variation.

P.J. Borandi, MBA is the Site Leader at PerkinElmer Genetics and is responsible for the day to day operations at the laboratory. Prior to taking on the role as Site Leader, he worked in the information technology field for over ten years with a specific concentration in health care information systems. He received a Bachelor of Science degree in Applied Mathematics from Indiana University of Pennsylvania and his Master of Business Administration (MBA) degree from Waynesburg University. He was an information technology consultant prior to joining PerkinElmer Genetics in 2003.

Dr. Joseph Quashnock is the CLIA Director of Record. He received his B.S. from The University of Dayton in Chemistry, his M.S. and Ph.D. in Biochemistry from Notre Dame University. He holds clinical laboratory director licenses in Georgia, Nevada, New Jersey, and New York and is licensed as a clinical laboratory scientist in California. He is board certified as both a high-complexity clinical laboratory director and a clinical consultant by the American Board of Bioanalysis. He is a fellow of the American Association for Clinical Chemistry. He served as a biochemist in hospital and reference laboratories for 10 years with the U.S. Army. He was the technical laboratory director with Laboratory Corporation of America and National Health Laboratories for 20 years before joining PerkinElmer Genetics in 2002.

Dr. Zhili Lin, received his M.D. degree from Shanghai Second Medical University and practiced as a physician for 3 years at No. 6 Peoples Hospital in Shanghai. He received his Ph.D. in Biochemistry from the Medical College of Virginia. Dr. Lin is board certified as a high-complexity laboratory director by the American Board of Bioanalysis. He is a fellow of the American Association for Clinical Chemistry. He did his first post-doctoral training investigating the molecular basis of Sojgren Larsson Syndrome. He joined PerkinElmer Genetics in 2001, and is involved in developing primary DNA testing for newborn screening using DNA microarray and LightTyper technologies. He is also involved in using lab automation systems to improve efficiency and accuracy of genetic testing.

James DiPerna is the Manager of Operations for Mass Spectrometry. He earned his B.S. in Biology from West Virginia University in 1990 and began working in newborn screening at Magee Women's Hospital in Pittsburgh in 1993. He helped implement and refine the MS/MS protocol currently used by PerkinElmer Genetics and he is a co-author on several peer reviewed published manuscripts related to MS/MS and newborn screening. He has been with the laboratory since its founding in October 1994.

Bethany A. Sgroi-Gaita, M.S., LGC received a Bachelor of Science Degree with Honors in Biology from The Pennsylvania State University---The Behrend College, Erie, PA. Subsequently, she obtained her Masters of Science Degree in Genetic Counseling from The University of Pittsburgh, Pittsburgh, PA. Bethany has been employed as a genetic counselor with PerkinElmer Genetics since 1996 during which time she has been instrumental in developing the follow-up and genetic counseling program at PerkinElmer Genetics. In addition to directly communicating with health care professionals about abnormal newborn screening results and recommendations, she has been directly involved with various state contract newborn screening data analysis projects and follow-up of abnormal results. Bethany is a licensed Genetic Counselor by the state of Pennsylvania.

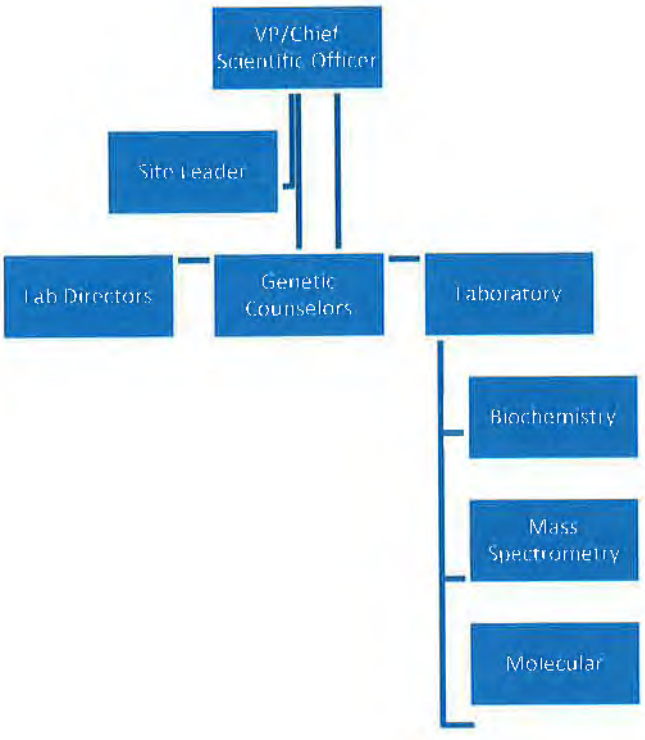
Meredith Patik, M.S., LGC received her Bachelor of Science Degree in Biopsychology from Russell Sage College Troy, NY. She obtained her Master's Degree in Human Genetics from The University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA. She spent two years at Children's Hospital of Pittsburgh, Department of Hematology/Oncology/BMT, Comprehensive Sickle Cell Center, providing education to parents and physicians on the importance of newborn screening and early intervention for sickle cell. Meredith joined PerkinElmer Genetics in September 2005, where she provides notification and education of abnormal newborn screening results to physicians and other health care professionals for short-term follow-up. She also provides statistical analysis of newborn screening results. Meredith is a licensed Genetic Counselor by the state of Pennsylvania.

Greg Nicholson is the Controller at PerkinElmer Genetics and has been in the position since November 2000. Greg is the sole financial employee on-site at the laboratory and has seen his role evolve over the years. He is responsible for all accounting and financial functions including billing, budgets, cost analysis, financial reporting, and financial performance review. Greg has a bachelor's degree in accounting from Penn State University and passed the Pennsylvania CPA exam in November 2002.

Susan Felinczak is the Contracts Manager at PerkinElmer Genetics and has been in the position since July 2003. Susan is responsible for contract administration, project management of state contracted clients, new client transition and training. Susan attends Duquesne University Division of Continuing Education, working towards completion of Bachelor of Science Organizational Leadership.

Organization Chart

High Level Organization Chart



The following are a list of references.

Name	Title	Entity	Telephone	E-mail
Julie Luedtke	Program Manager	Nebraska Health & Human Services	402-471-6733	Julie.Luedtke@nebraska.gov
Kelly Holland	Division Director	Pennsylvania Department of Health	717-783-8143	kholland@pa.gov
Beryl Polk, PhD	Director of Genetic Services	Mississippi State Department of Health	601-576-7619	Beryl.Polk@msdh.state.ms.us

DEVIATION
RFP Section VI, A, 2, i on page 39

Current: Any changes in proposed personnel shall only be implemented after written approval from the state.

Deviation: PerkinElmer Genetics will be solely responsible for any changes in personnel as long as the changes do not provide any impact to the service provided.

j. Subcontractors

PerkinElmer Genetics will not utilize any subcontractors. PerkinElmer Genetics will only utilize a subcontractor (if required) to implement an emergency disaster plan.

3. Technical Approach

a. Understanding of the Project Requirements

In conjunction with the NNSP, PerkinElmer Genetics has been proudly serving the babies and families of Nebraska since 2003. The successful collaboration has enabled the program to become one of the best in the country as evidenced by national recognition routinely received. The focus on metrics has driven continuous improvement for many years and has led to operational improvements by the submitters and the laboratory.

The additions to the current scope include new assays such as Pompe, MPS-I and XALD. PerkinElmer Genetics has validated assays for all 3 conditions and has surpassed 100,000 samples screened for each in 2017. This experience allows for a seamless implementation of the new screening requirements.

Another requirement is for sequencing services. PerkinElmer Genetics currently provides sequencing services for clients that require it. For example, one state client's algorithm requires sequencing for Pompe, MPS-I and XALD using a dried blood spot. This experience can enable the NNSP to keep the program on the cutting edge of newborn screening technology.

b. Proposed Development Approach

PerkinElmer will assign a project manager to ensure that all requirements are tracked and implemented on time. PerkinElmer will leverage its existing relationships with the NNSP and submitting facilities to ensure timely notification and implementation. With the exception of the new conditions, all other tasks are expected to continue without interruption. The tasks associated with the new condition implementation are described below.

c. Technical Considerations

As Outlined in Section O on page 33 of the RFP.

1. **Distribution and tracking of filter paper blood specimen collection kits;**

   PerkinElmer Genetics is responsible for ordering and maintaining a supply of filter papers for distribution to submitting facilities. Submitters can contact PerkinElmer Genetics Client Services at 1-866-463-6436 or via email to PerkinElmerGenetics.Information@perkinelmer.com to request supplies.

   Each request is tracked in the laboratory information system. The tracking includes a detailed list of filter paper numbers sent to the requesting facility. Prior to shipment, the shipping coordinator will review the usage and recent shipment history in an attempt to efficiently maintain the correct levels of inventory.

   Reports can be created that display shipment histories and details including which specific filter papers have been received at the laboratory.

2. **Rapid transport for specimens from the birthing hospitals/facilities to the laboratory;**

   PerkinElmer Genetics incurs all expenses related to the overnight courier service for in-bound sample delivery. The current primary courier is UPS with FedEx being another option. Deliveries are made to our Pittsburgh facility, six days a week: Monday through Saturday (excluding courier holidays). Saturday pickup service is available to each birth hospital based upon zip code availability.

   If not already established, in order to setup UPS Service, each identified Nebraska Birth Hospital listed in the RFP Appendix A will be sent an initial email with a "Request for Information Form". The collection site will provide PerkinElmer Genetics with the following:

   - Site address & location of pickup

- Contact Person
- Telephone Number
- Type of Service Required: Daily or Occasional (collection sites have the option, depending on number of births and specimens, to call the courier to schedule a pick-up instead of a daily pick-ups)
- Time Specimens will be ready for pickup

The collection site will be setup in the UPS ICVS system (Complete View Solution), a secure Web-based shipping application. This module will allow the collection site to print their shipping labels using a standard in-house printer. This application also provides shipment history with tracking capabilities and automatic Saturday delivery for shipments created on Fridays.

An initial supply of UPS Window Envelopes and Neon Orange Saturday Delivery stickers will be provided to all Nebraska birth hospitals. UPS Supplies may be re-ordered by contacting PerkinElmer Genetics Client Service Representatives at 1-866-463-6436.

Each collection site will be provided with:

- Facility specific ICVS Notification Instruction Sheet
- ICVS User Manual
- ICVS Application Training via conference call
    - Preparing Shipping Labels
        - Review importance of shipping specimens daily; no batching
        - Review of Specimen Handling requirements to ensure specimens are not exposed to heat and humidity
            - Air dry on a flat surface for 3-4 hours.
            - Avoid exposure to direct sunlight or heat.
            - Ship specimens immediately in the UPS Next Day envelope.
            - By eliminating risks for heat and humidity, submitter will avoid the need for a specimen re-collection.
    - Shipment History and Tracking Capabilities
    - Instructions for re-ordering Window Envelopes
    - Any possible interruption of service such as UPS Holiday Modified Pickup Schedules and weather delays are posted on the message board on ICVS

PerkinElmer Genetics will provide every Nebraska Birth Hospital with UPS Next Day Air Service Monday through Friday. The UPS ICVS shipping module will automatically code all Friday labels for Saturday delivery.

Saturday Request Pickups ordered through the UPS ICVS system will be delivered to PerkinElmer Genetics on Monday.

All Nebraska Birth Hospital UPS shipments will be monitored daily by a PerkinElmer Genetics Client Services Representative (CSR) through UPS Quantum View. The CSR will notify the Nebraska Department of Health by e-mail and the collection site via telephone that their shipment is experiencing an "Exception" (i.e. weather delay, sorting error, damaged or lost) with delivery. If a package is determined to be lost, the CSR will have UPS place a tracer on the package, provide updates to the birth hospital as received. The birth facility will be advised to contact parents to have specimens redrawn as a precautionary measure in case the package is not found or destroyed in shipment.

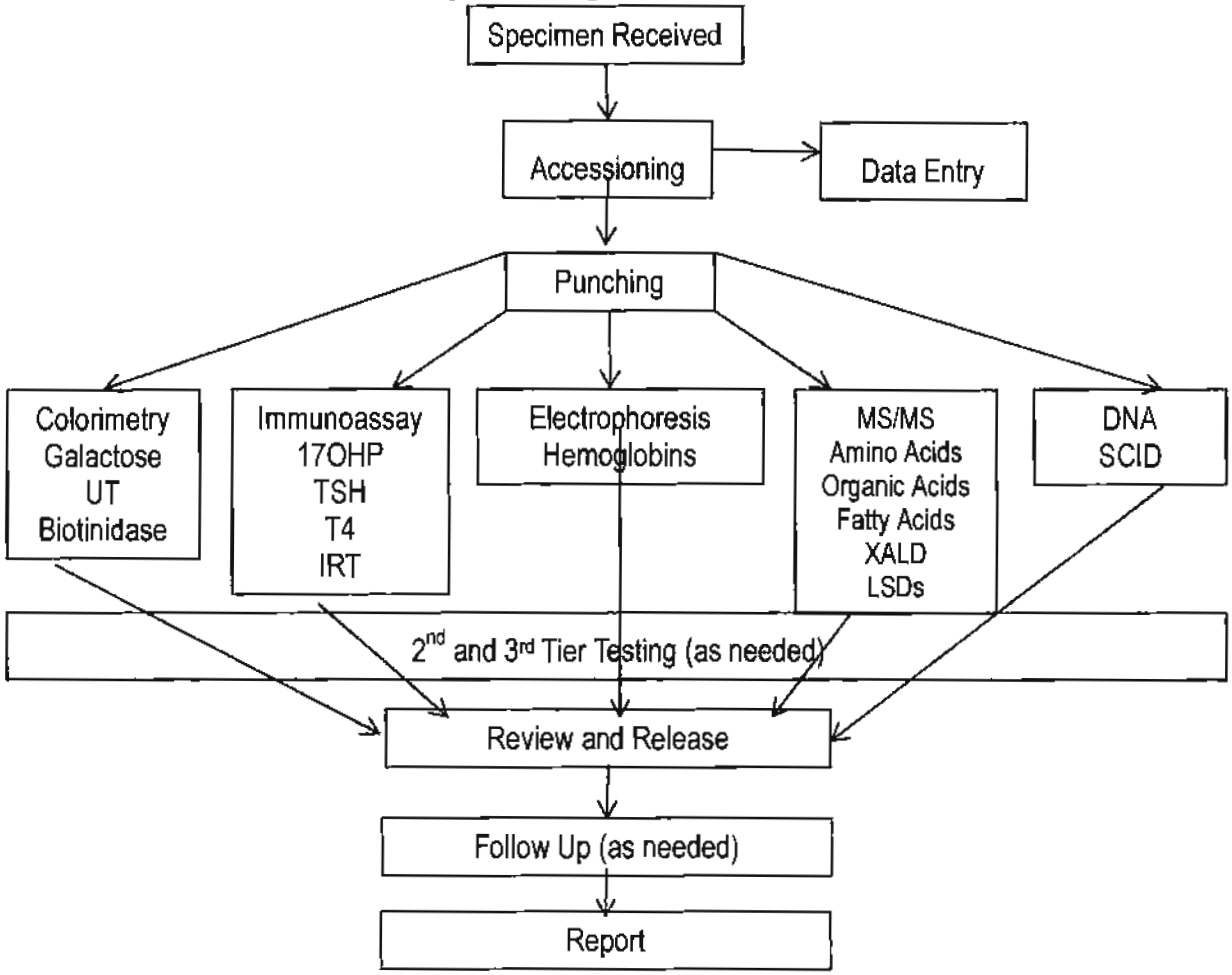
UPS issues or questions may be directed to PerkinElmer Genetics' Client Service Rep. at 1-866-463-6436 or via email to PerkinElmerGenetics.Information@perkinelmer.com.

3. **Accurate and timely laboratory testing and analysis;**

Overview of Laboratory Specimen Flow (General Example)

PerkinElmer Genetics

High Level Specimen Flow



Specimen Flow Detail

Specimens arrive typically between 9:00 - 10:00 AM via UPS, FedEx, DHL, and the US Mail. Envelopes are sorted by state and country. Each envelope is opened and the filter papers are consolidated. Accessions numbers, which run sequentially, are affixed to each specimen.

At this time the first quality assessment is made regarding the suitability of the specimen, it is inspected for obvious damage, sufficient quantity, and demographic information.

Beginning at approximately 10:00 AM, the specimens are "initialized" by assigning the accession number to the bar-coded identification number on the filter paper and then matching these numbers to the client. The initialization results in the ordering of the tests to be performed.

Beginning at approximately 10:30 AM, the specimens are delivered to the laboratory where the appropriate sample aliquot is taken for each test. This is done by a technologist who punches out a precise circle from the filter paper blood spot. This is the second assessment of the quality of the specimen for suitability of testing. The particular test to be performed is determined by the sorting done at the initialization of the specimen.

There are ten (10) punching stations in use. The manner in which the specimens are sorted describes the tests to be done. Each technologist is responsible for a testing station and will select and prepare the designated specimens for the tests ordered. The number of aliquots can range from one (1 punch) for a single repeat analysis to eight (8 punches) for a comprehensive screen. The technologist keeps track of the specimens on a punching log that follows the specimen through the laboratory.

Most tests are performed in micro titer trays that hold an array of 96 specimens in a twelve by eight pattern of wells (12 x 8). During the punching operation, calibrator and control specimens are included at predetermined positions. Each test requires specific reagents that are added in the appropriate sequence and at the appropriate time. The prepared micro titer trays are introduced to the proper analyzer.

The analyses are performed throughout the day with results being produced from the early afternoon to the next morning. All batches of analyses are reviewed for acceptance based upon clearly defined criteria of acceptance. This is the third assessment of the quality of the specimen for suitability of testing by comparing various analytes from the accession with expected results. By applying these criteria, it can be determined that a specimen may be unsuitable for testing due to interferences introduced through handling of the specimen.

If the quality control data for the analyte are acceptable, the results are assigned to the accession. A determination is then made as to whether:

- The results are released and the analysis finalized
- The specimen is analyzed again to verify the first results
- Additional analyses are performed (second tier or reflex testing)

The completed report is archived in the system computer, made available via internet, and printed and mailed to the client. In cases of critical results, the physician, submitter, and the Nebraska Department of Health are notified telephonically and the report is faxed to the client.

Filter paper cards are scanned for electronic image storage and then retained in a refrigerator until all analyses are done. Upon completion of analysis, specimens are transferred to long term storage under conditions specified by the client.

Quality Improvement and Assessment in Data Entry

Accessioning

Sorting - The majority of these specimens arrive via UPS. The envelopes are opened and the specimens are left in the envelopes until sorting is completed. When FedEx specimens arrive, those envelopes are sorted and placed into the corresponding groupings based on state. The specimens that include paperwork, High Risk patients, and Autopsies are given to a Specimen Processing technician and looked at on an individual basis. Postal delivery specimens also are sorted into the above state groupings. High Risk specimens from the mail are also given to a Specimen Processing technician to be examined on an individual basis.

Accessioning and Initialization - After sorting, placement, and examination, the accessioning and initialization process begins. Each specimen is examined for date of birth and whether it is a repeat. If the birth date is over 7 days or it is a repeat, the specimen is pulled and looked up in the Laboratory Information System for confirmation. These specimens are placed in the corresponding Priority section. As accessioning continues, an accession number (label) is placed on each individual specimen. These labels are in consecutive order.

Each specimen is initialized after the accessioning label is applied. The top copy is removed and given to the data entry department for demographic entry into the database. The lab copy with blood spots attached is scanned into the database to assign a filter paper, submitter, and filter paper type to each accessioned specimen. The specimens are then handed to the lab technician for punching.

Special Cases and Exceptions - There are many exceptions and special cases that arrive every day by either courier or postal mail. Each case is examined individually using the PerkinElmer Genetics system and assigned the appropriate tests. Following are the majority of these special circumstances:

- Requested Repeats - Repeats requested by PerkinElmer Genetics are marked RRP on the data entry copy and the requested tests are written on the lab copy of the filter paper itself for the technicians' reference. The previous accession number is also written on the data copy.
- Unrequested Repeats - Repeats NOT requested by PerkinElmer Genetics are marked URP on the data entry copy along with the accession number and the corresponding full panel is run on these specimens.
- 24HR Repeats - If the original specimen received was drawn at less than 24 hours of age, PerkinElmer Genetics requests a repeat. If a 24 HR repeat is received, it is marked 24RP on the data entry copy along with the accession number and the full panel is run.
- Specimens without blood applied - Specimens without blood applied to the filter paper received by Specimen Processing are marked UNACCEPTABLE NO BLOOD APPLIED and placed behind all other specimens for the day. These

specimens are put on the UNACCEPTABLE LIST that is then given to the lab supervisor.

Administrative Policies -

- Contracts - Contracts for each specimen are assigned during the Initialization process and are determined by Submitter, Screening Group, and Filter Paper type. If an error is made concerning a Contract issue, the error is given to a Specimen Processing technician and the corrections are made.
- Incorrect Ordering of Tests - Tests are assigned during the Initialization process according to Submitter, Screening Group, and Filter Paper type. If a specimen has incorrect tests assigned to it, the specimen is re-accessioned (labeled) and processed immediately for correction of tests ordered.
- Additional Tests - If a submitter requests additional testing, the request must be in writing. If specimen report is already released, it may be reaccessioned and processed for requested tests.
- Missing Demographics - Specimens received with missing demographics, including Date of Birth, are processed on date received without a delay. The Data Entry or Client Services Staff calls the submitter to obtain the missing information and the changes are made.
- PKU Monitoring - All PKU Monitors are marked PK on lab copy for technicians and PK on data entry copy and placed in PK stack for processing.

Intra-Laboratory Quality Assurance

Comparison of Methods

In order to assure precision and reliability of test results when utilizing different methodologies or analytical systems, it is necessary to run patient samples in parallel on all available methods or assay systems and compare the results.

Twice a year, three samples will be selected for each test for which multiple methodologies or assay systems exist. These samples will be tested in parallel (on the same day) utilizing the various methods and assay systems in the laboratory.

The results will be evaluated and clinical assessments made to classify the test results as "Within Normal Limits" or "Outside Normal Limits". All testing methods should be in agreement for clinical assessment for each sample. The results are recorded on the "Method Comparison Form", reviewed by the laboratory supervisor, signed, dated, and kept on file in the laboratory.

Any samples that do not match for clinical assessment will be brought to the attention of the laboratory director. The laboratory director will determine the appropriate course of action. Actions may include: testing of additional samples, re-calibration of one or more systems, adjusting cutoff levels for one or more systems or methods, contacting the kit or system manufacturer for assistance, or discontinuing use of one method or analytical system.

Validation of Cut-off Values

New methods and cut-off values will be validated by running a minimum of 500 specimens with known results. The data will be subjected to statistical treatment that may include such comparisons as:

- Student "t" test
- Linear regression
- 2 X 2 table analysis
- Xi Squared
- Standard deviation
- Distribution analyses such as:
    - Bar Graph
    - Kolmogorov-Smirnov test

The data will be evaluated by the laboratory director who will accept the new method or require further evaluation.

Values in current use were determined from the patient population screened by PerkinElmer Genetics. Currently, there are data for over 6 million patients in our system. When changes are necessary, clients are notified via letter and with notations on the report of any revision of cutoff values. Notification of such changes is made in close coordination with clients.

Verification of New Instrument

Before a new instrument is used to report patient results, the laboratory must verify that it will produce accurate results on a consistent and reliable basis. The laboratory verifies the accuracy, precision, and the reportable range for an existing method on the new instrument by:

- A comparison of instruments experiment to estimate inaccuracy or bias
- A replication experiment to estimate imprecision
- A linearity type experiment to estimate imprecision
- A linearity type experiment to determine the reportable range

Collection of patient values to verify the reference range or document that the manufacturer's ranges or textbook ranges are appropriate for the method being used.

For a previously established method, QC data and patient test performance data are adequate.

The following minimum number of runs and data points will be collected:

- Three (3) runs with at least 20 patients in each batch.
- At least three QC points for each QC level used will be included in each run.
- The three (3) runs can be done consecutively on the same day or over several days.

The data will be subjected to statistical analyses to evaluate the correlation coefficient and the coefficient of variation. The laboratory director will review and approve the use of the new instrument.

Verification of New Reagent Lot

In order to insure satisfactory and consistent test kit performance when changing from one lot number to another, it is necessary to run all assay control material in parallel between the current and new lot numbers. If the new kit lot contains a new lot of control samples, run the old and new controls in parallel on both lot numbers.

Additionally, retest at least two (2) patients whose values are approximately 15-20% above the cutoff for that assay with both lot numbers. These values should agree within 20% of each other and remain above the cutoff. If such patient samples are not available, it is documented that they could not be run and the new lot will be monitored carefully for at least the first week of use.

Assayed and external control samples must fall within ±2 SD of the mean value based upon the coefficient of variation established for the old lot number. New lot numbers of controls are initially evaluated according to the ranges provided with the kit. After 10 - 20 assays, the laboratory will calculate the acceptable range that will be used for the new controls.

Any problems with the new lot will be brought to the attention of the manufacturer for assistance or replacement of the test kits of the lot number in question.

Parallel testing is performed as soon as possible when a new lot number of kits is received in the lab and preferably, while there is still an adequate supply of the old lot number. Results are recorded on the "Lot Number Validation Form," signed by the laboratory supervisor, and kept on file in the laboratory.

Quality Assurance/Overview of Quality Management

PerkinElmer Genetics is committed to report accurate and precise results and achieves this with its Internal and External Quality Assurance Programs.

Internal Quality Control

The Laboratory Director establishes the reference ranges for each assay. This is accomplished through literature review, expert consultation, manufacturer consultation, and laboratory data comparison.

The Laboratory Director, Supervisors, Technologists, and Genetic Counselors monitor the Quality Assurance criteria as necessary. The Quality Assurance activities are discussed at periodic Quality Assurance meetings.

A case management list including unacceptable specimens and inconclusive and abnormal results is maintained in the laboratory computer system and is monitored by the Genetic Counselors and Client Services Staff. This list may be sorted in various ways. Utilizing this list, the Genetic Counselors and Client Services Staff contact the submitter, physician and Nebraska Department of Health to request a repeat specimen or further testing.

The Laboratory maintains ongoing collaboration with the Nebraska Department of Health for long term management of the disorders detected in the screening program.

PerkinElmer Genetics currently and plans to continue participating in External Quality Control programs variously referred to as Survey or Proficiency Testing programs. The samples are distributed by the Quality Control Manager and testing is performed by following the same procedures used for patient samples. No communication or collaboration with other laboratories regarding proficiency testing specimens is permitted.

The Newborn Screening Quality Assurance Program is provided by the Centers for Disease Control and Prevention (CDC). PerkinElmer Genetics also performs the CDC TRECs XALD and LSD surveys. Specimens are received on a quarterly basis for testing of Cystic Fibrosis, Hemoglobinopathies, Total Galactose, Galactose-1-Phosphate Uridyltransferase activity, Biotinidase activity, 17-alpha Hydroxyprogesterone, Thyroid Stimulating Hormone (TSH), Phenylalanine, Methionine, and Leucine. Results are due 4 weeks after receipt of the survey.

Assays, for which there are no external proficiency surveys, will be evaluated semiannually by repeating the analysis of a specimen. This may be done in conjunction with annual competency testing.

Any errors in proficiency testing results are documented on the report form and in the laboratory Quality Assurance records. Records of the results of investigation of the failure and corrective actions are maintained.

Evaluation of Quality Control Results - This laboratory primarily performs screening tests on specimens to identify which patients should be subjected to the scrutiny of more precise diagnostic procedures. The dried blood spot specimen has an inherent error due to the variability of the pre-analytical collection procedure, specimen preparation, specimen storage, and specimen transportation. The variability is further complicated by the physiological variation of the baby's hematocrit. Although many of the results produced by this laboratory are quantitative, they are viewed as qualitative in that the quantitative answer is converted to a "normal" or "abnormal" report result. A screening laboratory, therefore, uses quality control data slightly differently than a diagnostic

laboratory because a "normal" or "abnormal" answer is based upon the patient's value being either higher or lower than a single decision point or cutoff. Diagnostic tests require sufficient quality control specimens that cover the entire dynamic range of the assay.

All assays include quality control specimens that are run with each batch of specimens and are analyzed in the same manner as patient specimens. Individual laboratory procedures contain information on the quality control materials used for that procedure and guidelines for control performance and corrective actions.

All assays with satisfactory control results are reviewed by lead technologist or supervisor before release. The purpose of the review is to ensure that control values are acceptable, double check patient results for correct entry of results in the database, check the correct logging of samples into the re-test or secondary testing lists, and provide a general review of the assay for sources of error. Documentation of the review of the controls is written on the assay run sheet along with any action taken, the date, and initials of those reviewing and approving the assay.

All control values are always recorded. If there is a known reason for the failure of a control (e.g., a contaminated well, spilled reagents, etc.), then that control value is recorded but the value is deleted from the data base and is not used in any decision regarding the evaluation of the assay. The reason a control value is deleted from the data base is documented on the work sheet and exceptions log.

Controls for qualitative tests produce either a positive or a negative result. Failure to produce proper results requires review by the department director. Documentation of action taken is recorded in the quality control exceptions log.

Controls for quantitative results have established ranges, based upon statistical and historical data; the values are not necessarily a simple standard deviation calculation. The values used for the decision level ranges are defined as Accept, Watch, and Action. When the range is exceeded, it is noted on the work sheet and recorded in the Exceptions Log along with the decision made. In all cases, the director determines the ranges.

- Accept range - all patient results may be released without comment.
- Watch range - patient results may be released after a supervisor evaluates them in the light of the control value, the decision is documented in the exceptions log.
- Action range - control values and patient values must be evaluated by the department director. The action taken is recorded in the quality control exceptions log.

The following outlines a general decision tree regarding the acceptance or rejection of patient values based upon quality control values. Additional training is provided to the supervisors to assist them in recognizing significant information based upon the evaluation of the patient and quality control data.

Assays in which an abnormal result is an elevated value:

- QC at the decision point is high either at the Watch or Action level - all patients above the decision point are repeated and all patients' results below the decision point may be released because, upon repeat analysis, it is expected that all results will be lower. Therefore, values below the cutoff will be even lower than before. All patients above the cutoff are repeated.
- QC at the decision point is low at the Action level, since most assays have multi-level QC points - all patients that are equal to or below the acceptable QC value that is below the decision point may be released. The director, based upon experience with the assay, may release some patient results that are below the cutoff. All other patients are analyzed again.
- QC at the decision point is low at the Watch level, since most assays have multi-level QC points - all patients that are equal to or below the acceptable QC value that is below the decision point may be released. The supervisor, based upon experience with the assay, may release some patient results that are below the cutoff. All other patients are analyzed again.

Any QC poiuts at the Watch or Action level either high or low that are above or below the decision point have little or no impact on the assay. The director or supervisor, based upon experience, may release any or all of the patient values.

Assays in which an abnormal result is a low value:

- QC at the decision point is low either at the Watch or Action level - all patients below the decision point are repeated and all patients' results above the decision point may be released because, upon repeat analysis, it is expected that all results will be higher. Therefore, values above the cutoff will be even higher than before. All patients below the cutoff are repeated.
- QC at the decision point is high at the Action level, since most assays have multi-level QC points - all patients that are equal to or above the acceptable QC value that is above the decision point may be released. The director, based upon experience with the assay, may release some patient results that are above the cutoff. All other patients are analyzed again.
- QC at the decision point is high at the Watch level, since most assays have multi-level QC points - all patients that are equal to or above the acceptable QC value that is above the decision point may be released. The supervisor, based upon experience with the assay, may release some patient results that are above the cutoff. All other patients are analyzed again.

Any QC points at the Watch or Action level either high or low that are above or below the decision point have little or no impact on the assay. The director or supervisor, based upon experience, may release any or all of the patient values.

Standard Operating Procedures (SOP) - All analytical methods used will have a written SOP describing the manner in which the procedure is performed. The format will present a logical, clear, and concise narrative of the proper protocol to follow for the analysis. All sections must consult with laboratory director in the development and approval of SOPs.

When available, a copy of the original publication describing the method used is kept in the procedure manual. Current package inserts for each kit used will be maintained for reference; however, a written SOP is required.

SOPs shall be reviewed by the laboratory director at least biennially and when a new laboratory director is appointed

Quality Management Committee - The Quality Management Committee consists of a representative from: each of the technical sections of the laboratory; Genetic Counselors, Client Services; Specimen Processing; Information Technology; additional ad hoc members as needed. Meetings are held at least quarterly and all laboratory personnel are permitted to attend and speak. Quality Management Meeting Agenda will include but are not limited to the following items:

- Incident Reports
- Proficiency Surveys
- Turnaround Time
- Unacceptable Specimens
- Complaints
- Quality Monitors
- Inspections
- IT Backup Tapes
- Safety
- Ergonomics
- Old/New Business

Minutes of the meeting will include a summary of the points discussed and a list of members in attendance. A log of the meetings will be maintained.

Total Quality Management includes the regular evaluation of the client's perception of the laboratory. Client input is encouraged and when received is incorporated into the laboratory's operation. The Quality Management Committee will select key performance indicators to monitor. A baseline will be established and then a goal set for the improvement to be acceptable. The length of time to monitor an indicator and the achievement of the goal will be determined by the Quality Management Committee. The results of the monitoring will be maintained in the Quality Management Log.

Quality Management Policy

The purpose of this policy is "to monitor and evaluate the ongoing and overall quality of the total testing process" as required by CLIA 1988. The following areas are covered by this policy:

- Patient test management systems
- Erroneous Report Corrective Actions
- Calibration and Verification
- Quality control
- Audits
- Review of Quality Assessments
- Correlation of different systems or sites
- Relationship of patient information to test results
- Personnel qualifications
- Personnel training and evaluation
- Continuing Education
- Licensure and Accreditation
- Privacy (confidentiality)
- Communication
- Institution of new policies
- Complaint investigation
- Incident Management Investigation (Sentinel Event)

Patient Test Management Systems

Samples for newborn screening shall be collected, handled, and shipped as described in the "Implementation Protocol" provided to participating hospitals. Newborn screening samples should be obtained between 24 and 48 hours after birth. Blood spot samples for high-risk screening are obtained, handled, and shipped in the same way for infants, and obtained by finger stick for older patients. All samples must be appropriately labeled and accompanied by a written order that includes the patient's name and other relevant information. Specimens that do not conform to established guidelines shall be rejected and another sample requested. A log of rejected samples shall be kept.

Testing may only be performed upon the written request or electronic request of a person authorized by law to order the test. An oral request must be followed by a written request.

Each sample is given a unique identification (accession) number. Samples are stored in an appropriate manner, in numerical order. Result reports shall indicate both patient name and sample ID number.

When testing is requested that is not done in this laboratory, samples may be referred to another properly licensed and certified laboratory.

Erroneous Report Corrective Actions

If an erroneous report is sent to a submitter, a corrected or amended laboratory report is sent as soon as possible. The corrected report is clearly marked "Corrected Laboratory Report" and the previously reported value is included and the date of the correction. In the event that sequential corrections of a report are made, all previous reported information is listed (in sequential order) and all dates of correction are documented. The client will be called with the information regarding a corrected report before the new report is sent.

Calibration and Calibration Verification

Calibration is carried out according to the manufacturer's instructions regarding the method and equipment used. It is the process of running a calibrator as an "unknown" or patient sample to verify that the calibration is acceptable. Acceptable error is determined for each procedure. If the calibration verification specimen does not fall within the acceptable error, the failure is brought to the attention of the supervisor who will determine the course of action.

It should be noted that some calibrators cannot be used as an unknown; in this case, the calibration is verified with a consensus standard such as a proficiency survey or quality control specimen.

Quality Control

Appropriate controls for the assay shall be included with each run, or as determined for each procedure. The appropriate source material for the assay (e.g., whole blood spot, plasma, urine) shall be used as a control, when available. Control results shall be reviewed weekly by the general or section supervisor and at least monthly by the section supervisor (or designee) who will evaluate the data for trends and other potential problems.

Control samples must yield satisfactory values in order for the run to be accepted. Acceptability criteria for each test are described in the procedure manuals. If controls are out of the acceptable range, the scientist performing the test shall consider obvious sources of error, and correct any error found before repeating the assay. If no obvious source of error can be identified, the general supervisor, laboratory, or section director shall be notified as soon as possible.

When a control value is unacceptable, and the operator cannot correct the error, the general supervisor, laboratory, or section director will review all aspects of the assay to determine the source of the problem. After the most likely source of the difficulty is identified, it will be corrected and the run repeated. If the controls are still out of the acceptable range, the situation will be reexamined and altered until the problem is solved.

All instruments used in the laboratory will be calibrated and monitored appropriately for proper function and these actions shall be documented. All refrigerators, freezers, incubators, and water baths will be monitored every day of use for temperature and these records shall be reviewed monthly. All pH meters will be checked for calibration the day of use. Balances shall be checked annually. All other instruments will be monitored according to the manufacturer's instructions. All maintenance and repair work will be recorded and the documents will be kept in the laboratory. All service calls will be documented as to the problem encountered and action taken to resolve the problem. All such resolutions shall be tested and documented preferably with the service representative on the premises.

Audits

Monthly, one (1) patient record will be selected and examined for:

- Documentation
- Patient number and sample log-in
- Quality of results (QC check)
- Turnaround time for results.

The records examined shall be representative of all areas of the laboratory, e.g., newborn screening, high risk screening, diagnostic testing, postmortem screening, molecular testing, etc. and shall include both normal and abnormal results. If any substantial problems are uncovered, one (1) more record will be pulled from the appropriate area and examined in the same manner. If 2 or more instances of the same problem are encountered a plan for correction will be formulated and put into place.

Review of Quality Assurance Assessments with Staff

A quarterly Quality Management Meeting will be held to evaluate the overall operation of the laboratory including turnaround time, repeat requests, unacceptable specimens, failed runs, etc. Written documentation of these evaluations will be maintained in the laboratory. All quality assurance assessments will be reviewed with the laboratory staff in a timely manner.

Correlation of Test Results

In the case of more than one instrument being used to perform a particular assay, the instruments will be monitored and calibrated as necessary to ensure that results correlate between the instruments.

Relationship of Patient Information to Test Results

Results shall correlate with the clinical history of the patient. In cases where a clinical history is not available, the results shall be correlated with the patient's demographic information and the results of the re-analysis of the specimen or the results from a new a

new sample requested, as appropriate. Such cases will be handled by the Genetic Counselors or Laboratory Director who will contact the patient's physician for more information or assistance when necessary.

Personnel Qualifications

Testing performed at PerkinElmer Genetics, Inc. is in the high-complexity category. Personnel qualifications have been previously described in this document (see "Personnel Qualifications" in section entitled "Contractor Staffing, Capacity, and Administration").

Personnel training and evaluation

New employees will be given adequate training in the theory and practice of the testing performed in this laboratory under the direction of established employees and the section supervisor. The training process will be determined by the section supervisor.

Privacy (Confidentiality)

All information regarding patient names, clinical histories, test results, and other personal information, will be kept private. Only those physicians and other authorized persons directly involved with the case will be given results, unless requested in writing by the patient to do otherwise.

Any information regarding HIV testing results on any specimens sent to this laboratory will be kept private. This information will not be noted on result reports and will not be divulged to any outside parties under any circumstances.

Communication

Communication between the laboratory and its clients, patients, and other professionals is a critical part of the operation. Different types of communication will be handled by different staff members. Requests for information must be referred to the appropriate individual or department. It is imperative that any inquiry requiring data, such as the interpretation of results, methodology, and clarification of remarks, that cannot be found in PerkinElmer Genetics literature or the PerkinElmer Genetics web site be properly "triaged" in the following order to a doctoral level individual. The Laboratory Director will coordinate responses with other directors as follows:

- The Department Director
- The Clinical Consultant
- General information regarding sample requirements, turnaround time, billing, etc.: Client Service Representative, supervisors, laboratory or section director
- Taking of clinical history by phone: Genetic Counselors, laboratory director, section director

- Reporting of abnormal results to state coordinator, hospital coordinator, laboratory, or doctor: Genetic Counselors, supervisors, laboratory, or section director
- Reporting of normal results: Client Service Representatives, supervisors, section director, or laboratory director
- Genetic counseling: genetic counselor or laboratory director

Documentation of communication regarding a patient that requires follow-up must be recorded in that patient's record (electronic or written) at the time of contact and shall include:

- The date
- With whom the communication was made
- The name of the person making the call
- The nature of the communication

Samples that are insufficient in quantity (Quantity Not Sufficient - QNS) or unacceptable shall be brought to the attention of a supervisor as soon as possible. If necessary, the Client Service Department, will contact the submitter, physician, and the Nebraska Department of Health to request a new sample. A list of rejected specimens will be maintained.

Unusual test requests, requests for special handling, requests for special billing, etc. shall be brought to the attention of the general supervisor, section director, or laboratory director.

Any problems with any aspect of the laboratory operation shall be brought to the attention of the general supervisor, section director, or laboratory director.

Technical inquiries regarding the interpretation of results, methodology, and clarification of remarks will be forwarded to the Laboratory Director who will oversee, direct, collate, and provide the client with a response that has been prepared by the appropriate laboratory personnel. These responses will be made a matter of record.

Institution of New Policies

Any new policy instituted in the laboratory, or the organization as a whole shall be put in writing and a copy retained in the laboratory manual. The laboratory director must approve and sign all policies and SOPs. Copies of the new policy shall be distributed to all affected staff members.

Incident Management and Sentinel Events

An incident is not just an error, it is an occurrence, either random or systemic, which potentially or significantly causes injury to a patient or is a failure of a quality monitoring system in the laboratory. A sentinel event is one in which the result was death, serious physical or psychological injury occurred, or risk thereof (near miss).

Any of the above incidents that were caused by the failure of instrumentation will require evaluation and if appropriate will be reported as required by the FDA medical device reporting program. This will include the submission of FDA form 3500A within ten (10) working days from the time the failure was discovered.

All incidents will be brought to the attention of the Laboratory Director who will refer them to the Quality Management Committee for investigation. If it is determined that it is a sentinel event, the Laboratory Director will determine to which if any agencies the incident is reported and will cause any reports to be made.

The Quality Management Committee will prepare a written report of its findings to include:

- A chronology of the incident
- Determine the true cause of the incident
- Determination of patients affected
- List of healthcare providers to be notified of the incident
- A plan of action to include a schedule of events to prevent a recurrence of the same or similar incident
- Determine if it is a sentinel event in which the result was either serious physical or psychological injury occurred or risk thereof

The Laboratory Director will approve the committee's report and assign an individual to follow the course of action to completion. The responsible individual will report (in writing) the progress and final implementation of the plan to the Laboratory Director. The Quality Management Committee will review and follow up as necessary the documentation of the implemented plan.

4. **Accurate and timely communication of results;**

Results Reporting Overview

The goal of result reporting is to notify the physician of record/designated responsible parties of abnormal results as soon as the determination is made.

Average approximate turn-around-times:

Facility Shipment to Receipt < 1.5 days*
Lab Receipt to Report < 1.7 days
Birth to Report < 5.5 days*
*Facility must ensure proper collection and shipping practices are followed.

All released screening results can be accessed via the secure website (https://resultsportal.perkinelmergenetics.com) 24 hours a day. The web site is encrypted using the Secured Sockets Layer (SSL) protocol and is password protected in compliance with HIPAA standards.

For timeliness reasons, PerkinElmer Genetics promotes the use of the secure website for retrieval of all results. In addition, PerkinElmer Genetics will accommodate specific results delivery requests including fax or overnight delivery.

Written Notification - A written report of all abnormal laboratory findings will be sent to the hospital/physician of record and the department of health.

Results Reporting Procedure

The goal of result reporting is to notify the physician of record of all abnormal screening results as soon as the determination is made. All normal, unacceptable, and inadequate test results will be sent by mail to the submitter within 3 days of receipt of the specimen unless additional testing is required.

Reporting requirements - A roster of clients and designated contact persons is kept in the Laboratory Information System. All calls for repeat specimens, laboratory results, and any written or verbal communication related to testing results will be directed to the identified contact person or designee.

The submitter, physician and the NNSP will be notified by telephone of any unacceptable and inadequate specimen within 24 hours of receiving the specimen. Written reports of normal, unacceptable, and inadequate test results will be sent to the submitter no later than 24 hours following the day when the testing is completed.

Abnormal results fall into one of two categories:

- Abnormal findings requiring immediate physician notification - The Genetic Counselors will notify the physician of record, the Department of Health and submitter contact person immediately by phone and will document all attempted

and successful contacts with these individuals in the laboratory information system.

- Abnormal findings that require a repeat request - The Genetic Counselors will telephone the physician of record, Department of Health, and submitter contact person and request a repeat specimen for the patient in question.

Critical Value Notification – Abnormal test results that meet critical reporting criteria will be called to the physician of record, Department of Health, and submitter contact person. An example of a proposed result notification process is provided below. This approach is customized to meet the needs of the Nebraska Newborn Screening Program.

Points of Contact During PerkinElmer Genetics' Normal Business Hours/Days:

Client Services Department
Phone: +1 (412) 220-2300
Toll Free: +1 (866) 463-6436
Fax: +1 (412) 220-0784
Email: PerkinElmerGenetics.Information@PerkinElmer.com

Points of Contact For Other Than Normal Business Hours:

Genetic Counseling Department
Phone: +1 (412) 220-2300 (follow prompts to page an on-call genetic counselor)
Toll Free: +1 (866) 463-6436

Due to the importance of communicating these complex screening test results to care providers, PerkinElmer Genetics maintains a Genetic Counselors who hold Master's level credentials in Human Genetics / Genetic Counseling. These staff members are further trained by PerkinElmer Genetics to provide technical support to clients (physicians and outside follow-up staff) regarding testing methods, results interpretation and clinical significance of test outcomes. The Genetic Counselors are available routinely 24 hours a day, 7 days per week to our clients. If additional technical information is required, our Technical Staff are available for support.

For test results that are Inconclusive for testing, PerkinElmer Genetics' Genetic Counselors also call and fax to relay results and request that a repeat specimen be submitted. Unacceptable results are handled by the Client Services group.

In all cases of abnormal results, hard copy (by USPS) and electronic versions (via secured internet access) of the reports are also made available according to client specifications.

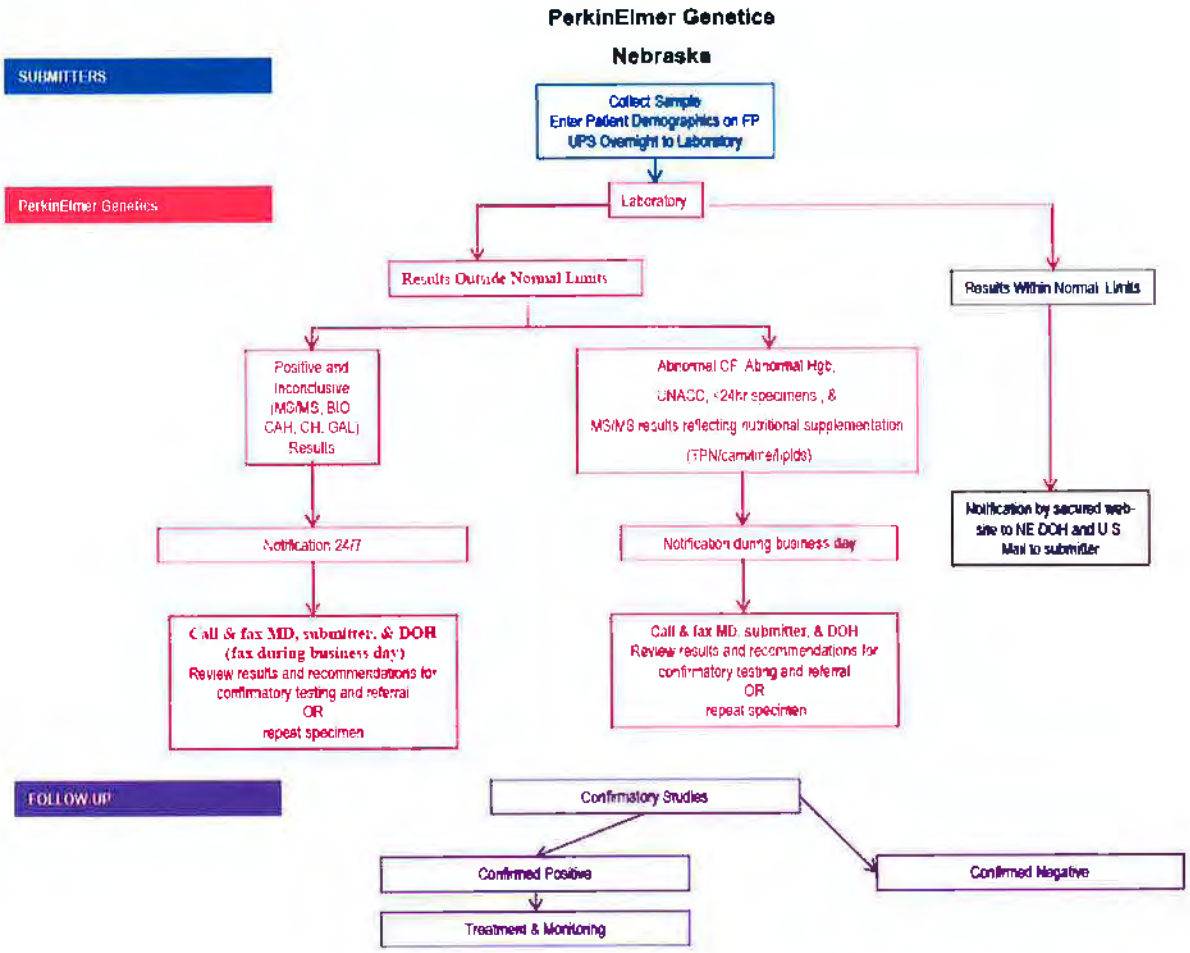
Result Reporting Format

Result reporting formats are routinely customized to meet the needs of the client. Appendix H shows an example of a current Nebraska Newborn Screening Program report. It is expected that the current report format will continue to be used but an alternate one can be created if desired.

After Hours Results Notification and Support

All PerkinElmer Genetics clients have a results notification flow process that allows for seamless integration of laboratory testing and follow-up. In some cases, after hours and holiday coverage for notification of health care providers of positive results is supported by PerkinElmer Genetics Genetic Counselors. In other cases, the Health Department will have someone on call for after-hours clinical notification. In either case, the Genetic Counselors will be available 24 hours a day, 7 days a week to provide contact to the indicated individuals.

The following represents a possible notification flow diagram process. It is anticipated that there will be further modifications to this process based on the needs of the Nebraska Newborn Screening Program related to the additions of Pompe, MPS-I and XALD.



Urgent results may include all disorders. Exception lists can be developed in conjunction with the Nebraska Newborn Screening Program. Some clients do not require after hours notification for select disorders based on clinical utility (e.g., Hemoglobinopathies, Congenital Hypothyroidism, and Biotinidase Deficiency have been excluded for certain clients).

Business hours will be established in conjunction with Nebraska Newborn Screening Program. After hours contact (including weekend and holidays) as well as disaster back-up (where Nebraska Newborn Screening Program Staff are unable to support short term follow-up) can be provided by PerkinElmer Genetics Genetic Counselors.

5. **Accurate, timely and comprehensive electronic reporting of data (demographic and test results, follow-up and quality assurance reports);**

PerkinElmer Genetics has collaborated with the Nebraska Newborn Screening Program to create a web based system that helps to manage the day to day activities of the department. The system has been in place for 14 years and continues to evolve to keep pace with the NNSP's needs.

The current system has the ability to capture all demographic information required on the NNSP collection and reporting form filter paper collection device and is entered into an electronic database the day the forms are received. The database system has unlimited availability during each 24 hour period for data transmission and data access, with the exception for routine technical maintenance of the database system. The electronic data system ensures standard SSL (Secure Sockets Layer) 128-bit encryption necessary for transmission of data.

Test result information is entered within 24 hours of completion of the tests. The system allows secure remote access for tracking of all Nebraska newborn's specimens. It is used by the NNSP to generate reports and letters.

Timely and accurate data entry is required to facilitate the NNSP follow-up component which will contact the primary care physician with recommendations on all abnormal screening results, unsatisfactory, drawn early, and post-transfusion specimens and which will maintain follow-up until adequate specimens are submitted, diagnosis is ruled out, or diagnosis of the infant is confirmed and the infant is in treatment or according to NNSP written procedures that the infant is determined lost to follow-up.

A computerized system is maintained and updated to allow remote access by or transmission to the NNSP to the database containing all the information from the Nebraska Newborn Screening Program Collection and Reporting form on Nebraska specimens including: the date and time each sample was collected, date each sample was received from the specimen submitter, the date the laboratory tests were completed; the date results of the laboratory analyses were reported to or made available for access by the NNSP; the status of laboratory analysis (e.g. in progress, completed, or not done and reason why), results and other actions. This system allows the NNSP to search for information, and report results of laboratory analysis on individual specimens to hospitals, and to the physician of record upon request. PerkinElmer Genetics provides reports of all test results to the submitter. When applicable, written reports to the submitter are in electronic format for incorporation into each hospital/submitter's electronic medical records. The electronic data system is HL7 compliant and capable of interfacing with hospital laboratory information systems or other health information exchanges in Nebraska to facilitate adoption of electronic medical records by providers. PerkinElmer Genetics has over 10 years of experience with HL7 messaging for newborn screening. Approximately 60,000 HL7 orders are received each year along with over 100,000 HL7 results being sent per year. Specifically in Nebraska, PerkinElmer Genetics has implemented HL7 messaging for over 60% of the samples

collected on Nebraska babies. PerkinElmer Genetics will continue to work with other facilities that desire an interface.

The data system currently has the ability to produce reports of tests missing, unsatisfactory specimens, drawn early, transfused specimens, Inconclusive cystic fibrosis, newborns with meconium ileus or other bowel obstruction, out of hospital births, presumptive positives and confirmed positives that are necessary for follow-up and tracking. The data system currently has the ability to produce reports of low T4s with low TSHs for information purposes only (not for required physician reporting). All reports listed in Appendix D of the RFP with the exception of the ones expected in 2018 are currently available in the data system used by the NNSP.

The data system currently can produce quality assurance reports necessary for monitoring of turnaround times, missing demographic information from the filter paper cards, statistical averages including mean, median, quarterly percentiles of all lab results producing a quantitative value, age at collection, and hospital QA reports comparing hospital numbers with State averages and percentiles of performance on multiple measures. The NNSP currently has the ability to access a database of scanned images of dried blood spot filter paper devices received at the laboratory. PerkinElmer Genetics currently performs daily monitoring using a UPS electronic tracking report to identify any specimen shipments not received by 4 days from shipment. The laboratory follows up with the submitter and if necessary the shipper, the day an exception is identified. Exceptions are reported to the NNSP program manager, and a weekly report is routinely submitted.

All initial, repeat and confirmatory test results are reported to the NNSP or made available electronically within 24 hours of test completion. A mechanism is available for the NNSP to enter/edit data or have data entered on confirmatory test results obtained from other laboratories or physicians/health care providers. Confirmatory tests used to aid in diagnosis may be done at various laboratories within and outside of Nebraska and may or may not be completed at the laboratory. When these are not done at the screening laboratory the NNSP follow-up program in the Department of Health and Human Services will track and monitor and has the capacity to enter these results into the Nebraska data.

The electronic data system currently has the capacity to produce template letters populated with patient and health care practitioner demographic information, and test results for all abnormal screen results, as well as second request letters and letters for specimens collected too early, unsatisfactory specimens, transfused specimens and any other results requiring follow-up.

6. **Collection and remittance of the per infant screened administrative fees to the State (Or amount specified in 181 NAC 2 Section 010 as promulgated);**

Current Billing Procedures

The billing procedures that are currently used by PerkinElmer Genetics for Nebraska samples is expected to be the same as described in the RFP. Below are details.

Samples screened in the laboratory are logged into the laboratory information system (LIS) as received and invoiced bi-monthly. The billing periods are based on samples received the 1st through the 15th and the 16th through the last day of the month. All services described in the RFP and the per infant screened administrative fee are covered by one description and one price on each invoice. Detailed billing files from the LIS are transferred to our billing system at the end of each billing period, and designated payers for each submitter are invoiced within 3-4 business days after each period ends. Each payer receives a summary invoice and a supporting detail list of each sample charged within the period. All invoicing and collections activities are performed from our Pittsburgh office. All invoices are Net 30 Days.

Repeat Samples' Billing

A) Samples received in the laboratory found to be repeat specimens are put into one of three categories within the Lab Information System:

1) Twenty-four Hour Repeat (24RP) – repeat sample required because first sample drawn within 24 hours of birth
2) Requested Repeat (RRP) – repeat sample requested by PerkinElmer Genetics
3) Unrequested Repeat (URP) – repeat sample NOT requested by PerkinElmer Genetics

Samples designated as Twenty-four Hour (24RP) and Requested Repeats (RRP) will be marked as "No Charge" in the Lab Information System and will not be charged to the designated payer.

Samples designated as Unrequested Repeats (URP) will be charged to the designated payer per usual fees.

B) All Nebraska samples are also reviewed at the end of each billing period prior to invoice creation. All samples are searched for a matching Newborn ID in the LIS and will not be charged if a previous sample is found for the same Newborn ID.

Administrative Fee Procedures

Two reports are run from the accounts receivable system at the end of each month: all Nebraska invoices from the previous month and all Nebraska payments received in the current month. For example, the reports showing October 2018 samples invoiced and November 2018 payments will be run at the end of November 2018 to calculate the administrative fee due December 15, 2018. A new report showing the detailed items of each invoice is created to calculate the fee due using the two reports mentioned above and any unpaid invoices from previous months. All unpaid invoices are listed and all payments received in the current month are applied to calculate the administrative fee. The fee is calculated by taking the number of samples paid in the period and multiplying that total by the per sample administrative fee. The report showing the calculation is sent along with the payment to the Nebraska Department of Health and Human Services before the 45-day deadline.

7. **Participation in quality assurance programs and reporting of quality assurance data;**

PerkinElmer Genetics currently and plans to continue participating in External Quality Control programs variously referred to as Survey or Proficiency Testing programs. The samples are distributed by the Quality Control Manager and testing is performed by following the same procedures used for patient samples. No communication or collaboration with other laboratories regarding proficiency testing specimens is permitted.

The Newborn Screening Quality Assurance Program is provided by the Centers for Disease Control and Prevention (CDC). PerkinElmer Genetics also performs the CDC TRECs, XALD and LSD surveys. Specimens are received on a quarterly basis for testing of Cystic Fibrosis, Hemoglobinopathies, Total Galactose, Galactose-1-Phosphate Uridyltransferase activity, Biotinidase activity, 17-alpha Hydroxyprogesterone, Thyroid Stimulating Hormone (TSH), Phenylalanine, Methionine, and Leucine. Results are due 4 weeks after receipt of the survey.

Assays, for which there are no external proficiency surveys, will be evaluated semiannually by repeating the analysis of a specimen. This may be done in conjunction with annual competency testing.

Any errors in proficiency testing results are documented on the report form and in the laboratory Quality Assurance records. Records of the results of investigation of the failure and corrective actions are maintained.

Copies of the report are currently provided to the NNSP and will continue if awarded the contract.

Below is a copy of the most recent certificate of participation issued for the CDC Quality Assurance Program. Additional certificates from other external proficiency testing programs can be found on the web at http://www.perkinelmer.com/genetics/about/lab-accreditations.html.


CERTIFICATE of PARTICIPATION 2016

Presented to

PerkinElmer Genetics, Inc.
Bridgeville, Pennsylvania

For participating in the
Newborn Screening Quality Assurance Program

Carla Cuthbert

Carla Cuthbert, PhD, FCCMG, FACMG
Chief, Newborn Screening and Molecular Biology Branch

National Center for Environmental Health
Division of Laboratory Sciences

CDC

8. **Back-up laboratory testing assurances in the event of an emergency, disaster or other hazard preventing testing at the contracted laboratory.**

PerkinElmer Genetics is committed to working with the NNSP to find a qualified laboratory that will assist in the event of an emergency, disaster or other hazard.

d. Detailed Project Work Plan

The work plan shall address how the bidder will collaborate with the NNSP to plan for July 1, 2018 implementation, of all contract project and technical requirements, the plan for sustaining compliance with all requirements, and the plan for implementing any proposed new conditions testing. The work plan will also describe how capacity to meet all contract requirements will be maintained in the event the bidder's specimen volume processed annually should increase by more than five percent (5%).

PerkinElmer Genetics will assign a project manager to ensure that all requirements are tracked and implemented on time. If necessary, routine conference calls will be scheduled to ensure the tasks are progressing as planned. Additionally, PerkinElmer Genetics will leverage its existing relationships with the NNSP and submitting facilities to ensure timely notification and implementation. With the exception of the new conditions, all other tasks are expected to continue without interruption. The tasks associated with the new condition implementation are described below in the grid.

A critical step will be the creation of the testing and follow up algorithms related to the new disorders of Pompe, MPS-I and XALD. PerkinElmer Genetics will work closely with the NNSP and Advisory Committee members to ensure this task is completed in a timely manner.

In parallel, PerkinElmer Genetics will begin working with the existing submitters who have an electronic interface established. The interfaces will have to be modified to incorporate the new disorders. PerkinElmer Genetics will use the experience gained with other established interfaces that have Pompe, MPS-I and XALD included.

As it has in the past, PerkinElmer Genetics will work closely with the NNSP to track progress of the new disorders post implementation. This will include collaborating with the Advisory Committee to review data and adjust algorithms if necessary.

PerkinElmer Genetics processes over 330,000 samples per year inclusive of Nebraska samples. It has the capacity to handle approximately 50% more with the current equipment. In addition, the laboratory will be relocating in 2018 to a larger facility that provides other expansion options.

e. Deliverables and Due Dates

Based on an estimated contract award date of March 26, 2018:

Deliverable	Responsible Party	Due Date
Contract Negotiations	PerkinElmer/NNSP	April 2, 2018
Create Algorithms for New Conditions	PerkinElmer/NNSP	April 20, 2018
Approval of New Algorithms	NNSP	April 27, 2017
Notify Submitters of New Conditions/Algorithms	PerkinElmer/NNSP	April 30, 2018
Software Modifications	PerkinElmer/NNSP	May 18, 2018
HL7 Interface Updates	PerkinElmer/Submitters	June 15, 2018
Go Live	All	July 1, 2018

Note: Some tasks will be addressed in parallel

Sections II through VI

II. TERMS AND CONDITIONS

Bidders should complete Sections II through VI as part of their proposal. Bidder is expected to read the Terms and Conditions and should initial either accept, reject, or reject and provide alternative language for each clause. The bidder should also provide an explanation of why the bidder rejected the clause or rejected the clause and provided alternate language. By signing the RFP, bidder is agreeing to be legally bound by all the accepted terms and conditions, and any proposed alternative terms and conditions submitted with the proposal. The State reserves the right to negotiate rejected or proposed alternative language. If the State and bidder fail to agree on the final Terms and Conditions, the State reserves the right to reject the proposal. The State of Nebraska is soliciting proposals in response to this RFP. The State of Nebraska reserves the right to reject proposals that attempt to substitute the bidder's commercial contracts and/or documents for this RFP.

The bidders should submit with their proposal any license, user agreement, service level agreement, or similar documents that the bidder wants incorporated in the Contract. The State will not consider incorporation of any document not submitted with the bidder's proposal as the document will not have been included in the evaluation process. These documents shall be subject to negotiation and will be incorporated as addendums if agreed to by the Parties.

If a conflict or ambiguity arises after the Addendum to Contract Award have been negotiated and agreed to, the Addendum to Contract Award shall be interpreted as follows:

1. If only one Party has a particular clause then that clause shall control;
2. If both Parties have a similar clause, but the clauses do not conflict, the clauses shall be read together;
3. If both Parties have a similar clause, but the clauses conflict, the State's clause shall control.

A. GENERAL

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:
D			

The contract resulting from this RFP shall incorporate the following documents:

1. Request for Proposal and Addenda;

2. Amendments to the RFP;
3. Questions and Answers;
4. Contractor's proposal (RFP and properly submitted documents);
5. The executed Contract and Addendum One to Contract, if applicable ; and,
6. Amendments/Addendums to the Contract.

These documents constitute the entirety of the contract.

Unless otherwise specifically stated in a future contract amendment, in case of any conflict between the incorporated documents, the documents shall govern in the following order of preference with number one (1) receiving preference over all other documents and with each lower numbered document having preference over any higher numbered document: 1) Amendment to the executed Contract with the most recent dated amendment having the highest priority, 2) executed Contract and any attached Addenda, 3) Amendments to RFP and any Questions and Answers, 4) the original RFP document and any Addenda, and 5) the Contractor's submitted Proposal.

Any ambiguity or conflict in the contract discovered after its execution, not otherwise addressed herein, shall be resolved in accordance with the rules of contract interpretation as established in the State of Nebraska.

B. NOTIFICATION

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Contractor and State shall identify the contract manager who shall serve as the point of contact for the executed contract.

Communications regarding the executed contract shall be in writing and shall be deemed to have been given if delivered personally or mailed, by U.S. Mail, postage prepaid, return receipt requested, to the parties at their respective addresses set forth below, or at such other addresses as may be specified in writing by either of the parties. All notices, requests, or communications shall be deemed effective upon personal delivery or three (3) calendar days following deposit in the mail.

Vendor Contract Manager	Julie Luedtke
Vendor	Department of Health and Human Services
Vendor Street Address	301 Centennial Mall South, PO Box 95026
Vendor City, State, Zip	Lincoln, NE 68508-5026

C. GOVERNING LAW (Statutory)

Notwithstanding any other provision of this contract, or any amendment or addendum(s) entered into contemporaneously or at a later time, the parties understand and agree that, (1) the State of Nebraska is a sovereign state and its authority to contract is therefore subject to limitation by the State's Constitution, statutes, common law, and regulation; (2) this contract will be interpreted and enforced under the laws of the State of Nebraska; (3) any action to enforce the provisions of this agreement must be brought in the State of Nebraska per state law; (4) the person signing this contract on behalf of the State of Nebraska does not have the authority to waive the State's sovereign immunity, statutes, common law, or regulations; (5) the indemnity, limitation of liability, remedy, and other similar provisions of the final contract, if any, are entered into subject to the State's Constitution, statutes, common law, regulations, and sovereign immunity; and, (6) all terms and conditions of the final contract, including but not limited to the clauses concerning third party use, licenses, warranties, limitations of liability, governing law and venue, usage verification, indemnity, liability, remedy or other similar provisions of the final contract are entered into specifically subject to the State's Constitution, statutes, common law, regulations, and sovereign immunity.

The Parties must comply with all applicable local, state and federal laws, ordinances, rules, orders, and regulations.

D. BEGINNING OF WORK

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The bidder shall not commence any billable work until a valid contract has been fully executed by the State and the successful Contractor. The Contractor will be notified in writing when work may begin.

E. CHANGE ORDERS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The State and the Contractor, upon the written agreement, may make changes to the contract within the general scope of the RFP. Changes may involve specifications, the quantity of work, or such other items as the State may find necessary, desirable or required by State Statute or Regulation. Corrections of any deliverable, service, or work required pursuant to the contract shall not be deemed a change. The Contractor may not claim forfeiture of the contract by reasons of such changes.

The Contractor shall prepare a written description of the work required due to the change and an itemized cost sheet for the change. Changes in work and the amount of compensation to be paid to the Contractor shall be determined in accordance with applicable unit prices if any, a pro-rated value, or through negotiations. The State shall not incur a price increase for changes that should have been included in the Contractor's proposal, were foreseeable, or result from difficulties with or failure of the Contractor's proposal or performance.

No change shall be implemented by the Contractor until approved by the State, and the Contract is amended to reflect the change and associated costs, if any. If

there is a dispute regarding the cost, but both parties agree that immediate implementation is necessary, the change may be implemented, and cost negotiations may continue with both Parties retaining all remedies under the contract and law.

F. NOTICE OF POTENTIAL CONTRACTOR BREACH

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:
			Delete the first sentence and replace with: "If Contractor knows that it has breached, or anticipates that it will breach the contract, the Contractor shall give written notice to the State as soon as practicable."

If Contractor breaches the contract or anticipates breaching the contract, the Contractor shall immediately give written notice to the State. The notice shall explain the breach or potential breach, a proposed cure, and may include a request for a waiver of the breach if so desired. The State may, in its discretion, temporarily or permanently waive the breach. By granting a waiver, the State does not forfeit any rights or remedies to which the State is entitled by law or equity, or pursuant to the provisions of the contract. Failure to give immediate notice, however, may be grounds for denial of any request for a waiver of a breach.

G. BREACH

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:
			Delete the last sentence of the section.

Either Party may terminate the contract, in whole or in part, if the other Party breaches its duty to perform its obligations under the contract in a timely and proper manner. Termination requires written notice of default and a thirty (30) calendar day (or longer at the non-breaching Party's discretion considering the gravity and nature of the default) cure period. Said notice shall be delivered by Certified Mail, Return Receipt Requested, or in person with proof of delivery. Allowing time to cure a failure or breach of contract does not waive the right to immediately terminate the contract for the same or different contract breach which may occur at a different time. In case of default of the Contractor, the State may contract the service from other sources and hold the Contractor responsible for any excess cost occasioned thereby.
The State's failure to make payment shall not be a breach, and the Contractor shall retain all available statutory remedies and protections.

H. NON-WAIVER OF BREACH

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The acceptance of late performance with or without objection or reservation by a Party shall not waive any rights of the Party nor constitute a waiver of the requirement of timely performance of any obligations remaining to be performed.

I. SEVERABILITY

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

If any term or condition of the contract is declared by a court of competent jurisdiction to be illegal or in conflict with any law, the validity of the remaining terms and conditions shall not be affected, and the rights and obligations of the parties shall be construed and enforced as if the contract did not contain the provision held to be invalid or illegal.

J. INDEMNIFICATION

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:
			a. In Section 1.: delete the phrase "personal injury, death, or property loss or damage" and replace it with "personal injury or death." b. In Section 2.: delete the phrase "trademark, or confidential information of any third party" and replace it with "trademark, or confidential information of any third party in connection with performance of the Contractor's obligations under this Contract."

1. **GENERAL**

The Contractor agrees to defend, indemnify, and hold harmless the State and its employees, volunteers, agents, and its elected and appointed officials ("the indemnified parties") from and against any and all third party claims, liens, demands, damages, liability, actions, causes of action, losses, judgments, costs, and expenses of every nature, including investigation costs and expenses, settlement costs, and attorney fees and expenses ("the claims"), sustained or asserted against the State for personal injury, death, or property loss or damage, arising out of, resulting from, or attributable to the willful misconduct, negligence, error, or omission of the Contractor, its employees, Subcontractors, consultants, representatives, and agents, resulting from this contract, except to the

extent such Contractor liability is attenuated by any action of the State which directly and proximately contributed to the claims.

2. **INTELLECTUAL PROPERTY**

The Contractor agrees it will, at its sole cost and expense, defend, indemnify, and hold harmless the indemnified parties from and against any and all claims, to the extent such claims arise out of, result from, or are attributable to, the actual or alleged infringement or misappropriation of any patent, copyright, trade secret, trademark, or confidential information of any third party by the Contractor or its employees, Subcontractors, consultants, representatives, and agents; provided, however, the State gives the Contractor prompt notice in writing of the claim. The Contractor may not settle any infringement claim that will affect the State's use of the Licensed Software without the State's prior written consent, which consent may be withheld for any reason.

If a judgment or settlement is obtained or reasonably anticipated against the State's use of any intellectual property for which the Contractor has indemnified the State, the Contractor shall, at the Contractor's sole cost and expense, promptly modify the item or items which were determined to be infringing, acquire a license or licenses on the State's behalf to provide the necessary rights to the State to eliminate the infringement, or provide the State with a non-infringing substitute that provides the State the same functionality. At the State's election, the actual or anticipated judgment may be treated as a breach of warranty by the Contractor, and the State may receive the remedies provided under this RFP.

3. **PERSONNEL**

The Contractor shall, at its expense, indemnify and hold harmless the indemnified parties from and against any claim with respect to withholding taxes, worker's compensation, employee benefits, or any other claim, demand, liability, damage, or loss of any nature relating to any of the personnel, including subcontractor's and their employees, provided by the Contractor.

4. **SELF-INSURANCE**

The State of Nebraska is self-insured for any loss and purchases excess insurance coverage pursuant to Neb. Rev. Stat. § 81-8,239.01 (Reissue 2008). If there is a presumed loss under the provisions of this agreement, Contractor may file a claim with the Office of Risk Management pursuant to Neb. Rev. Stat. §§ 81-8,829 – 81-8,306 for review by the State Claims Board. The State retains all rights and immunities under the State Miscellaneous (Section 81-8,294), Tort (Section 81-8,209), and Contract Claim Acts (Section 81-8,302), as outlined in Neb. Rev. Stat. § 81-8,209 et seq. and under any other provisions of law and accepts liability under this agreement to the extent provided by law.

5. The Parties acknowledge that Attorney General for the State of Nebraska is required by statute to represent the legal interests of the State, and that any provision of this indemnity clause is subject to the statutory authority of the Attorney General.

K. ATTORNEY'S FEES

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:
			Clarifying language: In the event of any litigation, appeal, or other legal action to enforce any provision of the contract, the Parties agree to pay all of their own expenses of such action.

In the event of any litigation, appeal, or other legal action to enforce any provision of the contract, the Parties agree to pay all expenses of such action, as permitted by law and if order by the court, including attorney's fees and costs, if the other Party prevails.

L. PERFORMANCE BOND

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor will be required to supply a bond executed by a corporation authorized to contract surety in the State of Nebraska, payable to the State of Nebraska, which shall be valid for the life of the contract to include any renewal and/or extension periods. The amount of the bond must be $100,000.00. The bond will guarantee that the Contractor will faithfully perform all requirements, terms and conditions of the contract. Failure to comply shall be grounds for forfeiture of the bond as liquidated damages. Amount of forfeiture will be determined by the agency based on loss to the State. The bond will be returned when the service has been satisfactorily completed as solely determined by the State, after termination or expiration of the contract.

M. ASSIGNMENT, SALE, OR MERGER

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Either Party may assign the contract upon mutual written agreement of the other Party. Such agreement shall not be unreasonably withheld.

The Contractor retains the right to enter into a sale, merger, acquisition, internal reorganization, or similar transaction involving Contractor's business. Contractor agrees to cooperate with the State in executing amendments to the contract to allow for the transaction. If a third party or entity is involved in the transaction, the Contractor will remain responsible for performance of the contract until such time as the person or entity involved in the transaction agrees in writing to be contractually bound by this contract and perform all obligations of the contract.

N. CONTRACTING WITH OTHER NEBRASKA POLITICAL SUB-DIVISIONS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor may, but shall not be required to, allow agencies, as defined in Neb. Rev. Stat. §81-145, to use this contract. The terms and conditions, including price, of the contract may not be amended. The State shall not be contractually obligated or liable for any contract entered into pursuant to this clause. A listing of Nebraska political subdivisions may be found at the website of the Nebraska Auditor of Public Accounts.

O. FORCE MAJEURE

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:
			Delete the second sentence and replace with: "The Party so affected shall, as soon as practicable, make a written request for relief to the other Party, and shall have the burden of proof to justify the request."

Neither Party shall be liable for any costs or damages, or for default resulting from its inability to perform any of its obligations under the contract due to a natural or manmade event outside the control and not the fault of the affected Party ("Force Majeure Event"). The Party so affected shall immediately make a written request for relief to the other Party, and shall have the burden of proof to justify the request. The other Party may grant the relief requested; relief may not be unreasonably withheld. Labor disputes with the impacted Party's own employees will not be considered a Force Majeure Event.

P. CONFIDENTIALITY

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:
			Delete the last sentence of the first paragraph and replace with: "Should said confidentiality be breached by a Party, the Party shall notify the other Party as soon as practicable after becoming aware of said breach and take immediate corrective action."

All materials and information provided by the Parties or acquired by a Party on behalf of the other Party shall be regarded as confidential information. All materials and information provided or acquired shall be handled in accordance with federal and state law, and ethical standards. Should said confidentiality be breached by a Party, the Party shall notify the other Party immediately of said breach and take immediate corrective action.

It is incumbent upon the Parties to inform their officers and employees of the penalties for improper disclosure imposed by the Privacy Act of 1974, 5 U.S.C. 552a. Specifically, 5 U.S.C. 552a (i)(1), which is made applicable by 5 U.S.C. 552a (m)(1), provides that any officer or employee, who by virtue of his/her employment or official position has possession of or access to agency records which contain individually identifiable information, the disclosure of which is prohibited by the Privacy Act or regulations established thereunder, and who

knowing that disclosure of the specific material is prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000.

Q. OFFICE OF PUBLIC COUNSEL (Statutory)

If it provides, under the terms of this contract and on behalf of the State of Nebraska, health and human services to individuals; service delivery; service coordination; or case management, Contractor shall submit to the jurisdiction of the Office of Public Counsel, pursuant to Neb. Rev. Stat. §§ 81-8,240 et seq. This section shall survive the termination of this contract.

R. EARLY TERMINATION

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contract may be terminated as follows:

1. The State and the Contractor, by mutual written agreement, may terminate the contract at any time.
2. The State, in its sole discretion, may terminate the contract for any reason upon thirty (30) calendar day's written notice to the Contractor. Such termination shall not relieve the Contractor of warranty or other service obligations incurred under the terms of the contract. In the event of termination the Contractor shall be entitled to payment, determined on a pro rata basis, for products or services satisfactorily performed or provided.
3. The State may terminate the contract immediately for the following reasons:
   - **a.** if directed to do so by statute;
   - **b.** Contractor has made an assignment for the benefit of creditors, has admitted in writing its inability to pay debts as they mature, or has ceased operating in the normal course of business;
   - **c.** a trustee or receiver of the Contractor or of any substantial part of the Contractor's assets has been appointed by a court;
   - **d.** fraud, misappropriation, embezzlement, malfeasance, misfeasance, or illegal conduct pertaining to performance under the contract by its Contractor, its employees, officers, directors, or shareholders;
   - **e.** an involuntary proceeding has been commenced by any Party against the Contractor under any one of the chapters of Title 11 of the United States Code and (i) the proceeding has been pending for at least sixty (60) calendar days; or (ii) the Contractor has

consented, either expressly or by operation of law, to the entry of an order for relief; or (iii) the Contractor has been decreed or adjudged a debtor;

f. a voluntary petition bas been filed by the Contractor under any of the chapters of Title 11 of the United States Code;

g. Contractor intentionally discloses confidential information;

h. Contractor has or announces it will discontinue support of the deliverable; and,

i. In the event funding is no longer available.

S. CONTRACT CLOSEOUT

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:
			In Section 4: Delete the section and replace with: "Reasonably cooperate with any successor Contactor, person or entity in the assumption of any or all of the obligations of this contract, at the sole expense of such successor Contactor, person or entity." In Section 5: Delete the section and replace with: "Reasonably cooperate with any successor Contactor, person or entity with the transfer of information or data related to this contract, at the sole expense of such successor Contactor, person or entity."

Upon contract closeout for any reason the Contractor shall within 30 days, unless stated otherwise herein:

1. Transfer all completed or partially completed deliverables to the State;
2. Transfer ownership and title to all completed or partially completed deliverables to the State;
3. Return to the State all information and data, unless the Contractor is permitted to keep the information or data by contract or rule of law. Contractor may retain one copy of any information or data as required to comply with applicable work product documentation standards or as are automatically retained in the course of Contractor's routine back up procedures;
4. Cooperate with any successor Contactor, person or entity in the assumption of any or all of the obligations of this contract;
5. Cooperate with any successor Contactor, person or entity with the transfer of information or data related to this contract;
6. Return or vacate any state owned real or personal property; and,
7. Return all data in a mutually acceptable format and manner.

Nothing in this Section should be construed to require the Contractor to surrender intellectual property, real or personal property, or information or data owned by the Contractor for which the State has no legal claim.

III. CONTRACTOR DUTIES

A. INDEPENDENT CONTRACTOR / OBLIGATIONS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:
			The State reserves the right to ~~require~~ request that the Contractor ~~to~~ reassign or remove from the project any Contractor or subcontractor employee. delete the word "insure" and replace with "ensure."

It is agreed that the Contractor is an independent contractor and that nothing contained herein is intended or should be construed as creating or establishing a relationship of employment, agency, or a partnership.

The Contractor is solely responsible for fulfilling the contract. The Contractor or the Contractor's representative shall be the sole point of contact regarding all contractual matters.

The Contractor shall secure, at its own expense, all personnel required to perform the services under the contract. The personnel the Contractor uses to fulfill the contract shall have no contractual or other legal relationship with the State; they shall not be considered employees of the State and shall not be entitled to any compensation, rights or benefits from the State, including but not limited to, tenure rights, medical and hospital care, sick and vacation leave, severance pay, or retirement benefits.

By-name personnel commitments made in the Contractor's proposal shall not be changed without the prior written approval of the State. Replacement of these personnel, if approved by the State, shall be with personnel of equal or greater ability and qualifications.

All personnel assigned by the Contractor to the contract shall be employees of the Contractor or a subcontractor, and shall be fully qualified to perform the work required herein. Personnel employed by the Contractor or a subcontractor to fulfill the terms of the contract shall remain under the sole direction and control of the Contractor or the subcontractor respectively.

With respect to its employees, the Contractor agrees to be solely responsible for the following:

1. Any and all pay, benefits, and employment taxes and/or other payroll withholding;
2. Any and all vehicles used by the Contractor's employees, including all insurance required by state law;
3. Damages incurred by Contractor's employees within the scope of their duties under the contract;
4. Maintaining Workers' Compensation and health insurance that complies with state and federal law and submitting any reports on such insurance to the extent required by governing law; and
5. Determining the hours to be worked and the duties to be performed by the Contractor's employees.
6. All claims on behalf of any person arising out of employment or alleged employment (including without limit claims of discrimination alleged against the Contractor, its officers, agents, or subcontractors or subcontractor's employees)

If the Contractor intends to utilize any subcontractor, the subcontractor's level of effort, tasks, and time allocation should be clearly defined in the bidder's proposal. The Contractor shall agree that it will not utilize any subcontractors not specifically included in its proposal in the performance of the contract without the prior written authorization of the State.

The State reserves the right to require the Contractor to reassign or remove from the project any Contractor or subcontractor employee.

Contractor shall insure that the terms and conditions contained in any contract with a subcontractor does not conflict with the terms and conditions of this contract.

The Contractor shall include a similar provision, for the protection of the State, in the contract with any Subcontractor engaged to perform work on this contract.

B. EMPLOYEE WORK ELIGIBILITY STATUS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor is required and hereby agrees to use a federal immigration verification system to determine the work eligibility status of employees physically performing services within the State of Nebraska. A federal immigration verification system means the electronic verification of the work authorization program authorized by the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, 8 U.S.C. 1324a, known as the E-Verify Program, or an equivalent federal program designated by the United States Department of Homeland Security or other federal agency authorized to verify the work eligibility status of an employee.

If the Contractor is an individual or sole proprietorship, the following applies:

1. The Contractor must complete the United States Citizenship Attestation Form, available on the Department of Administrative Services website at http://das.nebraska.gov/materiel/purchasing.html

   The completed United States Attestation Form should be submitted with the RFP response.

2. If the Contractor indicates on such attestation form that he or she is a qualified alien, the Contractor agrees to provide the US Citizenship and Immigration Services documentation required to verify the Contractor's lawful presence in the United States using the Systematic Alien Verification for Entitlements (SAVE) Program.

3. The Contractor understands and agrees that lawful presence in the United States is required and the Contractor may be disqualified or the contract terminated if such lawful presence cannot be verified as required by Neb. Rev. Stat. §4-108.

C. COMPLIANCE WITH CIVIL RIGHTS LAWS AND EQUAL OPPORTUNITY EMPLOYMENT / NONDISCRIMINATION (Statutory)

The Contractor shall comply with all applicable local, state, and federal statutes and regulations regarding civil rights laws and equal opportunity employment. The Nebraska Fair Employment Practice Act prohibits Contractors of the State of Nebraska, and their Subcontractors, from discriminating against any employee or

applicant for employment, with respect to hire, tenure, terms, conditions, compensation, or privileges of employment because of race, color, religion, sex, disability, marital status, or national origin (Neb. Rev. Stat. §48-1101 to 48-1125). The Contractor guarantees compliance with the Nebraska Fair Employment Practice Act, and breach of this provision shall be regarded as a material breach of contract. The Contractor shall insert a similar provision in all Subcontracts for services to be covered by any contract resulting from this RFP.

D. COOPERATION WITH OTHER CONTRACTORS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Contractor may be required to work with or in close proximity to other contractors or individuals that may be working on same or different projects. The Contractor shall agree to cooperate with such other contractors or individuals, and shall not commit or permit any act which may interfere with the performance of work by any other contractor or individual. Contractor is not required to compromise Contractor's intellectual property or proprietary information unless expressly required to do so by this contract.

E. PERMITS, REGULATIONS, LAWS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contract price shall include the cost of all royalties, licenses, permits, and approvals, whether arising from patents, trademarks, copyrights or otherwise, that are in any way involved in the contract. The Contractor shall obtain and pay for all royalties, licenses, and permits, and approvals necessary for the execution of the contract. The Contractor must guarantee that it has the full legal right to the materials, supplies, equipment, software, and other items used to execute this contract.

F. OWNERSHIP OF INFORMATION AND DATA / DELIVERABLES

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The State shall have the unlimited right to publish, duplicate, use, and disclose all information and data developed or obtained by the Contractor on behalf of the State pursuant to this contract.

The State shall own and hold exclusive title to any deliverable developed as a result of this contract. Contractor shall have no ownership interest or title, and shall not patent, license, or copyright, duplicate, transfer, sell, or exchange, the design, specifications, concept, or deliverable.

G. INSURANCE REQUIREMENTS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:
			Add the following sentence to Section 2: "Notwithstanding anything else in this Section, contractor may self-insure for Cyber Liability in lieu of obtaining insurance otherwise required under this Section."

The Contractor shall throughout the term of the contract maintain insurance as specified herein and provide the State a current Certificate of Insurance/Acord Form (COI) verifying the coverage. The Contractor shall not commence work on the contract until the insurance is in place. If Contractor subcontracts any portion of the Contract the Contractor must, throughout the term of the contract, either:

1. Provide equivalent insurance for each subcontractor and provide a COI verifying the coverage for the subcontractor;
2. Require each subcontractor to have equivalent insurance and provide written notice to the State that the Contractor has verified that each subcontractor has the required coverage; or,
3. Provide the State with copies of each subcontractor's Certificate of Insurance evidencing the required coverage.

The Contractor shall not allow any Subcontractor to commence work until the Subcontractor has equivalent insurance. The failure of the State to require a COI, or the failure of the Contractor to provide a COI or require subcontractor

insurance shall not limit, relieve, or decrease the liability of the Contractor hereunder.

In the event that any policy written on a claims-made basis terminates or is canceled during the term of the contract or within one (1) years of termination or expiration of the contract, the contractor shall obtain an extended discovery or reporting period, or a new insurance policy, providing coverage required by this contract for the term of the contract and one (1) years following termination or expiration of the contract.

If by the terms of any insurance a mandatory deductible is required, or if the Contractor elects to increase the mandatory deductible amount, the Contractor shall be responsible for payment of the amount of the deductible in the event of a paid claim.

Notwithstanding any other clause in this Contract, the State may recover up to the liability limits of the insurance policies required herein.

1. **WORKERS' COMPENSATION INSURANCE**
   The Contractor shall take out and maintain during the life of this contract the statutory Workers' Compensation and Employer's Liability Insurance for all of the contactors' employees to be engaged in work on the project under this contract and, in case any such work is sublet, the Contractor shall require the Subcontractor similarly to provide Worker's Compensation and Employer's Liability Insurance for all of the Subcontractor's employees to be engaged in such work. This policy shall be written to meet the statutory requirements for the state in which the work is to be performed, including Occupational Disease. **The policy shall include a waiver of subrogation in favor of the State. The COI shall contain the mandatory COI subrogation waiver language found hereinafter**. The amounts of such insurance shall not be less than the limits stated hereinafter. For employees working in the State of Nebraska, the policy must be written by an entity authorized by the State of Nebraska Department of Insurance to write Workers' Compensation and Employer's Liability Insurance for Nebraska employees.

2. **COMMERCIAL GENERAL LIABILITY INSURANCE AND COMMERCIAL AUTOMOBILE LIABILITY INSURANCE**
   The Contractor shall take out and maintain during the life of this contract such Commercial General Liability Insurance and Commercial Automobile Liability Insurance as shall protect Contractor and any Subcontractor performing work covered by this contract from claims for damages for bodily injury, including death, as well as from claims for property damage, which may arise from operations under this contract, whether such operation be by the Contractor or by any Subcontractor or by anyone directly or indirectly employed by either of them, and the amounts of such insurance shall not be less than limits stated hereinafter.

The Commercial General Liability Insurance shall be written on an **occurrence basis**, and provide Premises/Operations, Products/Completed Operations, Independent Contractors, Personal Injury, and Contractual Liability coverage. **The policy shall include the State, and others as required by the contract documents, as Additional Insured(s). This policy shall be primary, and any insurance or self-insurance carried by the State shall be considered secondary and non-contributory. The COI shall contain the mandatory CO1 liability waiver language found hereinafter.** The Commercial Automobile Liability Insurance shall be written to cover all Owned, Non-owned, and Hired vehicles.

REQUIRED INSURANCE COVERAGE (The contractor shall obtain and maintain during the life of this contract Medical Malpractice and verify that medical providers shall, at the time of award, be qualified and shall, for the duration of the contract, remain qualified under the Nebraska Hospital-Medical Liability Act. By submitting a proposal, bidders certify that they are so qualified. Such qualification will be confirmed with the Nebraska Department of Insurance. Any disqualification from the fund may result in disqualification of the bidder or immediate termination of an awarded contract.)

COMMERCIAL GENERAL LIABILITY	
General Aggregate	$2,000,000
Products/Completed Operations Aggregate	$2,000,000
Personal/Advertising Injury	$1,000,000 per occurrence
Bodily Injury/Property Damage	$1,000,000 per occurrence
Medical Payments	$10,000 any one person
Damage to Rented Premises (Fire)	$300,000 each occurrence
Contractual	Included
Independent Contractors	Included
If higher limits are required, the Umbrella/Excess Liability limits are allowed to satisfy the higher limit.	
WORKER'S COMPENSATION	
Employers Liability Limits	$500K/$500K/$500K
Statutory Limits- All States	Statutory - State of Nebraska
Voluntary Compensation	Statutory
COMMERCIAL AUTOMOBILE LIABILITY	
Bodily Injury/Property Damage	$1,000,000 combined single limit
Include All Owned, Hired & Non-Owned Automobile liability	Included
Motor Carrier Act Endorsement	Where Applicable
UMBRELLA/EXCESS LIABILITY	
Over Primary Insurance	$5,000,000 per occurrence
PROFESSIONAL LIABILITY	
Professional liability (Medical Malpractice)	Limits consistent with Nebraska Medical Malpractice Cap
Qualification Under Nebraska Excess Fund	
CYBER LIABILITY	
Breach of Privacy, Security Breach, Denial of Service, Remediation, Fines and Penalties	$3,000,000
MANDATORY COI SUBROGATION WAIVER LANGUAGE	
"Workers' Compensation policy shall include a waiver of subrogation in favor of the State of Nebraska."	
MANDATORY COI LIABILITY WAIVER LANGUAGE	
"Commercial General Liability & Commercial Automobile Liability policies shall name the State of Nebraska as an Additional Insured and the policies shall be primary and any insurance or self-insurance carried by the State shall be considered secondary and non-contributory as additionally insured."	

If the mandatory COI subrogation waiver language or mandatory COI liability waiver language on the COI states that the waiver is subject to, condition upon, or otherwise limit by the insurance policy, a copy of the relevant sections of the policy must be submitted with the COI so the State can review the limitations imposed by the insurance policy.

3. **EVIDENCE OF COVERAGE**

The Contractor shall furnish the Contract Manager, with a certificate of insurance coverage complying with the above requirements prior to beginning work at:

Newborn Screening Program Manager
Nebraska Department of Health and Human Services
Attn: Julie Luedtke
301 Centennial Mall South, PO Box 95026
Lincoln, NE 68508-5026

These certificates or the cover sheet shall reference the RFP number, and the certificates shall include the name of the company, policy numbers, effective dates, dates of expiration, and amounts and types of coverage afforded. If the State is damaged by the failure of the Contractor to maintain such insurance, then the Contractor shall be responsible for all reasonable costs properly attributable thereto.

Reasonable notice of cancellation of any required insurance policy must be submitted to the contract manager as listed above when issued and a new coverage binder shall be submitted immediately to ensure no break in coverage.

4. **DEVIATIONS**

The insurance requirements are subject to limited negotiation. Negotiation typically includes, but is not necessarily limited to, the correct type of coverage, necessity for Workers' Compensation, and the type of automobile coverage carried by the Contractor.

H. ANTITRUST

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor hereby assigns to the State any and all claims for overcharges as to goods and/or services provided in connection with this contract resulting from antitrust violations which arise under antitrust laws of the United States and the antitrust laws of the State.

I. CONFLICT OF INTEREST

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

By submitting a proposal, bidder certifies that there does not now exist a relationship between the bidder and any person or entity which is or gives the appearance of a conflict of interest related to this RFP or project.

The bidder certifies that it shall not take any action or acquire any interest, either directly or indirectly, which will conflict in any manner or degree with the performance of its services hereunder or which creates an actual or an appearance of conflict of interest.

The bidder certifies that it will not knowingly employ any individual known by bidder to have a conflict of interest.

The Parties shall not knowingly, for a period of two years after execution of the contract, recruit or employ any employee or agent of the other Party who has worked on the RFP or project, or who had any influence on decisions affecting the RFP or project.

J. ADVERTISING

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor agrees not to refer to the contract award in advertising in such a manner as to state or imply that the company or its services are endorsed or preferred by the State. Any publicity releases pertaining to the project shall not be issued without prior written approval from the State.

K. NEBRASKA TECHNOLOGY ACCESS STANDARDS (Statutory)

Contractor shall review the Nebraska Technology Access Standards, found at http://nitc.nebraska.gov/standards/2-201.html and ensure that products and/or services provided under the contract are in compliance or will comply with the applicable standards to the greatest degree possible. In the event such standards change during the Contractor's performance, the State may create an amendment to the contract to request the contract comply with the changed standard at a cost mutually acceptable to the parties.

L. DISASTER RECOVERY/BACK UP PLAN

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor shall have a disaster recovery and back-up plan, of which a copy should be provided upon request to the State, which includes, but is not limited to equipment, personnel, facilities, and transportation, in order to continue services as specified under the specifications in the contract in the event of a disaster.

M. DRUG POLICY

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Contractor certifies it maintains a drug free work place environment to ensure worker safety and workplace integrity. Contractor agrees to provide a copy of its drug free workplace policy at any time upon request by the State.

IV.PAYMENT

A. INSPECTION AND APPROVAL

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Final inspection and approval of all work required under the contract shall be performed by the designated State officials.

The State and/or its authorized representatives shall have the right to enter any premises where the Contractor or Subcontractor duties under the contract are being performed, and to inspect, monitor or otherwise evaluate the work being performed. All inspections and evaluations shall be at reasonable times and in a manner that will not unreasonably delay work.

B. PAYMENT

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Payee shall pay the laboratory according to Section VII. Cost Proposal Requirements.

C. RIGHT TO AUDIT (First Paragraph is Statutory)

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The State shall have the right to audit the Contractor's performance of this contract upon a 30 days' written notice. Contractor shall utilize generally accepted accounting principles, and shall maintain the accounting records, and other records and information relevant to the contract (Information) to enable the State to audit the contract. The State may audit and the Contractor shall maintain, the Information during the term of the contract and for a period of five (5) years after the completion of this contract or until all issues or litigation are resolved, whichever is later. The Contractor shall make the Information available to the State at Contractor's place of business or a location acceptable to both Parties during normal business hours. If this is not practical or the Contractor so elects, the Contractor may provide electronic or paper copies of the Information. The State reserves the right to examine, make copies of, and take notes on any Information relevant to this contract, regardless of the form or the Information, how it is stored, or who possesses the Information. Under no circumstance will the Contractor be required to create or maintain documents not kept in the ordinary course of contractor's business operations, nor will contractor be required to disclose any information, including but not limited to product cost data, which is confidential or proprietary to contractor.

V. PROJECT DESCRIPTION AND SCOPE OF WORK

The bidder should provide the following information in response to this RFP.

A. PROJECT OVERVIEW – no response required
B. PROJECT ENVIORNMENT – no response required
C. OVERVIEW OF THE REQUIREMENTS

This section provides an overview of the requirements for the newborn screening contractor for the Nebraska Newborn Screening Laboratory Services. Also provided is a general description of the testing requirements, telecommunications needs, consultation, documentation, and technical support. Because Technical Requirements are integral to the provision of the Project Requirements, most are embedded in this section.

The Contractor shall comply with the requirements in Neb.Rev.Stat. §71-519 and Regulations Title 181, NAC 2.

The contractor will analyze blood specimens submitted by the birth hospitals and other designees from the State of Nebraska. The State estimates that biochemical and molecular tests will likely be run on approximately 33,000 samples annually. These tests include:

Targeted Conditions and Laboratory Testing

The bidder must provide a response to C.1 through C.32 in the following table. Diseases to be screened are specified in C.1 through C.30. Other testing specifications are indicated in Appendix F, Newborn Screening Matrix. The bidder must provide responses to requirements C.33 through C.43 as indicated in Appendix F.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

1. Argininosuccimic acidemia (ASA). Currently screened using proprietary interpretation method of tandem mass spectrometry.

2. Beta-ketothiolase Deficiency (Mitochondrial Acetoacetyl-CoA Thiolase Deficiency or 3-ketothiolase Deficiency or BKT). Currently screened using proprietary interpretation method of tandem mass spectrometry.

3. Biotinidase deficiency (BIO): Currently, the sample is tested by an assay which yields a quantitative, numerical result for conversion of a labeled

conjugated biotin substrate to a measureable colored product. The numerical value obtained representing the enzymatic activity of biotinidase is reported with the clinically significant cut-off. Two sets of cut-offs are utilized, lesser elevations are reported as inconclusive and repeat tests are requested. Reflex testing on DNA is conducted on all positive initial screens and all inconclusive repeat screens. Significant elevations are reported as positive screens and confirmatory testing is recommended. Semi-quantitative methods incorporating fluoroscopic measure may be acceptable with sufficient documentation of validity, sensitivity/specificity.

4. Carnitine Uptake Defect (CUD): Currently screened using proprietary interpretation method of tandem mass spectrometry.

5. Citrullinemia (CIT): Currently screened using proprietary interpretation method of tandem mass spectrometry.

6. Congenital Adrenal Hyperplasia (CAH): Currently screening test is Steroid 17-alpha hydroxy progesterone (17-OHP) using an FDA approved non-isotopic imunoassay for 17-OHP. A subset of specimens with elevated 17-OHP adjusted by birth weight reflex to an extracted 17-OHP assay. Lesser elevations of 17-OHP and extracted OHP are reported as inconclusive and repeat specimens are requested. Significant elevations of 17-OHP for term babies are reported out as positive. Significant elevations of 17-OHP for low birth weight babies in the critical cut-off range are reported as preliminary Positive, pending the extracted results.

7. Congenital Primary Hypothyroidism (CPH): Thyroxine (T4) and Thyroid stimulating hormone (TSH) by radioimmunoassay (RIA) or preferably enzyme immunoassay (EIA) for congenital primary hypothyroidism. Currently the lowest 10% of T4's reflex to TSH. TSH's greater than 20 are reported as presumptive positive.

8. Cystic Fibrosis (CF): A combination IRT/DNA screen is currently used. Initial Immunoreactive trypsinogen results in the top 1.2% of the run reflex to DNA for the ΔF508 mutation. If no ΔF508 is found the test result is reported as inconclusive and a repeat specimen is requested. If one copy of ΔF508 is present, the specimen is reflexed again to a 39 mutation + 4 polymorphism panel. Whether one or two mutations, the infant is recommended for referral to an Accredited CF Center. If the inconclusives on repeat continue to be elevated, they reflex at that point to the 39 mutation + 4 polymorphisms panel. Whether zero, one or two mutations, the infant is recommended for referral to an Accredited CF Center at that point. Specimens collected at day of life 12 or later have a cut-off of 80 ng/mL instead of the 1.2%, but elevations would follow the same reflex pattern. Specimens from babies with reported meconium ileus or bowel obstruction are screening using the DNA panel.

9. Galactosemia (GAL): Currently Total galactose and uridyl transferase (UT) are assayed on all specimens. Percent Galactose-1-phosphate (Gal-1-P) is reported for all samples with total galactose elevated. Specimens with galactose results < 15 mg/dl are reported as normal. Specimens with galactose levels >15 mg/dl to < 30 mg/dl are reported as inconclusive. Specimens with galactose levels > 30 mg/dl are reported as positive. Repeats with gal ≥20 are positive. All samples with UT > 40μMol are reported as normal. Samples with UT < 40 μMol will be reported as positive and will reflex to DNA mutations.

10. Glutaric Acidemia type 1 (GAI): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious of GA-I reflex to DNA mutations. Repeat screening results that continue to be abnormal reflex to DNA mutations.

11. Hemoglobinopathies: Isoelectric focusing is currently done to detect hemoglobins F, A, S, C, D, E, O-Arab, Barts and other variant hemoglobins greater than A. When variant hemoglobin appears greater than hemoglobin A, the test reflexes to check for the presence of selected beta thalassemia mutations. Barts Hemoglobin, and Hemoglobin E are important to the Nebraska population to identify clinically significant thalassemias. Screening results indicating a possible clinically significant Hemoglobinopathy reflex to DNA mutations for S, C, D, E and O-Arab. Preference for sequencing of Hgb. Barts as a reflex test.

12. Homocystinuria (HCY): Currently screened using proprietary interpretation method of tandem mass spectrometry.

13. Isovaleric Acidemia (IVA): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for IVA reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

14. Long-chain Hydroxyacyl-CoA Dehydrogenase Deficiency (3-Hydroxy Long Chain Acyl-CoA Dehydrogenase Deficiency or LCHAD): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for LCHAD reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

15. Maple Syrup Urine Disease (MSUD): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for MSUD reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

16. Medium Chain Acyl Co-A Dehydrogenase Deficiency (MCAD): Currently screened using proprietary interpretation method of Tandem Mass Spectrometry analysis. Screening results highly suspicious for MCAD reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

17. Methylmalonic Acidemia (Mutase Deficiency): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for MMA reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

18. Methylmalonic Acidemia (Cbl. A, B): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for MMA reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

19. *Muccopolysaccharidosis Type I (MPS-I): Primary screen may be MS/MS or Digital Microfluidics. For repeat screens that continue to be out of range reflex testing of DNA sequencing is preferred *** To be added effective July 1, 2018**.

20. Multiple Carboxylase Deficiency: Currently screened using proprietary interpretation method of tandem mass spectrometry.

21. Phenylketonuria (PKU): Currently screened using proprietary interpretation method of tandem mass spectrometry.

22. *Pompe Disease (PD): Primary screen may be MS/MS or Digital Microfluidics. For repeat screens that continue to be out of range reflex testing of DNA sequencing is preferred. *** To be added effective July 1, 2018.**

23. Propionic (PA): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for PA reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

24. Severe Combined Immune Deficiency (SCID): To be screened using PCR to identify copy numbers of TRECS (T-Cell Receptor Excision Circles), with Beta- Actin reflex testing to verify amplification of DNA.).

25. Tri-Functional Protein Deficiency (TFP): Currently screened using proprietary interpretation method of tandem mass spectrometry.

26. Tyrosinemia (TYR): Currently screened using proprietary interpretation method of tandem mass spectrometry and includes analysis of succinylacetone (SUAC).

27. Very Long Chain Acyl-CoA Dehydrogenase Deficiency (VLCAD): Currently screened using proprietary interpretation method of tandem mass spectrometry.

28. *X-linked Adrenoleukodystophy (X-ALD): Primary screen via FIA-MS/MS, reflex to HPLC for out of range screen results. For repeat screens that continue to be out of range reflex testing of DNA sequencing is preferred. *** To be added effective July 1, 2018.**

29. 3-Hydroxy 3-Methyl Glutaric Aciduria (HMG): Currently screened using proprietary interpretation method of tandem mass spectrometry.

30. 3-Methylcrotonyl-CoA Carboxylase Deficiency (3-MCC): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for 3-MCC reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

31. All specimens collected at less than 24 hours of age are tested for all conditions except CAH, CPH, and CF. When MPS-I, PD and X-ALD are added these will be excluded from testing on specimens collected at < 24 hours of age. All initial specimens collected at > 24 hours of age are tested for all conditions. All repeat specimens collected at > 24 hours of age and collected due to the initial specimen being less than 24 hours at collection will be tested for all conditions exceot for SCID and BIO if prior results were normal. All repeat specimens collected due to the initial specimen being unsatisfactory will be tested for only those conditions not able to be tested on the former unsatisfactory specimen. All repeat specimens collected due to a prior inconclusive screening result will be tested for the condition found inconclusive. All repeat specimens collected due to being a required 28 day or discharge specimen for newborns < 2000 grams admitted to the NICU, will be tested for CAH and CPH and any analyte for which a prior abnormal result was reported. All of the above requested repeats shall be tested at no additional charge and so costs shall be considered and included in the per-infant testing fee when determining the total bid.

32. Any proposed changes during the course of the contract to screening methods, cut-offs, normal reference ranges, or algorithms must be mutually agreed upon between the laboratory and the State. For changes proposed by the laboratory, scientific rationale supporting the proposal

must be made available by the laboratory to the NNSP and representatives of its Newborn Screening Advisory Committee for consideration.

D. FILTER PAPER

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contractor will purchase the Nebraska Newborn Screening Program Collection and Reporting Form (See Appendix E) filter paper collection devices, as required for the collection and identification of the blood specimens and for providing the necessary clinical information. The laboratory may recover the cost of the filter paper in its single fee per infant screened charge to hospitals. The contractor will distribute supplies of the filter paper collection devices to all Nebraska birthing facility submitters.

The laboratory must document tracking of which filter paper specimen collection devices were provided to which birthing hospital/facility and communicate this information to the NNSP as requested. All costs associated with this transport shall be incurred by the laboratory and incorporated into the per-infant screened laboratory charges. The bidder must pro-actively work with submitters to reduce the risk of expired filter paper being used to collect dried blood spot specimens.

Residual dried blood spots will be stored at a facility that provides security, confidentiality, stability of temperature and humidity (refrigerated in sealed bags of low gas permeability) and retrievability for 90 days. Within 30 days following the 90 day period left over filter paper blood spots shall be disposed of in a manner that ensures confidentiality. No filter paper blood spots can be used for research without the explicit consent of the newborn's parent/legal guardian, and approval by an Institutional Review Board (IRB) and approval by the Department of Health and Human Services Chief Medical Officer. Documentation of the storage, use and disposal of the residual dried blood spots shall be in compliance with 181 NAC 2. Documentation of the storage, use and disposal of the residual dried blood spots shall be made available to the NNSP upon request at no additional charge. Destruction manifests or other documentation demonstrating compliance with disposal requirements in 181 NAC 2 must be made available to the NNSP upon request.

The NNSP has a procedure for the retrieval of residual dried blood spots for use by the patient's physician for clinical diagnostic testing purposes. The laboratory will accommodate up to 100 requests for residual blood spot specimens per year to be retrieved and returned to the patient's physician with appropriately signed documentation of parent/guardian release and physician request at no additional charge.

E. SPECIMAN SHIPPING

The bidder should provide the following information in response to this RFP

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contractor will arrange for daily courier pick-up service at designated locations within each Nebraska birthing hospital and birthing facility (See Appendix A for the list of facilities) for next day delivery to the screening laboratory and provide for tracking of such specimens (with exceptions for weekend and holiday days when no transport service is available). A minimum of five (5) day a week pick up and overnight delivery is expected for all birthing hospitals/facilities. Six (6) day a week pick-up including Saturdays shall be provided for all hospitals where a commercial courier or shipper is available to provide that service in their community. Saturday delivery to the laboratory shall be provided for specimens shipped Fridays. For hospitals that do not have specimens to be transported daily (hospitals with few births), the contractor does not have to ensure daily pick-up. However, the contractor shall ensure procedures are in place to courier these infrequent specimens within 24 hours of collection (with exceptions for weekend and holiday days when no transport service is available). The contractor will provide to the NNSP a list of facilities with the name of their associated courier identified, daily and weekend order-by and pick up times. The contractor shall also monitor the courier service for performance and timeliness and communicate to the NNSP within 48 hours of identifying any delays or exceptions.

F. REPORTING

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contractor will report all results to the NNSP according to these technical requirements. The laboratory reports newborn screening results needing follow-up via telephone to the NNSP, the newborn's physician or designee, and the submitter (facility submitting the specimen) as soon as the results are available including afterhours weekdays, weekends and holidays. Exceptions to after normal business hours reporting include specimens collected at less than 24 hours of age, unsatisfactory specimens, transfused specimens, specimens with multiple amino acid elevations indicating likely hyperalimentation, non-clinically significant hemoglobinopathy abnormalities, positive and inconclusive Cystic Fibrosis results and inconclusive biotinidase (likely partial or carrier) deficiency results. Weekend after-hours reporting is also not conducted for SCID, Pompe, X-ALD and MPS-I. The laboratory also faxes all reports that are phoned, during weekday working hours, to the physician, submitter & NNSP.

All initial repeat and confirmatory test results must be reported to the NNSP and submitters or made available electronically within 24 hours of test completion.

The laboratory test results report format and explanatory comments will be determined, as mutually agreed upon by the laboratory and the NNSP. The laboratory test results report format will include identification for each disorder screened by tandem mass spectrometry (MS/MS) and any other multiplex method; the name of the condition screened, the analyte or test name, the numerical value when available for quantitative or semi-quantitative assays, the unit of measure, other values such as the alpha description for hemoglobinopathies, a relative interpretation (WNL for within normal limits), and identify the cut-off or reference range (expected normal) for each analyte. Comments must be agreed to by the NNSP, and should identify for which condition the screening test abnormality is "inconclusive" or "preliminary positive" or "positive" and recommended next steps (e.g. repeat dried blood spot filter paper specimen or confirmatory testing, and or referral to pediatric sub specialist). Laboratory report comments relative to specimens drawn early, unsatisfactory specimens, transfused specimens, and specimens collected post-hyperalimentation must also be developed in collaboration with and agreed to by the NNSP.

For conditions screened by MS/MS the laboratory report will list a result for the acylcarnitine profile and the amino acid profile as WNL, abnormal or positive, and "see comment". Comments for MS/MS will describe which analytes are abnormal, the degree to which they are abnormal, provide the numerical value of the screening result and expected (normal) reference value or range, using the same unit of measure, as well as any ratios applied by the laboratory. It will provide an interpretation that at a minimum distinguishes between results which urgently require confirmatory testing and/or referral to a pediatric sub specialist, vs. those which require repeat testing via dried blood spot filter paper specimens. A list of conditions screened by MS/MS at the laboratory will also be listed separately on the laboratory report.

Any proposed changes to laboratory report format, content or language must be mutually agreed upon in writing between the laboratory and the NNSP before such changes are implemented.

Complete MS/MS screening profile results including specific analyte values and ratios will be provided by the laboratory to the NNSP upon request for all babies that are confirmed positive.

The contractor will report every "positive" and/or abnormal screening result immediately via phone and in writing to the Nebraska Newborn Screening Program (NNSP), the submitter and the physician identified on the filter paper collection device (and alternate physician when discovered that the physician on the filter paper collection device is no longer seeing the baby). This notification is expected whenever the results become available on a 24 hour, seven day a week basis regardless of time. The written notification (fax) may be sent the following business day when the results are first available and reported on the weekend or after hours. After normal business hours reporting exceptions are positive, abnormal or inconclusive results for BIO, CF, Hgb's, SCID, PD, MPS-I and X-ALD which are only required to be phoned to the NNSP, submitter and physician via phone, and in writing, during normal business hours .

The contractor will report immediately via phone and in writing to the NNSP, the submitter and the physician every abnormal screening result that is "inconclusive" or in need of a repeat dried blood spot specimen only, on a 24 hour, seven day a week basis. These following exceptions need only be reported within twenty-four (24) hours and during normal business hours Monday through Friday: results indicating possible hyperalimentation (multiple amino acids elevated), specimens collected post transfusion, specimens collected too early at < 24 hours of age, unsatisfactory specimens, abnormal hemoglobinopathy results not expected to be clinically significant to the newborn; specimens that are considered abnormal (AF) or unreliable because of transfusion, and any abnormal results for BIO, CF, MPS-I, PD, and X-ALD. Specimens with substantially abnormal or clinically significant results on a post transfusion result still require notification after normal working hours and on weekends. Depending on the screening algorithm proposed by the laboratory other abnormalities may be included in the "Monday through Friday" only expected reporting period, if mutually agreed upon by the NNSP. Unsatisfactory specimens must be reported by phone to the submitter and physician within 24 hours of when they are determined to be unsatisfactory, and in writing to the NNSP and submitter within 24 hours of this determination.

The contractor will document communication with submitters and physicians regarding unsatisfactory specimens, drawn early specimens, presumptive positive, inconclusive or abnormal,

initial or repeat specimen screening results, confirmatory test results conducted by the laboratory, and reporting of laboratory errors. Laboratory (testing and reporting) errors shall be reported to the NNSP, physician and submitter within 24 hours of discovery of each error.

G. DATA SYSTEM REQUIREMENTS

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

All demographic information required on the NNSP collection and reporting form (See Appendix E) filter paper collection device must be entered into an electronic database the day the forms are received. The database system must have unlimited availability during each 24 hour period for data transmission and data access, with the exception for routine technical maintenance of the database system. The electronic data system must ensure standard SSL (Secure Sockets Layer) 128-bit encryption necessary for transmission of data, or other security measures of equal or higher quality.

Demographic information must be entered the day the specimen is received, and test result information must be entered within 24 hours of completion of the tests. The system will allow secure remote access for tracking of all Nebraska newborn's specimens. It will also be used by the NNSP to generate reports and letters. All newborn laboratory test and result data shall be kept in the computerized record system accessible to the laboratory performing the services for a period no less than 25 years from the date of the test, and to the NNSP for a period no less than 29 years from the date of the test.

Timely and accurate data entry is required to facilitate the NNSP follow-up component which will contact the primary care physician with recommendations on all abnormal screening results, unsatisfactory, drawn early, and post-transfusion specimens and which will maintain follow-up until adequate specimens are submitted, diagnosis is ruled out, or diagnosis of the infant is confirmed and the infant is in treatment or according to NNSP written procedures that the infant is determined lost to follow-up.

Data entry errors shall be reported by phone to the NNSP within 24 hours of discovery of such error.

Electronically transmit or allow electronic access to test results and other data via a secure connection. All electronic transmissions of data must meet all State and Federal security requirements including those in the Bureau of Information Services Security Manual and Health Information Portability and Accountability Act (HIPAA) and regulations and be compatible with provisions of the Health Information Technology for Economic and Clinical Health (HITECH Act). The laboratory IT personnel will provide training to the Nebraska Newborn Screening Program Manager and follow-up personnel on how to use the applications.
The contractor shall support a comprehensive data export from the laboratory data in comma delimited format for an upload to an SQL server maintained by the Department of Administrative Services Office of the Chief Information Officer. The data shall be uploaded weekly and include all data including comments-field content.

The bidder's capacity to export comma delimited text files compliant with Health Level Seven (HL7) standards to the Nebraska Department of Health and Human Services so that the data can be integrated into tables in the Nebraska Vital Records electronic registration system or other database system. The export files will need to maintain the referential integrity of the data and be exported to a Nebraska FTP (file transfer protocol) site.
A computerized system shall be maintained and updated to allow remote access by or transmission to the NNSP to the database containing all the information from the Nebraska Newborn Screening

Program Collection and Reporting form on Nebraska specimens including: the date and time each sample was collected, date each sample was received from the specimen submitter, the date the laboratory tests were completed; the date results of the laboratory analyses were reported to or made available for access by the NNSP; the status of laboratory analysis (e.g. in progress, completed, or not done and reason why), results and other actions. This system will allow the NNSP to search for information, and report results of laboratory analysis on individual specimens to hospitals, and to the physician of record upon request. This does not eliminate the requirement for written reports of all test results to be provided by the laboratory to the submitter. Written reports to the submitter may be in electronic format for incorporation into each hospital/submitter's electronic medical records or printed in hard copy. The electronic data system must be HL7 compliant and capable of interfacing with hospital laboratory information systems or other health information exchanges in Nebraska to facilitate adoption of electronic medical records by providers.

The data system must produce reports of tests missing, unsatisfactory specimens, drawn early, transfused specimens, Inconclusive cystic fibrosis, newborns with meconium ileus or other bowel obstruction, out of hospital births, presumptive positives and confirmed positives that are necessary for follow-up and tracking. The data system also must produce reports of low T4's with low TSH's for information purposes only (not for required physician reporting). See appendix D for a complete listing of required reports.

The data system must also produce quality assurance reports necessary for monitoring of turnaround times, missing demographic information from the filter paper cards, statistical averages including mean, median, quarterly percentiles of all lab results producing a quantitative value, age at collection, and hospital QA reports comparing hospital numbers with State averages and percentiles of performance on multiple measures (see Appendix E). The NNSP can access a database of scanned images of dried blood spot filter paper devices received at the laboratory. The laboratory performs daily monitoring using a UPS electronic tracking report to identify any specimen shipments not received by 4 days from shipment. The laboratory follows up with the submitter and if necessary the shipper, the day an exception is identified. Exceptions are reported to the NNSP program manager, and a weekly report is routinely submitted.

All initial, repeat and confirmatory test results must be reported to the NNSP or made available electronically within 24 hours of test completion. A mechanism must be specified for the NNSP to enter/edit data or have data entered on confirmatory test results obtained from other laboratories or physicians/health care providers. Confirmatory tests used to aid in diagnosis may be done at various laboratories within and outside of Nebraska and may or may not be completed at the laboratory. When these are not done at the screening laboratory the NNSP follow-up program in the Department of Health and Human Services will track and monitor and so must have the capacity to enter these results into the Nebraska data.

The electronic data system must have the capacity to produce template letters populated with patient and health care practitioner demographic information, and test results for all abnormal screen results, as well as second request letters and letters for specimens collected too early, unsatisfactory specimens, transfused specimens and any other results requiring follow-up.

The contractor must implement a procedure to identify and merge/eliminate duplicate records. Specifically, when multiple (two or more) records on the same infant are identified when the infant has more than one specimen, there must be a mechanism to merge these into one record.

The data system must have the capacity to close a record when confirmed negative, confirmed positive or determined lost to follow-up so these records do not remain on a "pending" report. The data system must also have the capacity to remove inconclusive abnormal results from reports as closed.

The data system must be able to generate ad-hoc reports for quality assurance on variable date ranges and variable data elements.

Other reports will need to be developed to differentiate and analyze data for NICU admissions vs other newborns screened from the regular nursery vs home births.
Other reports will need to be developed to function for follow-up and tracking and for quality assurance upon the implementation of screening for new disorders screened.

H. DATA SYSTEM FUTURE ENHANCEMENT

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The data system must enable the NNSP to attach and save as part of individual patient records, electronic documents of follow-up activities (letters, faxes, reports in scanned or other Microsoft Office readable format). This data capacity must be available by the end of the first year of the contract.

By the end of the first 2 year period of the contract, a mechanism will be developed for "closing" follow-up action on patient records to enable the pending action to be dropped from the active worksheet reports, while retaining the record in open status for any other pending/needed follow-up actions.

I. SPECIALISTS

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contractor shall maintain a listing of qualified specialists in pediatric endocrine, metabolic, hemoglobin disorders, immunodeficiencies, lysosomal storage diseases, pulmonology, molecular genetics and a laboratory specialist who have agreed to provide medical consultation to the laboratory. This medical consultation may be related to establishing and monitoring screening test algorithms, and test performance, interpretation of screening test results, and recommendations for further evaluation.

J. CONFIDENTIALITY AND ASSURANCES

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Strict confidentiality of medical information will be maintained in all stages of testing and reporting, and shall be consistent with all applicable federal and state laws.

The contractor agrees to comply with all Nebraska statutes and regulations relative to newborn screening, the quality assurance measures (See Appendix D), and applicable clinical and newborn screening laboratory regulations and standards and other applicable standards, including but not limited to Clinical & Laboratory Standards Institute (CLSI) standards, Clinical Laboratory Improvement Act (CLIA) requirements, College of Pathology (CAP) requirements, and participation in Centers for Disease Control and Prevention's (CDC) Newborn Screening Proficiency Testing Program. The contractor agrees to provide copies of performance reports from their laboratory's participation in the CDC proficiency testing, and copies of certificates from CLIA and CAP reviews.

K. CONSULTATION

The bidder should provide the following information in response to this RFP

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Provide consultation and education to the NNSP and others, upon request of the NNSP, and as needs are identified by the contracting laboratory, on:

1. Screening for all of the conditions required in the contract, to the NNSP and Nebraska Newborn Screening Technical Advisory Committee. Such consultation may be provided via writing, phone, and teleconference and includes specific results interpretation, and in general regarding the technology.

2. Accessing the laboratory results database.

Any problematic trends identified by the contracting lab with specimen collection, transport, testing, reporting or other communication problems.

L. DISASTER PREPAREDNESS

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contractor must have disaster response plans to provide laboratory testing of the newborn screening specimens in the event of emergency, man-made or natural disaster or other event causing a delay of 24 hours or more in testing, requiring specimens to be tested at another location until such time as the bidding laboratory is able to resume testing. The response plan must include written agreements with other laboratories, and shall specify responsibilities of each laboratory involved, for specimen transportation, testing and notification of the submitter, physician and NNSP of results. Bidders should reference NCCLS (CLSI) document X4-R Planning for Challenges to a Clinical Laboratory Operations Disaster. By signing the Request for Proposal for Contractual Services form, bidder guarantees compliance with the Emergency/Disaster Preparedness Agreement in Appendix C, of this proposal.

Testing delays (e.g. due to assay problems, equipment breakdown, reagent problems) of greater than 24 hours beyond the laboratory's standard operating procedures will be reported by phone to the NNSP once recognized. Plans to alleviate the delay should also be reported (e.g. new replacement parts or reagent ordered.

M. BILLING AND REMITTANCE OF FEES

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contractor must have procedures for billing submitters/hospitals will include a single fee per infant screened. The single fee per infant screened may cover the costs associated with the specimen collection kit, specimen transportation to the laboratory, testing, analysis, interpretation and consultation, reporting of results by phone, electronically and in writing, quality assurance and other documentation reporting requirements, and must include the per infant screened administrative fee. It shall be charged only once per infant screened whether or not one screen is sufficient or repeat screens are requested.

Requested repeat specimens will not be billed. Procedures must address how repeat specimens requested due to abnormal screening results, inconclusive screening results, transfused specimens, specimens collected at < 24 hours, unsatisfactory specimens and for NICU admissions < 2000 grams the 28-day/discharge specimens will be handled to assure no additional charges to the hospital or submitter are made for these.

The contractor must submit the monthly remittance of the per infant screened administrative fee specified in 181 NAC 2 to the NNSP.

N. WORK PLAN

The work plan shall address how the bidder will collaborate with the NNSP to plan for July 1, 2018 implementation, of all contract project and technical requirements, the plan for sustaining compliance with all requirements, and the plan for implementing any proposed new conditions testing. The work plan will also describe how capacity to meet all contract requirements will be maintained in the event the bidder's specimen volume processed annually should increase by more than five percent (5%).

O. TECHNICAL REQUIREMENTS

The bidder should provide the following information in response to this RFP

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Technical requirements are embedded in Section V.C Project Requirements as they are integral to the project requirements, and to avoid redundancy in the RFP and responses solicited. The technical requirements cover the following areas:

1. Distribution and tracking of filter paper blood specimen collection kits;
2. Rapid transport for specimens from the birthing hospitals/facilities to the laboratory;
3. Accurate and timely laboratory testing and analysis;
4. Accurate and timely communication of results;
5. Accurate, timely and comprehensive electronic reporting of data (demographic and test results, follow-up and quality assurance reports);
6. Collection and remittance of the per infant screened administrative fees to the State (Or amount specified in 181 NAC 2 Section 010 as promulgated;
7. Participation in quality assurance programs and reporting of quality assurance data; and,
8. Back-up laboratory testing assurances in the event of an emergency, disaster or other hazard preventing testing at the contracted laboratory.

The contract resulting from this RFP will be a fixed price per patient screened for providing newborn screening testing, specimen collection kits/shipment, data provision, technical assistance, clinical consultation and education to the NNSP.

P. LABORATORY PRACTICES

Explain laboratory policies and procedures that are or will be in place to address MMWR Recommendations and Reports "Using Tandem Mass Spectrometry for Metabolic Disease Screening Among Newborns," (April 13, 2001/Vol. 50/No. RR-3), and where there are variations from the recommended practices, explain why. Address this technical requirement for each of:

1. **Standard and Sample Preparation**
   - **a.** Sample preparation technique validation
   - **b.** Quality of reagents, buffers and solvents
   - **c.** Validation of methods
   - **d.** Use of internal standards for analysis, and where not available validation of other isotopes
   - **e.** Validation of dilutions of commercial standards or in-house preparations
   - **f.** Documentation of validation of
   - **g.** standards and quality control preparations
   - **h.** Safety recommendations, universal precautions, personal protective gear and environmental controls that are required.
   - **i.** Good laboratory and measurement practices to be followed

2. **Instrument**
   - **a.** Manufacturer's guidelines for power requirements, exhaust specifications, laboratory gas purity and pressure, and laboratory environment
   - **b.** Additional peripheral equipment for MS/MS and sample preparation equipment
   - **c.** Qualification and quantity recommendations for MS/MS operators
   - **d.** Manager and supervisor of MS/MS operations experience
   - **e.** Backup plan for instrument down time
   - **f.** Calibration procedures and scales
   - **g.** Daily instrument check solution

3. **Reducing Instrument-to-Instrument Variability**
   - **a.** Definition of minimum sensitivity threshold, and concentration calculations using ion ratios.

4. **Quality Control**
   - **a.** Quality control specimens, (which are used, concentrations of these, how used)
   - **b.** Use of reagent blank
   - **c.** Monitoring of daily patient mean or median for each analyte
   - **d.** Routine maintenance schedule
   - **e.** Participation in external quality-control and proficiency testing program(s).
   - **f.** Quality control protocol for determining run validity. Specify how each assay's performance is monitored. What quality control rules are used? What remedial action is taken if a run fails? What assurances are made that specimens are repeated if a run fails and what assurances are made that no data is reported from the bad run.

5. **Interpreting MS/MS Data and Reporting Results**
   - **a.** Description of how cut-off levels are/will be determined using statistical measurements in consultation with metabolic disease specialists and / or CLIR data analysis software.
   - **b.** How the laboratory has/will establish the cut-off values at which concentrations greater than "x" require immediate reporting and follow-up.
   - **c.** If the laboratory has/will establish ratios of different analytes for certain conditions screened by MS/MS, provide a rationale of why, and for which analytes, and what procedures are recommended for initial reporting, follow-up, consultation, confirmation and diagnosis.
   - **d.** If the laboratory has/will establish separate cut-offs dependent on age at time of specimen collection e.g. greater than seven (7) days of age, rational of why, and for which analytes, and what

procedures are recommended for initial reporting, follow-up, consultation, confirmation and diagnosis.

e. How the laboratory will report MS/MS results. If reports for MS/MS screening do not list values for all analytes, they must explicitly document for which disorders screened, results were normal. Written reports for all abnormal results must include the quantitative result of the abnormal metabolites, the normal reference range and or normal ratios, a detailed interpretation of the results, including an overview of the results' significance, possible differential diagnoses, recommendations for additional biochemical testing and confirmatory studies, and name and phone number of a laboratory representative available if the NNSP, newborn's physician, or Nebraska pediatric specialist has additional questions.

f. Specify hardware, operating systems, internet connectivity, and all software and technical support specifications necessary for the NNSP to successfully access or receive transmission of the laboratory's electronic database specific for Nebraska's newborn screening results and reports. Include for any export files a description of the file format. Explain assurances that the hardware and operating systems are secure.

g. Describe how the bidder will address accommodations for any future needs to make changes to the data collected and entered into the data system.

h. Describe current compatibility or plans to become compliant with HL7 coding requirements if not already compliant and how consultation will be provided to the NNSP in the event data is requested for an electronic download or interface with a State Health Information Exchange, and or State DHHS system (currently possible link/interface with the vital records data system) and to hospital/submitter's for download or interface with their LIMS systems.

i. Describe current compatibility or plans to ensure all patient specific data derived from the filter paper form and generated from testing and follow-up (including contact/comments) for all Nebraska babies screened, are/will be made available for upload or export to the Department of Health and Human Services for long-term data storage.

Q. PROJECT PLANNING AND MANAGEMENT

Bidder to describe the project planning process identifying who is/will be responsible for managing each step of the project plan. Provide a time line by which each component will be completed in order to fully implement the contract by the contract start date.

R. EVALUATE CURRENT PROJECT ENVIRONMENT

Bidder to describe any necessary changes or additions to the Bidder's current project environment that will need to take place in order to add the workload of the Nebraska specimens and other requirements of this RFP.

S. PERFORM IMPLEMENTATION

Bidder to identify resources (infrastructure of personnel, facilities, equipment, written procedures, ongoing staff development etc.) that will be committed to the project to ensure successful implementation.

T. PROVIDE POST IMPLEMENTATION SUPPORT

Bidder to identify resources that will be maintained in order to continue implementation of the contract. Demonstrated commitment to ongoing support must be evident.

U. DELIVERABLES

1. Purchase, distribute and track filter paper collection kits to all birthing hospitals/facilities in Nebraska.

2. Provide courier service for all birthing hospitals/facilities in Nebraska to transport newborn screening specimens from the birthing hospital/facility to the contractor's laboratory within 24 hours of pick-up (possibly excluding weekend/holiday days when no commercial transport service is available).

3. Laboratory testing in accordance with Neb. Rev. Stat. §§71-519 through 524 and regulations, including but not limited to 181 NAC 2, and in accordance with the contract resulting from this RFP on all specimens received.

4. Phone and written reporting of screening test results and acceptability of specimens (drawn early, unsatisfactory or transfused) as required in Nebraska regulations, including but not limited to 181 NAC 2 to the NNSP, submitter, and newborn's physician.

5. Timely electronic entry of all data required on the NNSP Collection and Reporting form (See Appendix E), and 24 hour access to this data by the NNSP, including follow-up and quality assurance report features specified in this RFP.

6. Consultation provided to NNSP, Nebraska's Newborn Screening Advisory Committee, primary care physicians and pediatric specialists in Nebraska.

7. Provision of quality assurance reports and provision of access to data for the NNSP to complete additional quality assurance reports as required in the contract resulting from this RFP.

8. Collection from hospitals, and remittance of the $10 per infant screened administrative fee.

9. Storage, disposal and retrieval of residual dried blood spots as specified in this RFP.

V. PAYMENT SCHEDULE

This is an exclusive contract to provide newborn screening testing services for all newborns born in the State of Nebraska and is not purchased by the State of Nebraska. Invoices for testing services are to be provided to specimen submitters.

The per-infant screened fee money (currently $10.00) shall be submitted monthly by the bidder awarded this contract, to the NNSP within 45 days following the end of each calendar month for which billing was submitted. (For example fees for specimens tested in January, billed and collected, shall be submitted to the NNSP by March 17.)

VI. PROPOSAL INSTRUCTIONS

No response required in this section

APPENDIX A – Nebraska Births 2016

No response required

APPENDIX B - Table of Test Results

Request for Proposal 5710 Z1

Tables to be completed by bidder and submitted with Proposal

Numbers for 2016:

Identify #'s in a footnote for any inconclusive screen results that required more than one repeat specimen to be collected and tested in order to resolve/define the case.

Condition/Analyte	# Screened	# **Inconclusive** (or borderline) on screen *	# Confirmed/ Diagnosed Positive	# Confirmed or repeated Negative	Inconclusive Rate
Argininosuccinic acidemia (Arg)	27,025	0	0	0	0
BIO	27,025	29	0	25	0.11
CAH (17-OHP)	27,025	31	0	27	0.11
CF (IRT/DNA)	27,025	261* (includes 1 mutation detected)	0	29	0.97
CIT (Cit)	27,025	1	0	0	0.004
CPH (T4/TSH)	27,025	0	0	0	0
CUD(low C0)	27,025	0	0	0	0
GA-I (C5DC or C10-OH, or C8 + C10)	27,025	0	0	0	0
GAL (Gal/GALT)	27,025	5	0	5	0.02
HCY (Met & Homocy)	27,025	105	0	0	0.39
Hgb's S, SC, Thal's	27,025	2	0	2	0.01
HMG (C5:OH, C6:DC w/ C5:OH)	27,025	0	0	0	0
IVA (C5, C6-DC, w/ C5-OH)	27,025	1	0	0	0.004
LCHAD (C16-OH, or C18:10OH with others)	27,025	0	0	0	0
MSUD (Val, Leu, and/or Isoleucine)	27,025	0	0	0	0
MCAD (C8, or C8 with others)	27,025	3	0	0	0.01
MMA (C3, C3:C2, C3:C16)	27,025	43	0	0	0.16
MMA cbl A, B (C3, C3:C3OH, C4DC, Met)					
MPS-I (IDUA)	0	0	0	0	0

MCD (C3 or C5OH)	27,025	0	0	0	0
PKU (Phe, Phe/Tyr)	27,025	5	0	1	0.02
PD (GAA)	0	0	0	0	0
PA (C3,C3:C2, C3:C16)	27,025	See MMA above	See MMA above	See MMA above	See MMA above
SCID (TRECS)	27,025	5	0	3	0.02
Tyr (Tyr)	27,025	37	2	0	0.14
TFP C16-OH, C18:1-OH with C16-OH)	27,025	0	0	0	0
VLCAD (C14, C14:1, C14:2, & C14:1/C12:1)	27,025	3	0	0	0.01
X-ALD (C26.OLC)	0	0	0	0	0
3-MCC (C5:OH or C5:1 w/ C5:OH)	27,025	1	0	0	0.004
Other MS/MS findings:					
Arg & Orn	27,025	1	0	0	0.004
Gly	27,025	3	0	0	0.01
Ala	27,025	2	0	0	0.01
Met & Tyr	27,025	19	0	0	0.07
FIGLU	27,025	1	0	0	0.004
C4	27,025	1	0	0	0.004
FC/C16	27,025	2	0	0	0.01
C3 & C8	27,025	1	0	0	0.004
C8 & C5DC	27,025	2	0	0	0.01

*Positive results include all abnormal results. Most often these results indicate the need for a repeat newborn screen and less frequently confirmatory/diagnostic testing.

Totals for 2016

Condition/ Analyte	# Screened	# **Positive** on screen	# Confirmed/ Diagnosed Positive	# Confirmed Negative	Presumptive Positive Rate
Argininosuccinic acidemia (Arg)	27,025	0	0	0	0
BIO	27,025	4	2	0	0.01
CAH (17-OHP)	27,025	8	2	6	0.03
CF (IRT/DNA)	27,025	11	8	0	0.04
CIT (Cit)	27,025	0	0	0	0
CPH (T4/TSH)	27,025	116	19	95	0.43
CUD(low C0)	27,025	0	0	0	0
GA-I (C5DC or C10-OH, or C8 + C10)	27,025	0	0	0	0
GAL (Gal/GALT)	27,025	2	1	0	0.01
HCY (Met &	27,025	4	1	0	0.01

Homocy)					
Hgb's S, SC, Thal's	27,025	12	12	0	0.04
HMG (C5:OH, C6:DC w/ C5:OH)	27,025	0	0	0	0
IVA (C5, C6-DC, w/ C5-OH)	27,025	0	0	0	0
LCHAD (C16-OH, or C18:10OH with others)	27,025	0	0	0	0
MSUD (Val, Leu, and/or Isoleucine)	27,025	0	0	0	0
MCAD (C8, or C8 with others)	27,025	1	1	0	0.004
MMA (C3, C3:C2, C3:C16)	27,025	2	1	0	0.01
MMA cbl A, B (C3, C3:C3OH, C4DC, Met)					
MPS-I (IDUA)	0	0	0	0	0
MCD (C3 or C5OH)	27,025	0	0	0	0
PKU (Phe, Phe/Tyr)	27,025	4	3	0	0.01
PD (GAA)	0	0	0	0	0
PA (C3,C3:C2, C3:C16)	27,025	See MMA above	See MMA above	See MMA above	See MMA above
SCID (TRECS)	27,025	3	0	0	0.01
Tyr (Tyr)	27,025	0	0	0	0
TFP C16-OH, C18:1-OH with C16-OH)	27,025	0	0	0	0
VLCAD (C14, C14:1, C14:2, & C14:1/C12:1)	27,025	3	2	0	0.01
X-ALD (C26.0)	0	0	0	0	0
3-MCC (C5:OH or C5:1 w/ C5:OH)	27,025	1	1	0	0.004
Other MS/MS findings	27,025	0	0	0	0

Unsatisfactory / Rejected Specimens
(Numerator: Total # unsatisfactory specimens 2016: 118
(Denominator: Total # initial specimens tested in 2016: 30,875

Reason specimen unsatisfactory / rejected	Number
Quantity not sufficient	28
Blood spots not soaked through	48
Specimen scratched or abraded	2
Specimen not dry before mailing	0
Oversaturated	13
Diluted, discolored or contaminated	6
Serum rings	1
Clotted or layered	7
Exposed to heat or humidity	1
Expired filter paper:	5
Other: >30 days since collection	2
Other: interfering substance	5

Note: Testing was performed by PerkinElmer Genetics, Inc. In addition, some data was used from the Nebraska data presented by the NNSP at the January 2017 newborn screening advisory committee. This data is for Nebraska screening only.

APPENDIX C – Emergency/Disaster Preparedness

No response required

APPENDIX D – Reports

No response required

APPENDIX E – Collection and Reporting Form

No response required

APPENDIX F – Newborn Screening Matrix

RFP Section Number	Requirement	Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	Notes/Comments:
V.C.33	For each condition screened, the instrumentation, method, screening algorithm or cut-offs must be clearly described. Flow-chart/algorithms to illustrate the test result reporting criteria are encouraged, but should not be considered an adequate replacement for a narrative, detailed description. The methods used must follow presently accepted good laboratory practice and be compliant with FDA, and CLIA regulations, and if available FDA approved products should be used. FDA cleared products are acceptable. Methods should have been routinely used by newborn screening programs for at least one (1) year and their performance documentation exists in Quality Control reports from CDC. For proprietary information, the proposal must provide a general overview, and assurance that written protocols, interpretation criteria and screening algorithms will be provided in writing to the NNSP within 30 days following contract award date. Bidders must complete Appendix B.	[redacted]			

V.C.34	For which disorders within these classifications, beyond those listed in Section V.C.1 - 30, their laboratory can reliably detect via tandem mass spectrometry or other multiplex testing and describe the informative markers evaluated and cut-offs or screening algorithms used to determine the need for additional follow up. The table in Appendix B must be completed identifying for each condition or analyte screened the number of specimens screened, number of abnormal screens reported out, and the number of confirmed conditions associated with that screen during the prior 2 year period. If the current method/algorithm has been used for less than 2 years, the available data described above, since using that method/algorithm.	[redacted]			
V.C.35	If any of this required information is proprietary, the following applies: By virtue of submitting a proposal the bidder agrees that if awarded the contract, the proprietary information will be provided to the NNSP within 30 days following contract award date.			✓	Bidder will provide information to the NNSP within 30 days following the contract award date. Proprietary information should not be distributed or made available to anyone outside of the NNSP.
V.C.36	Data for the laboratory regarding the false positive rate per year for each of the tests performed, (see tables in Appendix B), the percent of filter paper blood specimens identified as unsatisfactory and the reasons for rejection, the turn-around time from specimen receipt to reporting of results. Data for the laboratory regarding the false negative rate, explanations for errors and remedial actions. (Complete tables in Appendix B) and return with bidder's proposal response.	[redacted]			

V.C.37	For each analytical methodology and instrument used, available methods for backup/confirmation. (e.g. Beuter and Baluda back-up for Biotinidase testing if primary testing instrument were to be unavailable).	Complete **attached table below** for response to this requirement. **			
V.C.38	If not already described in Section V.C.1-30, specify any 2nd tier or reflex testing (E.g. a different test with a new punch from the same sample) proposed as part of the screen. If DNA is used as a 2nd tier or reflex test, specify which mutations or polymorphisms are tested for or if sequencing is proposed. The Department of Health and Human Services reserves the right to determine if sequencing will be allowed as part of the screening algorithm for any condition screened. (Include in response to B).				See Appendix G
V.C.39	For which type of results (e.g. unsatisfactory specimens, inconclusive or preliminary positive test results for "x" condition) a repeat dried blood spot filter paper specimen would be requested (vs. confirmatory serum, plasma or other test). Requested repeats for specimens collected at less than 24 hours, that are unsatisfactory, collected post transfusion, required due to infant's birthweights being less than 2000 grams, are indeterminate because of multiple elevations of amino acids indicating hyperalimentation, or requested because of inconclusive findings shall not be charged for separately.				

V.C.40	Describe any other newborn screening and confirmatory tests not described in Section V.C .1-30, available in bidder's laboratory; including for screening tests, the estimated incidence of the disorder and the observed incidence in bidder's laboratory. Include the false positive and false negative rate per year for each of these additional screening tests. Provide a separate schedule of costs for the addition of these tests. The schedule should list the additional cost for each individual test, and if available, the cost for groups of tests (e.g. multiplex format) for similar disorders.				N/A
V.C.41	Available, state of the art methodologies that may be currently used under research protocols or as a pilot. If it is the bidders intent to make this available to the NNSP, the test(s) should be detailed in regard to instrumentation, analytical staff, oversight, experience, backup, and ability to provide clinical consultation regarding the interpretation of new testing data.				N/A
V.C.42	Individually, list all analytical instruments available for this project, specifying if leased or owned, their age and support agreements (including repair histories, and average time for repair), current workload with these instruments, back up capabilities (such as duplicate instruments) and the laboratory's capacity to add the workload from the Nebraska newborns to be screened. Instrument replacement plans for aging equipment should also be described.				See Summary of Previous Work on Page 9
V.C.43	Other conditions may be detected by the acylcarnitine and amino acid profiles of tandem mass spectrometry beyond those included in the list from Section V.C.1-30. The bidder shall list other conditions that may be able to be detected by the proposed screening protocol.				See Appendix J

****Complete this table for response to V.C.33 and V.C.37.**

Condition Screened	Instrumentation *V.C.33*	Method *V.C.33*	Screening algorithm *V.C.33*	Cutoffs *V.C.33*	Flow Chart attached? *V.C.33*	Narrative description of algorithm *V.C.33*	Back up Methodology and instrument used in the event of equipment failure by the primary method. *V.C.37*
Argininosuccinic acidemia (ASA)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
BIO	Astoria-Pacific	Fluorometric	See below	See Flow Chart	Yes	See narrative below grid	Equipment Redundancy
CAH (17-OHP)	AutoDELFIA	Fluoroimmunometric	See below	See Flow Chart	Yes	See narrative below grid	Equipment Redundancy
CF (IRT/DNA)	AutoDELFIA Luminex	Fluoroimmunometric Allele Specific Primer Extension , flow cytometry	See below N/A	See Flow Chart N/A	Yes N/A	See narrative below grid N/A	Equipment Redundancy Equipment Redundancy
CIT (Cit)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
CPH (T4/TSH)	AutoDELFIA	Fluoroimmunometric	See below	See Flow Chart	Yes	See narrative below grid	Equipment Redundancy

CUD(low C0)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
GA-I (C5DC or C10-OH, or C8 + C10)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
GAL (Gal/GALT)	Astoria-Pacific	Fluorometric	See below	See Flow Chart	Yes	See narrative below grid	Equipment Redundancy
HCY (Met & Homocy)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
Hgb's S, SC, Thal's	PerkinElmer Resolve	Isoelectric Focusing	See below	See Flow Chart	Yes	See narrative below grid	Equipment Redundancy
HMG (C5:OH, C6:DC w/ CS:OH)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
IVA (CS, C6-DC, w/ CS-OH)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
LCHAD (C16-OH, or C18:10OH with others)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
MSUD (Val, Leu, and/or Isoleucine)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
MCAD (C8, or C8 with others)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy

MMA (C3, C3:C2, C3:C16)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
MMA cbl A, B (C3, C3:C3OH, C4DC, Met)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
MPS-I (IDUA)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
MCD (C3 or C5OH)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
PKU (Phe, Phe/Tyr)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
PD (GAA)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
PA (C3,C3:C2, C3:C16)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
SCID (TRECS)	Roche LightCycler 480 II	PCR and allele specific hybridization	See below	See narrative below grid	N/A	See narrative below grid	Equipment Redundancy
Tyr (Tyr)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
TFP C16-OH, C18:1-OH with C16-OH)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy

VLCAD (C14, C14:1, C14:2, & C14:1/C12:1)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
X-ALD (C26.OLC)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
3-MCC (C5:OH or C5:1 w/ CS:OH)	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy
Other MS/MS findings	Sciex	MS/MS	See below	Proprietary Interpretation guide	N/A	See narrative below grid	Equipment Redundancy

High Level Narrative Descriptions of Algorithms

BIO

Initial Sample

If the biotinidase value is greater than the cutoff, the result is reported as Within Normal Limits (WNL). Otherwise, the biotinidase is retested. If the G6PD and uridyltransferase values are below their respective cutoffs, the result is reported as unacceptable (UNACC). If not and the biotinidase value is less than or equal to another cutoff, BIO DNA analysis occurs. Otherwise, the result is reported as inconclusive.

Repeat Sample

If the biotinidase value is greater than the cutoff, the result is reported as WNL. Otherwise, if the G6PD and uridyltransferase values are above their respective cutoffs BIO DNA analysis occurs.

If the G6PD and uridyltransferase values are below their respective cutoffs and the initial sample was WNL, transfusion status is checked and result is reported as See Comments.

If the G6PD and uridyltransferase values are below their respective cutoffs and the initial sample was not WNL or UNACC, BIO DNA analysis occurs. Otherwise if the first sample was UNACC, the result is reported as UNACC with a note.

CAH (17-OHP)

Initial Sample

The CAH screening assay is not run on a first sample collected at less than 24 hours after birth. Cutoffs are established by birth weight ranges. If the sample is collected at greater than 24 hours after birth without an elevated CAH, the result is reported as within normal limits (WNL). If the result is elevated and the birth weight is less than 1.5 kg, an extraction is run and reported as Inconclusive if the extraction value is greater than or equal to the cutoff. Otherwise, the CAH result is reported as See Comments and the extraction as WNL.

If the birth weight is greater than or equal to 1.5 kg and the value does not fall into the critical category, an extraction is run. If extracted result is greater than or equal to the cutoff, the report is Inconclusive (INCON). If the extraction result is less than the cutoff, the 17OHP result is reported as See Comments and the extraction as WNL.

If the birth weight is greater than or equal to 1.5 kg and the CAH value falls into the critical category, an extraction is run. If the birth weight is less than or equal to 2.5 kg a preliminary report is issued as INCON while the extraction is pending. Once the extraction is complete, the report is amended to indicate positive if the extraction value is elevated. Otherwise, the report is amended and the CAH result is reported as See Comments and the extraction as WNL.

If the birth weight is greater than or equal to 1.5 kg and the CAH value falls into the critical category, an extraction is run. If the birth weight is greater than 2.5 kg a preliminary report is issued as positive. Once the extraction is complete, the report is amended to indicate Positive if the extraction value is elevated. Otherwise, the report is amended and the CAH is resulted as See Comments and the extraction as WNL.

Repeat Sample

CAH is run and if the CAH is not elevated, the result is WNL. If the repeat CAH value is greater than the initial CAH value, an extraction is run and if elevated, the result is reported as positive.

If the repeat CAH value is less than the original CAH value, an extraction is run. If the extracted value is elevated, the result is reported as INCON. Otherwise, the result is reported as See Comments with a note.

CF (IRT/DNA)

Initial Sample

The IRT is not run on samples collected greater than 90 days from birth and reported as unacceptable.

If the sample was collected at less than 90 days and value is not greater than the cutoff, the result is reported as within normal limits. Otherwise, a deltaF508 analysis is performed. If a copy is found, the Luminex CF panel is run and reported out based on the number of mutations found.

If no delF508 is found and the IRT is less than the cutoffs, it is reported as Within Normal Limits.

If no delF508 is found and the IRT is greater than or equal to the cutoffs, it is reported as Inconclusive and repeat specimen is requested.

Repeat Sample

The IRT is not run on samples collected greater than 90 days from birth and reported as unacceptable.

If the sample was collected at less than 90 days and value is not greater than the cutoff, the result is reported as within normal limits or continue to refer. Otherwise, the Luminex CF panel is run and reported out based on the number of mutations found. If no mutations are found, it is reported as Inconclusive with a recommendation for a sweat chloride testing.

CPH (T4/TSH)

Samples Collected Less Than or Equal to 7 Days

The CPH screening assay is not run on a sample collected at less than 24 hours after birth. If the sample is collected at greater than 24 hours and is unacceptable due to two sided or over spotting concerns, the T4 is run and reflexed to TSH if in the lowest 10% of the day's run and reported as unacceptable.

If the specimen is acceptable and the T4 is greater than the high standard, result is reported as See Comment. If the T4 is less than the high standard and not in the lowest 10%, the T4 is reported as Within Normal Limits (WNL) and the TSH is not run.

If the T4 value is part of the lowest 10%, the TSH is run. If the value is less than the cutoff, the TSH is reported as WNL. Otherwise, it is reported as positive with different comments when birth weight is greater than or equal to 2.5 kg.

Samples Collected After 7 Days

If the sample is collected at greater than 24 hours and is unacceptable due to two sided or over spotting concerns, the T4 is run and reflexed to TSH if in the lowest 10% of the day's run and reported as unacceptable.

If the specimen is acceptable and the T4 is greater than the high standard, result is reported as See Comment. If the T4 is less than the high standard and not in the lowest 10%, the T4 is reported as Within Normal Limits (WNL) and the TSH is not run.

If the T4 value is part of the lowest 10%, the TSH is run. If the value is less than the cutoff, the TSH is reported as WNL. Otherwise, it is reported as positive.

GAL (Gal/GALT)

Initial Sample

If the gal value is less than the cutoff, the result is reported as Within Normal Limits (WNL). Otherwise a modified gal procedure is performed. If the result of the modified gal procedure is within a specific cutoff range, the result is reported as Inconclusive. If the result of the modified gal procedure is greater than the cutoff, the result is reported as positive.

Repeat Sample

If the gal value is less than the cutoff, the result is reported as WNL. An additional comment is added if the value falls within a specific range. If the value is above the cutoff and below a secondary point, the uridyltransferase is evaluated and reported accordingly. For example, a uridyltransferase value greater than or equal to the cutoff will be reported as WNL. Otherwise, the result is reported as positive.

If the uridyltransferase is greater than the cutoff, the result is reported as WNL. However, if the result is less than or equal to the cutoff and the G6PD value is less than the cutoff and the biotinidase value is less than the cutoff, the result is reported as unacceptable.

If the G6PD or the biotinidase values are above the cutoff, the result is reported as positive.

Hgb's S, SC, Thal's

Hemoglobin AF

Initial Sample

If the sample was collected 6 months after birth and the result is AF, the report lists the Interpretation as Within Normal Limits (WNL) and the Result as AF.

If the sample was collected as less than or equal to 6 months after birth and the filter paper was marked as transfused, the result is reported as See Comments. The accompanying comments report Hemoglobin AF and state that transfusion may interfere with the interpretation of some results and the Nebraska Newborn Screening Program should be contacted for further information.

If a sample is not marked transfused but suspected that it is, a phone call is made to determine if there was or was not a transfusion. If it is determined that a transfusion did not occur, the result is reported as See Comments with accompanying comments stating Hemoglobin AF and requesting a repeat because an AF result is not expected in an infant <6 months old.

However, if it is determined that the collection date to transfused date was greater than or equal to 2 days, the result is reported as See Comments with accompanying comments stating Hemoglobin AF and requesting a repeat specimen 120 days after last transfusion since samples collected > or = 2 days are not reliable for some hemoglobinopathies.

If the collection date to transfused date is less than 2 days, the result is also reported as See Comments but with different accompanying comments stating Hemoglobin AF and recommending a repeat screen 2 days after the last transfusion since specimens collected at <2 days post transfusion are not reliable for some conditions on the screening panel. Also, since no screen was collected before transfusion, collect a repeat screen at 120 days after the last transfusion. If the newborn is <2000 grams at birth, a repeat at 28 days of life or at discharge, whichever occurs first, is also recommended.

Repeat Sample

If the sample was collected 6 months after birth and the result is AF, the report lists the Interpretation as Within Normal Limits (WNL) and the Result as AF.

If the sample was collected as less than or equal to 6 months after birth and the previous result was reported as FA, the new result is reported as See Comments with accompanying comments reporting Hemoglobin AF and stating that a previous filter paper was reported as FA,WNL. In newborns, AF is expected on post-transfusion specimens and to contact the Nebraska Newborn Screening Program for further information.

Otherwise, if the previous result was reported as AF then the new result is reported as See Comments with accompanying comments reporting Hemoglobin AF and stating that a previous filter paper on this newborn was reported as Hemoglobin AF. AF is expected on post-transfusion specimens and to contact the Nebraska Newborn Screening Program for further information.

Lastly, if the previous result was unacceptable, the process flow from the initial sample is used (see above).

Sequencing analysis is an option. Additional details and flow chart updates will have to be discussed between PerkinElmer Genetics and the NNSP.

SCID (TRECS)

The algorithm is broken in to 2 different scenarios where the weeks gestation is < 37 weeks and when the weeks gestation is >= 37 weeks.

Initial Sample Less than 37 Weeks Gestation

When the TRECs is greater than 25, the result is Within Normal Limits (WNL). No recollection required. If the TRECs equals 0 and the beta actin is greater than 5,000 the result is Inconclusive (INCON) otherwise the result is Failure to Amplify. Any recollection should follow the NICU protocol. If the TRECs is greater than 0 and less than or equal to 25 and the beta actin is greater than 10,000 the result is Inconclusive (INCON) otherwise the result is Failure to Amplify. Any recollection should follow the NICU protocol.

Repeat Sample Less than 37 Weeks Gestation with Failure to Amplify Result on the First

When the TRECs is greater than 25, the result is Within Normal Limits (WNL). No recollection required. If the TRECs equals 0 and the beta actin is greater than 5,000 the result is Inconclusive (INCON) otherwise the result is Failure to Amplify. Consultation with an immunologist. If the TRECs is greater than 0 and less than or equal to 25 and the beta actin is greater than 10,000 the result is Inconclusive (INCON) otherwise the result is Failure to Amplify. Consultation with an immunologist.

Repeat Sample Less than 37 Weeks Gestation with Inconclusive Result on the First

When the TRECs is greater than 25, the result is Within Normal Limits (WNL). No recollection required. If the TRECs equals 0 and the beta actin is greater than 5,000 the result is Presumed Positive and referred to flow cytometry. If the beta actin is less than or equal to 5,000, the result is Failure to Amplify and consultation is recommended. If the TRECs is greater than 0 and less than or equal to 25 and the beta actin is greater than 10,000 the result is Inconclusive (INCON) and recollect per NICU protocol. Otherwise the result is Failure to Amplify. Consultation with an immunologist.

Initial Sample Greater than or equal to 37 Weeks Gestation

When the TRECs is greater than 25, the result is Within Normal Limits (WNL). No recollection required. If the TRECs equals 0 and the beta actin is greater than 5,000 the result is Presumed Positive with a referral to flow cytometry. Otherwise the result is Failure to Amplify with a recollection requested. If the TRECs is between 0 and 25 and the beta actin is greater than 10,000 the result is Presumed Positive with a referral to flow cytometry. Otherwise the result is Failure to Amplify with a recollection requested.

Repeat Sample Greater than or equal to 37 Weeks Gestation with Failure to Amplify Result on the First

When the TRECs is greater than or equal to 25, the result is Within Normal Limits (WNL). No recollection required. If the TRECs equals 0 and the beta actin is greater than 5,000 the result is Presumed Positive. Otherwise, the result is Failure to Amplify. Both are referred to flow cytometry. If the TRECs is greater than 0 and less than or equal to 25 and the beta actin is greater than 10,000 the result is Presumed Positive. Otherwise, the result is Failure to Amplify. Both are referred to flow cytometry.

MPS-I (IDUA)

If initial sample is greater than or equal to the cutoff, the result is reported as Within Normal Limits (WNL). Otherwise, it is reported as Inconclusive and a repeat sample is requested. If the repeat sample is greater than or equal to the cutoff, the result is reported as WNL. Otherwise, sequencing analysis is performed.

PD (GAA)

If initial sample is greater than or equal to the cutoff, the result is reported as Within Normal Limits (WNL). Otherwise, it is reported as Inconclusive and a repeat sample is requested. If the repeat sample is greater than or equal to the cutoff, the result is reported as WNL. Otherwise, sequencing analysis is performed.

X-ALD (C26:LPC)

If the value on the initial sample is below the cutoff, the result is reported as Within Normal Limits (WNL). Otherwise, a second tier HPLC method is performed. If the result is below the cutoff, it is reported as WNL. If not, the result is reported as Inconclusive and a repeat sample is requested. The repeat sample will go directly to HPLC and if the result is below the cutoff, it is reported as WNL. Otherwise, sequencing analysis is performed.

Mass Spectrometry Disorders (other than IDUA, GAA and XALD)

The screening performed using mass spectrometry is addressed in the patented interpretation guides for samples collected at less than or equal to 7 days after birth and also after 7 days from birth. These guides can be shared with the NNSP only if requested due to their proprietary nature.

PerkinElmer Genetics' approach measures and interprets the entire family of analytes (acylcarnitines and amino acids), we are able to utilize more than one analyte as an indicator of possible disease. For example, both Phenylalanine and Tyrosine are used in PKU evaluation, and C6, C8 and C10 are used in MCAD analysis. Our interpretive algorithms highlight both key and supporting metabolites, to help identify abnormal specimens and characterize / differentiate specimen results more precisely (i.e., MADD versus MCAD where C8 may be the key metabolite in both cases, but the presence of other metabolites differentiates the disorders).

Experience interpreting such complex results has allowed us to develop a sophisticated interpretation matrix. Multiple quantitative values and metabolite combinations make interpretation using this approach more robust. 'If / Then' statements with particular responses for each outcome have been developed. For some diseases there are more than a half dozen possible interpretation schemes.

Finally, post-natal age is an important factor in optimal result interpretation. Newborn specimens collected up to 7 days are interpreted using one set of criteria. Specimens received from patients greater than 7 days of age utilize a different set of criteria. Using age adjusted MS/MS interpretation is vital to the optimal interpretation of results.

DNA analysis is performed for abnormal samples that meet algorithm criteria.

APPENDIX G – DNA Mutations and Molecular Confirmatory Testing

PerkinElmer Genetics routinely performs mutational analysis for the presence of the following alleles on all screen positive specimens. There is no additional charge for this service and results from second tier DNA analysis are delivered within the described turn-around-times listed earlier in this document.

All mutation analysis is performed using allele specific hybridization after polymerase chain reaction amplification. The platforms used for mutation identification relevant to the Nebraska Newborn Screening Program are the LightTyper® and the LightCycler® (Roche).

MUTATION ANALYSIS AVAILABLE FOR 2ND TIER TESTING AND CONFIRMATION*

Hemoglobinopathies	Hb S (A173T), Hb C (G172A), Hb E (G232A), Hb D (A121Q) and Hb O (E121K) □ Thalassaemias A(-29)G, C(-88)T, and IVS1+6 T>C
Galactosemia	N314D (Duarte) Q188R, S135L, K285N, and L195P (Classical)
Biotinidase Deficiency	G98:d7i3, Q456H, R157H, R538C, D252G and D444H; D444H;A171T, D444H; F403V, D444H;R157H
MCAD	A985G, T199C
LCHAD	G1528C
Glutaric Acidemia 1	A421V (Amish) R402W (Caucasian)
Propionic Acidemia	E168K (Spanish) 1218 Del14/Ins12 (Caucasian) 1170 InsT
Methylmalonic Acidemia	N219Y (Caucasian) G717V (African American)
3-methylcrotonyl-CoA Carboxylase Def.	518InsT (Mennonite)
Maple Syrup Urine Disease	Y438N (previously known as Y393N)
Isovaleric Acidemia	A282V

Cystic Fibrosis

Currently detects a total of 36 mutations and polymorphisms. Includes the 25 mutations and

4 polymorphisms recommended by the American College of Medical Genetics (ACMG) and the American College of Obstetricians and Gynecologists (ACOG).

621+1G>T	A455E	3120+1G>A	3849+10kbC>T
1717-1G>A	R553X	R334W	2789+5G>A
G542X	G551D	2184delA	1898+1G>A
W1282X	R117H*	1078delT	711+1G>T
N1303K	R1162X	ΔI507	G85E
ΔF508	R347P	I148T	R560T
3659delC			

*Reflex testing is performed for the intron 8 variants 5T/7T/9T.

In addition, mutation analysis is also performed for the following:

S1251N	2183AA>G	2143delT	711+ 5G>A	del exon 2,3(21kb)
E60X	3905insT	Q552X	394delTT	3199del6
				3272–26A>G

Molecular Confirmatory Testing

Molecular confirmatory testing is included at no additional charge as part of the screening process for Pompe, MPS-I, X-ALD. Hemoglobinopathy sequencing is also available. Per instruction, the cost for hemoglobinopathy sequencing has been included in a separate cost proposal.

Pompe, MPS-I, Hemoglobins:

A custom Agilent SureSelect enrichment kit is used to enrich the genes using genomic DNA extracted from DBS cards, followed by next-generation sequencing on the Illumina MiSeq with 100 base pair paired-end reads. This analysis detects single nucleotide, small indels and single and multi-exon deletions and duplications, which covers almost the entire mutation spectrum of the genes. Additional MLPA assay to detect deletions/ duplication is not required. All variants are Sanger confirmed.

X-ALD:

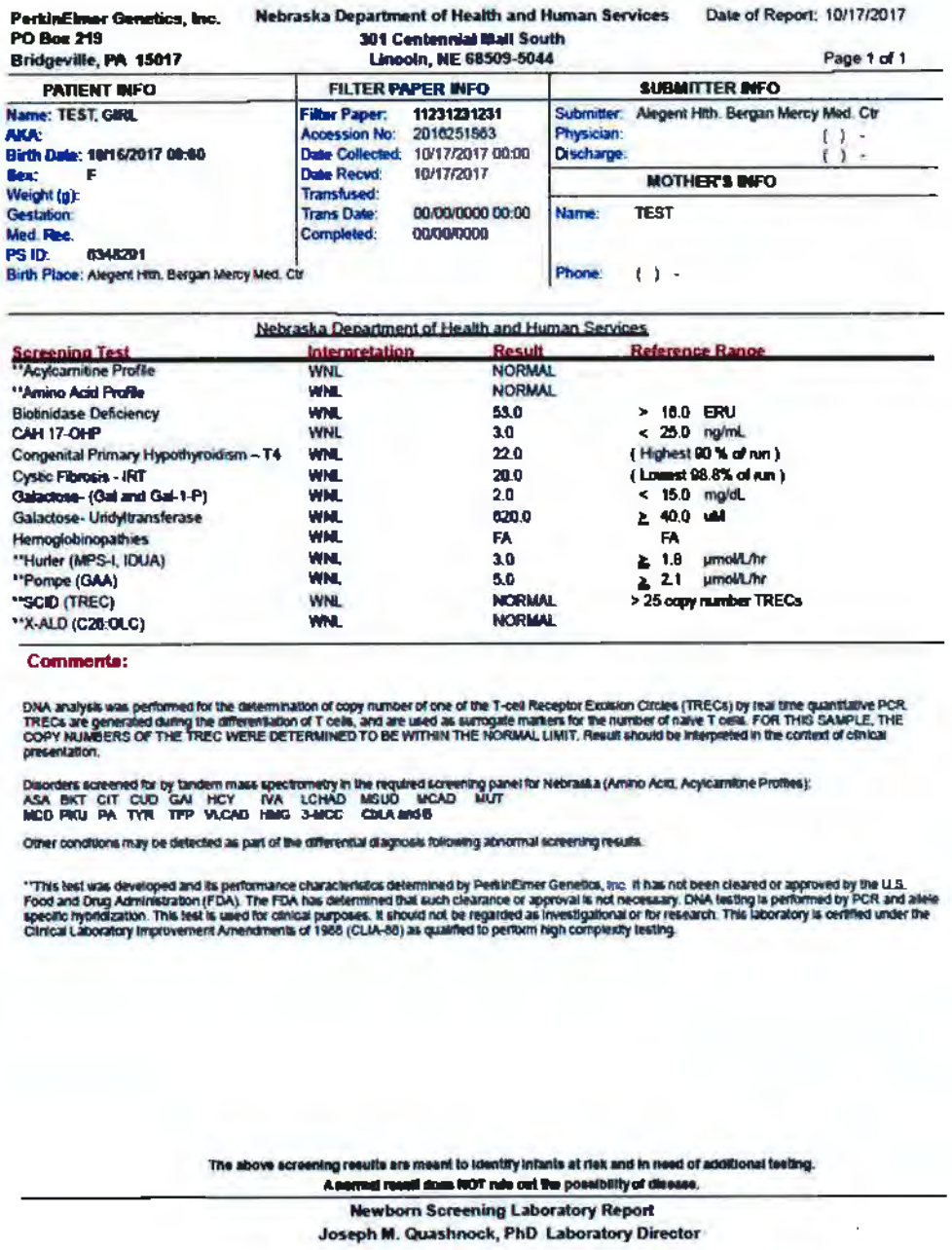
PCR amplification of the coding exons and immediate flanking intronic regions of the ABCD1 gene is performed using genomic DNA extracted from DBS cards. The PCR products are sequenced in the forward and reverse directions. This analysis cannot detect single and multi-exon deletions and duplications, or variants in regions not analyzed such as promoters, deep intronic regions, or long repetitive regions. Large deletions/ duplications type pathogenic variants constitute less than 2% of the mutation spectrum of the gene. MLPA assay to detect deletions/ duplication can be added to detect deletions/ duplications.

Analysis/ Interpretation and reporting

Variants are evaluated by their frequency as reported in public databases (e.g. exac.broadinstitute.org, www.ncbi.nih.gov/dbSNP, browser.1000genomes.org, evs.gs.washington.edu/EVS), ClinVar, Human Gene Mutation Database (HGMD) and published literature. In addition, Variants for the ABCD1 gene are evaluated using the Adrenoleukodystrophy Database (www.x-ald.nl). Variants that have a frequency greater than expected given the prevalence of disease are considered to be benign. Intronic variants greater than three nucleotides from an exon are not reported unless known or suspected to be pathogenic. In some cases, due to the complexity of the sequence, not all variants in the flanking intronic regions can be analyzed. The interpretation of variants is based on our current understanding of the genes. This understanding may change over time as more information becomes available. A list of all variants identified in this individual is available upon request.

APPENDIX H – Newborn Screening Reports – Nebraska Format

The example below is of a proposed lab report that includes the 3 new conditions. It is based off of the current report used by the Nebraska Newborn Screening Program. This example demonstrates the high degree of customization that can be provided to meet client requirements. This is a sample report for illustration purposes only.



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Date of Report: 10/17/2017
Page 1 of 1

PATIENT INFO		FILTER PAPER INFO		SUBMITTER INFO	
Name:	TEST, GIRL	Filter Paper:	11231231231	Submitter:	Alegent Hlth. Bergan Mercy Med. Ctr
AKA:		Accession No:	2016251563	Physician:	( ) -
Birth Date:	10/16/2017 00:00	Date Collected:	10/17/2017 00:00	Discharge:	( ) -
Sex:	F	Date Recvd:	10/17/2017	**MOTHER'S INFO**	
Weight (g):		Transfused:			
Gestation:		Trans Date:	00/00/0000 00:00	Name:	TEST
Med. Rec.		Completed:	00/00/0000		
PS ID:	6348291				
Birth Place:	Alegent Hlth. Bergan Mercy Med. Ctr			Phone:	( ) -

Nebraska Department of Health and Human Services

Screening Test	Interpretation	Result	Reference Range
**Acylcarnitine Profile	WNL	NORMAL	
**Amino Acid Profile	WNL	NORMAL	
Biotinidase Deficiency	WNL	53.0	> 16.0 ERU
CAH 17-OHP	WNL	3.0	< 25.0 ng/mL
Congenital Primary Hypothyroidism – T4	WNL	22.0	(Highest 90 % of run)
Cystic Fibrosis - IRT	WNL	20.0	(Lowest 98.8% of run)
Galactose- (Gal and Gal-1-P)	WNL	2.0	< 15.0 mg/dL
Galactose- Uridyltransferase	WNL	620.0	≥ 40.0 uM
Hemoglobinopathies	WNL	FA	FA
**Hurler (MPS-I, IDUA)	WNL	3.0	≥ 1.8 µmol/L/hr
**Pompe (GAA)	WNL	5.0	≥ 2.1 µmol/L/hr
**SCID (TREC)	WNL	NORMAL	> 25 copy number TRECs
**X-ALD (C26:0LC)	WNL	NORMAL	

Comments:

DNA analysis was performed for the determination of copy number of one of the T-cell Receptor Excision Circles (TRECs) by real time quantitative PCR. TRECs are generated during the differentiation of T cells, and are used as surrogate markers for the number of naive T cells. FOR THIS SAMPLE, THE COPY NUMBERS OF THE TREC WERE DETERMINED TO BE WITHIN THE NORMAL LIMIT. Result should be interpreted in the context of clinical presentation.

Disorders screened for by tandem mass spectrometry in the required screening panel for Nebraska (Amino Acid, Acylcarnitine Profiles):
ASA BKT CIT CUD GAI HCY IVA LCHAD MSUD MCAD MUT
MCD PKU PA TYR TFP VLCAD HMG 3-MCC C8/A and B

Other conditions may be detected as part of the differential diagnosis following abnormal screening results.

**This test was developed and its performance characteristics determined by PerkinElmer Genetics, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. DNA testing is performed by PCR and allele specific hybridization. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity testing.

The above screening results are meant to identify infants at risk and in need of additional testing.
A normal result does NOT rule out the possibility of disease.

Newborn Screening Laboratory Report
Joseph M. Quashnock, PhD Laboratory Director

The example below is of a DNA sequencing report for MPS-I.

PerkinElmer

DNA Sequencing Report

Client	SPECIMEN	PATIENT
Client Name: PKI Genetics Hospital/Institution: N/A Mailing Address: 90 Emerson Ln # 1403, Bridgeville, PA 15017 Fax Number: (412) 220-0784	Specimen Type: Dried blood spot Collection Date: 09/13/2017 Receive Date: 09/19/2017 Completion Date: 09/26/2017 Report Date: 09/26/2017	Patient's PKI ID: 21834 Date of Birth: 09/01/2017 Blood card ID: 150087094 Gender: Female Accession ID: 2017237608

Test Performed: Sequence analysis of the *IDUA* gene
Reason for Referral: Newborn screening results indicating deficiency of alpha-L-iduronidase

TEST RESULT SUMMARY

No pathogenic variants detected. However, one copy of a c.235G>A (p.A79T) pseudodeficiency allele and one copy of a c.667G>A (p.D223N) pseudodeficiency allele in the *IDUA* gene were detected. **Clinical and biochemical correlation is required.**

Gene OMIM	Associated Disease	Inheritance	Exon	DNA Change	Protein Change	dbSNP rsID	Zygosity	Classification
IDUA 252800	Mucopolysaccharidosis Type I (Hurler Syndrome)	Autosomal Recessive	2	c.235G>A	p.A79T	rs58037052	Heterozygous	Pseudodeficiency allele
			6	c.667G>A	p.D223N	rs183347428	Heterozygous	Pseudodeficiency allele

VARIANT INTERPRETATIONS

***IDUA* c.235G>A (p.A79T) – Pseudodeficiency allele.** The c.235G>A (p.A79T) pseudodeficiency allele results in the substitution of the alanine codon at amino acid position 79 with a threonine codon. This variant is a common *IDUA* pseudodeficiency allele[1] that results in decreased IDUA enzyme activity when measured using current artificial substrates but *no clinical evidence of disease has been reported*. Clinical and biochemical correlation is required.

1. Clarke et al. J Pediatr. 2016 Dec 7. pii: S0022-3476(16)31265-3. PMID: 27939258

***IDUA* c.667G>A (p.D223N) – Pseudodeficiency allele.** The c.667G>A (p.D223N) pseudodeficiency allele results in the substitution of the aspartic acid codon at amino acid position 223 with an asparagine codon. This variant is an *IDUA* pseudodeficiency allele[1] that results in decreased IDUA enzyme activity when measured using current artificial substrates but *no clinical evidence of disease has been reported*. Clinical and biochemical correlation is required.

1. Clarke et al. J Pediatr. 2016 Dec 7. pii: S0022-3476(16)31265-3. PMID: 27939258

Recommendations: These results must be interpreted in the context of this individual's clinical and biochemical profile. Genetic counseling is recommended. For more information, please contact the laboratory at 1-866-463-6436.

Gene Information: The *IDUA* gene encodes the alpha-L-iduronidase enzyme, a lysosomal enzyme that degrades heparin and dermatan sulfates. Pathogenic variants in the *IDUA* gene that decrease alpha-L-iduronidase enzyme activity

Patient's PKI ID: 21834 Accession ID: 2017237608 Blood card ID: 150087094

are known to cause mucopolysaccharidosis type I (MPS I), also known as Hurler syndrome or Scheie syndrome. MPS I is a multisystem disorder that can range from severe (Hurler syndrome) to attenuated (Scheie syndrome). Clinical features can include coarse facial features, hepatosplenomegaly, corneal clouding, progressive skeletal dysplasia, and inguinal or umbilical hernia. MPS I is inherited in an autosomal recessive pattern, meaning two pathogenic variants, one inherited from each parent, are required to cause disease. A variety of genetic aberrations including missense variants, splice site variants, and insertions/deletions have been implicated in the pathogenesis of this disease. Nucleotide numbering is based on GenBank accession number NM_000203.3; nucleotide 1 corresponds to the A of the start codon ATG.

1. GeneReviews: Mucopolysaccharidosis Type I (www.ncbi.nlm.nih.gov/books/NBK1162/) accessed 2/22/2017

METHODS AND LIMITATIONS

Sequence analysis cannot determine if two variants are on the same (in *cis*) or opposite (in *trans*) copies of a gene. Targeted testing of the parents of this individual to determine if the *IDUA* variants are on opposite chromosomes in this individual is available. For more information, please contact the laboratory at 1-866-463-6436.

A custom Agilent SureSelect enrichment kit was used to enrich the gene(s) of interest from this individual's genomic DNA, followed by next-generation sequencing on the Illumina MiSeq with 100 base pair paired-end reads. This analysis cannot detect single and multi-exon deletions and duplications, or variants in regions not analyzed such as promoters, deep intronic regions, or long repetitive regions.

Variants are evaluated by their frequency as reported in public databases (e.g. exac.broadinstitute.org, www.ncbi.nlm.nih.gov/dbSNP, browser.1000genomes.org, evs.gs.washington.edu/EVS). Variants that have a frequency greater than expected given the prevalence of disease are considered to be benign. Benign and likely benign variants are not reported. Intronic variants greater than three nucleotides from an exon are not reported unless known or suspected to be pathogenic. In some cases, due to the complexity of the sequence, not all variants in the flanking intronic regions are able to be analyzed. The interpretation of variants is based on our current understanding of the genes involved. This understanding may change over time as more information becomes available. A list of all variants identified in this individual is available upon request.

Possible sources of testing error include rare genetic variants that interfere with analysis, sample misidentification, and other sources. Pursuant to the requirements of CLIA '88, this test was developed and its performance validated by PerkinElmer Genetics. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes.

Babi Ramesh Reddy Nallamilli, PhD – Assistant Clinical Laboratory Director, PerkinElmer Genetics Laboratory
Alice K. Tanner, PhD, MS, CGC, FACMG – Clinical Laboratory Director, PerkinElmer Genetics Laboratory

APPENDIX I – Continuous Improvement Reports – Examples of Performance Data

Examples of a data feedback reports that have worked very successfully for some state clients are provided. These various reports can be flexibly integrated into an educational feedback program coordinated by the program to monitor and improve performance. Relevant metrics include unacceptable specimen rate, birth to collection time (reflects hospital specimen collection), and birth to receipt time (reflects batch shipping of specimens). Data can be compared to program goals and documented past performance to enhance compliance with newborn screening system parameters.

Below is an example of a QA report that is produced on a quarterly basis.

Hospital Report
Newborn Screening Specimen Collection & Handling Metrics
7/1/2017-9/30/2017
Date Of Report: 10/10/2017
TESTING LABORATORY: PerkinElmer Genetics, Inc.

Facility:	Any Nebraska Facility

Initial Specimens:	152
Repeat Specimens:	4

Performance Metrics and Benchmarks

Measure	Benchmark	State Performance	Facility Performance
A. initial specimens collected at > 48 hrs	<1.5%	0.68%	1.38%
B. Unsatisfactory specimens	<1%	0.40%	0.64%
C. Average time Birth to Collect	<= 1.4 days	1.14 day(s)	1.37 day(s)
D. Percent (non-NICU) initial specimens collected @ 24-48 hr	Not established - babies discharged <24 hours requiring early screen.	98.83%	96.62%
E. Average time Collect to Receipt	Average time received not > 2.25 days from collection	2.01 day(s)	1.97 day(s)
F1. Percent received within 3 days from collection	This measure being monitored over time to establish appropriate	88.56%	79.49%

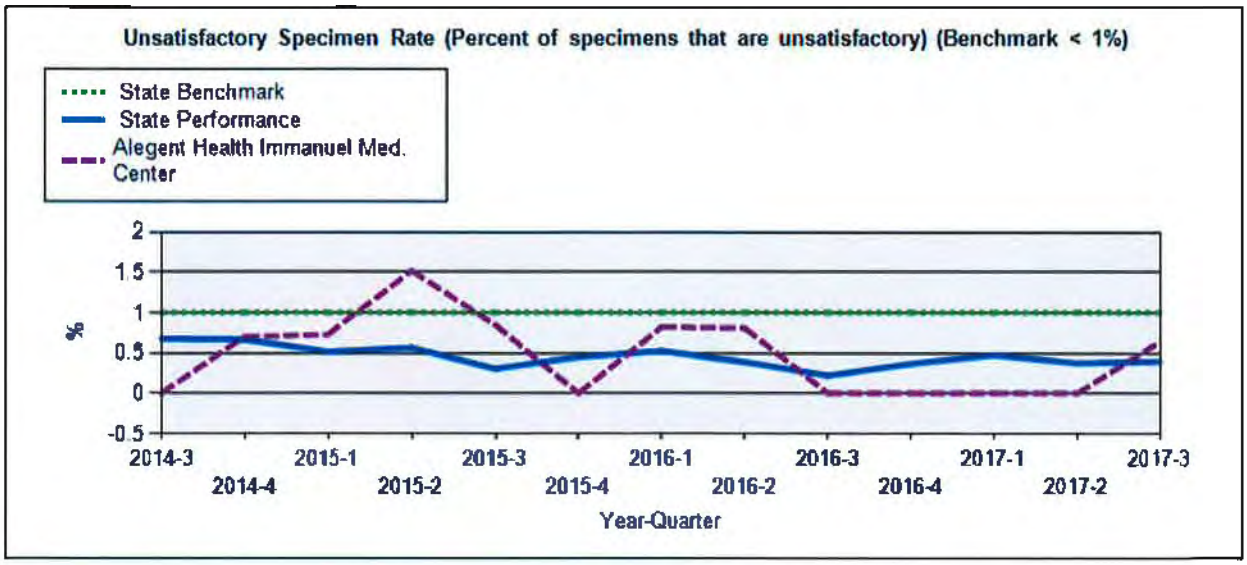
F1. Percent received within 3 days from collection	This measure being monitored over time to establish appropriate	88.56%	79.49%
F2. Percent received within 2 days from collection	Measure being monitored over time to establish appropriate benchmark.	58.07%	61.54%
F3. Percent received within 1 day from collection	This measure being monitored over time to establish appropriate	0.97%	0.00%
G. Average time Receipt to Result/Report for all results	Average in lab time not > 1.5 days	1.44 day(s)	1.49 day(s)
H. Average time Collect to Result (all results)	This measure being monitored over time to establish an appropriate	3.45 day(s)	3.46 day(s)
I. Percent of all results released 4 days from collection (day = 24 hours)	ACHDNC Rec: all by 5 days. Nebraska benchmark not established yet.	75.47%	86.67%
J. Percent of all results released 5 days from collection (day = 24 hours)	ACHDNC Rec: all by 5 days. Nebraska benchmark not established yet.	94.74%	85.90%
K. Percent of all results released 6 days from collection (day = 24 hours)	ACHDNC Rec: all by 5 days. Nebraska benchmark not established yet.	99.21%	96.79%
L. Percent of all results released > 6 days from collection (day = 24 hours)	ACHDNC Rec: all by 5 days. Nebraska benchmark not established yet.	0.79%	3.21%
M. Avg Age (birth to result for all initial specimens)	< 5 days	4.58 day(s)	4.86 day(s)
N1. Percent of results released within 5 days of age	ACHDNC Rec: all by 7 days. Nebraska benchmark not established yet.	70.47%	57.93%

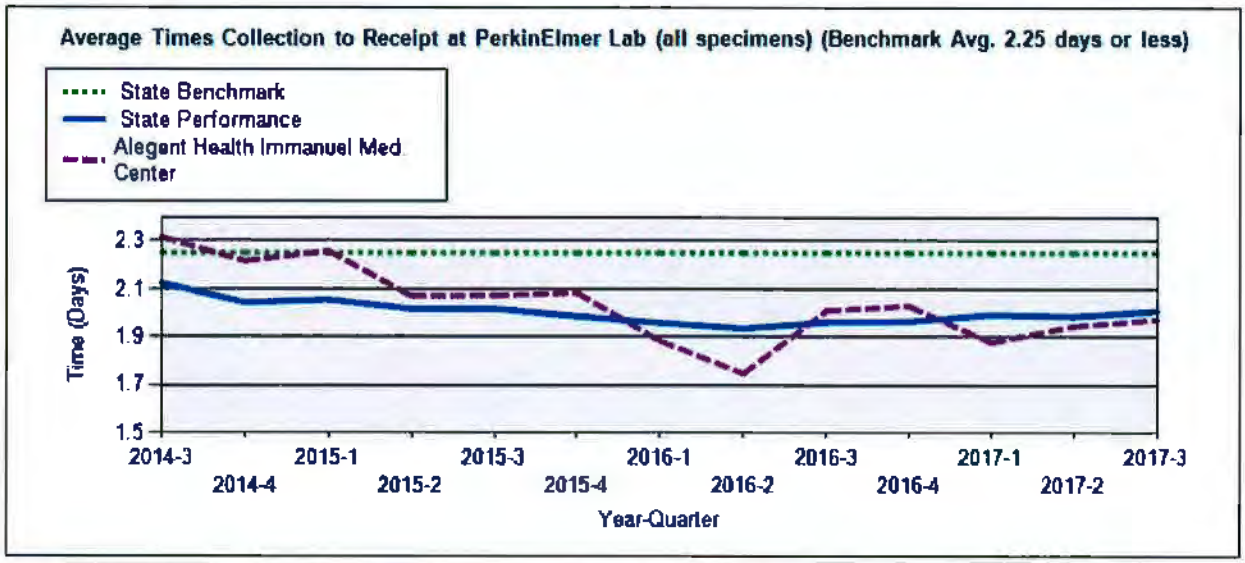
N2. Percent of results released within 6 days of age	ACHDNC Rec: all by 7 days. Nebraska benchmark not established yet.	93.40%	80.69%
N3. Percent of results released within 7 days of age	ACHDNC Rec: all by 7 days. Nebraska benchmark not established yet.	98.92%	96.55%
N4. Percent of results released after 7 days of age	ACHDNC Rec: all by 7 days. Nebraska benchmark not established yet.	1.08%	3.45%
O1. Number of presumptive positive results for non-critical conditions released by 7 days of age	ACHDNC Rec: all by 7 days. Nebraska benchmark not established yet.	15 / 16	0 / 0
O2. Percent of presumptive positive results for non-critical conditions released by 7 days of age	ACHDNC Rec: all by 7 days. Nebraska benchmark not established yet.	93.75%	N/A
P1. Number of presumptive positive results for critical conditions released by 5 days of age	ACHDNC Rec: all by 5 days. Nebraska benchmark not established yet.	0 / 1	0 / 0
P2. Percent of presumptive positive results for critical conditions released by 5 days of age	ACHDNC Rec: all by 5 days. Nebraska benchmark not established yet.	0.00%	N/A

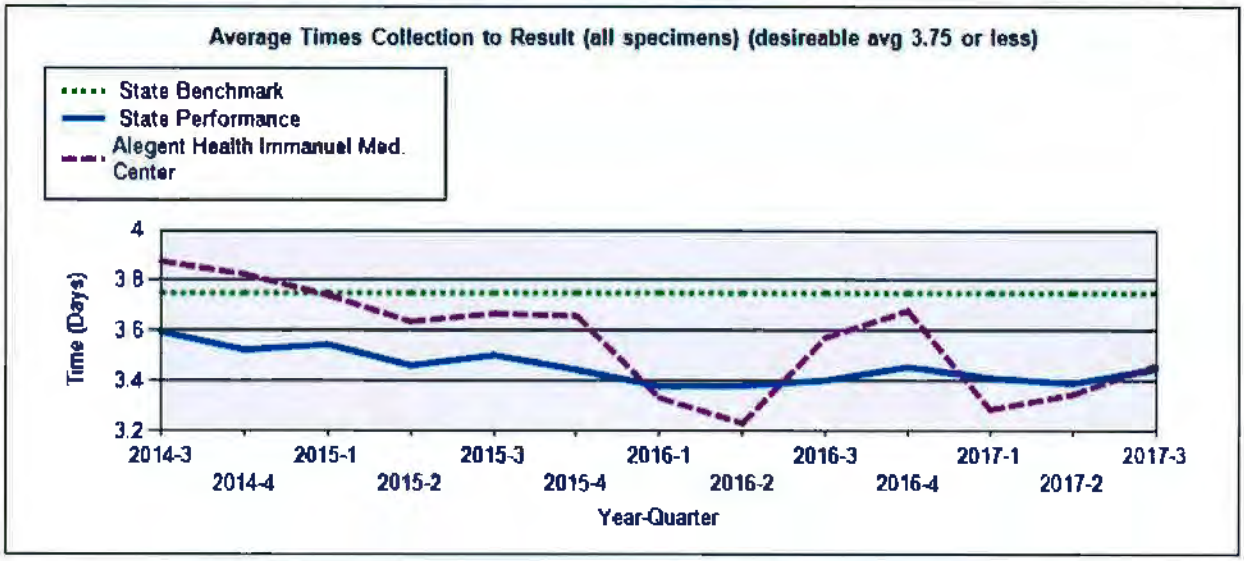
Critical conditions as determined by the ACHDNC are:
Propionic acidemia
Methylmalonic acidemia MMA (MUT)
Isovaleric acidemia
3-Hydroxy-3-methylglutaric aciduria
Multiple carboxylase deficiency
Beta ketothiolase deficiency
Glutaric aciduria type 1
Argininosuccinic aciduria
Citrullinemai type 1
Maple Syrup Urine disease
Medicum chain acyl-CoA-dehydrogenase deficiency
Very long chain acyl-CoA dehydrogenase deficiency
Long chain L-3-hydroxyacyl-CoA dehydrogenase deficiency
Trifunctional protein deficiency
Classic galactosemia
Congenital adrenal hyperplasia

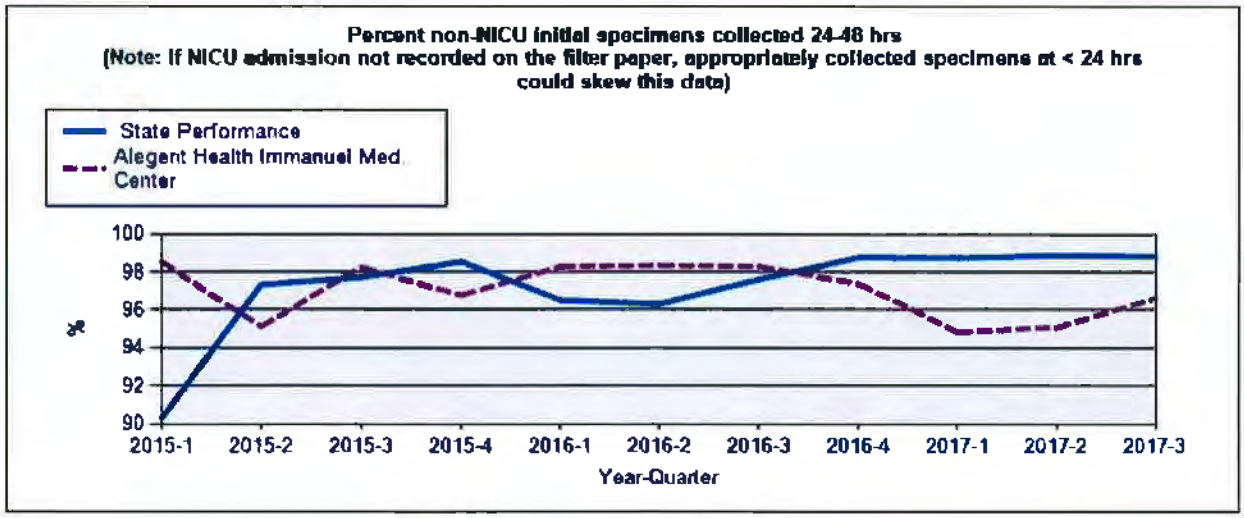
UNSATISFACTORY/UNACCEPTABLE SPECIMENS this period

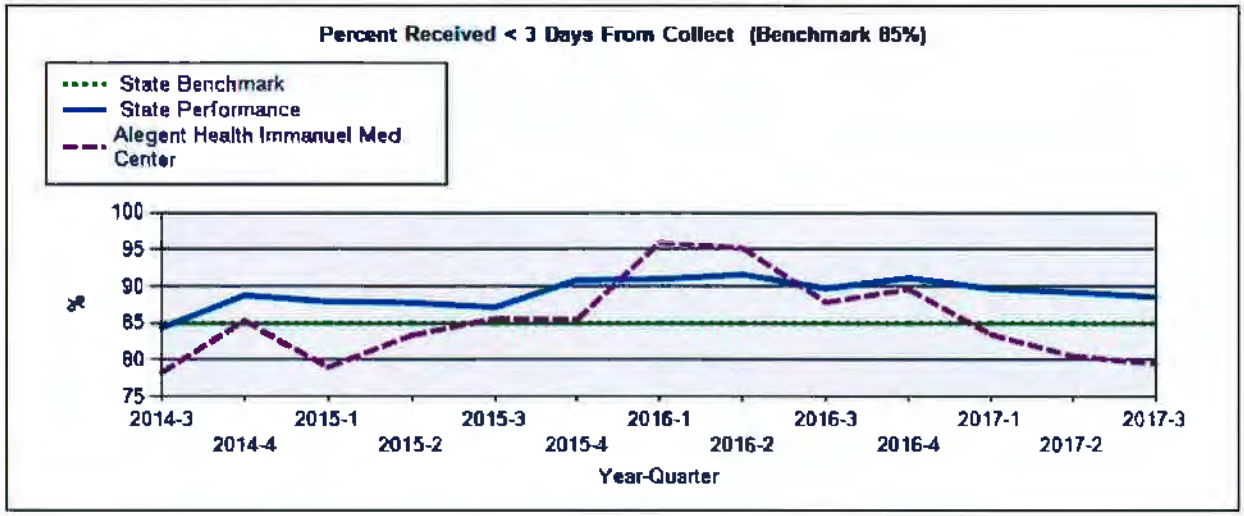
Filter Paper	Last Name	DOB	Collector	Date Collected	Unsat Reasons	Tests Not able to be done
9741583	DOE	2017-08-05 02:54	204	2017-08-06 07:08	QNS for some tests, Quantity not sufficient to	IRT

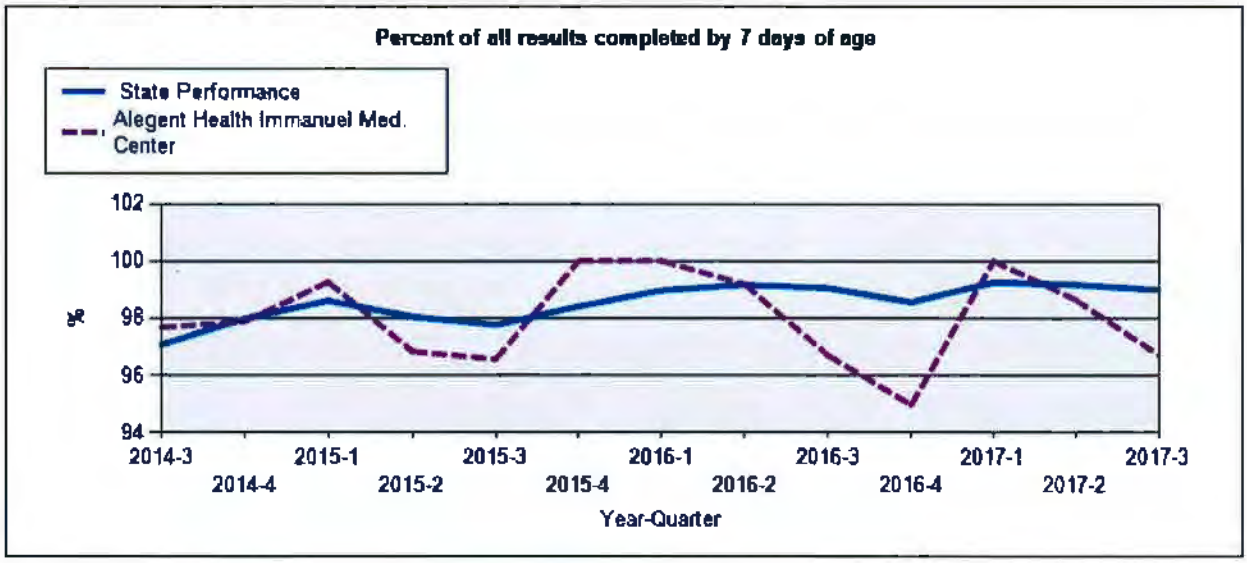



Average Times Collection to Receipt at PerkinElmer Lab (all specimens) (Benchmark Avg. 2.25 days or less)
State Benchmark
State Performance
Alegent Health Immanuel Med. Center
Time (Days)
2.3
2.1
1.9
1.7
1.5
2014-3
2014-4
2015-1
2015-2
2015-3
2015-4
2016-1
2016-2
2016-3
2016-4
2017-1
2017-2
2017-3
Year-Quarter


Average Times Collection to Result (all specimens) (desireable avg 3.75 or less)
State Benchmark
State Performance
Alegent Health Immanuel Med. Center
Time (Days)
4
3.8
3.6
3.4
3.2
2014-3
2014-4
2015-1
2015-2
2015-3
2015-4
2016-1
2016-2
2016-3
2016-4
2017-1
2017-2
2017-3
Year-Quarter


Percent non-NICU initial specimens collected 24-48 hrs
(Note: If NICU admission not recorded on the filter paper, appropriately collected specimens at < 24 hrs could skew this data)
State Performance
Alegent Health Immanuel Med Center
100
98
96
94
92
90
%
2015-1
2015-2
2015-3
2015-4
2016-1
2016-2
2016-3
2016-4
2017-1
2017-2
2017-3
Year-Quarter


Percent Received < 3 Days From Collect (Benchmark 85%)
State Benchmark
State Performance
Alegent Health Immanuel Med Center
100
95
90
85
80
75
%
2014-3
2014-4
2015-1
2015-2
2015-3
2015-4
2016-1
2016-2
2016-3
2016-4
2017-1
2017-2
2017-3
Year-Quarter


Percent of all results completed by 7 days of age
State Performance
Alegent Health Immanuel Med. Center
102
100
98
96
94
%
2014-3
2014-4
2015-1
2015-2
2015-3
2015-4
2016-1
2016-2
2016-3
2016-4
2017-1
2017-2
2017-3
Year-Quarter

APPENDIX J – Other conditions that may be detected by the acylcarnitine and amino acid profiles of tandem mass spectrometry

- **Fatty Acid Oxidation Disorders**
  - Carnitine/Acylcarnitine Translocase Deficiency (Translocase)
  - Carnitine/Acylcarnitine Transferase Deficiency Type I (1)
  - 2,4-Dienoyl-CoA Reductase Deficiency
  - Multiple Acyl-CoA Dehydrogenase Deficiency (MADD or Glutaric Acidemia-Type II)
  - Neonatal Carnitine Palmitoyl Transferase Deficiency Type II (CPT-II)
  - Short Chain Acyl-CoA Dehydrogenase Deficiency (SCAD)
  - Short Chain Hydroxy Acyl-CoA Dehydrogenase Deficiency (SCHAD)
- **Organic Acid Disorders**
  - Isobutyryl-CoA Dehydrogenase Deficiency
  - 2-Methylbutyryl-CoA Dehydrogenase Deficiency
  - 3-Methylglutaconyl-CoA Hydratase Deficiency
  - Malonic Aciduria
- **Amino Acid Disorders**
  - Argininemia
  - Carbamoylphosphate Synthetase Deficiency (1)
  - Hypermethioninemia
  - Hyperammonemia, Hyperornithinemia, Homocitrullinuria Syndrome (HHH) (1)
  - Hyperornithinemia with Gyral Atrophy (1)
  - 5-Oxoprolinuria (Pyroglutamic Aciduria) (1)
- **OTHER OBSERVATIONS**
  - Hyperalimentation
  - Liver Disease
  - Medium Chain Triglyceride Oil Administration
  - Presence of EDTA Anticoagulants in blood specimen
  - Treatment with Benzoate, Pyvalic Acid, or Valproic Acid

The analyses conducted by PerkinElmer Genetics produce results that can be used by qualified physicians in the diagnosis of disorders described herein. Evidence of these conditions will be detected in the vast majority of affected individuals; however, due to genetic variability, age of the patient at time of specimen collection, quality of the specimen, health status of the patient, and other variables, such conditions may not be detected in all affected patients.

(1) There is a lower probability of detection of this condition during the immediate newborn period.

APPENDIX K – Patents used in Newborn Screening - Tandem Mass Spectrometry and DNA Technologies

The following abstracts reference the patent protected technology used in performing newborn screening using tandem mass spectrometry and DNA based assays. Broadly speaking the described processes include method of sample preparation, analysis and characterization of results. The abstracts relevant to the disorders specified in the Nebraska RFP are presented.

United States Patent **6,258,605**

Chace **July 10, 2001**

Clinical method for the genetic screening of newborns using tandem mass spectrometry

Abstract

A method for screening newborns using electrospray tandem mass spectrometry. The method improves the current protocols that use tandem mass spectrometry by assuring accurate and consistent results at the clinical level through enhanced quality controls and quality assurance protocols as applied to the scan profiling and sample preparation of blood spots from newborns. Specific additives are used in precise concentrations of internal standards, employing detailed controls adapted to distinguish twenty metabolites, which are scanned and vigorously compared to known spectra results. Revealing peaks, metabolite concentration, and scan intensities in the quality assurance steps are then compared to a range of thresholds to determine whether or not the sample is contaminated, drug-ridden, diagnosable, or unacceptable. All spectra results and quality assurance flags are organized in spreadsheet form and exported to a database where values are compiled and stored for daily output results and trend analysis. The method provides for high-throughput and quality results, having a consistent predictability for genetically testing newborns efficiently and accurately.

Inventors: **Chace; Donald H.** (Pittsburgh, PA)
Assignee: **Neo Gen Screening, Inc.** (Bridgeville, PA)
Appl. No.: **277119**
Filed: **March 26, 1999**
Current U.S. Class: **436/86**; 436/173
Intern'l Class: G01N 033/68; G01N 024/00
Field of Search: 436/86,173

United States Patent ***6,455,321***
Chace **September 24, 2002**

Method for interpreting tandem mass spectrometry data for clinical diagnosis

Abstract

A method for interpreting data that is produced after a group of amino acids and acylcarnitines are derivatized from blood spots taken from newborn babies and scanned by a tandem mass spectrometer. Concentration levels of each metabolite, which are directly proportional to the butyl ester fragment after derivatization, are compared to threshold flags for determining a significance of any deviation of the metabolite relative to the flag threshold. The threshold flags are diagnostic limits to the data retrieved from each blood spot. The data includes metabolite concentrations and molar ratios of metabolites with other metabolites. Samples are labeled normal for a disease if the concentration of any of the metabolite concentrations or molar ratio concentration do not deviate from the flag threshold, but, in contrast, the sample must be further evaluated if a value is elevated or deficient to some degree. Thus, as each metabolite fragments at a different mass to charge value (m/z), corresponding data is compared to the respective flag thresholds for determining a next course of action that must be taken to ultimately assist a physician in the diagnosis of a genetic disorder resulting from an elevation or deficiency of the metabolite particular for that disorder.

Inventors: **Chace; Donald H.** (Pittsburgh, PA)
Assignee: **Neo Gen Screening, Inc.** (Bridgeville, PA)
Appl. No.: **464132**
Filed: **December 16, 1999**
Current U.S. Class: **436/173**; 436/86; 702/22; 702/23; 702/27
Intern'l Class: G01N 024/00
Field of Search: 436/86,173 702/22,23,27

United States Patent Application **20030124581**
Kind Code **A1**
Dobrowolski, Steven F. ; et al. **July 3, 2003**

Newborn screening for hemoglobinopathy by DNA microarray analysis

Abstract

A method and an associated microarray for detecting hemoglobinopathies by DNA microarray analysis is disclosed for a newborn screening protocol. A fragment of the human beta-globin gene is amplified and immobilized on a glass substrate and is allowed to hybridize with fluorescent dye-labeled oligonucleotide probes matched to either wild type or mutant S, C, and E alleles of the beta-globin gene. The resulting hybridized microarray slide is scanned and analyzed to reveal normal gene sequence or single nucleotide polymorphisms.

Inventors: **Dobrowolski, Steven F.**; *(Park City, UT)* ; **Lin, *Zhili***; *(Pittsburgh, PA)*
Correspondence Name and Address: **MCKAY & ASSOCIATES, PC.**
801 MCNEILLY ROAD
PITTSBURGH
PA
15226
US

Serial No.: **246869**
Series Code: **10**
Filed: **September 19, 2002**
U.S. Current Class: **435/6**; 435/91.2
U.S. Class at Publication: **435/6**; 435/91.2
Intern'l Class: C12Q 001/68; C12P 019/34

APPENDIX L – Bibliography of Articles Cited

Citations referenced in this RFP are presented in the order which they appear in text.

[1] Chace DH, Pons R, Chiriboga CA, McMahon D, Tein I, Naylor EW, et al. Neonatal Blood Carnitine Concentrations: Normative Data by Electrospray Tandem Mass Spectrometry. Pediatr Res 2003.

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[4] Center for Disease Control and Prevention, Using Tandem Mass Spectrometry for Metabolic Disease Screening Among Newborns: A Report of a Workgroup. MMWR 2001; 50 (No. RR-3).

[5] Chace US patent 6,258,605B1, July 10, 2001; and Chace US patent 6,455,321, September 24, 2002.

[6] Chace, DH, Hillman SL, Van Hove, JK, Naylor EW, Rapid Diagnosis of MCAD Deficiency. Quantitative analysis of Octanoylcarnitine and other Acylcarntines by MS/MS, Clin Chem, 43, 2106, 1997.

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[9] Chace DH, Chairman of Mass Spectrometry Clinical Laboratory Standards Committee. Clinical Laboratory Standards Institute (formerly NCCLS), (*in preparation*), 2005.

[10] Chace DH. Clinical Analysis: Inborn Errors of Metabolism. In: Worsfold P, Townshend A, Poole, C, ed. Encyclopedia of Analytical Science. Second ed: Elsevier Academic Press; 2005.

[11] Chace DH, Kalas TA. A biochemical perspective on the use of tandem mass spectrometry for newborn screening and clinical testing. Clin Biochem., 38(4):296-309, 2005.

[12] Chace DH, Sherwin JE, Hillman SL, Lorey F, Cunningham GC. Use of phenylalanine-to-tyrosine ratio determined by tandem mass spectrometry to improve newborn screening for

Phenylketonuria of early discharge specimens collected in the first 24 hours. Clin Chem., 44(12):2405-9, 1998.

[13] Lin Z, Suzow JG, Fontain JM, Naylor EW. A Simple Automated DNA Extraction Method for Dried Blood Specimens collected on Filter Paper, J of Assoc. Lab. Automation, Oct;10(5):310-4, 2005.

[14] Lin Z, Suzow JG, Dobrowolski SF, Naylor EW. A DNA Micro array Genotyping Method for Newborn Screening of Sickle Cell Disease (*Pending*).

[15] U.S. Patent 10/246,869; Newborn Screening for Hemoglobinopathy by DNA Micro array Analysis filed 9/19/2002.

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INNOVATING FOR A HEALTHIER WORLD

2016 Annual Report

PerkinElmer
For the Better

Dear Fellow Shareholders,

2016 was an important year in PerkinElmer's evolution as we took pivotal steps to fundamentally shift our portfolio and organization to be further aligned with our customers and better positioned to accelerate future growth.

At the same time, we continued to improve our operational execution, as evidenced by our strong financial performance, delivering adjusted operating margin expansion of 140 basis points, adjusted EPS growth of 12% and free cash flow growth of 23%. This improved profitability was achieved at the same time that we increased our investments in R&D as well as in new tools to facilitate innovation.

While we have made strides to strengthen PerkinElmer from within, we have been actively improving our structure and portfolio to more acutely shape the Company for accelerated growth. Over the past year and a half, we signed or closed on several acquisitions representing approximately $350 million in value. We completed our purchase of Vanadis, giving us access to a potentially disruptive technology in non-invasive prenatal screening. We acquired Bioo Scientific, expanding our food detection capabilities and our genomics offerings for next generation sequencing. Our acquisition of Delta Instruments also grew our food franchise with market-leading analyzers for testing in dairy applications. In December, we signed a definitive agreement to acquire Tulip Group, propelling PerkinElmer as a leading in-vitro diagnostics provider in India, and then closed on this transaction in January. In addition, we announced three divestitures that will enable us to redeploy approximately $300 million into areas more aligned with our growth priorities.

To facilitate this transition, we have created a more effective operating structure to better align with our customers' requirements and our focus areas for growth. The result of these efforts was the formation of two new reporting segments, Discovery & Analytical Solutions (DAS) and Diagnostics, which replaced our former reporting segments. DAS, with its larger, unified R&D and commercial teams, will better serve and innovate for applications-oriented customers. Our Diagnostics segment will focus on clinically-oriented customers and expand our addressable markets. We also evolved our mission to "innovating for a healthier world", reflecting how our solutions and expertise help unlock insights to protect the health of our families, environment and food supply.

As we execute on our objectives, we never lose sight of the remarkable difference we are making on lives around the world. Last year, our quantitative pathology solutions played a crucial role in a first-of-its-kind skin cancer study published in the *New England Journal of Medicine*. In addition, government agencies adopted our portable detection technologies to identify toxic chemicals in the air in real-time. And in China, we saw more of our analytical solutions used to test for pesticides in food to help protect millions of citizens.

Clearly 2016 was a year in which we elevated PerkinElmer's technological, operational and organizational capabilities. We enter 2017 with a number of exciting developments that will strengthen PerkinElmer's future growth and profitability. First, this year we are amplifying how we innovate through more targeted R&D spending, as well as innovating alongside external collaborators across our end markets. As we did in 2016, we will continue to discriminate our investments towards the fast growing areas of food safety, pharmaceutical and biotech services, reproductive health, and emerging market diagnostics. A key differentiator for PerkinElmer is the unparalleled value we bring to our customers by providing them with complete solutions uniquely developed to meet business-critical needs. Second, essential to creating breakthrough solutions is better understanding our customers' most difficult problems and most challenging needs. By evolving and innovating how and where customers need us, we will be better positioned to enhance the customer experience and increase long-term customer loyalty. Third, from an operational standpoint, we will continue the implementation of Lean to support product quality improvements, expand gross margins, and augment our customer service processes. Furthermore, this year our goal to advance our operational excellence will pair with our objectives to broaden PerkinElmer's global reach and diversity of talent.

In closing, I am confident in the critical role PerkinElmer will continue to play in the future of health. Thanks to the ongoing support from employees, customers and shareholders, we can realize even greater opportunities to achieve profitable growth while advancing our mission of innovating for a healthier world.

Sincerely,

Robert F. Friel
Chairman, Chief Executive Officer and President
PerkinElmer, Inc.

CORPORATE GOVERNANCE

BOARD OF DIRECTORS

Robert F. Friel
Chairman, Chief Executive Officer
and President
PerkinElmer, Inc.

Peter Barrett
Partner, Atlas Venture

Samuel R. Chapin
Retired Executive Vice Chairman
Bank of America Merrill Lynch

Sylvie Grégoire, PharmD
Advisor to biotechnology companies

Nicholas A. Lopardo
Chairman and Chief Executive Officer
Susquehanna Capital Management Group

Alexis P. Michas
Managing Partner
Juniper Investment Company, LLC

Vicki L. Sato, PhD
Professor of Management Practice
Harvard Business School

Kenton J. Sicchitano
Retired Global Managing Partner
PricewaterhouseCoopers LLP

Patrick J. Sullivan
Chief Executive Officer and Chairman
Insulet Corporation

Frank Witney, PhD
Former Chief Executive Officer
Affymetrix, Inc.

CORPORATE OFFICERS

Robert F. Friel
Chairman, Chief Executive Officer
and President

James Corbett
Executive Vice President and President,
Discovery & Analytical Solutions

Deborah Butters
Senior Vice President and Chief Human
Resources Officer

Joel S. Goldberg
Senior Vice President, Administration, General
Counsel and Secretary

Prahlad Singh
Senior Vice President and President, Diagnostics

Daniel R. Tereau
Senior Vice President, Strategy and Business
Development

Frank A. Wilson
Senior Vice President and Chief Financial
Officer

Andrew Okun
Vice President and Chief Accounting Officer

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended January 1, 2017

Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-5075

PerkinElmer, Inc.

(Exact name of registrant as specified in its charter)

Massachusetts	**04-2052042**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
940 Winter Street, Waltham, Massachusetts	**02451**
(Address of Principal Executive Offices)	*(Zip Code)*

(Registrant's telephone number, including area code): (781) 663-6900

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $1 Par Value	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the common stock, $1 par value per share, held by non-affiliates of the registrant on July 1, 2016, was $5,650,129,129 based upon the last reported sale of $52.66 per share of common stock on July 1, 2016.

As of February 24, 2017, there were outstanding 109,787,006 shares of common stock, $1 par value per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of PerkinElmer, Inc.'s Definitive Proxy Statement for its Annual Meeting of Shareholders to be held on April 25, 2017 are incorporated by reference into Part III of this Form 10-K.

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PART I

Item 1. *Business*

Overview

We are a leading provider of products, services and solutions for the diagnostics, food, environmental, industrial, life sciences research and laboratory services markets. Through our advanced technologies and differentiated solutions, we address critical issues that help to improve lives and the world around us.

We realigned our businesses at the beginning of the fourth quarter of fiscal year 2016 to better organize around customer requirements, positioning us to grow in attractive end markets and expand share with our core product offerings. We created two new reporting segments, Discovery & Analytical Solutions and Diagnostics, which will enable us to deliver improved customer focus, more value-add collaboration and breakthrough innovations. Our Diagnostics business became a standalone reporting segment targeted towards better meeting the needs of clinically-oriented customers, especially within the growing areas of reproductive health, emerging market diagnostics and applied genomics. Microfluidics and automation products within our former research business were moved to a new applied genomics group within the Diagnostics segment. Our former environmental health business and the remaining products within the legacy research business were combined to form our new Discovery & Analytical Solutions reporting segment, focused on better serving and innovating for applications-oriented customers. Discovery & Analytical Solutions customers span the environmental, food, industrial, life sciences research and laboratory services markets.

We are a Massachusetts corporation, founded in 1947. Our headquarters are in Waltham, Massachusetts, and we market our products and services in more than 150 countries. As of January 1, 2017, we employed approximately 8,000 employees in our continuing operations. Our common stock is listed on the New York Stock Exchange under the symbol "PKI" and we are a component of the S&P 500 Index.

We maintain a website with the address http://www.perkinelmer.com. We are not including the information contained in our website as part of, or incorporating it by reference into, this annual report on Form 10-K. We make available free of charge through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports, as soon as reasonably practicable after we electronically file these materials with, or otherwise furnish them to, the Securities and Exchange Commission.

Our Strategy

Our strategy is to develop and deliver innovative products, services and solutions in high-growth markets that utilize our knowledge and expertise to address customers' critical needs and drive scientific breakthroughs. To execute on our strategy and accelerate revenue growth, we focus on broadening our offerings through both the acquisition of innovative technology and investment in research and development. Our strategy includes:

- Achieving significant growth in both of our new core business segments, Discovery & Analytical Solutions and Diagnostics, through strategic acquisitions and licensing;
- Accelerating innovation through both internal research and development and third-party collaborations and alliances;
- Strengthening our position within key markets, by expanding our product and service offerings and maintaining superior product quality;
- Utilizing our share repurchase programs to help drive shareholder value; and
- Attracting, retaining and developing talented and engaged employees.

Recent Developments

As part of our strategy to grow our core businesses, we have recently taken the following actions:

Strategic Business Realignment:

We realigned our businesses at the beginning of the fourth quarter of fiscal year 2016 to better organize around customer requirements, positioning us to grow in attractive end markets and expand share with our core product offerings. We created two new operating segments, Discovery & Analytical Solutions and Diagnostics, which will enable us to deliver improved customer focus, more value-add collaboration and breakthrough innovations. The results reported for fiscal year 2016 reflect this new alignment of our operating segments. Financial information in this report relating to fiscal years 2015 and 2014 has been retrospectively adjusted to reflect this change to our operating segments.

Acquisitions in Fiscal Year 2016:

We completed the acquisition of two businesses in fiscal year 2016 for a total consideration of $72.2 million in cash. The acquired businesses were Bioo Scientific Corporation, which was acquired for total consideration of $63.5 million in cash and one other business acquired for a total consideration of $8.8 million in cash. We reported the operations for these acquisitions within the results of our Diagnostics and Discovery & Analytical Solutions segments from the acquisition dates.

Restructuring:

During fiscal year 2016, we recorded pre-tax restructuring charges of $0.6 million in our Diagnostics segment and $5.9 million in our Discovery & Analytical Solutions segment related to a workforce reduction from restructuring activities. Our management approved these plans principally to focus resources on higher growth product lines and end markets. We also recorded pre-tax restructuring reversals of $0.3 million in our Diagnostics segment and $1.2 million in our Discovery & Analytical Solutions segment related to lower than expected costs associated with workforce reductions. This pre-tax restructuring activity has been reported as restructuring and contract termination charges and is included as a component of income from continuing operations. We expect no significant impact on future operating results or cash flows from the restructuring activities executed in fiscal year 2016.

As part of our ongoing business strategy, we also took the following actions:

Share Repurchase Program:

On October 23, 2014, our Board of Directors (our "Board") authorized us to repurchase up to 8.0 million shares of common stock under a stock repurchase program (the "Repurchase Program"). On July 27, 2016, our Board authorized us to immediately terminate the Repurchase Program and further authorized us to repurchase up to 8.0 million shares of common stock under a new stock repurchase program (the "New Repurchase Program"). The New Repurchase Program will expire on July 26, 2018 unless terminated earlier by our Board, and may be suspended or discontinued at any time. During the fiscal year 2016, we repurchased 3.2 million shares of common stock in the open market at an aggregate cost of $148.2 million, including commissions, under the Repurchase Program. No shares remain available for repurchase under the Repurchase Program due to its cancellation. As of January 1, 2017, 8.0 million shares remained available for repurchase under the New Repurchase Program. From January 2, 2017 through February 24, 2017, there were no stock repurchases under the New Repurchase Program.

Business Segments and Products

We report our business in two segments: Discovery & Analytical Solutions and Diagnostics. We realigned our businesses at the beginning of the fourth quarter of the fiscal year 2016 to better position us to grow in attractive end markets and expand share with our core product offerings through an improved customer focus, more value-add collaboration and breakthrough innovations. The results reported for fiscal year 2016 reflect this new alignment of our operating segments. Financial information in this report relating to fiscal years 2015 and 2014 has been retrospectively adjusted to reflect the changes in our operating segments.

Discovery & Analytical Solutions Segment

Our comprehensive portfolio of technologies helps life sciences researchers better understand diseases and develop treatments. In addition, we help accelerate scientists' ability to detect, monitor and manage contaminants and toxic chemicals

impacting our environment and food supply. Our new Discovery & Analytical Solutions segment serves the environmental, food, industrial, life sciences research and laboratory services markets, and generated revenue of $1,513.0 million in fiscal year 2016.

Environmental Market:

For the environmental market, we develop and provide analytical technologies, solutions and services that enable our customers to understand the characterization and health of many aspects of our environment, including air, water and soil.

Our technologies are used to detect and help reduce the impact products and industrial processes may have on our environment. For example, we have solutions to help ensure compliance with regulatory standards that protect the purity of the world's water supply by detecting harmful substances, including trace metals such as lead, and organic pollutants such as pesticides and benzene. We provide the tools needed to test functionality, meet quality specifications and safety standards, and innovate for next generation products.

Food Market:

We provide a variety of solutions that help farmers and food producers provide a growing population with food that is safe, nutritious and appealing. Our instruments confirm food quality, including the level of moisture in grain or the level of fat in butter. Our instruments are also used to detect the presence of potentially dangerous contaminants, such as lead and mercury in milk. Our solutions can also be used to identify the origin of food products such as olive oil, which helps prevent counterfeiting. Our methods and analyses are transferable throughout the supply chain so our customers are able to keep pace with industry standards as well as governmental regulations and certifications.

Industrial Market:

We provide analytical instrumentation for the industrial market which includes the chemical, electronics, energy, lubricant, petrochemical and polymer industries. Our industrial instrumentation is primarily used by customers focusing on quality assurance standards.

Life Sciences Research Market:

In the life science research market, we provide a broad suite of solutions including reagents, informatics, and detection and imaging technologies that enable scientists to improve life science research and facilitate the drug discovery processes. These products, solutions and services support pharmaceutical and biotech companies, and academic institutions globally in creating better therapeutics by helping to bring products to market faster and more efficiently. Our research portfolio includes a wide range of systems consisting of imaging, detection and extraction instrumentation for use on in vitro, ex vivo, and in vivo models, analysis hardware and software, plus a wide range of consumable products including drug discovery and research reagents.

Laboratory Services Market:

We provide services designed to enable our customers in the laboratory services market throughout the world to increase efficiencies and production time while reducing maintenance costs of their labs. Our OneSource laboratory service business is aligned with customers' needs to accelerate science by enabling efficiency gains within their labs.

Principal Products:

Our principal products and services for Discovery & Analytical Solutions applications include the following:

Environmental, Food & Industrial:

- The Clarus® series of gas chromatographs, gas chromatographs/mass spectrometers and the TurboMatrix™ family of sample-handling equipment are used to identify and quantify compounds in the environmental, forensics, food and beverage, hydrocarbon processing/biofuels, materials testing, pharmaceutical and semiconductor industries.

- The Altus® UPLC® and HPLC advanced liquid chromatography systems providing high throughput and resolution chromatographic separations.
- AxION® 2 TOF MS is designed to simplify and streamline virtually any analytical workflow and provides mass accuracy, full spectrum capability, speed, sensitivity, and dynamic range.
- AxION® Direct Sample Analysis (DSA®) is a sample introduction system that enables direct sample analysis with minimal sample preparation and no chromatography.
- The Torion® T-9 portable GC/MS, a fast person-portable GC/MS system, enabling rapid detection and actionable results to potentially hazardous and emergency environmental conditions.
- Our atomic spectroscopy family of instruments, including the AAnalyst™/PinAAcle® series of atomic absorption spectrometers, the Avio™/Optima® family of inductively coupled plasma ("ICP") optical emission spectrometers and the NexION® family of ICP mass spectrometers are used in the environmental and chemical industries, among others, to determine the elemental content of a sample.
- Our infrared spectroscopy family, including the Spectrum Two™ spectrometer, a compact and portable instrument, used for high-speed infrared analysis for unknown substance identification, material qualification or concentration determination in fuel and lubricant analysis, polymer analysis and pharmaceutical and environmental applications. This includes the Frontier™ IR and NIR spectrometers designed to provide high sensitivity and flexibility to address a range of sample types. Spotlight™ IR systems, designed for scientists whose samples demand higher sensitivity and simpler analysis and workflows.
- The LAMBDA™ UV/Vis, a series of spectrophotometers that provide sampling flexibility to enable measuring of a wide range of sample types, including liquids, powders and solid materials, both in regulated industries as well as QC/QA and research applications.
- The 2400 Series II CHNS/O Elemental Analyzer is one of the leading organic elemental analyzers. It is ideal for the rapid determination of carbon, hydrogen, nitrogen, sulfur, and oxygen content in organic and other types of materials.
- Our thermal analysis family includes DSC series that offers exclusive HyperDSC capability for unparalleled sensitivity and new insights into material processes.
- Our Thermogravimetric (TG) and Simultaneous Thermal Analysis (STA) instruments, which can be coupled to Fourier Transform Infrared (FT-IR), Mass Spectrometry (MS), or Gas Chromatography/Mass Spectrometry (GC/MS) to provide greater analysis power and knowledge.
- Perten's Falling Number and Glutomatic instruments determine the bread baking quality of wheat and flour.

Life Sciences Research and Laboratory Services:

- Phenoptics™ quantitative pathology research solutions provide oncologists and cancer immunologists a new way to visualize and measure tumor cells and multiple immune-cell phenotypes simultaneously in FFPE tissue by combining the power of Opal®™ multiplexed immunohistochemistry reagents with the Mantra™ or Vectra® 3 Multispectral Imaging System, enabling visualization and analysis of complex cell interactions in ways that are difficult to achieve with other methods.
- Radiometric detection solutions, including over 1,100 radiochemicals NEN and the Tri-carb®, Quantulus™ GCT families of liquid scintillation analyzers, Wizard²® Gamma counters and MicroBeta²® plate based LSA, are used for beta, gamma and luminescence counting in microplate and vial formats utilized in research, environmental and drug discovery applications.
- The Opera® Phenix™ high content screening system is used for sensitive and high speed phenotypic drug screening of complex cellular models.
- The Operetta® CLS™ high content analysis system enables scientists to reveal fine sub-cellular details from everyday assays as well as more complex studies, for example using live cells, 3D and stem cells.
- The Columbus™ image data storage and analysis system provides a single solution to the storage and analysis of high content data from any major high content screening system, helping to visualize and analyze high content images via the Internet.
- The EnSight™ multimode plate reader benchtop system offers well plate imaging alongside label-free and labeled detection technologies for target-based and phenotypic assays.

- The EnVision® multilabel plate reader is targeted towards a wide range of high-throughput screening applications, including those using AlphaScreen®, AlphaLISA® and/or AlphaPlex® technologies.
- A wide range of homogeneous biochemical and cell based assay reagents, including LANCE® *Ultra*™ and Alpha™ Technology assay platforms used for the detection of drug discovery targets such as G-protein coupled receptors ("GPCR"), kinases, biomarkers and the modification of epigenetic enzymes.
- A broad portfolio of recombinant GPCR and Ion Channel cell lines, including over 300 products and 120 ready-to-use frozen cell lines for a wide range of disease areas.
- AlphaScreen®, AlphaLISA® and AlphaPlex® research assays, including over 500 no-wash biomarker detection kits for both biotherapeutics and small molecule drug discovery and development in a variety of therapeutic areas including cancer, inflammation, metabolic disorders, neurodegeneration and virology.
- TSA® Plus biotin kits can increase sensitivity of histochemistry and cytochemistry as much as 10 to 20 times.
- In vivo imaging technologies and reagents for preclinical research, including the IVIS® Spectrum™ series and the FMT® series for 3D imaging, including the Spectrum™ BL for 2D and 3D optical imaging, and the IVIS® Lumina™ series for 2D imaging, along with a suite of bioluminescent and fluorescent imaging agents, cell lines and dyes. These technologies are designed to provide for non-invasive longitudinal monitoring of disease progression, cell trafficking and gene expression patterns in living animals and are complemented by a broad portfolio of fluorescent and bioluminescent in vivo imaging reagents that can be useful for identifying, characterizing and quantifying a range of disease biomarkers and therapeutic efficacy in living animal models.
- The G4 PET/X-ray and G8 PET/CT preclinical imaging systems deliver PET imaging with an intuitive user interface and efficient workflows, ensuring subject monitoring throughout preparation and imaging.
- Quantum GX™ microCT platform is an in vivo microCT scanner that offers industry leading microCT resolution for pre-clinical imaging applications or eight second scan times for higher throughput with lower doses of radiation. With Quantum GX™, 3D data from the IVIS® and FMT® imaging platforms can be coregistered with microCT.
- Opal® 4, 5, 6, and 7 color multiplexed staining kits for amplified detection of immunohistochemistry utilized for multiple biomarker assessment in a single FFPE tumor cross section.
- Vectra® 3 and inForm® software providing the power of multiplexed biomarker imaging in tissue and quantitative analysis, all within a familiar digital workflow to accelerate cancer immunology research.
- AlphaPlex™ reagent technology, a homogeneous, all-in-one-well multiplexing reagent system for performing ultra-sensitive immunoassay analyses.
- High Content Profiler™ powered by TIBCO® Spotfire® technology provides automated workflows for quality control and hit classification for truly multi-parametric cellular drug screens.
- Lead Discovery™ powered by TIBCO® Spotfire® adds chemical intelligence to the TIBCO® Spotfire® business intelligence platform, enabling scientific professionals to derive new information from chemical structures relevant to experimental data.
- Informatics platforms including E-Notebook for Chemistry and Biology, Elements®, iLab™, ChemDraw® and ChemOffice®, integrated suites that focus on the complex and varied needs of understanding and managing data for productivity and collaboration.
- ChemDraw® and Chem3D® mobile apps for the iPad® device, chemical structure drawing and visualization apps, available in multiple languages and feature our Flick-to-Share® technology.
- Licensing for the exclusive, worldwide rights to the TIBCO® Spotfire® software platform in certain scientific research and development markets, and certain clinical markets through an exclusive strategic relationship with TIBCO Software, Inc.
- OneSource® Laboratory Services, a comprehensive portfolio of multivendor instrument management, QA/QC, lab relocation and regulatory compliance services. OneSource® programs are tailored to the specific needs and goals of individual customers and offer a series of informatics-based consulting, planning and management offerings to assist in laboratory productivity and the optimization of complex Information Technology platforms.
- OneSource® Mobile Application provides instant mobile access to service activity and equipment data including the ability to open a service call, check service history and view future scheduled events.
- OneSource® Dashboard, a TIBCO® Spotfire® technology driven interactive graphical platform provides visibility to a customer's global asset population, service event and downtime distribution, as well as key performance indicators to assist in asset operation.

New Products:

New products introduced or acquired for Discovery & Analytical Solutions applications in fiscal year 2016 include the following:

Environmental, Food & Industrial:

- The Avio™ 200 is the smallest ICP-OES on the market, offering the lowest argon consumption of any ICP, the fastest ICP startup and the widest linear range with dual viewing technology for use in a variety of labs.
- QSight Triple Quad LC/MS/MS is a flow-based mass spectrometry system that provides high sensitivity and enables high levels of efficiency and productivity to meet both standard and regulatory requirements.
- The Delta range of milk quality analyzers help ensure the quality of dairy products and are used at Central Milk Testing labs as well as dairy processing facilities around the world.
- The Bioo Scientific test kits for detection of toxins, veterinary drug residues and contaminants enable rapid and easy testing at different steps in the food value chain.

Life Sciences Research:

- The Operetta® CLS™ high content analysis system enables scientists to reveal fine sub-cellular details from everyday assays as well as more complex studies, for example using live cells, 3D and stem cells.
- Alpha™ SureFire® Ultra Multiplex Assays are used for the rapid, sensitive and quantitative detection of phosphoproteins in cells, combined with the measurement of the total amount of the same protein in a single well.
- CellCarrier® Ultra 384-well microplates used in high content imaging applications such as phenotypic screening and three-dimensional disease model studies.
- PerkinElmer Signals™ for Translational, a cloud-based data management, aggregation and analysis platform, integrates experimental and clinical research data from many sources and relates the data to scientifically meaningful concepts. The platform also enables support for the complete precision medicine workflow, from data acquisition to biomarker discovery and validation.
- Clinical Data Review analytical solution provides medical monitors, safety review teams, biostatisticians, data managers, pharmacologists, and others who analyze clinical data, a powerful advanced analytics solution for overcoming data review challenges. The solution enhances clinical data management and medical review workflows, allowing organizations to make informed decisions on the safety and efficacy of therapeutics earlier in their development.

Brand Names:

Our Discovery & Analytical Solutions segment offers additional products under various brand names, including:

Environmental and Food:

AAnalyst™, Altus®, Aquamatic™, Avio™, AxION®, Clarus®, DairyGuard™, Falling Number®, Frontier™, Glutomatic™, Honigs Regression™, HyperDSC®, Inframatic™, LAMBDA™, NexION®, OilExpress™, OilPrep™, Optima™, Perten®, Perten Instruments®, PinAAcle®, QSight™, Spectrum™, Spectrum Two™, Spotlight™, Supra-clean®, Supra-d™, Supra-poly®, Syngistix™, Torion®, TurboMatrix™ and Ultraspray®.

Life Sciences Research:

AlphaLISA®, AlphaPlex™, AlphaScreen®, Alpha™ SureFire®, Cell carrier™, cell::explorer®™, Chem3D®, ChemDraw®, ChemOffice®, Columbus™ Elements®, EnLite™, EnSight™, EnSpire®, EnVision®, EZ-Reader™, FMT®, Geospiza®, IHigh Content Profiler™, inForm®, IVIS®, LANCE®, Living Image®, Mantra™, MicroBeta2®, NEN®, Nuance®, OneSource®, Opal®, Opera Phenix™, Operetta CLS™, PerkinElmer Signals™ for Translational, Phenoptics™, Quantulus™ GCT, Quantum™, Tri-Carb®, Vectra®, VICTOR®™, ViewLux™, VivoTag® and Wizard2®.

Diagnostics Segment

We offer instruments, reagents, assay platforms, and software to hospitals, medical labs, clinicians, and medical research professionals to help improve the health of families. Our new Diagnostics segment is especially focused on reproductive health, emerging market diagnostics, and applied genomics. Our Diagnostics business generated revenue of $602.5 million in fiscal year 2016.

Diagnostics Market:

We provide early detection for genetic disorders from pregnancy to early childhood, as well as flat panel X-ray detectors and infectious disease testing for the diagnostics market. Our screening products are designed to provide early and accurate insights into the health of expectant mothers during pregnancy and into the health of their babies. Our instruments, reagents and software test and screen for genetic abnormalities, disorders and diseases, including Down syndrome, hypothyroidism, infertility and various metabolic conditions. We also develop the technologies that enable and support sample-to-sequencer workflow using next-generation DNA sequencing for applications in oncology, genetic testing and drug discovery.

Our flat panel X-ray detectors are used within X-ray imaging systems to allow physicians to make fast and accurate diagnoses of conditions ranging from broken bones to breast cancer. In addition, our flat panel X-ray detectors are used within oncology radiation therapy systems to support more accurate tumor treatment.

Principal Products:

Our principal products and services for Diagnostics applications include the following:

Diagnostics:

- The DELFIA® Xpress screening platform, a complete solution for prenatal and maternal health screening, which includes a fast continuous loading system. It is supported by kits for both first and second trimester analyses for prenatal screening and clinically validated LifeCycle™ software.
- The NeoGram™ MS/MS AAAC in vitro diagnostic kit is used to support detection of metabolic disorders in newborns through tandem mass spectrometry.
- The NeoBase™ Non-derivatized MS/MS kit analyzes newborn blood samples for measurement of amino acids and other metabolic analytes for specific diseases.
- The GSP® Neonatal hTSH, T4 17α-OHP, GALT IRT, BTD, PKU, Total Galactose and G6PD kits are used for screening congenital neonatal conditions from a drop of blood.
- The Specimen Gate® informatics data management solution is designed specifically for newborn screening laboratories.
- The XRpad® family of amorphous silicon (a-Si) flat panel cassette X-ray detectors enables X-ray system manufacturers to upgrade their systems from film to digital and to produce exceptional image resolution and diagnostic capability for radiography especially when imaging small anatomical features such as bone fractures and lung nodules.
- ViaCord® umbilical cord blood banking services for the banking of stem cells harvested from umbilical cord blood and cord tissue, for potential therapeutic application in transplant and regenerative medicine.
- The XRD™ family of a-Si flat panel X-ray detectors provides imaging for medical applications such as radiation therapy and veterinary imaging as well as industrial imaging applications including pipeline inspection, manufacturing inspection and 3D Cone Beam CT.
- The Dexela® family of CMOS flat panel X-ray detectors provides imaging for orthopedic surgery, mammography, dental, and industrial imaging applications such as PCB inspection and 3D Cone Beam CT.
- An expanded portfolio of molecular-based infectious disease screening technologies for blood bank and clinical laboratory settings in China. The tools include a qualitative 3-in-1 assay for the detection of hepatitis B, hepatitis C and HIV, as well as assays for other communicable diseases.
- The EnLite™ Neonatal TREC™ System, a screening test for Severe Combined Immunodeficiency, consisting of EnLite™ Neonatal TREC™ reagent kits, the Victor EnLite™ instrument and EnLite™ Workstation software.

Applied Genomics

- Automated liquid handling platforms (JANUS®, Sciclone® and Zephyr®) that offer a choice of robotic solutions in genomics, biotherapeutics, high throughput screening and high content analysis to assist life science research from bench to clinic.
- Next-generation sequencing automation and nucleic acid quantitation, including LabChip® GX Touch electrophoresis, as well as Sciclone®, Zephyr® and JANUS® automated liquid handling workstations for library preparation.
- JANUS® BioTx™ Workstation for automated small scale purification offers column, tip and plate based chromatography on a single platform.
- The LabChip GXII® Touch provides a means of characterizing multiple protein product attributes for research labs through QC.
- The cell::explorer®™ automated workstation allows integration of multiple laboratory instrumentation using a centralized robotic interface, allowing high throughput and turnkey-application focused solutions.

New Products:

Significant new products introduced or acquired for Diagnostics applications in fiscal year 2016 include the following:

Diagnostics:

- A comprehensive portfolio of Next-Generation Sequencing ("NGS") Library Prep and multiplexing kits designed to increase sensitivity, flexibility and speed for speed for sequencing platforms, offered through our acquisition of Bioo Scientific.
- Automated, precise, cost-effective Non-Invasive Prenatal Testing ("NIPT") utilizing molecular technology not requiring sequencing technology, offered through our acquisition of Vanadis Diagnostics.
- The XRD 4343RF, which supports a full 43 × 43 cm2 (17 × 17 in2) field of view providing superior imaging for fluoroscopy, radiography and cone beam CT applications. The detector offers frame rates up to 85 fps and has a direct deposited Cesium Iodide scintillator for superior image quality.
- The Dexela 2315NDT, a fast, high resolution X-ray detector for use in realtime, 2D and 3D industrial imaging.

Brand Names:

Our Diagnostics segment offers additional products under various brand names, including AutoDELFIA®, BACS-on-Beads®, Bioo Scientific, BoBs®, Datalytix™, Dexela®, Dexela® CMOS FPDs™, Evolution™, FragilEase™, Genoglyphix®, GSP®, iLab™, JANUS®, LabChip®, LifeCycle™, LimsLink™, MultiPROBE®, Pannoramic™, Sciclone®, Specimen Gate®, TRIO™, Twister®, Vanadis, VariSpec™, ViaCord®, XRD™, XRpad® and Zephyr®.

Marketing

All of our businesses market their products and services primarily through their own specialized sales forces. As of January 1, 2017, we employed approximately 3,700 sales and service representatives operating in approximately 35 countries and marketing products and services in more than 150 countries. In geographic regions where we do not have a sales and service presence, we utilize distributors to sell our products.

Raw Materials, Key Components and Supplies

Each of our businesses uses a wide variety of raw materials, key components and supplies that are generally available from alternate sources of supply and in adequate quantities from domestic and foreign sources. We generally have multi-year contracts, with no minimum purchase requirements, with our suppliers. For certain critical raw materials, key components and supplies required for the production of some of our principal products, we have qualified only a limited or a single source of supply. We periodically purchase quantities of some of these critical raw materials in excess of current requirements, in anticipation of future manufacturing needs. With sufficient lead times, we believe we would be able to qualify alternative suppliers for each of these raw materials and key components. See the applicable risk factor in "Item 1A. Risk Factors" for an additional description of this risk.

Intellectual Property

We own numerous United States and foreign patents and have patent applications pending in the United States and abroad. We also license intellectual property rights to and from third parties, some of which bear royalties and are terminable in specified circumstances. In addition to our patent portfolio, we possess a wide array of unpatented proprietary technology and know-how. We also own numerous United States and foreign trademarks and trade names for a variety of our product names, and have applications for the registration of trademarks and trade names pending in the United States and abroad. We believe that patents and other proprietary rights are important to the development of both of our reporting segments, but we also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain the competitive position of both of our reporting segments. We do not believe that the loss of any one patent or other proprietary right would have a material adverse effect on our overall business or on any of our reporting segments.

In some cases, we may participate in litigation or other proceedings to defend against or assert claims of infriugement, to enforce our patents or our licensors' patents, to protect our trade secrets, know-how or other intellectual property rights, or to determine the scope and validity of our or third parties' intellectual property rights. Litigation of this type could result in substantial cost to us and diversion of our resources. An adverse outcome in any litigation or proceeding could subject us to significant liabilities or expenses, require us to cease using disputed intellectual property or cease the sale of a product, or require us to license the disputed intellectual property from third parties.

Backlog

We believe that backlog is not a meaningful indicator of future business prospects for either of our business segments due to the short lead time required for a majority of our sales. Therefore, we believe that backlog information is not material to an understanding of our business.

Competition

Due to the range and diversity of our products and services, we face many different types of cnmpetition and competitors. Our competitors range from foreign and domestic organizations, which produce a comprehensive array of goods and services and that may have greater financial and other resources than we do, to more narrowly focused firms producing a limited number of goods or services for specialized market segments.

We compete on the basis of service level, price, technological innovation, operatioual efficiency, product differentiation, product availability, quality and reliability. Competitors range from multinational organizations with a wide range of products to specialized firms that in some cases have well-established market positions. We expect the proportion of large competitors to iucrease through the continued consolidation of competitors.

Research and Development

Research and development expenditures were $124.3 million duriug fiscal year 2016, $112.5 million during fiscal year 2015, and $108.1 million during fiscal year 2014.

We have a broad product basc, and we do not expect any single research and development project to have significant costs. To accelerate our growth initiatives, we directed our research and development efforts in fiscal years 2016, 2015 and 2014 primarily toward our Diagnostics segment, and the environmental, food, life sciences research and laboratory services markets within our Discovery & Analytical Solutions segment. We expect to continue our strong investments in research and development to drive growth during fiscal year 2017, and to continue to emphasize the Diagnostics segment, and the environmental, food, life sciences research and laboratory services markets within our Discovery & Analytical Solutions segment.

Environmental Matters

Our operations are subject to various foreign, federal, state and local environmental and safety laws and regulations. These requirements include those governing uses, emissions and discharges of hazardous substances, the remediation of contaminated soil and groundwater, the regulation of radioactive materials, and the health and safety of our employees.

We may have liability under the Comprehensive Environmental Response Compensation and Liability Act and comparable state statutes that impose liability for investigation and remediation of contamination without regard to fault, in connection with materials that we or our former businesses sent to various third-party sites. We have incurred, and expect to incur, costs pursuant to these statutes.

We are conducting a number of environmental investigations and remedial actions at our current and former locations and, along with other companies, have been named a potentially responsible party ("PRP") for certain waste disposal sites. We accrue for environmental issues in the accounting period that our responsibility is established and when the cost can be reasonably estimated. We have accrued $9.9 million and $11.8 million as of January 1, 2017 and January 3, 2016, respectively, which represents our management's estimate of the cost of the remediation of known environmental matters, and does not include any potential liability for related personal injury or property damage claims. During fiscal year 2014, we recorded a benefit of $2.3 million for cost reimbursements related to a particular site, of which $1.2 million was for future monitoring and mitigation activities. Our environmental accrual is not discounted and does not reflect the recovery of any material amounts through insurance or indemnification arrangements. The cost estimates are subject to a number of variables, including the stage of the environmental investigations, the magnitude of the possible contamination, the nature of the potential remedies, possible joint and several liability, the time period over which remediation may occur, and the possible effects of changing laws and regulations. For sites where we have been named a PRP, our management does not currently anticipate any additional liability to result from the inability of other significant named parties to contribute. We expect that the majority of such accrued amounts could be paid out over a period of up to ten years. As assessment and remediation activities progress at each individual site, these liabilities are reviewed and adjusted to reflect additional information as it becomes available. There have been no environmental problems to date that have had, or are expected to have, a material adverse effect on our consolidated financial statements. While it is possible that a loss exceeding the amounts recorded in the consolidated financial statements may be incurred, the potential exposure is not expected to be materially different from those amounts recorded.

We may become subject to new or unforeseen environmental costs or liabilities. Compliance with new or more stringent laws or regulations, stricter interpretations of existing laws, or the discovery of new contamination could cause us to incur additional costs.

Employees

As of January 1, 2017, we employed approximately 8,000 employees in our continuing operations. Several of our subsidiaries are parties to contracts with labor unions and workers' councils. As of January 1, 2017, we estimate that we employed an aggregate of approximately 1,700 union and workers' council employees. We consider our relations with our employees to be satisfactory.

Financial Information About Business Segments

The results reported for fiscal year 2016 reflect the new alignment of our operating segments and the placement of our Medical Imaging business into discontinued operations due to its pending sale. Financial information in the table below relating to fiscal years 2015 and 2014 has been retrospectively adjusted to reflect both our new segment structure and the exclusion of our Medical Imaging business from continuing operations.

We have included the expenses for our corporate headquarters, such as legal, tax, audit, human resources, information technology, and other management and compliance costs, as well as the activity related to the mark-to-market adjustment on postretirement benefit plans, as "Corporate" below. We have a process to allocate and recharge expenses to the reportable segments when these costs are administered or paid by the corporate headquarters based on the extent to which the segment benefited from the expenses. These amounts have been calculated in a consistent manner and are included in our calculations of

segment results to internally plan and assess the performance of each segment for all purposes, including determining the compensation of the business leaders for each of our operating segments.

The table below sets forth revenue and operating income (loss) from continuing operations by operating segment for the fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Discovery & Analytical Solutions			
Product revenue	$ 934,098	$ 968,034	$ 944,446
Service revenue	578,886	560,385	539,694
Total revenue	1,512,984	1,528,419	1,484,140
Operating income from continuing operations[1]	207,487	173,668	162,074
Diagnostics			
Product revenue	462,798	427,068	428,290
Service revenue	139,735	149,336	157,450
Total revenue	602,533	576,404	585,740
Operating income from continuing operations	138,909	135,572	124,610
Corporate			
Operating loss from continuing operations[2][3]	(63,330)	(58,314)	(121,677)
Continuing Operations			
Product revenue	$ 1,396,896	$ 1,395,102	$ 1,372,736
Service revenue	718,621	709,721	697,144
Total revenue	2,115,517	2,104,823	2,069,880
Operating income from continuing operations	283,066	250,926	165,007
Interest and other expense, net	38,998	42,119	41,139
Income from continuing operations before income taxes	$ 244,068	$ 208,807	$ 123,868

(1) Legal costs for a particular case in our Discovery & Analytical Solutions segment were $0.8 million for fiscal year 2015.

(2) Activity related to the mark-to-market adjustment on postretirement benefit plans has been included in the Corporate operating loss from continuing operations, and in the aggregate constituted a pre-tax loss of $15.3 million in fiscal year 2016, a pre-tax loss of $12.4 million in fiscal year 2015, and pre-tax loss of $75.4 million in fiscal year 2014.

(3) Includes expenses related to litigation with Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (collectively, "Enzo"). Enzo filed a complaint in 2002 that alleged that we separately and together with other defendants breached distributorship and settlement agreements with Enzo, infringed Enzo's patents, engaged in unfair competition and fraud, and committed torts against Enzo by, among other things, engaging in commercial development and exploitation of Enzo's patented products and technology. We entered into a settlement agreement with Enzo dated June 20, 2014 and during fiscal year 2014 paid $7.0 million into a designated escrow account to resolve this matter, of which $3.7 million had been accrued in previous years and $3.3 million was recorded during fiscal year 2014. In addition, $3.4 million of expenses were incurred and recorded in preparation for the trial during fiscal year 2014.

Discontinued operations have not been included in the preceding table.

Additional information relating to our reporting segments is as follows for the fiscal years ended:

	Depreciation and Amortization Expense			Capital Expenditures		
	January 1, 2017	January 3, 2016	December 28, 2014	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)			(In thousands)	
Discovery & Analytical Solutions	$ 72,484	$ 74,177	$ 72,288	$ 21,486	$ 18,175	$ 18,234
Diagnostics	25,339	29,728	36,146	8,556	6,854	7,196
Corporate	2,149	1,459	2,031	1,660	3,189	1,722
Continuing operations	$ 99,972	$ 105,364	$ 110,465	$ 31,702	$ 28,218	$ 27,152
Discontinued operations	$ 6,266	$ 6,643	$ 6,610	$ 1,302	$ 1,414	$ 2,133

	Total Assets		
	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Discovery & Analytical Solutions	$ 2,612,757	$ 2,546,583	$ 2,614,911
Diagnostics	1,505,381	1,459,854	1,343,110
Corporate	31,171	28,497	28,482
Current and long-term assets of discontinued operations	127,374	131,361	141,073
Total assets	$ 4,276,683	$ 4,166,295	$ 4,127,576

Financial Information About Geographic Areas

Both of our reporting segments conduct business in, and derive substantial revenue from, various countries outside the United States. During fiscal year 2016, we had $1,273.2 million in sales from our international operations, representing approximately 60% of our total sales. During fiscal year 2016, we derived approximately 75% of our international sales from our Discovery & Analytical Solutions segment and approximately 25% of our international sales from our Diagnostics segment. We anticipate that sales from international operations will continue to represent a substantial portion of our total sales in the future.

We are exposed to the risks associated with international operations, including exchange rate fluctuations, regional and country-specific political and economic conditions, foreign receivables collection concerns, trade protection measures and import or export licensing requirements, tax risks, staffing and labor law concerns, intellectual property protection risks, and differing regulatory requirements. Additional geographic information is discussed in Note 23 to our consolidated financial statements included in this annual report on Form 10-K.

Item 1A. ***Risk Factors***

The following important factors affect our business and operations generally or affect multiple segments of our business and operations:

If the markets into which we sell our products decline or do not grow as anticipated due to a decline in general economic conditions, or there are uncertainties surrounding the approval of government or industrial funding proposals, or there are unfavorable changes in government regulations, we may see an adverse effect on the results of our business operations.

Our customers include pharmaceutical and biotechnology companies, laboratories, academic and research institutions, public health authorities, private healthcare organizations, doctors and government agencies. Our quarterly revenue and results of operations are highly dependent on the volume and timing of orders received during the quarter. In addition, our revenues and earnings forecasts for future quarters are often based on the expected trends in our markets. However, the markets we serve do not always experience the trends that we may expect. Negative fluctuations in our customers' markets, the inability of our customers to secure credit or funding, restrictions in capital expenditures, general economic conditions, cuts in government

funding or unfavorable changes in government regulations would likely result in a reduction in demand for our products and services. In addition, government funding is subject to economic conditions and the political process, which is inherently fluid and unpredictable. Our revenues may be adversely affected if our customers delay or reduce purchases as a result of uncertainties surrounding the approval of government or industrial funding proposals. Such declines could harm our consolidated financial position, results of operations, cash flows and trading price of our common stock, and could limit our ability to sustain profitability.

Our growth is subject to global economic and political conditions, and operational disruptions at our facilities.

Our business is affected by global economic and political conditions as well as the state of the financial markets, particularly as the United States and other countries balance concerns around debt, inflation, growth and budget allocations in their policy initiatives. There can be no assurance that global economic conditions and financial markets will not worsen and that we will not experience any adverse effects that may be material to our consolidated cash flows, results of operations, financial position or our ability to access capital, such as the adverse effects resulting from a prolonged shutdown in government operations both in the United States and internationally. Our business is also affected by local economic environments, including inflation, recession, financial liquidity and currency volatility or devaluation. Political changes, some of which may be disruptive, could interfere with our supply chain, our customers and all of our activities in a particular location.

While we take precautions to prevent production or service interruptions at our global facilities, a major earthquake, fire, flood, power loss or other catastrophic event that results in the destruction or delay of any of our critical business operations could result in our incurring significant liability to customers or other third parties, cause significant reputational damage or have a material adverse effect on our business, operating results or financial condition.

Certain of these risks can be hedged to a limited degree using financial instruments, or other measures, and some of these risks are insurable, but any such mitigation efforts are costly and may not always be fully successful. Our ability to engage in such mitigation efforts has decreased or become even more costly as a result of recent market developments.

If we do not introduce new products in a timely manner, we may lose market share and be unable to achieve revenue growth targets.

We sell many of our products in industries characterized by rapid technological change, frequent new product and service introductions, and evolving customer needs and industry standards. Many of the businesses competing with us in these industries have significant financial and other resources to invest in new technologies, substantial intellectual property portfolios, substantial experience in new product development, regulatory expertise, manufacturing capabilities, and established distribution channels to deliver products to customers. Our products could become technologically obsolete over time, or we may invest in technology that does not lead to revenue growth or continue to sell products for which the demand from our customers is declining, in which case we may lose market share or not achieve our revenue growth targets. The success of our new product offerings will depend upon several factors, including our ability to:

- accurately anticipate customer needs,
- innovate and develop new reliable technologies and applications,
- successfully commercialize new technologies in a timely manner,
- price our products competitively, and manufacture and deliver our products in sufficient volumes and on time, and
- differentiate our offerings from our competitors' offerings.

Many of our products are used by our customers to develop, test and manufacture their products. We must anticipate industry trends and consistently develop new products to meet our customers' expectations. In developing new products, we may be required to make significant investments before we can determine the commercial viability of the new product. If we fail to accurately foresee our customers' needs and future activities, we may invest heavily in research and development of products that do not lead to significant revenue. We may also suffer a loss in market share and potential revenue if we are unable to commercialize our technology in a timely and efficient manner.

In addition, some of our licensed technology is subject to contractual restrictions, which may limit our ability to develop or commercialize products for some applications.

We may not be able to successfully execute acquisitions or divestitures, license technologies, integrate acquired businesses or licensed technologies into our existing businesses, or make acquired businesses or licensed technologies profitable.

We have in the past supplemented, and may in the future supplement, our internal growth by acquiring businesses and licensing technologies that complement or augment our existing product lines, such as our acquisition of Bioo Scientific in the third quarter of fiscal year 2016. However, we may be unable to identify or complete promising acquisitions or license transactions for many reasons, such as:

- competition among buyers and licensees,
- the high valuations of businesses and technologies,
- the need for regulatory and other approval, and
- our inability to raise capital to fund these acquisitions.

Some of the businesses we acquire may be unprofitable or marginally profitable, or may increase the variability of our revenue recognition. If, for example, we are unable to successfully commercialize products and services related to significant in-process research and development that we have capitalized, we may have to impair the value of such assets. Accordingly, the earnings or losses of acquired businesses may dilute our earnings. For these acquired businesses to achieve acceptable levels of profitability, we would have to improve their management, operations, products and market penetration. We may not be successful in this regard and may encounter other difficulties in integrating acquired businesses into our existing operations, such as incompatible management, information or other systems, cultural differences, loss of key personnel, unforeseen regulatory requirements, previously undisclosed liabilities or difficulties in predicting financial results. Additionally, if we are not successful in selling businesses we seek to divest, the activity of such businesses may dilute our earnings and we may not be able to achieve the expected benefits of such divestitures. As a result, our financial results may differ from our forecasts or the expectations of the investment community in a given quarter or over the long term.

To finance our acquisitions, we may have to raise additional funds, either through public or private financings. We may be unable to obtain such funds or may be able to do so only on terms unacceptable to us. We may also incur expenses related to completing acquisitions or licensing technologies, or in evaluating potential acquisitions or technologies, which may adversely impact our profitability.

We may not be successful in adequately protecting our intellectual property.

Patent and trade secret protection is important to us because developing new products, processes and technologies gives us a competitive advantage, although it is time-consuming and expensive. We own many United States and foreign patents and intend to apply for additional patents. Patent applications we file, however, may not result in issued patents or, if they do, the claims allowed in the patents may be narrower than what is needed to protect fully our products, processes and technologies. The expiration of our previously issued patents may cause us to lose a competitive advantage in certain of the products and services we provide. Similarly, applications to register our trademarks may not be granted in all countries in which they are filed. For our intellectual property that is protected by keeping it secret, such as trade secrets and know-how, we may not use adequate measures to protect this intellectual property.

Third parties may also challenge the validity of our issued patents, may circumvent or "design around" our patents and patent applications, or may claim that our products, processes or technologies infringe their patents. In addition, third parties may assert that our product names infringe their trademarks. We may incur significant expense in legal proceedings to protect our intellectual property against infringement by third parties or to defend against claims of infringement by third parties. Claims by third parties in pending or future lawsuits could result in awards of substantial damages against us or court orders that could effectively prevent us from manufacturing, using, importing or selling our products in the United States or other countries.

If we are unable to renew our licenses or otherwise lose our licensed rights, we may have to stop selling products or we may lose competitive advantage.

We may not be able to renew our existing licenses, or licenses we may obtain in the future, on terms acceptable to us, or at all. If we lose the rights to a patented or other proprietary technology, we may need to stop selling products incorporating that technology and possibly other products, redesign our products or lose a competitive advantage. Potential competitors could in-license technologies that we fail to license and potentially erode our market share.

Our licenses typically subject us to various economic and commercialization obligations. If we fail to comply with these obligations, we could lose important rights under a license, such as the right to exclusivity in a market. In some cases, we could lose all rights under the license. In addition, rights granted under the license could be lost for reasons out of our control. For example, the licensor could lose patent protection for a number of reasons, including invalidity of the licensed patent, or a third-party could obtain a patent that curtails our freedom to operate under one or more licenses.

If we do not compete effectively, our business will be harmed.

We encounter aggressive competition from numerous competitors in many areas of our business. We may not be able to compete effectively with all of these competitors. To remain competitive, we must develop new products and periodically enhance our existing products. We anticipate that we may also have to adjust the prices of many of our products to stay competitive. In addition, new competitors, technologies or market trends may emerge to threaten or reduce the value of entire product lines.

Our quarterly operating results could be subject to significant fluctuation, and we may not be able to adjust our operations to effectively address changes we do not anticipate, which could increase the volatility of our stock price and potentially cause losses to our shareholders.

Given the nature of the markets in which we participate, we cannot reliably predict future revenue and profitability. Changes in competitive, market and economic conditions may require us to adjust our operations, and we may not be able to make those adjustments or make them quickly enough to adapt to changing conditions. A high proportion of our costs are fixed, due in part to our research and development and manufacturing costs. As a result, small declines in sales could disproportionately affect our operating results in a quarter. Factors that may affect our quarterly operating results include:

- demand for and market acceptance of our products,
- competitive pressures resulting in lower selling prices,
- changes in the level of economic activity in regions in which we do business,
- changes in general economic conditions or government funding,
- settlements of income tax audits,
- expenses incurred in connection with claims related to environmental conditions at locations where we conduct or formerly conducted operations,
- differing tax laws and changes in those laws, or changes in the countries in which we are subject to taxation,
- changes in our effective tax rate,
- changes in industries, such as pharmaceutical and biomedical,
- changes in the portions of our revenue represented by our various products and customers,
- our ability to introduce new products,
- our competitors' announcement or introduction of new products, services or technological innovations,
- costs of raw materials, energy or supplies,
- changes in healthcare or other reimbursement rates paid by government agencies and other third parties for certain of our products and services,

- our ability to realize the benefit of ongoing productivity initiatives,
- changes in the volume or timing of product orders,
- fluctuation in the expense related to the mark-to-market adjustment on postretirement benefit plans,
- changes in our assumptions underlying future funding of pension obligations,
- changes in assumptions used to determine contingent consideration in acquisitions, and
- changes in foreign currency exchange rates.

A significant disruption in third-party package delivery and import/export services, or significant increases in prices for those services, could interfere with our ability to ship products, increase our costs and lower our profitability.

We ship a significant portion of our products to our customers through independent package delivery and import/export companies, including UPS and Federal Express in the United States; TNT, UPS and DHL in Europe; and UPS in Asia. We also ship our products through other carriers, including national trucking firms, overnight carrier services and the United States Postal Service. If one or more of the package delivery or import/export providers experiences a significant disruption in services or institutes a significant price increase, we may have to seek alternative providers and the delivery of our products could be prevented or delayed. Such events could cause us to incur increased shipping costs that could not be passed on to our customers, negatively impacting our profitability and our relationships with certain of our customers.

Disruptions in the supply of raw materials, certain key components and other goods from our limited or single source suppliers could have an adverse effect on the results of our business operations, and could damage our relationships with customers.

The production of our products requires a wide variety of raw materials, key components and other goods that are generally available from alternate sources of supply. However, certain critical raw materials, key components and other goods required for the production and sale of some of our principal products are available from limited or single sources of supply. We generally have multi-year contracts with no minimum purchase requirements with these suppliers, but those contracts may not fully protect us from a failure by certain suppliers to supply critical materials or from the delays inherent in being required to change suppliers and, in some cases, validate new raw materials. Such raw materials, key components and other goods can usually be obtained from alternative sources with the potential for an increase in price, decline in quality or delay in delivery. A prolonged inability to obtain certain raw materials, key components or other goods is possible and could have an adverse effect on our business operations, and could damage our relationships with customers.

We are subject to the rules of the Securities and Exchange Commission requiring disclosure as to whether certain materials known as conflict minerals (tantalum, tin, gold, tungsten and their derivatives), which may be contained in our products are mined from the Democratic Republic of the Congo and adjoining countries. As a result of these rules, we may incur additional costs in complying with the disclosure requirements and in satisfying those customers who require that the components used in our products be certified as conflict-free, and the potential lack of availability of these materials at competitive prices could increase our production costs.

The manufacture and sale of products and services may expose us to product liability claims for which we could have substantial liability.

We face an inherent business risk of exposure to product liability claims if our products, services or product candidates are alleged or found to have caused injury, damage or loss. We may in the future be unable to obtain insurance with adequate levels of coverage for potential liability on acceptable terms or claims of this nature may be excluded from coverage under the terms of any insurance policy that we can obtain. If we are unable to obtain such insurance or the amounts of any claims successfully brought against us substantially exceed our coverage, then our business could be adversely impacted.

If we fail to maintain satisfactory compliance with the regulations of the United States Food and Drug Administration and other governmental agencies in the United States and abroad, we may be forced to recall products and cease their manufacture and distribution, and we could be subject to civil, criminal or monetary penalties.

Our operations are subject to regulation by different state and federal government agencies in the United States and other countries, as well as to the standards established by international standards bodies. If we fail to comply with those regulations or standards, we could be subject to fines, penalties, criminal prosecution or other sanctions. Some of our products are subject to regulation by the United States Food and Drug Administration and similar foreign and domestic agencies. These regulations govern a wide variety of product activities, from design and development to labeling, manufacturing, promotion, sales and distribution. If we fail to comply with those regulations or standards, we may have to recall products, cease their manufacture and distribution, and may be subject to fines or criminal prosecution.

We are also subject to a variety of laws, regulations and standards that govern, among other things, the importation and exportation of products, the handling, transportation and manufacture of toxic or hazardous substances, and our business practices in the United States and abroad such as anti-bribery, anti-corruption and competition laws. This requires that we devote substantial resources to maintaining our compliance with those laws, regulations and standards. A failure to do so could result in the imposition of civil, criminal or monetary penalties having a material adverse effect on our operations.

Changes in governmental regulations may reduce demand for our products or increase our expenses.

We compete in markets in which we or our customers must comply with federal, state, local and foreign regulations, such as environmental, health and safety, and food and drug regulations. We develop, configure and market our products to meet customer needs created by these regulations. Any significant change in these regulations could reduce demand for our products or increase our costs of producing these products.

The healthcare industry is highly regulated and if we fail to comply with its extensive system of laws and regulations, we could suffer fines and penalties or be required to make significant changes to our operations which could have a significant adverse effect on the results of our business operations.

The healthcare industry, including the genetic screening market, is subject to extensive and frequently changing international and United States federal, state and local laws and regulations. In addition, legislative provisions relating to healthcare fraud and abuse, patient privacy violations and misconduct involving government insurance programs provide federal enforcement personnel with substantial powers and remedies to pursue suspected violations. We believe that our business will continue to be subject to increasing regulation as the federal government continues to strengthen its position on healthcare matters, the scope and effect of which we cannot predict. If we fail to comply with applicable laws and regulations, we could suffer civil and criminal damages, fines and penalties, exclusion from participation in governmental healthcare programs, and the loss of various licenses, certificates and authorizations necessary to operate our business, as well as incur liabilities from third-party claims, all of which could have a significant adverse effect on our business.

Economic, political and other risks associated with foreign operations could adversely affect our international sales and profitability.

Because we sell our products worldwide, our businesses are subject to risks associated with doing business internationally. Our sales originating outside the United States represented the majority of our total revenue in fiscal year 2016. We anticipate that sales from international operations will continue to represent a substantial portion of our total revenue. In addition, many of our manufacturing facilities, employees and suppliers are located outside the United States. Accordingly, our future results of operations could be harmed by a variety of factors, including:

- changes in actual, or from projected, foreign currency exchange rates,
- changes in a country's or region's political or economic conditions, particularly in developing or emerging markets,
- longer payment cycles of foreign customers and timing of collections in foreign jurisdictions,
- embargoes, trade protection measures and import or export licensing requirements,

- policies in foreign countries benefiting domestic manufacturers or other policies detrimental to companies headquartered in the United States,
- differing tax laws and changes in those laws, or changes in the countries in which we are subject to tax,
- adverse income tax audit settlements or loss of previously negotiated tax incentives,
- differing business practices associated with foreign operations,
- difficulty in transferring cash between international operations and the United States,
- difficulty in staffing and managing widespread operations,
- differing labor laws and changes in those laws,
- differing protection of intellectual property and changes in that protection,
- increasing global enforcement of anti-bribery and anti-corruption laws, and
- differing regulatory requirements and changes in those requirements.

If we do not retain our key personnel, our ability to execute our business strategy will be limited.

Our success depends to a significant extent upon the continued service of our executive officers and key management and technical personnel, particularly our experienced engineers and scientists, and on our ability to continue to attract, retain, and motivate qualified personnel. The competition for these employees is intense. The loss of the services of key personnel could have a material adverse effect on our operating results. In addition, there could be a material adverse effect on us should the turnover rates for key personnel increase significantly or if we are unable to continue to attract qualified personnel. We do not maintain any key person life insurance policies on any of our officers or employees.

Our success also depends on our ability to execute leadership succession plans. The inability to successfully transition key management roles could have a material adverse effect on our operating results.

If we experience a significant disruption in, or breach in security of, our information technology systems, or inadvertent transfer of information, or if we fail to implement new systems, software and technologies successfully, our business could be adversely affected.

We rely on several centralized information technology systems throughout our company to develop, manufacture and provide products and services, keep financial records, process orders, manage inventory, process shipments to customers and operate other critical functions. Our information technology systems may be susceptible to damage, disruptions or shutdowns due to power outages, hardware failures, computer viruses, attacks by computer hackers, telecommunication failures, user errors, catastrophes or other unforeseen events. If we were to experience a prolonged system disruption in the information technology systems that involve our interactions with customers or suppliers, it could result in the loss of sales and customers and significant incremental costs, which could adversely affect our business. In addition, security breaches of our information technology systems or inadvertent transfer of information could result in the misappropriation or unauthorized disclosure of confidential information belonging to us or to our employees, partners, customers or suppliers, which could result in our suffering significant financial or reputational damage.

We have a substantial amount of outstanding debt, which could impact our ability to obtain future financing and limit our ability to make other expenditures in the conduct of our business.

We have a substantial amount of debt and other financial obligations. Our debt level and related debt service obligations could have negative consequences, including:

- requiring us to dedicate significant cash flow from operations to the payment of principal and interest on our debt, which reduces the funds we have available for other purposes, such as acquisitions and stock repurchases;
- reducing our flexibility in planning for or reacting to changes in our business and market conditions; and

- exposing us to interest rate risk since a portion of our debt obligations are at variable rates.

In addition, we may incur additional indebtedness in the future to meet future financing needs. If we add new debt, the risks described above could increase.

Restrictions in our senior unsecured revolving credit facility and other debt instruments may limit our activities.

Our senior unsecured revolving credit facility, senior unsecured notes due in 2021 ("2021 Notes") and senior unsecured notes due in 2026 ("2026 Notes") include restrictive covenants that limit our ability to engage in activities that could otherwise benefit our company. These include restrictions on our ability and the ability of our subsidiaries to:

- pay dividends on, redeem or repurchase our capital stock,
- sell assets,
- incur obligations that restrict our subsidiaries' ability to make dividend or other payments to us,
- guarantee or secure indebtedness,
- enter into transactions with affiliates, and
- consolidate, merge or transfer all, or substantially all, of our assets and the assets of our subsidiaries on a consolidated basis.

We are also required to meet specified financial ratios under the terms of certain of our existing debt instruments. Our ability to comply with these financial restrictions and covenants is dependent on our future performance, which is subject to prevailing economic conditions and other factors, including factors that are beyond our control, such as foreign exchange rates, interest rates, changes in technology and changes in the level of competition. In addition, if we are unable to maintain our investment grade credit rating, our borrowing costs would increase and we would be subject to different and potentially more restrictive financial covenants under some of our existing debt instruments.

Any future indebtedness that we incur may include similar or more restrictive covenants. Our failure to comply with any of the restrictions in our senior unsecured revolving credit facility, the 2021 Notes, the 2026 Notes or any future indebtedness may result in an event of default under those debt instruments, which could permit acceleration of the debt under those debt instruments, and require us to prepay that debt before its scheduled due date under certain circumstances.

The approval of the Brexit Referendum in the U.K. may have an adverse impact on our results of operations.

In a referendum vote held on June 23, 2016, the United Kingdom voted to leave the European Union. Nearly 3% of our net sales from continuing operations in 2016 came from the U.K. At this time, we are not able to predict the impact that this vote will have on the economy in Europe, including in the U.K., or on the Great Britain Pound (the "GBP") or other European exchange rates. Weakening of economic conditions or economic uncertainties tend to harm our business, and if such conditions emerge in the U.K. or in the rest of Europe, it may have a material adverse effect on our sales. In addition, any significant weakening of the GBP to the U.S. dollar will have an adverse impact on our European revenues due to the importance of U.K. sales.

Our results of operations will be adversely affected if we fail to realize the full value of our intangible assets.

As of January 1, 2017, our total assets included $2.7 billion of net intangible assets. Net intangible assets consist principally of goodwill associated with acquisitions and costs associated with securing patent rights, trademark rights, customer relationships, core technology and technology licenses and in-process research and development, net of accumulated amortization. We test certain of these items—specifically all of those that are considered "non-amortizing"—at least annually for potential impairment by comparing the carrying value to the fair market value of the reporting unit to which they are assigned. All of our amortizing intangible assets are also evaluated for impairment should events occur that call into question the value of the intangible assets.

Adverse changes in our business, adverse changes in the assumptions used to determine the fair value of our reporting units, or the failure to grow our Discovery & Analytical Solutions and Diagnostics segments may result in impairment of our intangible assets, which could adversely affect our results of operations.

Our share price will fluctuate.

Over the last several years, stock markets in general and our common stock in particular have experienced significant price and volume volatility. Both the market price and the daily trading volume of our common stock may continue to be subject to significant fluctuations due not only to general stock market conditions but also to a change in sentiment in the market regarding our operations and business prospects. In addition to the risk factors discussed above, the price and volume volatility of our common stock may be affected by:

- operating results that vary from our financial guidance or the expectations of securities analysts and investors,
- the financial performance of the major end markets that we target,
- the operating and securities price performance of companies that investors consider to be comparable to us,
- announcements of strategic developments, acquisitions and other material events by us or our competitors, and
- changes in global financial markets and global economies and general market conditions, such as interest or foreign exchange rates, commodity and equity prices and the value of financial assets.

Dividends on our common stock could be reduced or eliminated in the future.

On October 26, 2016, we announced that our Board had declared a quarterly dividend of $0.07 per share for the fourth quarter of fiscal year 2016 that was paid in February 2017. On January 27, 2017, we announced that our Board had declared a quarterly dividend of $0.07 per share for the first quarter of fiscal year 2017 that will be payable in May 2017. In the future, our Board may determine to reduce or eliminate our common stock dividend in order to fund investments for growth, repurchase shares or conserve capital resources.

Item 1B. ***Unresolved Staff Comments***

Not applicable.

Item 2. ***Properties***

As of January 1, 2017, our continuing operations occupied 2,566,797 square feet in over 121 locations. We own 317,809 square feet of this space, and lease the balance. We conduct our operations in manufacturing and assembly plants, research laboratories, administrative offices and other facilities located in 16 states and 31 foreign countries.

Facilities outside of the United States account for approximately 1,438,823 square feet of our owned and leased property, or approximately 56% of our total occupied space.

Our real property leases are both short-term and long-term. We believe that our properties are well-maintained and are adequate for our present requirements.

The following table indicates, as of January 1, 2017, the approximate square footage of real property owned and leased attributable to the continuing operations of our reporting segments:

	Owned	Leased	Total
		(In square feet)	
Discovery & Analytical Solutions	105,020	1,561,535	1,666,555
Diagnostics	212,789	632,111	844,900
Corporate offices	—	55,342	55,342
Continuing operations	317,809	2,248,988	2,566,797

Item 3. ***Legal Proceedings***

We are subject to various claims, legal proceedings and investigations covering a wide range of matters that arise in the ordinary course of our business activities. Although we have established accruals for potential losses that we believe are probable and reasonably estimable, in the opinion of our management, based on its review of the information available at this time, the total cost of resolving these contingencies at January 1, 2017 should not have a material adverse effect on our consolidated financial statements included in this annual report on Form 10-K. However, each of these matters is subject to uncertainties, and it is possible that some of these matters may be resolved unfavorably to us.

Item 4. ***Mine Safety Disclosures***

Not applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

Listed below are our executive officers as of February 28, 2017. No family relationship exists between any one of these executive officers and any of the other executive officers or directors.

Name	Position	Age
Robert F. Friel	Chairman, Chief Executive Officer and President	61
Frank A. Wilson	Senior Vice President and Chief Financial Officer	58
Joel S. Goldberg	Senior Vice President, Administration, General Counsel and Secretary	48
James Corbett	Executive Vice President and President, Discovery & Analytical Solutions	54
Prahlad Singh	Senior Vice President and President, Diagnostics	52
Daniel R. Tereau	Senior Vice President, Strategy and Business Development	50
Deborah Butters	Senior Vice President, Chief Human Resources Officer	47
Andrew Okun	Vice President and Chief Accounting Officer	47

Robert F. Friel, 61. Mr. Friel currently serves as our Chairman, Chief Executive Officer and President. Prior to being appointed President and Chief Executive Officer in February 2008 and Chairman in April 2009, Mr. Friel had served as President and Chief Operating Officer since August 2007, and as Vice Chairman and President of our Life and Analytical Sciences unit since January 2006. Mr. Friel was our Executive Vice President and Chief Financial Officer, with responsibility for business development and information technology in addition to his oversight of the finance functions, from October 2004 until January 2006. Mr. Friel joined PerkinElmer in February 1999 as our Senior Vice President and Chief Financial Officer. Prior to joining PerkinElmer, he held several senior management positions with AlliedSignal, Inc., now Honeywell International. He received a Bachelor of Arts degree in economics from Lafayette College and a Master of Science degree in taxation from Fairleigh Dickinson University. Mr. Friel is currently a director of NuVasive, Inc. and Xylem Inc., and previously served as a director of CareFusion Corporation until its acquisition by Becton, Dickinson and Company in March 2015. He also previously served on the national board of trustees for the March of Dimes Foundation.

Frank A. Wilson, 58. Mr. Wilson joined us in May 2009 as our Senior Vice President and Chief Financial Officer. Prior to joining us, Mr. Wilson held key financial and business management roles over 12 years at the Danaher Corporation, including Corporate Vice President of Investor Relations; Group Vice President of Business Development; Group Vice President of Finance for Danaher Motion Group; President of Gems Sensors; and Group Vice President of Finance for the Industrial Controls Group. Mr. Wilson is currently a director of Sparton Corporation. Previously, Mr. Wilson worked for several years at AlliedSignal Inc., now Honeywell International, where he last served as Vice President of Finance and Chief Financial Officer for Commercial Aviation Systems. His earlier experience includes PepsiCo Inc. in financial and controllership positions of increasing responsibility, E.F. Hutton and Company, and KPMG Peat Marwick. Mr. Wilson received a Bachelor's degree in business administration from Baylor University and is also a Certified Public Accountant.

Joel S. Goldberg, 48. Mr. Goldberg joined us as our Senior Vice President, General Counsel and Secretary in July 2008. Prior to joining us, Mr. Goldberg spent seven years at Millennium Pharmaceuticals, Inc., where he most recently served as Vice President, Chief Compliance Officer and Secretary. During his seven years with Millennium, he focused in the areas of mergers and acquisitions, strategic alliances, investment and financing transactions, securities and healthcare related compliance, and employment law. Previously, he was an associate of the law firm Edwards & Angell, LLP. Mr. Goldberg graduated from the Northeastern University School of Law and also holds a Master of Business Administration from Northeastern University. He completed his undergraduate degree at the University of Wisconsin-Madison.

James Corbett, 54. Mr. Corbett was appointed President of our Discovery & Analytical Solutions business and Executive Vice President of PerkinElmer in October 2016. Mr. Corbett was appointed President of our Human Health business in March 2014 and has been a Senior Vice President and officer of PerkinElmer since February 2012. Mr. Corbett was appointed President of the Diagnostics business in May 2010 and was appointed President of the Life Sciences and Technology business in May 2013. Mr. Corbett joined the Company in October of 2007 through our acquisition of ViaCord, where he served as President. Prior to joining ViaCord, he co-founded CADx Systems, a company focused on the oncology market, where he held

the position of Executive Vice President and Director with responsibility for worldwide sales and marketing, technical support and business development. Following the 2004 acquisition of CADx by iCAD, Inc., he was named Chief Commercial Officer. In addition, Mr. Corbett worked for Abbott Laboratories for 14 years in a variety of sales and marketing positions including Worldwide Marketing Manager for Abbott Diagnostics Immunoassay Systems and Region Manager for Abbott Diagnostics. Mr. Corbett holds a Bachelor of Science degree in business from the University of Massachusetts. Mr. Corbett also serves on the national board of trustees for the March of Dimes Foundation and on the board of directors for the Analytical, Life Science & Diagnostics Association.

Prahlad Singh, 52. Mr. Singh joined PerkinElmer as the President of our Diagnostics business in May 2014. He has been a Senior Vice President and officer of PerkinElmer since September 2016. Prior to joining PerkinElmer, Mr. Singh was General Manager of GE Healthcare's Women's Health Business from 2012 to 2014. In this role, he had worldwide responsibility for GE Healthcare's Mammography and Bone Densitometry businesses. Before that, Mr. Singh held senior executive level roles in Strategy, Business Development and Mergers & Acquisitions at both GE Healthcare from 2011 to 2012 and Philips Healthcare from 2007 to 2011. From 1995 to 2007, he held leadership roles of increasing responsibility at DuPont Pharmaceuticals and subsequently Bristol Myers Squibb Medical Imaging which included managing the Asia Pacific and Middle East region. Mr. Singh holds a doctoral degree in chemistry from the University of Missouri-Columbia and a Master of Business Administration from Northeastern University. His research work has resulted in several issued patents and publications in peer reviewed journals.

Daniel R. Tereau, 50. Mr. Tereau was appointed Senior Vice President, Strategy and Business Development in January 2016 and had joined the Company in April 2014 as a Vice President, Strategy and Business Development. He is responsible for leading PerkinElmer's overall strategic planning, business development, and corporate marketing activities. Prior to joining PerkinElmer, Mr. Tereau served on Novartis' leadership team as Senior Vice President and Global Head of Strategy, Business Development and Licensing from 2011 to 2014, where he was responsible for global strategy and business development for the Consumer Health division. Prior to 2011, Mr. Tereau held similar roles at Thermo Fisher Scientific and GE Healthcare. Mr. Tereau holds a Bachelor of Science degree in finance from Ferris State University, a Juris Doctorate from Wayne State University, and earned his Master of Business Administration from Yale University. He also serves on the board of directors for SeraCare Life Sciences, Inc.

Deborah Butters, 47. Ms. Butters joined PerkinElmer in July 2016 as Senior Vice President, Chief Human Resources Officer. Prior to joining us, she served as Head of North America Human Resources at IBM, where she led all aspects of the Human Resource function for IBM's largest geography, which included 35,000 employees and was responsible for over $30B of IBM's revenue. During her 17 year career there, she significantly helped shape IBM's HR programs and practices, including leading its enterprise-wide, people transformation strategy to optimize employee engagement and business performance. Ms. Butters was with Lotus Development for eight years prior to its acquisition by IBM. Ms. Butters' experiences working in the United Kingdom and Germany for Lotus Development, and in Switzerland and the United States for IBM, ranged from leading functional roles across workforce planning and talent management, to serving in five HR business partner roles in both software and consulting within IBM and Lotus Development, with the largest being IBM's North America Consulting business. Ms. Butters holds a Bachelor of Science degree from the University of Bath and a diploma in Human Resources from London University.

Andrew Okun, 47. Mr. Okun serves as our Vice President and Chief Accounting Officer, a position in which he has served since April 2011. Mr. Okun joined us in 2001 and has served in financial and controllership positions of increasing responsibility, including Director of Finance for the Optoelectronics business from 2001 through 2005, Vice President of Finance from 2005 through 2009 and Vice President and Corporate Controller from 2009 through 2011. Prior to joining us, Mr. Okun most recently worked for Honeywell International as a Site Controller as well as for Coopers & Lybrand. Mr. Okun is a Certified Public Accountant and earned his Master of Business Administration from the University of Virginia. He completed his undergraduate degree at the University of Santa Barbara.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Price of Common Stock

Our common stock is listed and traded on the New York Stock Exchange. The following table sets forth the high and low per share closing sale prices for our common stock on that exchange for each quarter in fiscal years 2016 and 2015.

	2016 Fiscal Quarters			
	First	Second	Third	Fourth
High	$53.01	$55.56	$56.92	$56.43
Low	41.45	48.58	51.94	49.95
	2015 Fiscal Quarters			
	First	Second	Third	Fourth
High	$51.09	$54.29	$53.00	$54.36
Low	42.66	50.30	44.45	46.74

As of February 24, 2017, we had approximately 4,079 holders of record of our common stock.

Stock Repurchase Program

We did not repurchase any of our common stock under our share repurchase program during the fourth quarter of fiscal year 2016.

Dividends

During fiscal years 2016 and 2015, we declared regular quarterly cash dividends on our common stock. The table below sets forth the cash dividends per share that we declared on our common stock during each of those fiscal years, by quarter.

	2016 Fiscal Quarters				2016 Total
	First	Second	Third	Fourth	
Cash dividends declared per common share	$ 0.07	$ 0.07	$ 0.07	$ 0.07	$ 0.28
	2015 Fiscal Quarters				**2015 Total**
	First	Second	Third	Fourth	
Cash dividends declared per common share	$ 0.07	$ 0.07	$ 0.07	$ 0.07	$ 0.28

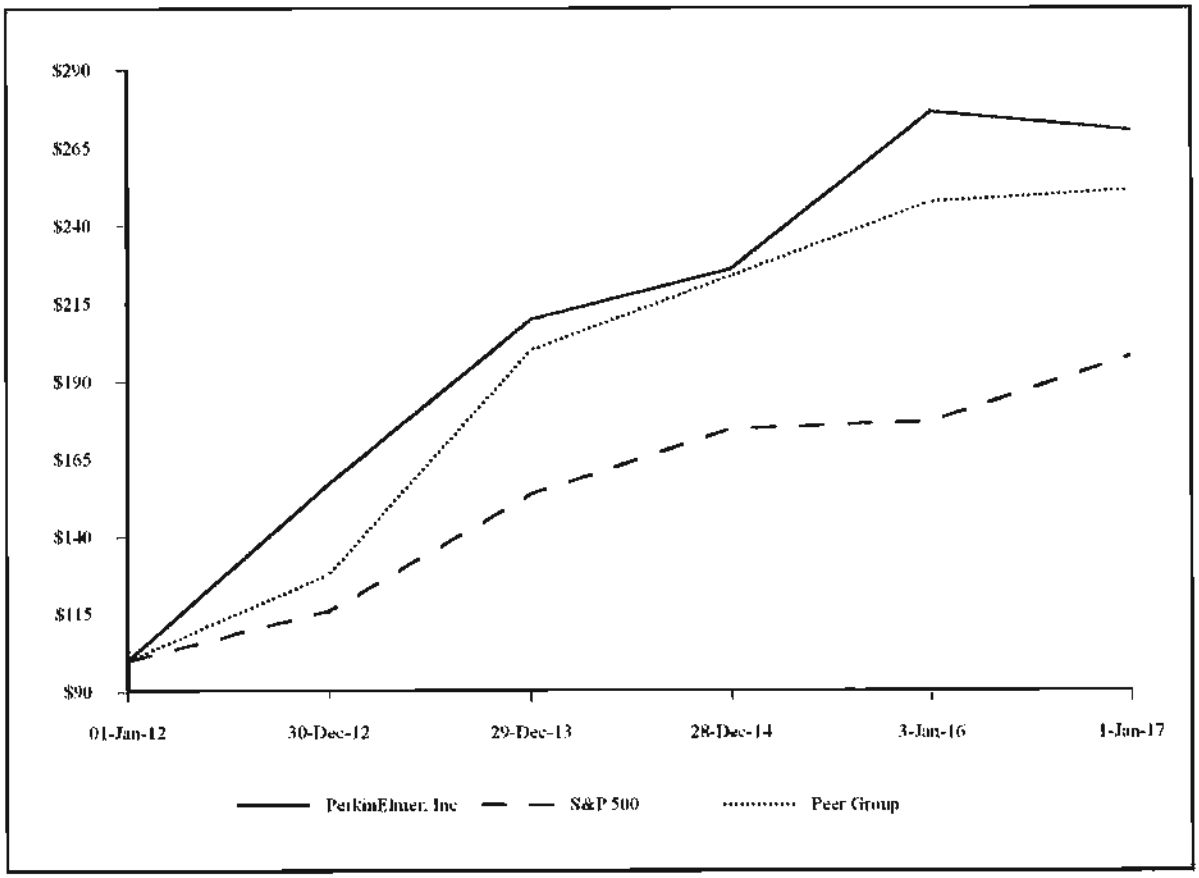
While it is our current intention to pay regular quarterly cash dividends, any decision to pay future cash dividends will be made by our Board and will depend on our earnings, financial condition and other factors. Our Board may reduce or eliminate our common stock dividend in order to fund investments for growth, repurchase shares or conserve capital resources. For further information related to our stockholders' equity, see Note 19 to our consolidated financial statements included in this annual report on Form 10-K.

Stock Performance Graph

Set forth below is a line graph comparing the cumulative total shareholder return on our common stock against the cumulative total return of the S&P Composite-500 Index and a Peer Group Index for the five fiscal years from January 1, 2012 to January 1, 2017. Our Peer Group Index consists of Agilent Technologies Inc., Thermo Fisher Scientific Inc. ("Thermo Fisher"), and Waters Corporation. The peer group is the same as the peer group used in the stock performance graph in our Annual Report on Form 10-K for the fiscal year ended January 3, 2016, except that it does not include Affymetrix, Inc., which has been excluded due to its acquisition by Thermo Fisher during fiscal year 2016.

Comparison of Five-Year Cumulative Total Return
PerkinElmer, Inc. Common Stock, S&P Composite-500 and
Peer Group Index

TOTAL RETURN TO SHAREHOLDERS
(Includes reinvestment of dividends)



	01-Jan-12	30-Dec-12	29-Dec-13	28-Dec-14	3-Jan-16	1-Jan-17
PerkinElmer, Inc.	$ 100.00	$ 156.82	$ 209.82	$ 226.00	$ 276.32	$ 270.47
S&P 500 Index	$ 100.00	$ 116.00	$ 153.58	$ 174.60	$ 177.01	$ 198.18
Peer Group	$ 100.00	$ 127.78	$ 199.93	$ 223.68	$ 247.56	$ 251.59

Item 6. ***Selected Financial Data***

The following table sets forth selected historical financial information as of and for each of the fiscal years in the five-year period ended January 1, 2017. We derived the selected historical financial information for the balance sheets for the fiscal years ended January 1, 2017 and January 3, 2016 and the statement of operations for each of the fiscal years in the three-year period ended January 1, 2017 from our audited consolidated financial statements which are included elsewhere in this annual report on Form 10-K. We derived the selected historical financial information for the statements of operations for the fiscal years ended December 29, 2013 and December 30, 2012 from our audited consolidated financial statements which are not included in this annual report on Form 10-K. We derived the selected historical financial information for the balance sheets as of December 28, 2014, December 29, 2013 and December 30, 2012 from our audited consolidated financial statements which are not included in this annual report on Form 10-K. We adjusted the information in the consolidated financial statements, where appropriate, for discontinued operations.

Our historical financial information may not be indicative of our future results of operations or financial position.

The following selected historical financial information should be read together with our "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, including the related notes, included elsewhere in this annual report on Form 10-K.

	Fiscal Years Ended				
	January 1, 2017	January 3, 2016	December 28, 2014	December 29, 2013	December 30, 2012
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 2,115,517	$ 2,104,823	$ 2,069,880	$ 1,996,959	$ 1,940,202
Operating income from continuing operations[1][2][3]	283,066	250,926	165,007	180,791	51,494
Interest and other expense, net[4]	38,998	42,119	41,139	64,110	47,956
Income from continuing operations before income taxes	244,068	208,807	123,868	116,681	3,538
Income from continuing operations, net of income taxes[5]	215,706	188,785	130,139	142,206	36,354
Income from discontinued operations and dispositions, net of income taxes[6][7]	18,593	23,640	27,639	25,006	33,586
Net income	$ 234,299	$ 212,425	$ 157,778	$ 167,212	$ 69,940
Basic earnings per share:					
Continuing operations	$ 1.97	$ 1.68	$ 1.16	$ 1.27	$ 0.32
Discontinued operations	0.17	0.21	0.25	0.22	0.30
Net income	$ 2.14	$ 1.89	$ 1.40	$ 1.49	$ 0.61
Diluted earnings per share:					
Continuing operations	$ 1.96	$ 1.67	$ 1.14	$ 1.25	$ 0.32
Discontinued operations	0.17	0.21	0.24	0.22	0.29
Net income	$ 2.12	$ 1.87	$ 1.39	$ 1.47	$ 0.61
Weighted-average common shares outstanding:					
Basic:	109,478	112,507	112,593	112,254	113,728
Diluted:	110,313	113,315	113,739	113,503	114,860
Cash dividends declared per common share	$ 0.28	$ 0.28	$ 0.28	$ 0.28	$ 0.28

	As of				
	January 1, 2017	January 3, 2016	December 28, 2014	December 29, 2013	December 30, 2012
			(In thousands)		
Balance Sheet Data:					
Total assets[6]	$ 4,276,683	$ 4,166,295	$ 4,127,576	$ 3,940,882	$ 3,894,451
Short-term debt	1,172	1,123	1,075	2,624	1,772
Long-term debt[4][8]	1,045,254	1,011,762	1,045,393	926,274	931,513
Stockholders' equity[1][9]	2,153,570	2,110,441	2,042,102	1,994,487	1,939,812
Common shares outstanding[9]	109,617	112,034	112,481	112,626	115,036

(1) Activity related to the mark-to-market adjustment on postretirement benefit plans was a pre-tax loss of $15.3 million in fiscal year 2016, a pre-tax loss of $12.4 million in fiscal year 2015, a pre-tax loss of $75.4 million in fiscal year 2014, a pre-tax income of $17.6 million in fiscal year 2013 and a pre-tax loss of $31.3 million in fiscal year 2012.

(2) We recorded pre-tax restructuring and contract termination charges, net, of $5.1 million in fiscal year 2016, $13.5 million in fiscal year 2015, $13.3 million in fiscal year 2014, $33.5 million in fiscal year 2013 and $25.0 million in fiscal year 2012.

(3) In fiscal year 2013, we recorded pre-tax impairment charges of $0.2 million as the carrying amounts of certain long-lived assets were not recoverable and exceeded their fair value. In fiscal year 2012, we recorded pre-tax impairment charges of $74.2 million as a result of a review of certain of our trade names within our portfolio as part of a realignment of our marketing strategy.

(4) In fiscal years 2016, 2015, 2014, 2013 and 2012, interest expense was $41.5 million, $38.0 million, $36.3 million, $49.9 million and $45.8 million, respectively. In fiscal year 2013, we redeemed all of our 6% senior unsecured notes due in 2015 (the "2015 Notes") that included a prepayment premium of $11.1 million, which is included in other expense, net, the write-off of $2.8 million for the remaining unamortized derivative losses for previously settled cash flow hedges, which is included in interest expense, and the write-off of $0.2 million for the remaining deferred debt issuance costs, which is included in interest expense.

(5) In fiscal years 2016 and 2015, provision for income tax on continuing operations was $28.4 million and $20.0 million, respectively. The higher provision for income taxes in fiscal year 2016 was primarily due to higher income in higher tax rate jurisdictions, partially offset by an increase in tax benefit of $3.2 million related to discrete items from $6.4 million in fiscal year 2015 to $9.6 million in fiscal year 2016. In fiscal years 2014, 2013 and 2012, tax benefit on continuing operations was $6.3 million, $25.5 million and $32.8 million, respectively. The benefit from income taxes in fiscal year 2014 was primarily due to losses in higher tax rate jurisdictions and a tax benefit of $7.1 million related to discrete items, partially offset by a provision for income taxes related to profits in lower tax rate jurisdictions. The benefit from income taxes in fiscal year 2013 was primarily due to a tax benefit of $24.0 million related to discrete items and losses in higher tax rate jurisdictions, partially offset by a provision for income taxes related to profits in lower tax rate jurisdictions. The benefit from income taxes in fiscal year 2012 was primarily due to a tax benefit of $7.0 million related to discrete items and losses in higher tax rate jurisdictions, which included pre-tax impairment charges of $74.2 million, partially offset by provision for income taxes related to profits in lower tax rate jurisdictions.

(6) In May 2014, we approved the shutdown of our microarray-based diagnostic testing laboratory in the United States. The shutdown resulted in a $0.1 million net pre-tax gain primarily related to the disposal of fixed assets, which was partially offset by the sale of a building in fiscal year 2014.

(7) In December 2016, we entered into a Master Purchase and Sale Agreement for the sale of our Medical Imaging business. We accounted for this business as discontinued operations beginning in 2016 and the financial information relating to fiscal years 2015, 2014, 2013 and 2012 has been retrospectively adjusted to reflect the inclusion of this business in discontinued operations.

(8) In July 2016, we issued and sold ten-year senior notes at a rate of 1.875% with a face value of €500.0 million and received €492.3 million of net proceeds from the issuance. The debt, which matures in July 2026, is unsecured.

(9) In fiscal year 2016, we repurchased in the open market 3.2 million shares of our common stock at an aggregate cost of $148.2 million, including commissions under a stock repurchase program authorized by our Board on October 23, 2014 ("the Repurchase Program"). In fiscal year 2015, we repurchased in the open market 1.5 million shares of our

common stock at an aggregate cost of $72.0 million, including commissions under the Repurchase Program. In fiscal year 2014, we repurchased in the open market 1.4 million shares of our common stock at an aggregate cost of $61.3 million, including commissions, under both the Repurchase Program and a stock repurchase program originally announced in October 2012 that expired in October 2014 (the "Former Repurchase Program"). In fiscal year 2013, we repurchased in the open market 3.6 million shares of our common stock at an aggregate cost of $123.0 million, including commissions, under the Former Repurchase Program. In fiscal year 2012, we did not repurchase any shares of our common stock. The repurchased shares have been reflected as additional authorized but unissued shares, with the payments reflected in common stock and capital in excess of par value.

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

This annual report on Form 10-K, including the following management's discussion and analysis, contains forward-looking information that you should read in conjunction with the consolidated financial statements and notes to consolidated financial stotements that we have included elsewhere in this annual report on Form 10-K. For this purpose, any statements contained in this report that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "plans," "anticipates," "expects," "will" and similar expressions are intended to identify forward-loaking statements. Our actual results may differ materially from the plans, intentions or expectations we disclose in the forward-looking statements we make. We have included important factors abave under the heading "Risk Factors" in Item 1A above that we believe could cause actual results to differ materially from the forward-looking statements we make. We are not obligated to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Accounting Period

Our fiscal year cnds on the Sunday nearest Decembcr 31. We report fiscal years undcr a 52/53 week format and as a result, certain fiscal years will contain 53 weeks. Each of the fiscal years ended January 1, 2017 ("fiscal year 2016") and December 28, 2014 ("fiscal year 2014") includcd 52 weeks. The fiscal year cndcd January 3, 2016 ("fiscal year 2015") included 53 wccks. The additional week in fiscal ycar 2015 has been reflected in our third quarter. The fiscal year ending December 31, 2017 will include 52 weeks.

Overview of Fiscal Year 2016

We realignccl our businesses at the beginning of the fourth quarter of fiscal year 2016 to better organize around customcr requirements, positioning us to grow in attractivc end markets and expand sharc with our core product offerings. We creatcd two new reporting segments, Discovery & Analytical Solutions and Diagnostics, which will enable us to deliver improved customer focus, more value-add collaboration and breakthrough innovations. Microfluidics and automation products within our former research business were moved to a new applied genomics group within tbe Diagnostics segment. In addition, we also moved our Medical Imaging business into discontinucd operations due to its pending sale. Thc rcsults reported for fiscal year 2016 reflect our new scgment structure and the exclusion of our Medical Imaging business from continuing operations. Financial information in this report relating to fiscal years 2015 and 2014 has been retrospectively adjusted to reflect these changes.

During fiscal year 2016, we continued to see good pcrformance from acquisitions, investments in our ongoing technology and sales and marketing initiatives. Our overall revcnue in fiscal year 2016 increased $10.7 million, or 1%, as compared to fiscal year 2015, reflecting an increasc of $26.1 million, or 5%, in our Diagnostics segment revenue, which was partially offset by a decrease of $15.4 million, or 1%, in our Discovery & Analytical Solutions segment revenue. The decrcase in our Discovery & Analytical Solutions segment was primarily driven by decreases in revenue in our academic and government product offerings within our life sciences research market and a decrease in our environmental and food businesses due to wcak harvest conditions, which were partially offsct by increased demand in our laboratory services business. The increase in our Diagnostics segment revenue during fiscal year 2016 was primarily duc to strong performance of our newborn and infcctious discase screeniug solutions in emerging markets such as China, as well as in Europe.

In our Discovery & Analytical Solutions segment, excluding the unfavorable impact of foreign currency cxchange, we experienced flat growth during fiscal year 2016 in scveral of our products within our life scicnce rcsearch end market, as compared to fiscal year 2015. During fiscal ycar 2016, we experienced increased demand for our OneSource laboratory servicc and informatics businesses. Our OneSource laboratory service business offcrs services designed to enable our customers to iucrease efficiencies and production time while reducing maintenancc costs, all of which continue to be critical for them. This was offset hy decreases in revenue in our environmental and food business due to weak harvest conditions as wcll as in our academic and govcrnment product offerings due to rcduced government funding. We anticipate that thc continued development of contaminant regulations and corresponding tcsting protocols will result in increased dcmand for efficient, analytically scnsitive and iuformation rich testing solutions.

In our Diagnostics segment, we experienced growth from continued expansion in our newborn screening, blood banking and screening businesses. Birth rates in the United States continue to stabilize and demand for greater access to newborn screening in rural areas outside the United States is also increasing, as evidenced by prenatal trends we saw during fiscal year 2016. The growth in our Diagnostics segment was partially offset by unfavorable impacts from foreign currency as the U.S. dollar strengthened. As the rising cost of healthcare continues to be one of the critical issues facing our customers, we anticipate that the benefits of providing earlier detection of disease, which can result in a reduction of long-term health care costs as well as create better outcomes for patients, are increasingly valued and we expect to see continued growth in these markets.

Our consolidated gross margins increased 209 basis points in fiscal year 2016, as compared to fiscal year 2015, primarily due to favorable changes in product mix, with an increase in sales of higher gross margin product offerings, and benefits from our initiatives to improve our supply chain. Our consolidated operating margin increased 146 basis points in fiscal year 2016, as compared to fiscal year 2015 primarily due to higher gross margins and lower costs as a result of cost containment and productivity initiatives, which were partially offset by increased costs related to investments in new product development.

We continue to believe that we are well positioned to take advantage of the spending trends in our end markets and to promote efficiencies in markets where current conditions may increase demand for certain services. Overall, we believe that our strategic focus on diagnostics and discovery and analytical solutions markets, coupled with our deep portfolio of technologies and applications, leading market positions, global scale and financial strength will provide us with a foundation for growth.

Consolidated Results of Continuing Operations

Revenue

2016 Compared to 2015. Revenue for fiscal year 2016 was $2,115.5 million, as compared to $2,104.8 million for fiscal year 2015, an increase of $10.7 million, or 1%, which includes an approximate 1% decrease in revenue attributable to changes in foreign exchange rates with minimal impact from acquisitions and divestitures. In addition, our fiscal year 2015 had an additional week, which consisted of 53 weeks, as compared to fiscal year 2016, which consisted of 52 weeks. The analysis in the remainder of this paragraph compares segment revenue for fiscal year 2016 as compared to fiscal year 2015 and includes the effect of foreign exchange rate fluctuations and acquisitions and divestitures. The total increase in revenue reflects an increase in our Diagnostics segment revenue of $26.1 million, or 5%, due to continued expansion in our newborn screening, blood banking and screening businesses. Our Discovery & Analytical Solutions segment revenue decreased by $15.4 million, or 1%, due to a decrease in environmental, food and industrial markets revenue of $20.8 million and life sciences research market revenue of $0.6 million, which was partially offset by an increase in laboratory services market revenue of $6.0 million. As a result of adjustments to deferred revenue related to certain acquisitions required by business combination rules, we did not recognize $0.7 million of revenue primarily related to our Diagnostics segment for fiscal year 2016 and $0.8 million for fiscal year 2015 that otherwise would have been recorded by the acquired businesses during each of the respective periods.

2015 Compared to 2014. Revenue for fiscal year 2015 was $2,104.8 million, as compared to $2,069.9 million for fiscal year 2014, an increase of $34.9 million, or 2%, which includes an approximate 3% increase in revenue attributable to acquisitions and divestitures and an approximate 6% decrease in revenue attributable to changes in foreign exchange rates. The analysis in the remainder of this paragraph compares segment revenue for fiscal year 2015 as compared to fiscal year 2014 and includes the effect of foreign exchange rate fluctuations and acquisitions and divestitures. The total increase in revenue reflects a $44.3 million, or 3%, increase in our Discovery & Analytical Solutions segment revenue, due to an increase in environmental, food and industrial markets revenue of $44.9 million and life sciences research market revenue of $11.6 million partially offset by a decrease in laboratory services market revenue of $12.2 million. Our Diagnostics segment revenue decreased by $9.3 million, or 2%. As a result of adjustments to deferred revenue related to certain acquisitions required by business combination rules, we did not recognize $0.8 million of revenue primarily related to our informatics business in our Diagnostics segment for fiscal year 2015 and $2.9 million for fiscal year 2014 that otherwise would have been recorded by the acquired businesses during each of the respective periods.

Cost of Revenue

2016 Compared to 2015. Cost of revenue for fiscal year 2016 was $1,102.2 million, as compared to $1,140.6 million for fiscal year 2015, a decrease of approximately $38.4 million, or 3%. As a percentage of revenue, cost of revenue decreased to 52.1% in fiscal year 2016 from 54.2% in fiscal year 2015, resulting in an increase in gross margin of approximately 209 basis points to 47.9% in fiscal year 2016 from 45.8% in fiscal year 2015. Amortization of intangible assets decreased and was $30.3 million for fiscal year 2016, as compared to $42.4 million for fiscal year 2015. The mark-to-market adjustment for postretirement benefit plans was a loss of $0.4 million for fiscal year 2016, as compared to a loss of $1.2 million for fiscal year 2015. Stock-based compensation expense was $1.0 million for fiscal year 2016, as compared to $1.3 million for fiscal year 2015. The amortization of purchase accounting adjustments to record the inventory from certain acquisitions added an incremental expense of $0.4 million for fiscal year 2016, as compared to $7.3 million for fiscal year 2015. Acquisition and divestiture-related expenses, contingent consideration and other costs added an incremental expense of $0.1 million for each of fiscal years 2016 and 2015. In addition to the factors noted above, the increase in gross margin was primarily the result of favorable changes in product mix, with an increase in sales of higher gross margin product offerings and benefits from our initiatives to improve our supply chain.

2015 Compared to 2014. Cost of revenue for fiscal year 2015 was $1,140.6 million, as compared to $1,135.3 million for fiscal year 2014, an increase of approximately $5.3 million, or 0.5%. As a percentage of revenue, cost of revenue decreased to 54.2% in fiscal year 2015 from 54.8% in fiscal year 2014, resulting in an increase in gross margin of approximately 66 basis points to 45.8% in fiscal year 2015 from 45.2% in fiscal year 2014. Amortization of intangible assets decreased and was $42.4 million for fiscal year 2015, as compared to $48.7 million for fiscal year 2014. The mark-to-market adjustment for postretirement benefit plans was a loss of $1.2 million for fiscal year 2015, as compared to a loss of $8.2 million for fiscal year 2014. Stock-based compensation expense was $1.3 million for fiscal year 2015, as compared to $1.4 million for fiscal year 2014. The amortization of purchase accounting adjustments to record the inventory from certain acquisitions was $7.3 million for fiscal year 2015, as compared to $2.4 million for fiscal year 2014. Acquisition and divestiture-related expenses, contingent consideration and other costs added an incremental expense of $0.1 million for each of fiscal years 2015 and 2014. In addition to the factors noted above, the increase in gross margin was primarily the result of benefits from our initiatives to improve our supply chain, which was partially offset by unfavorable changes in product mix, with an increase in sales of lower gross margin product offerings and negative impacts from foreign exchange rates.

Selling, General and Administrative Expenses

2016 Compared to 2015. Selling, general and administrative expenses for fiscal year 2016 were $600.9 million, as compared to $587.2 million for fiscal year 2015, an increase of approximately $13.7 million, or 2%. As a percentage of revenue, selling, general and administrative expenses increased to 28.4% in fiscal year 2016 from 27.9% in fiscal year 2015. Amortization of intangible assets increased and was $40.7 million for fiscal year 2016, as compared to $33.8 million for fiscal year 2015. The mark-to-market adjustment for postretirement benefit plans was a loss of $14.9 million for fiscal year 2016, as compared to a loss of $11.1 million for fiscal year 2015. Stock-based compensation expense decreased and was $15.2 million for fiscal year 2016, as compared to $15.5 million for fiscal year 2015. During fiscal year 2015, we recorded $0.8 million in legal costs for a particular case. Acquisition and divestiture-related expenses, contingent consideration and other costs added an incremental expense of $17.5 million for fiscal year 2016 as compared to $0.7 million for fiscal year 2015. In addition to the above items, the increase in selling, general and administrative expenses was primarily the result of costs related to growth investments, which was partially offset by the result of lower costs as a result of cost containment and productivity initiatives.

2015 Compared to 2014. Selling, general and administrative expenses for fiscal year 2015 were $587.2 million, as compared to $648.2 million for fiscal year 2014, a decrease of approximately $61.0 million, or 9%. As a percentage of revenue, selling, general and administrative expenses decreased to 27.9% in fiscal year 2015, compared to 31.3% in fiscal year 2014. Amortization of intangible assets increased and was $33.8 million for fiscal year 2015, as compared to $32.2 million for fiscal year 2014. The mark-to-market adjustment for postretirement benefit plans was a loss of $11.1 million for fiscal year 2015, as compared to loss of $67.0 million for fiscal year 2014. Stock-based compensation expense increased and was $15.5 million for fiscal year 2015, as compared to $12.2 million for fiscal year 2014. During fiscal year 2015, we recorded $0.8 million in legal costs for a particular case compared to $6.6 million for fiscal year 2014. During fiscal year 2014, we recorded a benefit of $2.3 million for cost reimbursements related to a particular site, of which $1.2 million was for future monitoring and mitigation

activities. Acquisition and divestiture-related expenses, contingent consideration and other costs added an incremental expense of $0.7 million for fiscal year 2015 and $3.1 million for fiscal year 2014. In addition to the above items, the decrease in selling, general and administrative expenses was primarily the result of lower costs as a result of cost containment and productivity initiatives, which was partially offset by the impact from foreign currency exchange rates, and the impact of an additional week during fiscal year 2015.

Research and Development Expenses

2016 Compared to 2015. Research and development expenses for fiscal year 2016 were $124.3 million, as compared to $112.5 million for fiscal year 2015, an increase of $11.7 million, or 10%. As a percentage of revenue, research and development expenses increased to 5.9% in fiscal year 2016, as compared to 5.3% in fiscal year 2015. Amortization of intangible assets was $0.5 million for each of fiscal years 2016 and 2015. The mark-to-market adjustment for postretirement benefit plans was a loss of $0.1 million for fiscal year 2015. Stock-based compensation expense increased and was $0.9 million for fiscal year 2016, as compared to $0.5 million for fiscal year 2015. In addition to the above items, the increase in research and development expenses was primarily the result of investments in new product development, primarily the results of our investments in Vanadis focused on non-invasive prenatal screening and ionics mass spectrometry focused on food and environmental safety applications. This was partially offset by lower costs as a result of cost containment and productivity initiatives. We directed research and development efforts similarly during fiscal years 2016 and 2015, primarily towards the diagnostics, environmental, food, life sciences research and laboratory services markets in order to help accelerate our growth initiatives. We have a broad product base, and we do not expect any single research and development project to have significant costs.

2015 Compared to 2014. Research and development expenses for fiscal year 2015 were $112.5 million, as compared to $108.1 million for fiscal year 2014, an increase of $4.5 million, or 4%. As a percentage of revenue, research and development expenses increased to 5.3% in fiscal year 2015, as compared to 5.2% in fiscal year 2014. Amortization of intangible assets decreased and was $0.5 million for fiscal year 2015, as compared to $0.6 million for fiscal year 2014. The mark-to-market adjustment for postretirement benefit plans was a loss of $0.1 million for fiscal year 2015, as compared to a loss of $0.2 million for fiscal year 2014. Stock-based compensation expense was $0.5 million for each of fiscal years 2015 and 2014. In addition to the above items, the increase in research and development expenses was primarily due to investments in new product development, the impact from foreign currency exchange rates and the impact of an additional week in fiscal year 2015.

Restructuring and Contract Termination Charges, Net

We have undertaken a series of restructuring actions related to the impact of acquisitions and divestitures, the alignment of our operations with our growth strategy, the integration of our business units and productivity initiatives. Restructuring and contract termination charges for fiscal year 2016 were $5.1 million, as compared to $13.5 million for fiscal year 2015 and $13.3 million for fiscal year 2014.

We implemented a restructuring plan in the third quarter of fiscal year 2016 consisting of workforce reductions principally intended to focus resources on higher growth product lines (the "Q3 2016 Plan"). We implemented a restructuring plan in the second quarter of fiscal year 2016 consisting of workforce reductions principally intended to focus resources on higher growth end markets (the "Q2 2016 Plan"). We implemented restructuring plans in the fourth quarter of fiscal year 2015, and the second and first quarters of fiscal year 2014 consisting of workforce reductions and the closure of excess facility space principally intended to focus resources on higher growth end markets (the "Q4 2015 Plan", "Q2 2014 Plan", and "Q1 2014 Plan", respectively). We implemented restructuring plans in the second quarter of fiscal year 2015 and the third quarter of fiscal year 2014 consisting of workforce reductions principally intended to realign resources to emphasize growth initiatives (the "Q2 2015 Plan" and "Q3 2014 Plan", respectively). All other previous restructuring plans were workforce reductions or the closure of excess facility space principally intended to integrate our businesses in order to realign operations, reduce costs, achieve operational efficiencies and shift resources into geographic regions and end markets that are more consistent with our growth strategy (the "Previous Plans").

The following table summarizes the number of employees reduced, the initial restructuring or contract termination charges by operating segment, and the dates by which payments were substantially completed, or the expected dates by which payments will be substantially completed, for restructuring actions implemented during fiscal years 2016, 2015 and 2014 in continuing operations:

	Workforce Reductions			Closure of Excess Facility			(Expected) Date Payments Substantially Completed by	
	Headcount Reduction	Diagnostics	Discovery & Analytical Solutions	Diagnostics	Discovery & Analytical Solutions	Total	Severance	Excess Facility
	(In thousands, except headcount data)							
Q3 2016 Plan	22	$ 41	$ 1,779	$ —	$ —	$ 1,820	Q4 FY2017	—
Q2 2016 Plan	72	561	4,106	—	—	4,667	Q3 FY2017	—
Q4 2015 Plan	174	1,315	9,980	—	285	11,580	Q1 FY2017	Q4 FY2017
Q2 2015 Plan	95	673	5,290	—	—	5,963	Q2 FY2016	—
Q3 2014 Plan	152	2,885	10,166	—	—	13,051	Q4 FY2015	—
Q2 2014 Plan	21	235	435		—	670	Q2 FY2015	—
Q1 2014 Plan	17	281	286	—	—	567	Q4 FY2014	—

We expect to make payments under the Previous Plans for remaining residual lease obligations, with terms varying in length, through fiscal year 2022.

We also have terminated various contractual commitments in connection with certain disposal activities and have recorded charges, to the extent applicable, for the costs of terminating these contracts before the end of their terms and the costs that will continue to be incurred for the remaining terms without economic benefit to us. We recorded additional pre-tax charges of $0.1 million, $0.1 million and $1.5 million in the Discovery & Analytical Solutions segment during fiscal years 2016, 2015 and 2014, respectively, as a result of these contract terminations.

At January 1, 2017, we had $10.5 million recorded for accrued restructuring and contract termination charges, of which $7.5 million was recorded in short-term accrued restructuring and $3.1 million was recorded in long-term liabilities. At January 3, 2016, we had $22.2 million recorded for accrued restructuring and contract termination charges, of which $17.0 million was recorded in short-term accrued restructuring and $5.1 million was recorded in long-term liabilities. The following table summarizes our restructuring accrual balances and related activity by restructuring plan, as well as contract termination accrual balances and related activity, during fiscal years 2016, 2015 and 2014 in continuing operations:

	Balance at December 29, 2013	2014 Charges and Changes in Estimates, Net	2014 Amounts Paid	Balance at December 28, 2014	2015 Charges and Changes in Estimates, Net	2015 Amounts Paid	Balance at January 3, 2016	2016 Charges and Changes in Estimates, Net	2016 Amounts Paid	Balance at January 1, 2017
					(In thousands)					
Severance:										
Q3 2016 Plan	—	$ —	$ —	$ —	$ —	$	$ —	$ 1,820	$ (612)	$ 1,208
Q2 2016 Plan	—	—	—	—	—	—	—	4,667	(3,231)	1,436
Q4 2015 Plan[1]	—	—	—	—	11,295	(925)	10,370	(953)	(8,198)	1,219
Q2 2015 Plan[2]	—	—	—	—	5,423	(4,322)	1,101	(533)	(370)	198
Q3 2014 Plan	—	13,051	(2,992)	10,059	(3,064)	(5,460)	1,535	—	(672)	863
Q2 2014 Plan	—	670	(419)	251	(179)	(13)	59	—	—	59
Q1 2014 Plan	—	567	(475)	92	(92)	—	—	—	—	—
Facility:										
Q4 2015 Plan			—	—	285	(26)	259	—	(248)	11
Previous Plans including 2013 plans	35,200	(2,508)	(19,572)	13,120	(204)	(4,222)	8,694	35	(3,299)	5,430
Restructuring	35,200	11,780	(23,458)	23,522	13,464	(14,968)	22,018	5,036	(16,630)	10,424
Contract Termination	300	1,545	(1,541)	304	83	(255)	132	88	(103)	117
Total Restructuring and Contract Termination	$ 35,500	$ 13,325	$ (24,999)	$ 23,826	$ 13,547	$ (15,223)	$ 22,150	$ 5,124	$ (16,733)	$ 10,541

(1) During fiscal year 2016, we recognized pre-tax restructuring reversals of $1.0 million in the Discovery & Analytical Solutions segment related to lower than expected costs associated with workforce reductions for the Q4 2015 Plan.

(2) During fiscal year 2016, we recognized pre-tax restructuring reversals of $0.1 million in the Diagnostics segments and $0.5 million in the Discovery & Analytical Solutions segments related to lower than expected costs associated with workforce reductions for the Q2 2015 Plan.

Interest and Other Expense, Net

Interest and other expense, net, consisted of the following:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Interest income	$ (702)	$ (673)	$ (667)
Interest expense	41,528	37,997	36,270
Gain on disposition of businesses and assets, net	(5,562)	—	—
Other expense, net	3,734	4,795	5,536
Total interest and other expense, net	$ 38,998	$ 42,119	$ 41,139

2016 Compared to 2015. Interest and other expense, net, for fiscal year 2016 was an expense of $39.0 million, as compared to an expense of $42.1 million for fiscal year 2015, a decrease of $3.1 million. The decrease in interest and other expense, net, in fiscal year 2016 as compared to fiscal year 2015 was primarily due to a gain on disposition of businesses and assets, net recognized in fiscal year 2016 which was partially offset by an increase in interest expense of $3.5 million for fiscal year 2016 as compared to fiscal year 2015 due to the issuance of the new higher interest rate 2026 Notes, which replaced our lower cost debt outstanding on our previous senior unsecured revolving credit facility. Other expenses for fiscal year 2016 decreased by $1.1 million as compared to fiscal year 2015, primarily due to expenses related to foreign currency transactions and translation of non-functioual currency assets and liabilities. A more complete discussion of our liquidity is set forth below under the heading "Liquidity and Capital Resources."

2015 Compared to 2014. Interest and other expense, net, for fiscal year 2015 was an expense of $42.1 million, as compared to an expense of $41.1 million for fiscal year 2014, an increase of $1.0 million. The increase in interest and other expense, net, in fiscal year 2015 as compared to fiscal year 2014 was primarily due to an increase in interest expense. Interest expense increased by $1.7 million in fiscal year 2015 as compared to fiscal year 2014, primarily due to increased debt outstanding on our previous senior unsecured revolving credit facility and higher variable interest rates, as well as an additional week during fiscal year 2015. Other expenses for fiscal year 2015 decreased by $0.7 million as compared to fiscal year 2014, primarily due to expenses related to foreign currency transactions and translation of non-functional currency assets and liabilities.

Provision for (Benefit from) Income Taxes

The effective tax rates on continuing operations were 11.6%, 9.6% and (5.1)% for fiscal years 2016, 2015 and 2014, respectively. Certain of our subsidiaries have, at various times, been granted tax relief in their respective countries, resultiug in lower income taxes thau would otherwise be the case under ordinary tax rates. A reconciliation of income tax expense at the U.S. federal statutory income tax rate to the recorded tax provision is as follows for the fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Tax at statutory rate	$ 85,424	$ 73,082	$ 43,354
Non-U.S. rate differential, net	(52,648)	(47,994)	(34,845)
U.S. taxation of multinational operations	6,941	1,732	2,367
State income taxes, net	1,509	80	1,352
Prior year tax matters	(9,621)	(6,387)	(7,146)
Federal tax credits	(7,189)	(2,096)	(3,399)
Change in valuation allowance	(2,755)	2,593	(7,679)
Non-deductible acquisition expense	5,701	—	—
Other, net	1,000	(988)	(275)
Total	$ 28,362	$ 20,022	$ (6,271)

The variation in our effective tax rate for each year is primarily a result of the recognition of earnings in foreign jurisdictious, predominantly Singapore, Finland, and China, which are taxed at rates lower than the U.S. federal statutory rate, resulting in a benefit from income taxes of $45.8 million in fiscal year 2016, $34.2 million in fiscal year 2015 and $29.1 million in fiscal year 2014. These amounts include $11.4 milliou iu fiscal year 2016, $8.3 million in fiscal year 2015 and $7.1 million in fiscal year 2014 of benefits derived from tax holidays in China and Singapore. The effect of these benefits derived from tax holidays on basic and diluted earnings per share for fiscal year 2016 was $0.10 and $0.10, respectively, for fiscal year 2015 was $0.07 and $0.07, respectively, and for fiscal year 2014 was $0.06 and $0.06, respectively. The tax holiday in China is scheduled to expire in fiscal year 2017 and the tax holiday in Singapore is scheduled to expire in fiscal year 2018.

Discontinued Operations

As part of our continuing efforts to focus on higher growth opportunities, we have discontinued certain businesses. When the discontinued operations represented a strategic shift that will have a major effect on our operations and financial statements, we accounted for these businesses as discontinued operations and accordingly, have presented the results of operations and related cash flows as discontinued operations. Any business deemed to be a discontinued operation prior to the adoption of Accounting Standards Update 2014-08, *Reporting Discontinued Operations and Disclosures of Disposals of Components of An Entity* ("ASU 2014-08"), continues to be reported as a discontinued operation, and the results of operations and related cash flows are presented as discontinued operations for all periods presented. Any remaining assets and liabilities of these businesses have been presented separately, and are reflected within assets and liabilities from discontinued operations in the accompanying condensed consolidated balance sheets as of January 1, 2017 and January 3, 2016.

In May 2014, our management approved the shutdown of our microarray-based diagnostic testing laboratory in the United States, which had been reported within our Diagnostics segment. We determined that, with the lack of adequate reimbursement from health care payers, the microarray-based diagnostic testing laboratory in the United States would need significant investment in its operations to reduce costs in order to effectively compete in the market. The shutdown of the microarray-based diagnostic testing laboratory in the United States resulted in a $0.1 million net pre-tax gain primarily related to the disposal of fixed assets, which was partially offset by the sale of a building in fiscal year 2014.

In August 1999, we sold the assets of our Technical Service business. We recorded pre-tax losses of $1.8 million in fiscal year 2016, $0.03 million in fiscal year 2015 and $0.2 million in fiscal year 2014 for a contingency related to this business. These losses were recognized as a loss on disposition of discontinued operations before income taxes.

During fiscal year 2016, we settled various commitments related to the divestiture of other discontinued operations and recognized a pre-tax loss of $1.1 million. This loss was recognized as a loss on disposition of discontinued operations before income taxes.

During fiscal year 2016, we sold PerkinElmer Labs, Inc. for cash consideration of $20.0 million, recognizing a pre-tax gain of $7.1 million. The sale generated a capital loss for tax purposes of $7.3 million, which resulted in an income tax benefit of $2.5 million that was recognized as a discrete benefit during the second quarter of 2016. PerkinElmer Labs, Inc. was a component of our Diagnostics segment. The pre-tax gain recognized in fiscal year 2016 is included in interest and other expense, net in the condensed consolidated statement of operations. The divestiture of PerkinElmer Labs, Inc. has not been classified as a discontinued operation in this Form 10-K because the disposition does not represent a strategic shift that will have a major effect on our operations and financial statements.

During fiscal year 2016, we entered into a letter of intent to contribute certain assets to an academic institution in the United Kingdom. We recognized a pre-tax loss of $1.6 million related to the write-off of assets in the second quarter of 2016 which is included in interest and other expense, net in the condensed consolidated statement of operations.

In December 2016, we entered into a Master Purchase and Sale Agreement (the "Agreement") with Varian Medical Systems, Inc. (the "Purchaser"), under which we agreed to sell to the Purchaser all of the outstanding equity interests in our wholly owned indirect subsidiaries PerkinElmer Medical Holdings, Inc. and Dexela Limited, together with certain assets relating to the business of designing, manufacturing and marketing flat panel x-ray detectors, and related software, accessories and ancillary products, to x-ray system manufacturers (the "Medical Imaging Business"), for cash consideration of approximately $276.0 million and the Purchaser's assumption of specified liabilities relating to the Medical Imaging Business (collectively, the "Transaction"). The Medical Imaging Business has been reported in the Diagnostics segment. The Agreement contemplates that the Purchaser will finance the Transaction through a debt financing and that, except as determined otherwise by the Purchaser, the closing will occur no earlier than April 2017. However, the closing of the Transaction is not conditioned upon the receipt of any such financing. The Transaction is subject to customary closing conditions, including the expiration of specified antitrust waiting periods. The Agreement contains certain termination rights and provides that under specified circumstances, upon termination of the Agreement, the Purchaser will be required to pay us a termination fee of up to $22.1 million. The sale of the Medical Imaging Business represents a strategic shift that will have a major effect on our operations and financial statements. Accordingly, we classified the assets and liabilities related to the Medical Imaging Business as assets

and liabilities of discontinued operations in our consolidated balance sheets and its results of operations are classified as income from discontinued operations in our consolidated statements of operations.

The summary pre-tax operating results of the discontinued operations, which include the periods prior to disposition and a $1.0 million pre-tax restructuring charge related to workforce reductions in the microarray-based diagnostic testing laboratory in the United States during fiscal year 2014, were as follows during the three fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Revenue	$ 146,217	$ 158,128	$ 168,124
Cost of revenue	95,395	97,777	100,512
Selling, general and administrative expenses	13,657	11,712	12,503
Research and development expenses	14,368	13,391	13,222
Restructuring and contract termination charges, net	568	43	1,111
Income from discontinued operations before income taxes	$ 22,229	$ 35,205	$ 40,776

We recorded a tax provision of $4.3 million, $11.5 million and $12.9 million on discontinued operations and dispositions in fiscal years 2016, 2015 and 2014.

Business Combinations

Acquisitions in fiscal year 2016

During the fiscal year 2016, we completed the acquisition of two businesses for a total consideration of $72.2 million in cash. The acquired businesses were Bioo Scientific Corporation, which was acquired for total consideration of $63.5 million in cash and one other business acquired for a total consideration of $8.8 million in cash. The excess of the purchase prices over the fair values of each of the acquired businesses' net assets represents cost and revenue synergies specific to us, as well as non-capitalizable intangible assets, such as the employee workforce acquired. As a result of the acquisitions, we recorded goodwill of $45.6 million, which is not tax deductible, and intangible assets of $19.9 million. We reported the operations for these acquisitions within the results of our Diagnostics and Discovery & Analytical Solutions segments from the acquisition dates. Identifiable definite-lived intangible assets, such as core technology, trade names and customer relationships, acquired as part of these acquisitions had a weighted average amortization period of 9.5 years.

Acquisitions in fiscal year 2015

During fiscal year 2015, we completed the acquisition of five businesses for a total consideration of $77.1 million in cash. The acquired businesses included Vanadis Diagnostics AB ("Vanadis"), which was acquired for total consideration of $35.1 million in cash, as further described in Note 21 to our consolidated financial statements included in this annual report on Form 10-K, and other acquisitions for an aggregate consideration of $42.0 million in cash. We have a potential obligation to pay the shareholders of Vanadis additional contingent consideration of up to $93.0 million, which at closing had an estimated fair value of $56.9 million. The excess of the purchase prices over the fair values of each of the acquired businesses' net assets represents cost and revenue synergies specific to us, as well as non-capitalizable intangible assets, such as the employee workforce acquired, and has been allocated to goodwill, of which $9.2 million is tax deductible. We reported the operations for all of these acquisitions within the results of our Diagnostics and Discovery & Analytical Solutions segments from the acquisition dates.

Acquisitions in fiscal year 2014

Acquisition of Perten Instruments Group AB. In December 2014, we acquired all of the outstanding stock of Perten Instruments Group AB ("Perten"). Perten is a provider of analytical instruments and services for quality control of food, grain, flour and feed. We expect this acquisition to enhance our industrial, environmental and safety business by expanding our product offerings to the academic and industrial end markets. We paid the shareholders of Perten $269.9 million in cash for the stock of Perten. The excess of the purchase price over the fair value of the acquired net assets represents cost and revenue synergies specific to us, as well as non-capitalizable intangible assets, such as the employee workforce acquired, and has been

allocated to goodwill, none of which is tax deductible. We have reported the operations for this acquisition within the results of our Discovery & Analytical Solutions segment from the acquisition date.

Other acquisitions in fiscal year 2014. In addition to the Perten acquisition, we completed the acquisition of two businesses in fiscal year 2014 for total consideration of $17.6 million in cash and $4.3 million of assumed debt. The excess of the purchase price over the fair value of each of the acquired businesses' net assets represents cost and revenue synergies specific to us, as well as non-capitalizable intangible assets, such as the employee workforce acquired, and has been allocated to goodwill, none of which is tax deductible. We reported the operations for these acquisitions within the results of our Diagnostics and Discovery & Analytical Solutions segments from the acquisition dates.

We do not consider the acquisitions completed during fiscal years 2016, 2015 and 2014, to be material to our consolidated results of operations; therefore, we are not presenting pro forma financial information of operations. During fiscal years 2016 and 2015, we recognized $80.7 million and $65.7 million, respectively, of revenue for Perten. We have determined that the presentation of the results of operations for each of the other acquisitions, from the date of acquisition, is impracticable due to the integration of the operations upon acquisition.

As of January 1, 2017, the allocations of purchase prices for acquisitions completed in fiscal years 2015 and 2014 were final. The preliminary allocations of the purchase prices for acquisitions completed in fiscal year 2016 were based upon initial valuations. Our estimates and assumptions underlying the initial valuations are subject to the collection of information necessary to complete our valuations within the measurement periods, which are up to one year from the respective acquisition dates. The primary areas of the preliminary purchase price allocations that are not yet finalized relate to the fair value of certain tangible and intangible assets acquired and liabilities assumed, assets and liabilities related to income taxes and related valuation allowances, and residual goodwill. We expect to continue to obtain information to assist in determining the fair values of the net assets acquired at the acquisition dates during the measurement periods. During the measurement periods, we will adjust assets or liabilities if new information is obtained about facts and circumstances that existed as of the acquisition dates that, if known, would have resulted in the recognition of those assets and liabilities as of those dates. With our adoption of Accounting Standards Update No. 2015-16, *Simplifying the Accounting for Measurement-Period Adjustments* ("ASU No. 2015-16") during 2015, these adjustments will be made in the periods in which the amounts are determined and the cumulative effect of such adjustments will be calculated as if the adjustments had been completed as of the acquisition dates. All changes that do not qualify as adjustments made during the measurement periods are also included in current period earnings.

During fiscal year 2016, we obtained information to assist in determining the fair values of certain tangible and intangible assets acquired and liabilities assumed as part of our acquisitions and adjusted our purchase price allocations. Based on this information, for acquisitions completed during fiscal year 2015, we recognized an increase in deferred taxes of $1.8 million, with a corresponding increase in goodwill.

Allocations of the purchase price for acquisitions are based on estimates of the fair value of the net assets acquired and are subject to adjustment upon finalization of the purchase price allocations. The accounting for business combinations requires estimates and judgments as to expectations for future cash flows of the acquired business, and the allocation of those cash flows to identifiable intangible assets, in determining the estimated fair values for assets acquired and liabilities assumed. The fair values assigned to tangible and intangible assets acquired and liabilities assumed, including contingent consideration, are based on management's estimates and assumptions, as well as other information compiled by management, including valuations that utilize customary valuation procedures and techniques. Contingent consideration is measured at fair value at the acquisition date, based on the probability that revenue thresholds or product development milestones will be achieved during the earnout period, with changes in the fair value after the acquisition date affecting earnings to the extent it is to be settled in cash. Increases or decreases in the fair value of contingent consideration liabilities primarily result from changes in the estimated probabilities of achieving revenue thresholds or product development milestones during the earnout period.

As of January 1, 2017, we may have to pay contingent consideration, related to acquisitions with open contingency periods, of up to $84.6 million. As of January 1, 2017, we have recorded contingent consideration obligations of $63.2 million, of which $15.4 million was recorded in accrued expenses and other current liabilities, and $47.8 million was recorded in long-term liabilities. As of January 3, 2016, we have recorded contingent consideration obligations of $57.4 million, of which $9.4

million was recorded in accrued expenses and other current liabilities, and $48.0 million was recorded in long-term liabilities. The expected maximum earnout period for acquisitions with open contingency periods does not exceed 3 years from the respective acquisition dates, and the remaining weighted average expected earnout period at January 1, 2017 was 1.75 years. If the actual results differ from the estimates and judgments used in these fair values, the amounts recorded in the consolidated financial statements could result in a possible impairment of the intangible assets and goodwill, require acceleration of the amortization expense of definite-lived intangible assets or the recognition of additional contingent consideration which would be recognized as a component of operating expenses from continuing operations.

In connection with the purchase price allocations for acquisitions, we estimate the fair value of deferred revenue assumed with our acquisitions. The estimated fair value of deferred revenue is determined by the legal performance obligation at the date of acquisition, and is generally based on the nature of the activities to be performed and the related costs to be incurred after the acquisition date. The fair value of an assumed liability related to deferred revenue is estimated based on the current market cost of fulfilling the obligation, plus a normal profit margin thereon. The estimated costs to fulfill the deferred revenue are based on the historical direct costs related to providing the services. We do not include any costs associated with selling effort, research and development, or the related fulfillment margins on these costs. In most acquisitions, profit associated with selling effort is excluded because the acquired businesses would have concluded the selling effort on the support contracts prior to the acquisition date. The estimated research and development costs are not included in the fair value determination, as these costs are not deemed to represent a legal obligation at the time of acquisition. The sum of the costs and operating income approximates, in theory, the amount that we would be required to pay a third-party to assume the obligation.

Contingencies, Including Tax Matters

We are conducting a number of environmental investigations and remedial actions at our current and former locations and, along with other companies, have been named a potentially responsible party ("PRP") for certain waste disposal sites. We accrue for environmental issues in the accounting period that our responsibility is established and when the cost can be reasonably estimated. We have accrued $9.9 million and $11.8 million as of January 1, 2017 and January 3, 2016, respectively, in accrued expenses and other current liabilities, which represents our management's estimate of the cost of the remediation of known environmental matters, and does not include any potential liability for related personal injury or property damage claims. During fiscal year 2014, we recorded a benefit of $2.3 million for cost reimbursements related to a particular site, of which $1.2 million was for future monitoring and mitigation activities. Our environmental accrual is not discounted and does not reflect the recovery of any material amounts through insurance or indemnification arrangements. The cost estimates are subject to a number of variables, including the stage of the environmental investigations, the magnitude of the possible contamination, the nature of the potential remedies, possible joint and several liability, the time period over which remediation may occur, and the possible effects of changing laws and regulations. For sites where we have been named a PRP, our management does not currently anticipate any additional liability to result from the inability of other significant named parties to contribute. We expect that the majority of such accrued amounts could be paid out over a period of up to ten years. As assessment and remediation activities progress at each individual site, these liabilities are reviewed and adjusted to reflect additional information as it becomes available. There have been no environmental problems to date that have had, or are expected to have, a material adverse effect on our consolidated financial statements. While it is possible that a loss exceeding the amounts recorded in the consolidated financial statements may be incurred, the potential exposure is not expected to be materially different from those amounts recorded.

Various tax years after 2010 remain open to examination by certain jurisdictions in which we have significant business operations, such as Finland, Germany, Italy, Netherlands, Singapore, the United Kingdom and the United States. The tax years under examination vary by jurisdiction. We regularly review our tax positions in each significant taxing jurisdiction in the process of evaluating our unrecognized tax benefits. We make adjustments to our unrecognized tax benefits when: (i) facts and circumstances regarding a tax position change, causing a change in management's judgment regarding that tax position; (ii) a tax position is effectively settled with a tax authority; and/or (iii) the statute of limitations expires regarding a tax position.

We are subject to various claims, legal proceedings and investigations covering a wide range of matters that arise in the ordinary course of our business activities. Although we have established accruals for potential losses that we believe are probable and reasonably estimable, in our opinion, based on our review of the information available at this time, the total cost

of resolving these contingencies at January 1, 2017 should not have a material adverse effect on our consolidated financial statements included in this annual report on Form 10-K. However, each of these matters is subject to uncertainties, and it is possible that some of these matters may be resolved unfavorably to us.

Reporting Segment Results of Continuing Operations

Beginning in the fourth quarter of fiscal year 2016, we realigned our businesses to better position us to grow in attractive end markets and expand share with our core product offerings. Diagnostics became a standalone operating segment and we formed a new operating segment, Discovery & Analytical Solutions. In addition, we moved our Medical Imaging Business into discontinued operations due to its pending sale. The results reported for fiscal year 2016 reflect our new segment structure and the exclusion of our Medical Imaging Business from continuing operations. Financial information in this report relating to fiscal years 2015 and 2014 has been retrospectively adjusted to reflect these changes.

Discovery & Analytical Solutions

2016 Compared to 2015. Revenue for fiscal year 2016 was $1,513.0 million, as compared to $1,528.4 million for fiscal year 2015, a decrease of $15.4 million, or 1%, which includes an approximate 1.0% decrease in revenue attributable to unfavorable changes in foreign exchange rates with minimal impact from acquisitions and divestitures. In addition, the fiscal year 2016 consisted of 52 weeks as compared to fiscal year 2015 which consisted of 53 weeks. The analysis in the remainder of this paragraph compares selected revenue by product type for fiscal year 2016, as compared to fiscal year 2015, and includes the effect of foreign exchange fluctuations and acquisitions and divestitures. The decrease in revenue in our Discovery & Analytical Solutions segment was a result of a decrease in environmental, food and industrial revenue of $20.8 million and a decrease in life sciences market revenue of $0.6 million, which was partially offset by an increase in laboratory services market revenue of $6.0 million. As a result of adjustments to deferred revenue related to certain acquisitions required by business combination rules, we did not recognize $27 thousand of revenue in our Discovery & Analytical Solutions segment for fiscal year 2015 that otherwise would have been recorded by the acquired businesses during each of the respective periods. In our environmental, food and industrial markets, revenue decreased due to weak harvest conditions. In our life sciences research market, we experienced decreases in revenue from our academic and government product offerings due to reduced government funding. In our laboratory services market, we had increased demand for our OneSource service offerings. Our OneSource laboratory service business offers services designed to enable our customers to increase efficiencies and production time while reducing maintenance costs, all of which continue to be critical for our customers.

Operating income from continuing operations for fiscal year 2016 was $207.5 million, as compared to $173.7 million for fiscal year 2015, an increase of $33.8 million, or 19%. Amortization of intangible assets decreased and was $53.3 million for fiscal year 2016 as compared to $54.6 million for fiscal year 2015. Restructuring and contract termination charges, net decreased and were $4.7 million for fiscal year 2016 as compared to $11.4 million for fiscal year 2015. Acquisition and divestiture-related costs, contingent consideration and other costs added an incremental expense of $0.6 million for fiscal year 2016, as compared to $0.4 million for fiscal year 2015. The amortization of purchase accounting adjustments to record the inventory from certain acquisitions added an incremental expense of $0.4 million in fiscal year 2016 as compared to $7.3 million in fiscal year 2015. In addition to the factors noted above, increased operating income for fiscal year 2016, was primarily due to favorable changes in product mix, with an increase in sales in higher gross margin product offerings, early benefits from our initiatives to improve our supply chain, and lower costs related to cost containment initiatives partially offset by increased costs related to investments in new product development and unfavorable impacts from foreign currency.

2015 Compared to 2014. Revenue for fiscal year 2015 was $1,528.4 million, as compared to $1,484.1 million for fiscal year 2014, an increase of $44.3 million, or 3%, which includes an approximate 5.0% increase in revenue attributable to the impact of acquisitions and divestitures and an approximate 7.0% decrease in revenue attributable to changes in foreign exchange rates. In addition, fiscal year 2015 consisted of 53 weeks as compared to fiscal year 2014 which consisted of 52 weeks. The analysis in the remainder of this paragraph compares selected revenue by product type for fiscal year 2015, as compared to fiscal year 2014, and includes the effect of foreign exchange fluctuations and acquisitions and divestitures. The increase in revenue in our Discovery & Analytical Solutions segment was a result of an increase in environmental, food and industrial markets revenue of $44.9 million and an increase in life sciences research market revenue of $11.6 million, which was partially offset by a decrease in revenue of $12.2 million from the laboratory services market. The increase in revenue was

primarily due to revenue from our acquisition of Perten in December 2014, as well as growth in our materials characterization product family within our environmental and industrial markets. In our life sciences research market, we experienced increased demand for our informatics business, as well as an increase in revenue from new product introductions, such as the Opera Phenix. In our laboratory services market, we had increased demand for our OneSource service offerings. The growth in our Discovery & Analytical Solutions segment was more than offset by unfavorable impacts from foreign currency as the U.S. dollar strengthened, particularly versus the Euro.

Operating income from continuing operations for fiscal year 2015 was $173.7 million, as compared to $162.1 million for fiscal year 2014, an increase of $11.6 million, or 7%. Amortization of intangible assets increased and was $54.6 million for fiscal year 2015 as compared to $52.9 million for fiscal year 2014. Restructuring and contract termination charges, net increased and were $11.4 million for fiscal year 2015 as compared to $10.9 million for fiscal year 2014. Legal costs for a particular case were $0.8 million in fiscal year 2015. Acquisition and divestiture-related expenses, contingent consideration and other costs increased expenses by $0.4 million for fiscal year 2015, as compared to $4.2 million for fiscal year 2014. The amortization of purchase accounting adjustments to record the inventory from certain acquisitions added an incremental expense of $7.3 million in fiscal year 2015 as compared to $2.4 million in fiscal year 2014. In addition to the factors noted above, the increase in operating income for fiscal year 2015 was primarily due to increased sales volume in the environmental, food, industrial and life sciences research markets and lower costs as a result of cost containment and productivity initiatives, which was partially offset by unfavorable impacts from foreign currency.

Diagnostics

2016 Compared to 2015. Revenue for fiscal year 2016 was $602.5 million, as compared to $576.4 million for fiscal year 2015, an increase of $26.1 million, or 5%, which includes an approximate 1% decrease in revenue attributable to changes in foreign exchange rates, and an approximate 2.0% decrease in revenue attributable to the impact of prior year acquisitions and divestitures. In addition, the fiscal year 2016 consisted of 52 weeks as compared to fiscal year 2015 which consisted of 53 weeks. As a result of adjustments to deferred revenue related to certain acquisitions as required by business combination rules, we did not recognize $0.7 million of revenue for fiscal year 2016 and $0.8 million for fiscal year 2015 that otherwise would have been recorded by the acquired businesses during each of the respective periods. In our diagnostics market, we experienced growth from continued expansion of our newborn and infectious disease screening solutions in key regions outside the United States, particularly in emerging markets such as China, as well as in Europe. Birth rates in the United States continue to stabilize and demand for greater access to newborn screening in rural areas outside the United States is also increasing, as evidenced by prenatal trends we saw during fiscal year 2016.

Operating income from continuing operations for fiscal year 2016 was $138.9 million, as compared to $135.6 million for fiscal year 2015, an increase of $3.3 million, or 2%. Amortization of intangible assets decreased and was $18.1 million for fiscal year 2016 as compared to $22.0 million for fiscal year 2015. Restructuring and contract termination charges, net decreased and were $0.4 million for fiscal year 2016 as compared to $2.1 million for fiscal year 2015. Acquisition and divestiture-related expenses, contingent consideration and other costs added an incremental expense of $17.7 million in fiscal year 2016, as compared to an incremental expense of $1.1 million for fiscal year 2015. In addition to the factors noted above, increased operating income for fiscal year 2016, as compared to fiscal year 2015 was primarily due to pricing initiatives and lower costs as a result of cost containment initiatives and benefits from our initiatives to improve our supply chain, which were partially offset by increased costs related to investments in new product development.

2015 Compared to 2014. Revenue for fiscal year 2015 was $576.4 million, as compared to $585.7 million for fiscal year 2014, a decrease of $9.3 million or 2%, which includes an approximate 4% decrease in revenue attributable to changes in foreign exchange rates and with minimal impact from acquisitions. In addition, fiscal year 2015 consisted of 53 weeks as compared to fiscal year 2014 which consisted of 52 weeks. The decrease in revenue in our Diagnostics segment was a result of unfavorable impacts from foreign currency which more than offset the growth we experienced in our diagnostics business. As a result of adjustments to deferred revenue related to certain acquisitions required by business combination rules, we did not recognize $0.8 million of revenue for fiscal year 2015 and $1.0 million for fiscal year 2014 that otherwise would have been recorded by the acquired businesses during each of the respective periods. Excluding the impact of unfavorable foreign

currency, we experienced growth in our diagnostics business from continued expansion of our newborn and infectious disease screening solutions in emerging markets such as China.

Operating income from continuing operations for fiscal year 2015 was $135.6 million, as compared to $124.6 million for fiscal year 2014, an increase of $11.0 million, or 9%. Amortization of intangible assets decreased and was $22.0 million for fiscal year 2015 as compared to $28.5 million for fiscal year 2014. Restructuring and contract termination charges, net decreased and were $2.1 million for fiscal year 2015 as compared to $2.4 million for fiscal year 2014. Acquisition and divestiture-related expenses and other costs added an incremental expense of $1.1 million in fiscal year 2015, as compared to decreasing expenses by $0.8 million for fiscal year 2014. In addition to the factors noted above, the increased operating income for fiscal year 2015 was primarily the result of increased sales volume and lower costs as a result of cost containment and productivity initiatives, which were partially offset by unfavorable impacts of foreign currency.

Liquidity and Capital Resources

We require cash to pay our operating expenses, make capital expenditures, make strategic acquisitions, service our debt and other long-term liabilities, repurchase shares of our common stock and pay dividends on our common stock. Our principal sources of funds are from our operations and the capital markets, particularly the debt markets. We anticipate that our internal operations will generate sufficient cash to fund our operating expenses, capital expenditures, smaller acquisitions, interest payments on our debt and dividends on our common stock. However, we expect to use external sources to satisfy the balance of our debt when due, any larger acquisitions and other long-term liabilities, such as contributions to our postretirement benefit plans.

Principal factors that could affect the availability of our internally generated funds include:

- changes in sales due to weakness in markets in which we sell our products and services, and
- changes in our working capital requirements.

Principal factors that could affect our ability to obtain cash from external sources include:

- financial covenants contained in the financial instruments controlling our borrowings that limit our total borrowing capacity,
- increases in interest rates applicable to our outstanding variable rate debt,
- a ratings downgrade that could limit the amount we can borrow under our senior unsecured revolving credit facility and our overall access to the corporate debt market,
- increases in interest rates or credit spreads, as well as limitations on the availability of credit, that affect our ability to borrow under future potential facilities on a secured or unsecured basis,
- a decrease in the market price for our common stock, and
- volatility in the public debt and equity markets.

Cash Flows

Fiscal Year 2016

Operating Activities. Net cash provided by continuing operations was $323.8 million for fiscal year 2016, as compared to net cash provided by continuing operations of $263.8 million for fiscal year 2015, an increase of $59.9 million. The cash provided by operating activities for fiscal year 2016 was principally a result of income from continuing operations of $215.7 million, and non-cash charges, including depreciation and amortization of $100.0 million, stock based compensation expense of $17.2 million, restructuring and contract termination charges, net, of $5.1 million, change in fair value of contingent consideration of $16.2 million, gain from disposition of businesses and assets, net of $5.6 million, and a loss related to our postretirement benefit plans, including the mark-to-market adjustment, in the fourth quarter of fiscal year 2016, of $14.5

million. These amounts were partially offset by a net decrease of $57.8 million in accrued expenses, other assets and liabilities and other items, and a net decrease in working capital of $18.5 million. The change in accrued expenses, other assets and liabilities and other items decreased cash provided by operating activities by $57.8 million for fiscal year 2016, primarily related to the timing of payments for taxes, defined benefit pension plans, royalties, restructuring, and salary and benefits. During fiscal year 2016, we made contributions of $9.6 million, in the aggregate, to pension plans outside of the United States. Contributing to the net decrease in working capital for fiscal year 2016, excluding the effect of foreign exchange rate fluctuations, was a decrease in inventory of $6.8 million and an increase in accounts payable of $30.7 million, which were partially offset by an increase in accounts receivable of $19.0 million. The decrease in inventory was primarily a result of higher sales volume late in the fourth quarter of the fiscal year, partially offset by the result of realigning operations, research and development resources, and production resources within our Discovery & Analytical Solutions and Diagnostics segments to ensure responsiveness to customer requirements as this realignment occurs. The increase in accounts payable was primarily a result of the timing of disbursements during the fourth quarter of fiscal year 2016. The increase in accounts receivable was a result of higher sales volume late in the fourth quarter of fiscal year 2016.

Investing Activities. Net cash used in the investing activities of our continuing operations was $99.5 million for fiscal year 2016, as compared to net cash used in the investing activities of our continuing operations of $99.4 million for fiscal year 2015, an increase of $0.1 million. For fiscal year 2016, we used $71.9 million of net cash for acquisitions, as compared to $72.0 million used in fiscal year 2015. Capital expenditures for fiscal year 2016 were $31.7 million, primarily for manufacturing equipment and other capital equipment purchases, as compared to $28.2 million for fiscal year 2015. These items were partially offset by cash proceeds of $21.0 million, net of $2.0 million in restricted cash from the sale of businesses in fiscal year 2016. An additional increase in restricted cash of $15.0 million in fiscal year 2016 further contributed to net cash used in investing activities, primarily related to the cash that was placed in escrow to facilitate our acquisition of Tulip Diagnostics Private Limited. That acquisition was completed subsequent to January 1, 2017.

Financing Activities. Net cash used in the financing activities of our continuing operations was $115.0 million for fiscal year 2016, as compared to $107.1 million for fiscal year 2015, an increase of $7.9 million. For fiscal year 2016, we repurchased 3.2 million shares of our common stock, including 75,198 shares of our common stock pursuant to our equity incentive plans, for a total cost of $151.8 million, including commissions. This compares to repurchases of 1.5 million shares of our common stock, including 95,129 shares of our common stock pursuant to our equity incentive plans, for a total cost of $76.4 million, including commissions, for fiscal year 2015. This use of cash in fiscal year 2016 was partially offset by proceeds from the issuance of common stock under stock plans of $14.4 million. This compares to proceeds from the issuance of common stock under stock plans of $14.9 million in fiscal year 2015. During fiscal year 2016, borrowings from our senior unsecured revolving credit facility totaled $420.5 million, which was more than offset by debt payments of $902.5 million. This compares to borrowings from our senior unsecured revolving credit facility of $451.0 million, which was more than offset by debt payments of $485.0 million in fiscal year 2015. During fiscal year 2016, proceeds from the sale of our senior unsecured debt was $546.2 million, and we paid $7.9 million for debt issuance costs. We paid $30.8 million and $31.6 million in dividends during fiscal years 2016 and 2015, respectively. We had net payments on other credit facilities of $1.1 million during fiscal years 2016 and 2015. During fiscal year 2016, we also received $1.9 million for the settlement of forward foreign exchange contracts, as compared to payments of $18.7 million in fiscal year 2015, and made $0.2 million in payments for acquisition-related contingent consideration, as compared to $0.1 million in fiscal year 2015.

Fiscal Year 2015

Operating Activities. Net cash provided by continuing operations was $263.8 million for fiscal year 2015, as compared to net cash provided by continuing operations of $247.9 million for fiscal year 2014, an increase of $15.9 million. The cash provided by operating activities for fiscal year 2015 was principally a result of income from continuing operations of $188.8 million, and non-cash charges, including depreciation and amortization of $105.4 million, stock based compensation expense of $17.3 million, restructuring and contract termination charges, net, of $13.5 million and loss related to our postretirement benefit plans, including the mark-to-market adjustment in the fourth quarter of fiscal year 2015, of $9.4 million. These amounts were partially offset by a net decrease of $35.8 million in accrued expenses, other assets and liabilities and other items, and a net increase in working capital of $34.8 million. The change in accrued expenses, other assets and liabilities and other items that decreased cash provided by operating activities by $35.8 million for fiscal year 2015, primarily related to the timing of

payments for taxes, defined benefit pension plans, royalties, restructuring, and salary and benefits. During fiscal year 2015, we made contributions of $14.9 million, in the aggregate, to pension plans outside of the United States and $20.0 million to our defined benefit pension plan in the United States. Contributing to the net increase in working capital for fiscal year 2015, excluding the effect of foreign exchange rate fluctuations, was an increase in inventory of $27.9 million and a decrease in accounts payable of $10.9 million, which were partially offset by a decrease in accounts receivable of $4.1 million. The increase in inventory was primarily a result of realigning operations, research and development resources and production resources within our Discovery & Analytical Solutions and Diagnostics segments to ensure responsiveness to customer requirements as this realignment occurs. The decrease in accounts payable was primarily a result of the timing of disbursements during the fourth quarter of fiscal year 2015. The decrease in accounts receivable was a result of strong performance in accounts receivables collections during the fourth quarter of fiscal year 2015.

Investing Activities. Net cash used in the investing activities of our continuing operations was $99.4 million for fiscal year 2015, as compared to net cash used in the investing activities of our continuing operations of $295.6 million for fiscal year 2014, a decrease of $196.2 million. For fiscal year 2015, we used $72.0 million of net cash for acquisitions, as compared to $271.5 million used in fiscal year 2014. Capital expenditures for fiscal year 2015 were $28.2 million, primarily for manufacturing equipment and other capital equipment purchases, as compared to $27.2 million in fiscal year 2014. These cash outflows were partially offset by proceeds from the settlement of life insurance policies of $0.8 million in fiscal year 2015, as compared to $0.5 million in fiscal year 2014.

Financing Activities. Net cash used in the financing activities of our continuing operations was $107.1 million for fiscal year 2015, as compared to net cash provided by the financing activities of our continuing operations of $30.9 million for fiscal year 2014, a change of $138.1 million. For fiscal year 2015, we repurchased 1.5 million shares of our common stock, including 95,129 shares of our common stock pursuant to our equity incentive plans, for a total cost of $76.4 million, including commissions. This compares to repurchases of 1.4 million shares of our common stock, including 98,269 shares of our common stock pursuant to our equity incentive plans, for a total cost of $65.5 million, including commissions, for fiscal year 2014. This use of cash in fiscal year 2015 was partially offset by proceeds from the issuance of common stock under stock plans of $14.9 million. This compares to proceeds from the issuance of common stock under stock plans of $24.5 million in fiscal year 2014. During fiscal year 2015, borrowings from our senior unsecured revolving credit facility totaled $451.0 million, which was more than offset by debt payments of $485.0 million. This compares to borrowings from our senior unsecured revolving credit facility of $475.0 million, which was partially offset by debt payments of $356.0 million in fiscal year 2014. We paid $31.6 million in dividends during both fiscal years 2015 and 2014. During fiscal year 2015, we made net payments of $1.1 million on other credit facilities primarily for lease payments for our financing lease obligations, as described below under financing lease obligations, as compared to $12.7 million during fiscal year 2014 . During fiscal year 2015, we also received $18.7 million for the settlement of forward foreign exchange contracts related to intercompany loans utilized to finance our acquisitions. We also made $0.1 million in payments for acquisition-related contingent consideration during fiscal year 2015, as compared to $0.9 million during fiscal year 2014.

Borrowing Arrangements

Senior Unsecured Revolving Credit Facility. On August 11, 2016, we terminated our previous senior unsecured revolving credit facility and entered into a new senior unsecured revolving credit facility with a five year term and an expansion of borrowing capacity from $700.0 million to $1.0 billion. The new senior unsecured revolving credit facility provides for $1.0 billion of revolving loans and has an initial maturity of August 11, 2021. As of January 1, 2017, undrawn letters of credit in the aggregate amount of $11.4 million were treated as issued and outstanding when calculating the borrowing availability under the new senior unsecured revolving credit facility. As of January 1, 2017, we had $988.6 million available for additional borrowing under the facility. We use the new senior unsecured revolving credit facility for general corporate purposes, which may include working capital, refinancing existing indebtedness, capital expenditures, share repurchases, acquisitions and strategic alliances. The interest rates under the senior unsecured revolving credit facility are based on the Eurocurrency rate or the base rate at the time of borrowing, plus a margin. The base rate is the higher of (i) the rate of interest in effect for such day as publicly announced from time to time by JP Morgan Chase Bank, N.A. as its "prime rate," (ii) the Federal Funds rate plus 50 basis points or (iii) an adjusted one-month Libor plus 1.00%. As of January 1, 2017, the new senior unsecured revolving credit facility had no outstanding borrowings, and $4.3 million of unamortized debt issuance costs. As of January 3, 2016, the

previous senior unsecured revolving credit facility had an aggregate carrying value of $479.6 million, which was net of $2.4 million of unamortized debt issuance costs. The credit agreement for the facility contains affirmative, negative and financial covenants and events of default. The financial covenants include a debt-to-capital ratio that remains applicable for so long as our debt is rated as investment grade. In the event that our debt is not rated as investment grade, the debt-to-capital ratio covenant is replaced with a maximum consolidated leverage ratio covenant and a minimum consolidated interest coverage ratio covenant. We were in compliance with all applicable covenants as of January 1, 2017.

5% Senior Unsecured Notes due in 2021. On October 25, 2011, we issued $500.0 million aggregate principal amount of senior unsecured notes due in 2021 (the "2021 Notes") in a registered public offering and received $496.9 million of net proceeds from the issuance. The 2021 Notes were issued at 99.372% of the principal amount, which resulted in a discount of $3.1 million. As of January 1, 2017, the 2021 Notes had an aggregate carrying value of $495.8 million, net of $1.7 million of unamortized original issue discount and $2.5 million of unamortized debt issuance costs. As of January 3, 2016, the 2021 Notes had an aggregate carrying value of $495.1 million, net of $2.0 million of unamortized original issue discount and $2.9 million of unamortized debt issuance costs. The 2021 Notes mature in November 2021 and bear interest at an annual rate of 5%. Interest on the 2021 Notes is payable semi-annually on May 15th and November 15th each year. Prior to August 15, 2021 (three months prior to their maturity date), we may redeem the 2021 Notes in whole or in part, at our option, at a redemption price equal to the greater of (i) 100% of the principal amount of the 2021 Notes to be redeemed, plus accrued and unpaid interest, or (ii) the sum of the present values of the remaining scheduled payments of principal and interest in respect to the 2021 Notes being redeemed, discounted on a semi-annual basis, at the Treasury Rate plus 45 basis points, plus accrued and unpaid interest. At any time on or after August 15, 2021 (three months prior to their maturity date), we may redeem the 2021 Notes, at our option, at a redemption price equal to 100% of the principal amount of the 2021 Notes to be redeemed plus accrued and unpaid interest. Upon a change of control (as defined in the indenture governing the 2021 Notes) and a contemporaneous downgrade of the 2021 Notes below investment grade, each holder of 2021 Notes will have the right to require us to repurchase such holder's 2021 Notes for 101% of their principal amount, plus accrued and unpaid interest.

1.875% Senior Unsecured Notes due 2026. On July 19, 2016, we issued €500.0 million aggregate principal amount of senior unsecured notes due in 2026 (the "2026 Notes") in a registered public offering and received approximately €492.3 million of net proceeds from the issuance. The 2026 Notes were issued at 99.118% of the principal amount, which resulted in a discount of €4.4 million. The 2026 Notes mature in July 2026 and bear interest at an annual rate of 1.875%. Interest on the 2026 Notes is payable annually on July 19th each year. The proceeds from the 2026 Notes were used to pay in full the outstanding balance of our previous senior unsecured revolving credit facility. As of January 1, 2017, the 2026 Notes had an aggregate carrying value of $517.8 million, net of $4.5 million of unamortized original issue discount and $4.8 million of unamortized debt issuance costs.

Prior to April 19, 2026 (three months prior to their maturity date), we may redeem the 2026 Notes in whole at any time or in part from time to time, at our option, at a redemption price equal to the greater of (i) 100% of the principal amount of the 2026 Notes to be redeemed, or (ii) the sum of the present values of the remaining scheduled payments of principal and interest in respect to the 2026 Notes being redeemed, discounted on an annual basis, at the applicable Comparable Government Bond Rate (as defined in the indenture governing the 2026 Notes) plus 35 basis points; plus, in each case, accrued and unpaid interest. In addition, at any time on or after April 19, 2026 (three months prior to their maturity date), we may redeem the 2026 Notes, at our option, at a redemption price equal to 100% of the principal amount of the 2026 Notes due to be redeemed plus accrued and unpaid interest.

Upon a change of control (as defined in the indenture governing the 2026 Notes) and a contemporaneous downgrade of the 2026 Notes below investment grade, we will, in certain circumstances, make an offer to purchase the 2026 Notes at a price equal to 101% of their principal amount plus any accrued and unpaid interest.

Financing Lease Obligations. In fiscal year 2012, we entered into agreements with the lessors of certain buildings that we are currently occupying and leasing to expand those buildings. We provided a portion of the funds needed for the construction of the additions to the buildings, and as a result we were considered the owner of the buildings during the construction period. At the end of the construction period, we were not reimbursed by the lessors for all of the construction costs. We are therefore deemed to have continuing involvement and the leases qualify as financing leases under sale-leaseback accounting guidance, representing debt obligations for us and non-cash investing and financing activities. As a result, we capitalized $29.3 million in

property, plant and equipment, net, representing the fair value of the buildings with a corresponding increase to debt. We have also capitalized $11.5 million in additional construction costs necessary to complete the renovations to the buildings, which were funded by the lessors, with a corresponding increase to debt. At January 1, 2017, we had $37.1 million recorded for these financing lease obligations, of which $1.2 million was recorded as short-term debt and $35.9 million was recorded as long-term debt. At January 3, 2016, we had $38.2 million recorded for these financing lease obligations, of which $1.1 million was recorded as short-term debt and $37.1 million was recorded as long-term debt. The buildings are being depreciated on a straight-line basis over the terms of the leases to their estimated residual values, which will equal the remaining financing obligation at the end of the lease term. At the end of the lease term, the remaining balances in property, plant and equipment, net and debt will be reversed against each other.

Dividends

Our Board declared a regular quarterly cash dividend of $0.07 per share in each quarter of fiscal years 2016 and 2015, resulting in an annual dividend rate of $0.28 per share. At January 1, 2017, we had accrued $7.7 million for dividends declared on October 26, 2016 for the fourth quarter of fiscal year 2016 that was paid in February 2017. On January 27, 2017, we announced that our Board had declared a quarterly dividend of $0.07 per share for the first quarter of fiscal year 2017 that will be payable in May 2017. In the future, our Board may determine to reduce or eliminate our common stock dividend in order to fund investments for growth, repurchase shares or conserve capital resources.

Contractual Obligations

The following table summarizes our contractual obligations at January 1, 2017 for continuing and discontinued operations. Purchase commitments are minimal and have been excluded from this table:

	Operating Leases	Sr. Unsecured Revolving Credit Facility Maturing 2021[1]	5.0% Sr. Notes Maturing 2021[2]	1.875% Sr. Notes Maturing 2026[3]	Financing Lease Obligations[4]	Employee Benefit Payments[5]	Unrecognized Tax Benefits[6]	Total
				(In thousands)				
2017	$ 49,788	$ —	$ 25,000	$ 9,882	$ 1,172	$ 28,705	$ —	$ 114,547
2018	33,944	—	25,000	9,882	1,367	29,192	—	99,385
2019	25,966	—	25,000	9,882	1,532	29,656	—	92,036
2020	20,806	—	25,000	9,882	1,597	30,180	—	87,465
2021	16,259	—	521,772	9,882	1,664	31,036	—	580,613
2022 and thereafter	52,111	—	—	571,927	29,742	160,073	—	813,853
Total	$ 198,874	$ —	$ 621,772	$ 621,337	$ 37,074	$ 308,842	$ —	$ 1,787,899

(1) The credit facility borrowings carry variable interest rates. As of January 1, 2017, we had no outstanding borrowings in our senior unsecured revolving credit facility.

(2) The 2021 Notes include interest obligations. As of January 1, 2017, the 2021 Notes had a carrying value of $495.8 million.

(3) The 2026 Notes include interest obligations. As of January 1, 2017, the 2026 Notes had a carrying value of $517.8 million.

(4) The financing lease obligations do not include interest obligations.

(5) Employee benefit payments only include obligations through fiscal year 2026.

(6) We have excluded $1.3 million, including accrued interest, net of tax benefits, and penalties, from our uncertain tax positions, as we cannot make a reasonably reliable estimate of the amount and period of related future payments.

As of January 1, 2017, we may have to pay the shareholders of our acquisitions contingent consideration of up to $84.6 million. The table above does not reflect any of these obligations as the timing and amounts are uncertain. For further information related to our contingent consideration obligations, see Note 21 to our consolidated financial statements included in this annual report on Form 10-K.

Capital Expenditures

During fiscal year 2017, we expect to invest an amount for capital expenditures similar to that in fiscal year 2016, primarily to introdnce new products, to improve onr operating processes, to shift the production capacity to lower cost locations, and to develop information technology. We expect to use our available cash and internally generated funds to fund these expenditurcs.

Other Potential Liquidity Considerations

At Jannary 1, 2017, we had cash and cash equivalents of $359.3 million, of which $348.5 million was held by our non-U.S. subsidiaries, and we had $988.6 million of additional horrowing capacity availahle under a senior unsecured revolving credit facility. We had no other liquid investments at January 1, 2017.

We utilize a variety of tax planning and financing strategies to ensure that our worldwide cash is available in the locations in which it is nceded. Of the $348.5 million of cash and cash equivalents held by our non-U.S. subsidiaries at January 1, 2017, we would incur U.S. taxes on approximately $322.5 million if transferred to the U.S. without proper planning. We expect the accumulated non-U.S. cash balances, which may not be transferred to the U.S. without incurring U.S. taxes, will remain outside of the U.S. and that we will meet U.S. liquidity needs through future cash flows, use of U.S. cash balances, external borrowings, or some combination of these sources.

On October 23, 2014, our Board authorized us to repurchase up to 8.0 million shares of common stock under a stock repurchase program (the "Repurchasc Program"). On July 27, 2016, thc Board authorizcd us to immcdiatcly terminatc the Repurchasc Program and further authorized us to repurchase up to 8.0 milliou shares of common stock under a uew stock repurchase program (the "New Repurchase Program"). The New Repurchase Program will expire on July 26, 2018 unless terminated earlier hy our Board, and may be suspended or discontinued at any time. During the fiscal year 2016, we repurchased 3.2 million shares of common stock in the open market at an aggregate cost of $148.2 million, including commissions, under the Repurchase Program. No shares remain available for repurchase under the Repurchase Program due to its cancellation. As of January 1, 2017, 8.0 million shares remained available for repurchase uuder the New Repurchase Program.

In addition, our Board has authorized us to repurchase shares of common stock to satisfy minimum statutory tax withholding obligations in connection with the vesting of restricted stock awards and restricted stock unit awards granted pursuant to our equity incentive plans and to satisfy obligations related to the exercise of stock options made pursuant to our equity incentive plans. During fiscal year 2016, we repurchased 75,198 shares of common stock for this purpose at an aggregate cost of $3.6 million.

The repurchased shares have been reflected as additional authorized but unissued shares, with the payments reflected in common stock and capital in excess of par value. Auy repurchased shares will be available for use in connection with corporate programs. If we continue to repurchase shares, the New Repurchase Program will be funded using onr existing financial resources, inclnding cash and cash equivalents, and our existing senior unsecured revolving credit facility.

Distressed global financial markets could adversely impact general economic conditions by reducing liquidity and credit availability, creating increased volatility in security prices, widening credit spreads and decreasing valuations of certain iuvestments. The wideuing of credit spreads may create a less favorable environment for certain of our businesses and may affect the fair value of financial instruments that we issue or hold. Increases in credit spreads, as well as limitations on the availability of credit at rates we consider to be reasonable, could affect our ability to borrow under future potential facilities on a secured or unsecured basis, which may adversely affect our liquidity and results of operations. In difficult global financial markets, we may be forced to fund our operations at a higher cost, or we may be unable to raise as much funding as we need to support our business activities.

Our pension plans have not experienced a material impact on liquidity or counterparty exposure due to the volatility and uncertainty in the credit markets. With respect to plans outside of the United States, we expect to contribute $7.6 million iu the aggregate during fiscal year 2017. During fiscal year 2016, we contributed $9.6 million, in the aggregate, to pension plans outside of the United States. We could potentially have to make additional funding payments in future periods for all pension

plans. During fiscal year 2015, we made contributions of $14.9 million, in the aggregate, to plans outside of the United States and $20.0 million to our defined benefit pension plan in the United States. During fiscal year 2014, we contributed $11.2 million, in the aggregate, to plans outside of the United States. We expect to use existing cash and external sources to satisfy future contributions to our pension plans.

Effects of Recently Issued and Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("the FASB") and are adopted by us as of the specified effective dates. Unless otherwise discussed, such pronouncements did not have or will not have a significant impact on our consolidated financial position, results of operations and cash flows or do not apply to our operations.

In January 2017, the FASB issued Accounting Standards Update No. 2017-04, *Intangibles-Goodwill and Other Topic (Topic 350), Simplifying the Test for Goodwill Impairment* ("ASU 2017-04"), which amends Topic 350 to simplify the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test. ASU 2017-04 requires that an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize the impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider the income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. The provisions of this guidance are to be applied on a prospective basis. ASU 2017-04 is effective for annual or any interim goodwill impairment tests in fiscal years beginning December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We intend to early adopt ASU 2017-04 and will apply the provisions of this standard in our interim or annual goodwill impairment tests subsequent to January 1, 2017.

In January 2017, the FASB issued Accounting Standards Update No. 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business* ("ASU 2017-01"), which amends Topic 805 to provide a screen to determine when a set is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. If the screen is not met, the standard (1) requires that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) removes the evaluation of whether a market participant could replace missing elements. The standard provides a framework to assist entities in evaluating whether both an input and a substantive process are present. The standard also provides a framework that includes two sets of criteria to consider that depend on whether a set has outputs and a more stringent criteria for sets without outputs. Lastly, the standard narrows the definition of the term "output" so that the term is consistent with how outputs are described in Topic 606. The provisions of this guidance are to be applied prospectively. ASU 2017-01 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted in limited circumstances. We are still evaluating the requirements of this guidance. The adoption is not expected to have a material impact on our consolidated financial position, results of operations and cash flows.

In November 2016, the FASB issued Accounting Standards Update No. 2016-18, *Statement of Cash Flows (Topic 230), Restricted Cash* ("ASU 2016-18"), which amends Topic 230 to add or clarify guidance on the classification and presentation of restricted cash in the statement of cash flows. The standard requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The provisions of this guidance are to be applied using a retrospective transition method to each period presented. ASU 2016-18 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. We are evaluating the requirements of this guidance. The adoption is not expected to have a material impact on our consolidated financial position, results of operations and cash flows.

In October 2016, the FASB issued Accounting Standards Update No. 2016-16, *Income Taxes (Topic 740), Intra-entity Transfer of Assets Other than Inventory* ("ASU 2016-16"). ASU 2016-16 removes the prohibition in ASC 740 against the immediate recognition of the current and deferred income tax effects of intra-entity transfers of assets other than inventory. The standard requires entities to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. The provisions of this guidance are to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. ASU 2016-16 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. We are evaluating the requirements of this guidance and have not yet determined the impact of adoption on our consolidated financial position, results of operations and cash flows.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, *Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). ASU 2016-15 addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows under Topic 230 and other topics. The provisions of this guidance are to be applied using a retrospective transition method to each period presented, and if it is impracticable to apply the amendments retrospectively for some of the issues, ASU 2016-15 allows the amendments for those issues to be applied prospectively as of the earliest date practicable. ASU 2015-16 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. We are evaluating the requirements of this guidance. The adoption is not expected to have a material impact on our consolidated financial position, results of operations and cash flows.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, *Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. The standard requires entities to use the expected loss impairment model and will apply to most financial assets measured at amortized cost and certain other instruments, including trade and other receivables, loans, held-to-maturity debt securities, net investments in leases and off-balance sheet credit exposures. Entities are required to estimate the lifetime "expected credit loss" for each applicable financial asset and record an allowance that, when deducted from the amortized cost basis of the financial asset, presents the net amount expected to be collected on the financial asset. The standard also amends the impairment model for available-for-sale ("AFS") debt securities and requires entities to determine whether all or a portion of the unrealized loss on an AFS debt security is a credit loss. An entity will recognize an allowance for credit losses on an AFS debt security as a contra-account to the amortized cost basis rather than as a direct reduction of the amortized cost basis of the investment. The provisions of this guidance are to be applied using a modified-retrospective approach. A prospective transition approach is required for debt securities for which an other-than-temporary impairment had been recognized before the effective date. ASU 2016-13 is effective for annual reporting periods beginning after December 15, 2019, and interim periods within those years. Early adoption is permitted for annual periods beginning after December 15, 2018, and interim periods therein. We are evaluating the requirements of this guidance and have not yet determined the impact of adoption on our consolidated financial position, results of operations and cash flows.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, *Compensatian Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting* ("ASU No. 2016-09"). The new standard simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory withholding requirements, as well as the related classification in the statement of cash flows. The new standard is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those years, with early adoption permitted. The standard requires an entity to recognize all excess tax benefits and tax deficiencies as income tax benefit or expense in the income statement as discrete items in the reporting period in which they occur, and such tax benefits and tax deficiencies are not included in the estimate of an entity's annual effective tax rate, applied on a prospective basis. Further, the standard eliminates the requirement to defer the recognition of excess tax benefits until the benefit is realized through a reduction to taxes payable. All excess tax benefits previously unrecognized, along with any valuation allowance, should be recognized on a modified retrospective basis as a cumulative adjustment to retained earnings as of the date of adoption. Under ASU No. 2016-09, an entity that applies the treasury stock method in calculating diluted earnings per share is required to exclude excess tax benefits and deficiencies from the calculation of assumed proceeds since such amounts are

recognized in the income statement. Excess tax benefits should also be classified as operating activities in the same manner as other cash flows related to income taxes on the statement of cash flows, as such excess tax benefits no longer represent financing activities since they are recognized in the income statement, and should be applied prospectively or retrospectively to all periods presented. We adopted ASU No. 2016-09 at the beginning of the first quarter of fiscal year 2016. We recorded a cumulative increase of $14.2 million in the beginning of the first quarter of fiscal year 2016 retained earnings with a corresponding increase in deferred tax assets related to the prior years' unrecognized excess tax benefits. Excess tax benefits related to exercised options and vested restricted stock and restricted stock units during the fiscal year 2016 have been recognized in the current period's income statement. We also excluded the excess tax benefits from the calculation of diluted earnings per share for fiscal year 2016. We applied the cash flow presentation section of the guidance on a prospective basis, and the prior period statement of cash flows was not adjusted. ASU No. 2016-09 also allows an entity to elect as an accounting policy either to continue to estimate the total number of awards for which the requisite service period will not be rendered or to account for forfeitures for service based awards as they occur. An entity that elects to account for forfeitures as they occur should apply the accounting change on a modified retrospective basis as a cumulative effect adjustment to retained earnings as of the date of adoption. We elected to account for forfeitures as they occur. The adoption of this accounting policy did not have a material impact on our consolidated financial position, results of operations and cash flows.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 requires organizations that lease assets to recognize assets and liabilities on the balance sheet related to the rights and obligations created by those leases, regardless of whether they are classified as finance or operating leases. Consistent with current guidance, the recognition, measurement, and presentation of expenses and cash flows arising from a lease primarily will depend on its classification as a finance or operating lease. ASU 2016-02 also requires new disclosures to help financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. The provisions of this guidance are effective for annual periods beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. ASU 2016-02 is to be applied using a modified retrospective approach. We are evaluating the requirements of this guidance and have not yet determined the impact of the adoption on our consolidated financial position, results of operations and cash flows.

In July 2015, the FASB issued Accounting Standards Update No. 2015-11, *Simplifying the Measurement of Inventory*. Under this new guidance, companies that use inventory measurement methods other than last-in, first-out or the retail inventory method should measure inventory at the lower of cost and net realizable value. The provisions of this guidance are to be applied prospectively and are effective for interim and annual periods beginning after December 15, 2016, with early adoption permitted. We are evaluating the requirements of this guidance. The adoption is not expected to have a material impact on our consolidated financial position, results of operations and cash flows.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"). Under this new guidance, an entity should use a five-step process to recognize revenue, depicting the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires new disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Subsequent to the issuance of the standard, the FASB decided to defer the effective date for one year to annual reporting periods beginning after December 15, 2017, with early adoption permitted for annual reporting periods beginning after December 15, 2016. In May 2016, the FASB also issued Accounting Standards Update No. 2016-12, *Revenue from Contracts with Customers (Topic 606), Narrow-Scope Improvements and Practical Expedients* ("ASU 2016-12"), which amended its revenue recognition guidance in ASU 2014-09 on transition, collectibility, non-cash consideration, contract modifications and completed contracts at transition and the presentation of sales and other similar taxes collected from customers. In April 2016, the FASB also issued Accounting Standards Update No. 2016-10, *Revenue from Contracts with Customers (Topic 606), Identifying Performance Obligations and Licensing* ("ASU 2016-10"), which amended its revenue recognition guidance in ASU 2014-09 on identifying performance obligations to allow entities to disregard items that are immaterial in the context of the contract, clarify when a promised good or service is separately identifiable (i.e., distinct within the context of the contract) and allow an entity to elect to account for the cost of shipping and handling performed after control of a good has been transferred to the customer as a fulfillment cost (i.e., an expense). ASU 2016-10 also clarifies how an entity should evaluate the nature of its promise in granting a license of

intellectual property ("IP") and requires entities to classify IP in one of two categories: functional IP or symbolic IP, which will determine whether it recognizes revenue over time or at a point in time. ASU 2016-10 also address how entities should consider license renewals and restrictions and apply the exception for sales- and usage-based royalties received in exchange for licenses of IP. In March 2016, the FASB also issued Accounting Standards Update No. 2016-08, *Revenue from Contracts with Customers (Topic 606), Principal versus Agent Considerations (Reporting Revenue Gross versus Net)* ("ASU 2016-08"), which amended the principal-versus-agent implementation guidance and illustrations in ASU 2014-09. ASU 2016-08 clarifies that an entity should evaluate when it is the principal or agent for each specified good or service promised in a contract with a customer. ASU 2016-12, ASU 2016-10, ASU 2016-08 and ASU 2014-09 may be adopted either using a full retrospective approach or a modified retrospective approach. We are evaluating the requirements of the foregoing standards and have not yet determined the impact of their adoption on our consolidated financial position, results of operations and cash flows. We intend to adopt these standards using the modified retrospective approach, and we do not intend to early adopt these standards. While we are currently evaluating the impact of the new revenue standard, we believe the key changes in the standard that impact revenue recognition relate to the accounting for certain transactions with multiple elements or "bundled" arrangements (for example, sales of software subscriptions for which we do not have VSOE for maintenance and/or support) because the requirement to have VSOE for undelivered elements under current accounting standards is eliminated under the new standard. Accordingly, we may be required to recognize as revenue a portion of the sales price upon delivery of the software, as compared to the current requirement of recognizing the entire sales price ratably over the maintenance period.

Application of Critical Accounting Policies and Estimates

The preparation of consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, warranty costs, bad debts, inventories, accounting for business combinations and dispositions, long-lived assets, income taxes, restructuring, pensions and other postretirement benefits, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in preparation of our consolidated financial statements.

Revenue recognition. We record product revenue when persuasive evidence of an arrangement exists, delivery has occurred, the price to the buyer is fixed or determinable, and collectability is reasonably assured. For products that include installation, and if the installation meets the criteria to be considered a separate element, we recognize product revenue upon delivery, and recognition of installation revenue is recognized when the installation is complete. For revenue that includes customer-specified acceptance criteria, we recognize revenue after the acceptance criteria have been met. Certain of our products require specialized installation. Revenue for these products is deferred until installation is completed. We defer revenue from services and recognize it over the contractual period, or as services are rendered.

In limited circumstances, we have arrangements that include multiple elements that are delivered at different points of time, such as revenue from products and services with a remaining service or storage component, including cord blood processing and storage. For these arrangements, the revenue is allocated to each of the deliverables based upon their relative selling prices as determined by a selling-price hierarchy. A deliverable in an arrangement qualifies as a separate unit of accounting if the delivered item has value to the customer on a stand-alone basis. A delivered item that does not qualify as a separate unit of accounting is combined with the other undelivered items in the arrangement and revenue is recognized for those combined deliverables as a single unit of accounting. The selling price used for each deliverable is based upon vendor-specific objective evidence ("VSOE") if such evidence is available, third-party evidence ("TPE") if VSOE is not available, and management's best estimate of selling price ("BESP") if neither VSOE nor TPE are available. TPE is the price of our or any competitor's largely interchangeable products or services in stand-alone sales to similarly-situated customers. BESP is the price

at which we would sell the deliverable if it were sold regularly on a stand-alone basis, considering market conditions and entity-specific factors.

Revenue from software licenses and services was 5% of our total revenue for each of fiscal years 2016, 2015 and 2014. We sell our software licenses with maintenance services and, in some cases, also with consulting services. For the undelivered elements, we determine VSOE of fair value to be the price charged when the undelivered element is sold separately. We determine VSOE for maintenance sold in connection with a software license based on the stated renewal rate method. We determine VSOE for consulting services by reference to the amount charged for similar engagements on a stand-alone basis.

We recognize revenue from software licenses sold together with maintenance and/or consulting services upon shipment using the residual method, provided that the above criteria have been met. If VSOE of fair value for the undelivered elements cannot be established, we defer all revenue from the arrangement until the earlier of the point at which such sufficient VSOE does exist or all elements of the arrangement have been delivered, or if the only undelivered element is maintenance, then we recognize the entire fee ratably over the maintenance period.

The majority of our sales relate to specific manufactured products or units rather than long-term customized projects, therefore we generally do not experience significant changes in original estimates. Further, we have not experienced any significant refunds or promotional allowances that require significant estimation.

Warranty costs. We provide for estimated warranty costs for products at the time of their sale. Warranty liabilities are estimated using expected future repair costs based on historical labor and material costs incurred during the warranty period.

Allowances for doubtful accounts. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We generally compute our allowance for doubtful accounts by (i) applying specific percentage reserves on accounts that are past due and deemed uncollectible; and (ii) specifically reserving for customers known to be in financial difficulty. Therefore, if the financial condition of our customers were to deteriorate beyond our estimates, we may have to increase our allowance for doubtful accounts. This would reduce our earnings. Accounts are written-off only when all methods of recovery have been exhausted.

Inventory valuation. We value inventory at the lower of cost or market. Inventories are accounted for using the first-in, first-out method. We periodically review these values to ascertain that market value of the inventory continues to exceed its recorded cost. Generally, reductions in value of inventory below cost are caused by our maintenance of stocks of products in excess of demand, or technological obsolescence of the inventory. We regularly review inventory quantities on hand and, when necessary, record provisions for excess and obsolete inventory based on either our estimated forecast of product demand and production requirements, or historical trailing usage of the product. If our sales do not materialize as planned or at historic levels, we may have to increase our reserve for excess and obsolete inventory. This would reduce our earnings. If actual market conditions are more favorable than anticipated, inventory previously written down may be sold, resulting in lower costs of sales and higher income from operations than expected in that period.

Business combinations. Business combinations are accounted for at fair value. Acquisition costs are expensed as incurred and recorded in selling, general and administrative expenses; previously held equity interests are valued at fair value upon the acquisition of a controlling interest; in-process research and development ("IPR&D") is recorded at fair value as an intangible asset at the acquisition date; restructuring costs associated with a business combination are expensed subsequent to the acquisition date; and changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition date affect income tax expense. Measurement period adjustments are made in the period in which the amounts are determined and the current period income effect of such adjustments will be calculated as if the adjustments had been completed as of the acquisition date. All changes that do not qualify as measurement period adjustments are also included in current period earnings. The accounting for business combinations requires estimates and judgment as to expectations for future cash flows of the acquired business, and the allocation of those cash flows to identifiable intangible assets, in determining the estimated fair value for assets acquired and liabilities assumed. The fair values assigned to tangible and intangible assets acquired and liabilities assumed, including contingent consideration, are based on management's estimates and assumptions, as well as other information compiled by management, including valuations that utilize customary valuation procedures and techniques. If the

actual results differ from the estimates and judgments used in these estimates, the amounts recorded in the financial statements could result in a possible impairment of the intangible assets and goodwill, require acceleration of the amortization expense of finite-lived intangible assets, or the recognition of additional consideration which would be expensed. The fair value of contingent consideration is remeasured each period based on relevant information and changes to the fair value are included in the operating results for the period.

Value of long-lived assets, including goodwill and other intangibles. We carry a variety of long-lived assets on our consolidated balance sheets including property and equipment, investments, identifiable intangible assets, and goodwill. We periodically review the carrying value of all of these assets based, in part, upon current estimated market values and our projections of anticipated future cash flows. We undertake this review (i) on an annual basis for assets such as goodwill and non-amortizing intangible assets and (ii) on a periodic basis for other long-lived assets when facts and circumstances suggest that cash flows related to those assets may be diminished. Any impairment charge that we record reduces our earnings. The goodwill impairment test consists of a two-step process. The first step is the comparison of the fair value to the carrying value of the reporting unit to determine if the carrying value exceeds the fair value. The second step measures the amount of an impairment loss, and is only performed if the carrying value exceeds the fair value of the reporting unit. We perform the annual impairment assessment on the later of January 1 or the first day of each fiscal year. This same impairment test will be performed at other times during the course of the year should an event occur which suggests that the recoverability of goodwill should be reconsidered. We completed the annual goodwill impairment test using measurement dates of January 4, 2016 and January 1, 2015, and concluded based on the first step of the process that there was no goodwill impairment. At January 4, 2016, the fair value exceeded the carrying value by more than 20.0% for each reporting unit. At the beginning of the fourth quarter of fiscal year 2016, we realigned our organization into two new operating segments. In conjunction with the realignment of our operating segments, we also redefined our reporting units based on our operating segments. We determined that the reporting units that should be used to test goodwill for impairment are environmental health excluding food, food, life sciences and technology, informatics, OneSource, diagnostics excluding cord blood, cord blood and medical imaging. As a result of the realignment, we reallocated goodwill from our life sciences and technology reporting unit to our diagnostics excluding cord blood reporting unit based on the relative fair value, determined using the income approach, of the applied genomics business which resulted in $125.8 million of goodwill being reallocated from our life sciences and technology reporting unit to our diagnostics excluding food reporting unit as of October 3, 2016. As of January 2, 2017, our Informatics reporting unit, which had a goodwill balance of $211.0 million, had a fair value that was less than 20% but greater than 10% more than its carrying value. Informatics is at increased risk of an impairment charge given its ongoing weakness due to a highly competitive industry. Despite the increased risk associated with this reporting unit, we do not believe there will be a significant change in the key estimates or assumptions driving the fair value of this reporting unit that would lead to a material impairment charge. While we believe that our estimates of current value are reasonable, if actual results differ from the estimates and judgments used including such items as future cash flows and the volatility inherent in markets which we serve, impairment charges against the carrying value of those assets could be required in the future.

Non-amortizing intangibles are also subject to an annual impairment test. The impairment test consists of a comparison of the fair value of the non-amortizing intangible asset with its carrying amount. If the carrying amount of a non-amortizing intangible asset exceeds its fair value, an impairment loss in an amount equal to that excess is recognized. In addition, we currently evaluate the remaining useful life of our non-amortizing intangible asset at least annually to determine whether events or circumstances continue to support an indefinite useful life. If events or circumstances indicate that the useful life of our non-amortizing intangible asset is no longer indefinite, the asset will be tested for impairment. This intangible asset will then be amortized prospectively over their estimated remaining useful life and accounted for in the same manner as other intangible assets that are subject to amortization.

Employee compensation and benefits. We sponsor both funded and unfunded U.S. and non-U.S. defined benefit pension plans and other postretirement benefits. Retirement and postretirement benefit plans are a significant cost of doing business, and represent obligations that will be ultimately settled far in the future, and therefore are subject to estimation. Retirement and postretirement benefit plan expenses are allocated to cost of revenue, research and development, and selling, general and administrative expenses, in our consolidated statements of operations. We immediately recognize actuarial gains and losses in operating results in the year in which the gains and losses occur. Actuarial gains and losses are measured annually as of the

calendar month-end that is closest to our fiscal year end and accordingly will be recorded in the fourth quarter, unless we are required to perform an interim remeasurement.

We recognized a loss of $14.5 million in fiscal year 2016, a loss of $9.4 million in fiscal year 2015 and a loss of $77.2 million in fiscal year 2014 for our retirement and postretirement benefit plans, which includes the charge for the mark-to-market adjustment for the postretirement benefit plans, which was recorded in the fourth quarter of each fiscal year. The loss or income related to the mark-to-market adjustment on postretirement benefit plans was a pre-tax loss of $15.3 million in fiscal year 2016, a pre-tax loss of $12.4 million in fiscal year 2015 and pre-tax loss of $75.4 million in fiscal year 2014. We expect income of approximately $4.5 million in fiscal year 2017 for our retirement and postretirement benefit plans, excluding the charge for or benefit from the mark-to-market adjustment. It is difficult to reliably calculate and predict whether there will be a mark-to-market adjustment in fiscal year 2017. Mark-to-market adjustments are primarily driven by events and circumstances beyond our control, including changes in interest rates, the performance of the financial markets and mortality assumptions. To the extent the discount rates decrease or the value of our pension and postretirement investments decrease, mark-to market charges to operations will be recorded in fiscal year 2017. Conversely, to the extent the discount rates increase or the value of our pension and postretirement investments increase more than expected, mark-to market income will be recorded in fiscal year 2017. Pension accounting is intended to reflect the recognition of future benefit costs over the employee's approximate service period based on the terms of the plans and the investment and funding decisions made. We are required to make assumptions regarding such variables as the expected long-term rate of return on assets, the discount rate applied and mortality assumptions, to determine service cost and interest cost, in order to arrive at expected pension income or expense for the year. Beginning in fiscal year 2016, the approach we use to calculate the service and interest components of net periodic benefit cost for certain non-US benefit plans was changed to provide a more precise measurement of service and interest costs. Prior to fiscal year 2016, we calculated these service and interest components utilizing a single weighted-average discount rate derived from a yield curve used to measure the benefit obligation at the beginning of the period. Beginning in fiscal year 2016, we have elected to utilize an approach that discounts the individual expected cash flows using the applicable spot rates derived from a yield curve over the projected cash flow period.

As of January 1, 2017, we estimate the expected long-term rate of return on assets in our pension and other postretirement benefit plans in the United States to be 7.25% and to be 6.00% for all plans outside the United States. In addition, as of January 1, 2017, we estimate the discount rate for our pension and other postretirement benefit plans in the United States to be 4.05% and to be 2.06% for all plans outside the United States. For the plans in the United States, we adopted the updated projection scale, MP-2015, that was published by the Society of Actuaries in 2015, as of January 3, 2016. The adoption of the updated projection scale resulted in a $6.8 million decrease to the projected benefit obligation as of January 3, 2016. During fiscal year 2016, the Society of Actuaries issued an updated projection scale, MP-2016, which reduced the life expectancy used to determine the projected benefit obligation. We adopted MP-2016, as of January 1, 2017. The adoption of the updated projection scale resulted in a $5.5 million decrease to the projected benefit obligation at January 1, 2017. We have analyzed the rates of return on assets used and determined that these rates are reasonable based on the plans' historical performance relative to the overall markets in the countries where we invest the assets, as well as our current expectations for long-term rates of returns for our pension and other postretirement benefit assets. Our management will continue to assess the expected long-term rate of return on plan assets assumptions for each plan based on relevant market conditions, and will make adjustments to the assumptions as appropriate. Discount rate assumptions have been, and continue to be, based on the prevailing market long-term interest rates corresponding with expected benefit payments at the measurement date.

If any of our assumptions were to change as of January 1, 2017, our pension plan expenses would also change.

		Increase (Decrease) at January 1, 2017	
	Percentage Point Change	Non-U.S.	U.S.
Pension plans discount rate	+0.25	(10,229)	(7,944)
	-0.25	10,850	8,317
Rate of return on pension plan assets	+1.00	(1,533)	(2,438)
	-1.00	1,533	2,438
Postretirement medical plans discount rate	+0.25	N/A	(92)
	-0.25	N/A	96
Rate of return on postretirement medical plan assets	+1.00	N/A	(155)
	-1.00	N/A	155

We have reduced the volatility in our healthcare costs provided to our retirees by adopting a defined dollar plan feature in fiscal year 2001. Under the defined dollar plan feature, our total annual liability for healthcare costs to any one retiree is limited to a fixed dollar amount, regardless of the nature or cost of the healthcare needs of that retiree. Our maximum future liability, therefore, cannot be increased by future changes in the cost of healthcare.

Restructuring activities. Our consolidated financial statements detail specific charges relating to restructuring activities as well as the actual spending that has occurred against the resulting accruals. Our pre-tax restructuring charges are estimates based on our preliminary assessments of (i) severance benefits to be granted to employees, based on known benefit formulas and contractual agreements, (ii) costs to abandon certain facilities based on known lease costs of sub-rental income and (iii) impairment of assets as discussed above under "Value of long-lived assets, including goodwill and other intangibles." Because these accruals are estimates, they are subject to change as a result of deviations from initial restructuring plans or subsequent information that may come to our attention. For example, actual severance costs may be less than anticipated if employees voluntarily leave prior to the time at which they would be entitled to severance, or if anticipated legal hurdles in foreign jurisdictions prove to be less onerous than expected. In addition, unanticipated successes or difficulties in terminating leases and other contractual obligations may lead to changes in estimates. When such changes in estimates occur, they are reflected in our consolidated financial statements on our consolidated statements of operations line entitled "restructuring and contract termination charges, net."

Dispositions. When we record the disposition of an asset or discontinuance of an operation, which meets the criteria to be reported as a discontinued operation, we make an estimate relative to the amount we expect to realize on the sale or disposition. This estimate is based on a variety of factors, including current interest in the market, alternative markets for the assets, and other relevant factors. If anticipated proceeds are less than the current carrying amount of the asset or operation, we record a loss. If anticipated proceeds are greater than the current carrying amount of the asset or operation, we recognize a gain net of expected contingencies when the transaction has been consummated. Accordingly, we may realize amounts different than were first estimated. During the fiscal year ended January 1, 2017, pre-tax gains from the disposition of discontinued operations was not material. Any such changes decrease or increase current earnings.

Income taxes. Our business operations are global in nature, and we are subject to taxes in numerous jurisdictions. Tax laws and tax rates vary substantially in these jurisdictions, and are subject to change given the political and economic climate in those countries. We report and pay income tax based on operational results and applicable law. Our tax provision contemplates tax rates currently in effect to determine our current tax provision as well as enacted tax rates expected to apply to taxable income in the fiscal years in which those temporary differences are expected to be recovered or settled to determine our deferred tax provision. Any significant fluctuation in rates or changes in tax laws could cause our estimates of taxes we anticipate either paying or recovering in the future to change. Such changes could lead to either increases or decreases in our effective tax rate.

Significant judgment is required in determining our worldwide provision for income taxes and recording the related tax assets and liabilities. In the ordinary course of our business, there are operational decisions, transactions, facts and circumstances, and calculations for which the ultimate tax determination is not certain. Furthermore, our tax positions are periodically subject to challenge by taxing authorities throughout the world. Every quarter we review our tax positions in each significant taxing jurisdiction in the process of evaluating our unrecognized tax benefits. Adjustments are made to our unrecognized tax benefits when: (i) facts and circumstances regarding a tax position change, causing a change in our judgment regarding that tax position; (ii) a tax position is effectively settled with a tax authority at a differing amount; and/or (iii) the statute of limitations expires regarding a tax position. Any significant impact as a result of changes in underlying facts, law, tax rates, tax audit, or review could lead to adjustments to our income tax expense, our effective tax rate, or our cash flow.

Additionally, we have established valuation allowances against a variety of deferred tax assets, including state net operating loss carryforwards, state income tax credit carryforwards, and certain foreign tax attributes. Valuation allowances take into consideration our ability to use these deferred tax assets and reduce the value of such items to the amount that is deemed more likely than not to be recoverable. In evaluating our ability to recover our deferred tax assets within the jurisdiction from which they arise, we consider all available positive and negative evidence, including reversals of deferred tax liabilities, projected future taxable income, tax-planning strategies, and results of recent operations. In projecting future taxable income, we begin with historical results adjusted for the results of discontinued operations and incorporate assumptions about the future pretax operating income adjusted for items that do not have tax consequences. These assumptions about future taxable income require significant judgment and are consistent with the plans and estimates we are using to manage the underlying business. Changes in our assumptions regarding the appropriate amount for valuation allowances could result in the increase or decrease in the valuation allowance, with a corresponding charge or benefit to our tax provision.

Taxes have not been provided on unremitted earnings of international subsidiaries that we consider indefinitely reinvested because we plan to keep these amounts indefinitely reinvested overseas except for instances where we can remit such earnings to the U.S. without an associated net tax cost. Our indefinite reinvestment determination is based on the future operational and capital requirements of our U.S. and non-U.S. operations. As of January 1, 2017, the amount of foreign earnings that we have the intent and ability to keep invested outside the U.S. indefinitely and for which no U.S. tax cost has been provided was approximately $1.1 billion. It is not practical to calculate the unrecognized deferred tax liability on those earnings.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

Quantitative and Qualitative Disclosures about Market Risk

Financial Instruments

Financial instruments that potentially subject us to concentrations of credit risk consist principally of temporary cash investments, derivatives, marketable securities and accounts receivable. We believe we had no significant concentrations of credit risk as of January 1, 2017.

We use derivative instruments as part of our risk management strategy only, and include derivatives utilized as economic hedges that are not designated as hedging instruments. By nature, all financial instruments involve market and credit risks. We enter into derivative instruments with major investment grade financial institutions and have policies to monitor the credit risk of those counterparties. We do not enter into derivative contracts for trading or other speculative purposes, nor do we use leveraged financial instruments. Approximately 60% of our business is conducted outside of the United States, generally in foreign currencies. As a result, fluctuations in foreign currency exchange rates can increase the costs of financing, investing and operating the business.

In the ordinary course of business, we enter into foreign exchange contracts for periods consistent with our committed exposures to mitigate the effect of foreign currency movements on transactions denominated in foreign currencies. The intent of these economic hedges is to offset gains and losses that occur on the underlying exposures from these currencies, with gains and losses resulting from the forward currency contracts that hedge these exposures. Transactions covered by hedge contracts include intercompany and third-party receivables and payables. The contracts are primarily in European and Asian currencies, have maturities that do not exceed 12 months, have no cash requirements until maturity, and are recorded at fair value on our

condensed consolidated balance sheets. The unrealized gains and losses on our foreign currency contracts are recognized immediately in interest and other expense, net. The cash flows related to the settlement of these hedges are included in cash flows from operating activities within our condensed consolidated statement of cash flows.

Principal hedged currencies include the British Pound, Euro, Japanese Yen and Singapore Dollar. We held forward foreign exchange contracts, designated as economic hedges, with U.S. dollar equivalent notional amounts totaling $137.5 million at January 1, 2017, $127.3 million at January 3, 2016 and $95.0 million at December 28, 2014, and the fair value of these foreign currency derivative contracts was insignificant. The gains and losses realized on these foreign currency derivative contracts are not material. The duration of these contracts was generally 30 days or less during each of fiscal years 2016, 2015 and 2014.

In addition, in connection with certain intercompany loan agreements utilized to finance our acquisitions and stock repurchase program, we enter into forward foreign exchange contracts intended to hedge movements in foreign exchange rates prior to settlement of such intercompany loans denominated in foreign currencies. We record these hedges at fair value on our condensed consolidated balance sheets. The unrealized gains and losses on these hedges, as well as the gains and losses associated with the remeasurement of the intercompany loans, are recognized immediately in interest and other expense, net. The cash flows related to the settlement of these hedges are included in cash flows from financing activities within our condensed consolidated statement of cash flows.

As of January 1, 2017, the outstanding forward exchange contracts designated as economic hedges, that were intended to hedge movements in foreign exchange rates prior to the settlement of certain intercompany loan agreements included combined Euro notional amounts of €58.6 million, combined U.S. Dollar notional amounts of $8.7 million and combined Swedish Krona notional amounts of kr969.5 million. The combined Euro notional amounts of these outstanding hedges was €107.4 million and €238.2 million as of January 3, 2016 and December 28, 2014, respectively. The net gains and losses on these derivatives, combined with the gains and losses on the remeasurement of the hedged intercompany loans were not material for the fiscal years ended January 1, 2017 and January 3, 2016. We paid $1.9 million and received $18.7 million during the fiscal years ended January 1, 2017 and January 3, 2016, respectively, from the settlement of these hedges.

During fiscal year 2016, we entered into a series of foreign currency forward contracts with a notional amount of €492.3 million to hedge our investments in certain foreign subsidiaries. Realized and unrealized translation adjustments from these hedges were included in the foreign currency translation component of accumulated other comprehensive income ("AOCI"), which offsets the translation adjustments on the underlying net assets of foreign subsidiaries. The cumulative translation gains or losses will remain in AOCI until the foreign subsidiaries are liquidated or sold. The foreign currency forward contracts were settled during fiscal year 2016 and we recorded a net realized foreign exchange gain in AOCI amounting to $1.8 million during the fiscal year 2016.

During fiscal year 2016, in connection with the issuance of the 2026 Notes, we designated the 2026 Notes to hedge our investments in certain foreign subsidiaries. Realized and unrealized translation adjustments from these hedges will be included in the foreign currency translation component of AOCI, which will offset translation adjustments on the underlying net assets of foreign subsidiaries. The cumulative translation gains or losses will remain in AOCI until the foreign subsidiaries are liquidated or sold. As of January 1, 2017, the total notional amount of foreign currency denominated debt designated to hedge investments in foreign subsidiaries was €495.8 million. The unrealized foreign exchange loss recorded in AOCI related to the net investment hedge was $23.8 million during the fiscal year 2016.

Market Risk

Market Risk. We are exposed to market risk, including changes in interest rates and currency exchange rates. To manage the volatility relating to these exposures, we enter into various derivative transactions pursuant to our policies to hedge against known or forecasted market exposures.

Foreign Exchange Risk. The potential change in foreign currency exchange rates offers a substantial risk to us, as approximately 60% of our business is conducted outside of the United States, generally in foreign currencies. Our risk

management strategy currently uses forward contracts to mitigate certain balance sheet foreign currency transaction exposures. The intent of these economic hedges is to offset gains and losses that occur on the underlying exposures, with gains and losses resulting from the forward contracts that hedge these exposures. Moreover, we are able to partially mitigate the impact that fluctuations in currencies have on our net income as a result of our manufacturing facilities located in countries outside the United States, material sourcing and other spending which occur in countries outside the United States, resulting in natural hedges.

Although we attempt to manage our foreign currency exchange risk through the above activities, when the U.S. dollar weakens against other currencies in which we transact business, sales and net income will in general be positively but not proportionately impacted. Conversely, when the U.S. dollar strengthens against other currencies in which we transact business, sales and net income will in general be negatively but not proportionately impacted.

Foreign Currency Risk- Value-at-Risk Disclosure. We utilize a Value-at-Risk model to determine the potential earning/fair value exposures presented by our foreign currency related financial instruments. As discussed above, we seek to minimize this exposure through our hedging program. Our Value-at-Risk computation is based on the Monte Carlo simulation, utilizing a 95% confidence interval and a holding period of 30 days. As of January 1, 2017, this computation estimated that there is a 5% chance that the market value of the underlying exposures and the corresponding derivative instruments either increase or decrease due to foreign currency fluctuations by more than $0.3 million. This Value-At-Risk measure is consistent with our financial statement disclosures relative to our foreign currency hedging program. Specifically, during each of the four quarters ended in fiscal year 2016, the Value-At-Risk ranged between $0.1 million and $0.6 million, with an average of approximately $0.3 million.

Interest Rate Risk. As of January 1, 2017, we had no outstanding borrowings under our senior unsecured revolving credit facility; however, as described above in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations-Liquidity and Capital Resources," amounts drawn under our senior unsecured revolving credit facility would bear interest at variable rates. Our cash and cash equivalents, for which we receive interest at variable rates, were $359.3 million at January 1, 2017. Fluctuations in interest rates can therefore have a direct impact on both our short-term cash flows, as they relate to interest, and our earnings. To manage the volatility relating to these exposures, we periodically enter into various derivative transactions pursuant to our policies to hedge against known or forecasted interest rate exposures.

Interest Rate Risk– Sensitivity. Our current earnings exposure for changes in interest rates can be summarized as follows:

(i) Changes in interest rates can cause our cash flows to fluctuate. An increase of 10%, or approximately 17 basis points, in current interest rates would cause our cash outflows to increase by $0.1 million for fiscal year 2017.

(ii) Changes in interest rates can cause our interest income and cash flows to fluctuate.

Item 8. ***Financial Statements and Supplemental Data***

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of PerkinElmer, Inc.
Waltham, Massachusetts

We have audited the accompanying consolidated balance sheets of PerkinElmer, Inc. and subsidiaries (the "Company") as of January 1, 2017 and January 3, 2016, and the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended January 1, 2017. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and the financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of PerkinElmer, Inc. and subsidiaries as of January 1, 2017 and January 3, 2016, and the results of their operations and their cash flows for each of the three years in the period ended January 1, 2017, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of January 1, 2017, based on the criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2017 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s / DELOITTE & TOUCHE LLP

Boston, Massachusetts
February 28, 2017

CONSOLIDATED STATEMENTS OF OPERATIONS

For the Fiscal Years Ended

	January 1, 2017	January 3, 2016	December 28, 2014
	(In thousands, except per share data)		
Revenue			
Product revenue	$ 1,396,896	$ 1,395,102	$ 1,372,736
Service revenue	718,621	709,721	697,144
Total revenue	2,115,517	2,104,823	2,069,880
Cost of product revenue	664,803	696,461	708,016
Cost of service revenue	437,361	444,131	427,266
Selling, general and administrative expenses	600,885	587,219	648,209
Research and development expenses	124,278	112,539	108,057
Restructuring and contract termination charges, net	5,124	13,547	13,325
Operating income from continuing operations	283,066	250,926	165,007
Interest and other expense, net	38,998	42,119	41,139
Income from continuing operations before income taxes	244,068	208,807	123,868
Provision for (benefit from) income taxes	28,362	20,022	(6,271)
Income from continuing operations	215,706	188,785	130,139
Income from discontinued operations before income taxes	22,229	35,205	40,776
Gain (loss) on disposition of discontinued operations before income taxes	619	(28)	(260)
Provision for income taxes on discontinued operations and dispositions	4,255	11,537	12,877
Income from discontinued operations and dispositions	18,593	23,640	27,639
Net income	$ 234,299	$ 212,425	$ 157,778
Basic earnings per share:			
Income from continuing operations	$ 1.97	$ 1.68	$ 1.16
Income from discontinued operations and dispositions	0.17	0.21	0.25
Net income	$ 2.14	$ 1.89	$ 1.40
Diluted earnings per share:			
Income from continuing operations	$ 1.96	$ 1.67	$ 1.14
Income from discontinued operations and dispositions	0.17	0.21	0.24
Net income	$ 2.12	$ 1.87	$ 1.39

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

For the Fiscal Years Ended

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Net income	$ 234,299	$ 212,425	$ 157,778
Other comprehensive loss			
Foreign currency translation adjustments	(54,077)	(70,178)	(52,951)
Unrecognized prior service costs, net of tax	(860)	(316)	146
Unrealized gains (losses) on securities, net of tax	32	(262)	14
Other comprehensive loss	(54,905)	(70,756)	(52,791)
Comprehensive income	$ 179,394	$ 141,669	$ 104,987

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED BALANCE SHEETS

As of the Fiscal Years Ended

	January 1, 2017	January 3, 2016
	(In thousands, except share and per share data)	
Current assets:		
Cash and cash equivalents	$ 359,265	$ 237,932
Accounts receivable, net	425,588	415,064
Inventories	246,847	259,486
Other current assets	99,246	64,347
Current assets of discontinued operations	58,985	56,332
Total current assets	1,189,931	1,033,161
Property, plant and equipment, net	145,494	137,564
Intangible assets, net	420,224	485,637
Goodwill	2,247,966	2,236,863
Other assets, net	204,679	198,041
Long-term assets of discontinued operations	68,389	75,029
Total assets	$ 4,276,683	$ 4,166,295
Current liabilities:		
Current portion of long-term debt	$ 1,172	$ 1,123
Accounts payable	168,033	140,980
Accrued restructuring and contract termination charges	7,479	17,042
Accrued expenses and other current liabilities	399,700	382,334
Current liabilities of discontinued operations	26,971	20,006
Total current liabilities	603,355	561,485
Long-term debt	1,045,254	1,011,762
Long-term liabilities	459,544	465,490
Long-term liabilities of discontinued operations	14,960	17,117
Total liabilities	2,123,113	2,055,854
Commitments and contingencies (see Notes 13 and 16)		
Stockholders' equity:		
Preferred stock—$1 par value per share, authorized 1,000,000 shares; none issued or outstanding	—	—
Common stock—$1 par value per share, authorized 300,000,000 shares; issued and outstanding 109,617,000 and 112,034,000 shares at January 1, 2017 and January 3, 2016, respectively	109,617	112,034
Capital in excess of par value	26,130	52,932
Retained earnings	2,118,684	1,991,431
Accumulated other comprehensive loss	(100,861)	(45,956)
Total stockholders' equity	2,153,570	2,110,441
Total liabilities and stockholders' equity	$ 4,276,683	$ 4,166,295

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

For the Three Fiscal Years Ended January 1, 2017

	Common Stock Amount	Capital in Excess of Par Value	Retained Earnings	Accumulated Other Comprehensive Income (loss)	Total Stockholders' Equity
			(In thousands)		
Balance, December 29, 2013	$ 112,626	$ 119,906	$ 1,684,364	$ 77,591	$ 1,994,487
Net income	—	—	157,778	—	157,778
Other comprehensive loss	—	—	—	(52,791)	(52,791)
Dividends	—	—	(31,597)	—	(31,597)
Exercise of employee stock options and related income tax benefits	1,024	23,431	—	—	24,455
Issuance of common stock for employee stock purchase plans	61	2,478	—	—	2,539
Purchases of common stock	(1,448)	(64,081)	—	—	(65,529)
Issuance of common stock for long-term incentive program	218	7,662	—	—	7,880
Stock compensation	—	4,880	—	—	4,880
Balance, December 28, 2014	$ 112,481	$ 94,276	$ 1,810,545	$ 24,800	$ 2,042,102
Net income	—	—	212,425	—	212,425
Other comprehensive loss	—	—	—	(70,756)	(70,756)
Dividends	—	—	(31,539)	—	(31,539)
Exercise of employee stock options and related income tax benefits	849	16,491	—	—	17,340
Issuance of common stock for employee stock purchase plans	78	3,608	—	—	3,686
Purchases of common stock	(1,595)	(74,844)	—	—	(76,439)
Issuance of common stock for long-term incentive program	221	9,098	—	—	9,319
Stock compensation	—	4,303	—	—	4,303
Balance, January 3, 2016	$ 112,034	$ 52,932	$ 1,991,431	$ (45,956)	$ 2,110,441
Adjustment to recognize prior year's unrecognized excess tax benefits upon adoption of ASU 2016-09 (see Note 1)	—	177	14,051	—	14,228
Net income	—	—	234,299	—	234,299
Other comprehensive loss	—	—	—	(54,905)	(54,905)
Dividends	—	—	(30,629)	—	(30,629)
Exercise of employee stock options and related income tax benefits	576	13,842	—	—	14,418
Issuance of common stock for employee stock purchase plans	50	2,413	—	—	2,463
Purchases of common stock	(3,275)	(58,058)	(90,468)	—	(151,801)
Issuance of common stock for long-term incentive program	232	10,193	—	—	10,425
Stock compensation	—	4,631	—	—	4,631
Balance, January 1, 2017	$ 109,617	$ 26,130	$ 2,118,684	$ (100,861)	$ 2,153,570

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Fiscal Years Ended

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Operating activities:			
Net income	$ 234,299	$ 212,425	$ 157,778
Income from discontinued operations and dispositions, net of income taxes	(18,593)	(23,640)	(27,639)
Income from continuing operations	215,706	188,785	130,139
Adjustments to reconcile income from continuing operations to net cash provided by continuing operations:			
Restructuring and contract termination charges, net	5,124	13,547	13,325
Depreciation and amortization	99,972	105,364	110,465
Stock-based compensation	17,158	17,278	14,057
Pension and other postretirement expense	14,511	9,381	77,182
Change in fair value of contingent consideration	16,183	—	—
Deferred taxes	(6,526)	(6,571)	(33,351)
Contingencies and non-cash tax matters	(291)	(5,342)	(7,605)
Amortization of deferred debt issuance costs and accretion of discounts	2,137	1,496	1,434
(Gains) losses on disposition of businesses and assets, net	(5,562)	—	108
Amortization of acquired inventory revaluation	396	7,275	2,425
Excess tax benefit from exercise of common stock options	—	(2,435)	—
Changes in assets and liabilities which provided (used) cash, excluding effects from companies acquired:			
Accounts receivable, net	(18,960)	4,061	(12,059)
Inventories	6,752	(27,931)	(19,443)
Accounts payable	30,716	(10,897)	2,847
Accrued expenses and other	(53,540)	(30,177)	(31,622)
Net cash provided by operating activities of continuing operations	323,776	263,834	247,902
Net cash provided by operating activities of discontinued operations	26,839	23,264	33,695
Net cash provided by operating activities	350,615	287,098	281,597
Investing activities:			
Capital expenditures	(31,702)	(28,218)	(27,152)
Proceeds from disposition of businesses	21,000	—	—
Proceeds from dispositions of property, plant and equipment, net	—	—	2,531
Changes in restricted cash balances	(16,959)	59	—
Proceeds from surrender of life insurance policies	44	757	490
Activity related to acquisitions, net of cash and cash equivalents acquired	(71,924)	(72,040)	(271,477)
Net cash used in investing activities of continuing operations	(99,541)	(99,442)	(295,608)
Net cash used in investing activities of discontinued operations	(1,302)	(1,414)	(289)
Net cash used in investing activities	(100,843)	(100,856)	(295,897)
Financing activities:			
Payments on revolving credit facility	(902,507)	(485,000)	(356,000)
Proceeds from revolving credit facility	420,507	451,000	475,000
Proceeds from sale of senior debt	546,190	—	—
Payments of debt financing costs	(7,868)	—	(1,845)
Net payments on other credit facilities	(1,096)	(1,072)	(12,675)
Settlement of cash flow hedges	(1,900)	18,706	—
Payments for acquisition-related contingent consideration	(155)	(103)	(855)

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Excess tax benefit from exercise of common stock options	—	2,435	—
Proceeds from issuance of common stock under stock plans	14,418	14,905	24,455
Purchases of common stock	(151,801)	(76,439)	(65,529)
Dividends paid	(30,799)	(31,571)	(31,620)
Net cash (used in) provided by financing activities	(115,011)	(107,139)	30,931
Effect of exchange rate changes on cash and cash equivalents	(13,428)	(15,992)	(15,052)
Net increase in cash and cash equivalents	121,333	63,111	1,579
Cash and cash equivalents at beginning of year	237,932	174,821	173,242
Cash and cash equivalents at end of year	$ 359,265	$ 237,932	$ 174,821
Supplemental disclosures of cash flow information			
Cash paid during the year for:			
Interest	$ 30,718	$ 31,741	$ 30,320
Income taxes	$ 43,549	$ 49,275	$ 40,638

The accompanying notes are an integral part of these consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1: Nature of Operations and Accounting Policies

Nature of Operations: PerkinElmer, Inc. is a leading provider of products, services and solutions to the diagnostics, research, environmental, industrial, food and laboratory services markets. Through its advanced technologies and differentiated solutions, critical issues are addressed that help to improve lives and the world around us. The results are reported withiu two reporting segments: Diagnostics and Discovery & Analytical Solutions.

The consolidated financial statements include the accounts of PerkinElmer, Inc. and its subsidiaries (the "Company"). All intercompany balances and transactions have been eliminated in consolidation.

The Company realigned its businesses at the beginning of the fourth quarter of fiscal year 2016 to better organize around customer requirements, position the Company to grow in attractive end markets and expand share with the Company's core product offerings. The Company created two new operating segments, Discovery & Analytical Solutions and Diagnostics, which will enable the Company to deliver improved customer focus, more value-add collaboration and breakthrough iunovations. The Company's Diagnostics business became a standalone operating segment targeted towards better meeting the needs of clinically-oriented customers, especially within the growing areas of reproductive health, emerging market diagnostics and applied genomics. The new Diagnostics operating segment includes the products and services of the Company's diagnostics business, formerly in the Human Health segment, and the Company's microfluidics and automation products, formerly within the research business in the Human Health segment. The Company's new Discovery & Analytical Solutions operating segment combines the Company's former environmental health business, formerly in the Environmental Health segment, and the remaining products and services within the research business, formerly in the Human Health segment. The Discovery & Analytical Solutions operating segment will advance the Company's success in serving and innovating for its applications-oriented customers in the environmental, food, industrial, life sciences and laboratory services markets.

The Company's fiscal year ends on the Sunday nearest December 31. The Company reports fiscal years under a 52/53 week format and as a result, certain fiscal years will contain 53 weeks. Each of the fiscal years ended January 1, 2017 and December 28, 2014 included 52 weeks. The fiscal year ended January 3, 2016 included 53 weeks. The additional week in fiscal year 2015 has been reflected in the Company's third quarter. The fiscal year ending December 31, 2017 will include 52 weeks.

Accounting Policies and Estimates: The preparation of consolidated financial statements in accordance with United States ("U.S.") Generally Accepted Accounting Principles ("GAAP") requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, the Company evaluates its estimates. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

Revenue Recognition: The Company's product revenue is recorded when persuasive evidence of an arrangement exists, delivery has occurred, the price to the buyer is fixed or determinable, and collectability is reasonably assured. For products that include installation, and if the installation meets the criteria to be considered a separate element, product revenue is recognized upon delivery, and installation revenue is recognized when the installation is complete. For revenue that includes customer-specified acceptance criteria, revenue is recognized after the acceptance criteria have been met. Certain of the Company's products require specialized installation. Revenue for these products is deferred until installation is completed. Revenue from services is deferred and recognized over the contractual period, or as services are rendered.

In limited circumstances, the Company has arrangements that include multiple elements that are delivered at different points of time, such as revenue from products and services with a remaining service or storage component, including cord blood processing and storage. For these arrangements, the revenue is allocated to each of the deliverables based upon their relative selling prices as determined by a selling-price hierarchy. A deliverable in an arrangement qualifies as a separate unit of accounting if the delivered item has value to the customer on a stand-alone basis. A delivered item that does not qualify as a

separate unit of accounting is combined with the other undelivered items in the arrangement and revenue is recognized for those combined deliverables as a single unit of accounting. The selling price used for each deliverable is based upon vendor-specific objective evidence ("VSOE") if such evidence is available, third-party evidence ("TPE") if VSOE is not available, and management's best estimate of selling price ("BESP") if neither VSOE nor TPE are available. TPE is the price of the Company's or any competitor's largely interchangeable products or services in stand-alone sales to similarly-situated customers. BESP is the price at which the Company would sell the deliverable if it were sold regularly on a stand-alone basis, considering market conditions and entity-specific factors.

Revenue from software licenses and services was 5% of the Company's total revenue for each of fiscal years 2016, 2015 and 2014. The Company sells its software licenses with maintenance services and, in some cases, also with consulting services. For the undelivered elements, the Company determines VSOE of fair value to be the price charged when the undelivered element is sold separately. The Company determines VSOE for maintenance sold in connection with a software license based on the stated renewal rate method. The Company determines VSOE for consulting services by reference to the amount charged for similar engagements on a stand-alone basis.

The Company recognizes revenue from software licenses sold together with maintenance and/or consulting services upon shipment using the residual method, provided that the above criteria have been met. If VSOE of fair value for the undelivered elements cannot be established, the Company defers all revenue from the arrangement until the earlier of the point at which such sufficient VSOE does exist or all elements of the arrangement have been delivered, or if the only undelivered element is maintenance, then the Company recognizes the entire fee ratably over the maintenance period.

The Company recognizes revenue from the grant of certain intellectual property rights for patented technologies it owns. These rights typically include a combination of the following: the grant of a non-exclusive, retroactive and future license to patented technologies, a covenant-not-to-sue, the release of the licensee from certain claims, and the dismissal of any pending litigation. The intellectual property rights granted may be perpetual in nature, extending until the expiration of the related patents, or can be granted for a defined timeframe. For these arrangements, the revenue is allocated to each of the deliverables based upon their relative selling prices as determined by the selling-price hierarchy. In the case where the agreement includes the dismissal of any pending litigation, the Company allocates between revenue and litigation settlement using the residual method. The Company recognizes revenue when the earnings process is complete and upon the execution of the agreement, when collectability is reasonably assured, or upon receipt of the minimum upfront fee for term agreement renewals, and when all other revenue recognition criteria have been met.

Service revenues represent the Company's service offerings including service contracts, field service including related time and materials, diagnostic testing, cord blood processing and storage, and training. Service revenues are recognized as the service is performed. Revenues for service contracts and storage contracts are recognized over the contract period.

The Company sells products and accessories predominantly through its direct sales force. As a result, the use of distributors is generally limited to geographic regions where the Company has no direct sales force. The Company does not offer product return or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to its customers, including its distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers. Sales incentives related to distributor revenue are also the same as those for end-user customers.

Warranty Costs: The Company provides for estimated warranty costs for products at the time of their sale. Warranty liabilities are estimated using expected future repair costs based on historical labor and material costs incurred during the warranty period.

Shipping and Handling Costs: The Company reports shipping and handling revenue in revenue, to the extent they are billed to customers, and the associated costs in cost of product revenue.

Inventories: Inventories, which include material, labor and manufacturing overhead, are valued at the lower of cost or market. Inventories are accounted for using the first-in, first-out method of determining inventory costs. Inventory quantities

on-hand are regularly reviewed, and where necessary, provisions for excess and obsolete inventory are recorded based primarily on the Company's estimated forecast of product demand and production requirements.

Income Taxes: The Company uses the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax bases. This method also requires the recognition of future tax benefits such as net operating loss carryforwards, to the extent that realization of such benefits is more likely than not. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the fiscal years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established for any deferred tax asset for which realization is not more likely than not. With respect to earnings expected to be indefinitely reinvested offshore, the Company does not accrue tax for the repatriation of such foreign earnings.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions and other issues. These reserves are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. Potential interest and penalties associated with such uncertain tax positions is recorded as a component of income tax expense. See Note 6 below for additional details.

Property, Plant and Equipment: The Company depreciates property, plant and equipment using the straight-line method over its estimated useful lives, which generally fall within the following ranges: buildings- 10 to 40 years; leasehold improvements-estimated useful life or remaining term of lease, whichever is shorter; and machinery and equipment- 3 to 7 years. Certain tooling costs are capitalized and amortized over a 3-year life, while repairs and maintenance costs are expensed.

Asset Retirement Obligations: The Company records obligations associated with its lease obligations, the retirement of tangible long-lived assets and the associated asset retirement costs in accordance with authoritative guidance on asset retirement obligations. The Company reviews legal obligations associated with the retirement of long-lived assets that result from contractual obligations or the acquisition, construction, development and/or normal use of the assets. If it is determined that a legal obligation exists, regardless of whether the obligation is conditional on a future event, the fair value of the liability for an asset retirement obligation is recognized in the period in which it is incurred, if a reasonable estimate of fair value can be made. The fair value of the liability is added to the carrying amount of the associated asset, and this additional carrying amount is depreciated over the life of the asset. The difference between the gross expected future cash flow and its present value is accreted over the life of the related lease as interest expense. The amounts recorded in the consolidated financial statements are not material to any year presented.

Pension and Other Postretirement Benefits: The Company sponsors both funded and unfunded U.S. and non-U.S. defined benefit pension plans and other postretirement benefits. The Company immediately recognizes actuarial gains and losses in operating results in the year in which the gains and losses occur. Actuarial gains and losses are measured annually as of the calendar month-end that is closest to the Company's fiscal year end and accordingly will be recorded in the fourth quarter, unless the Company is required to perform an interim remeasurement. The remaining components of pension expense, primarily service and interest costs and assumed return on plan assets, are recorded on a quarterly basis. The Company's funding policy provides that payments to the U.S. pension trusts shall at least be equal to the minimum funding requirements of the Employee Retirement Income Security Act of 1974. Non-U.S. plans are accrued for, but generally not fully funded, and benefits are paid from operating funds.

Translation of Foreign Currencies: For foreign operations, asset and liability accounts are translated at current exchange rates; income and expenses are translated using weighted average exchange rates for the reporting period. Resulting translation adjustments, as well as translation gains and losses from certain intercompany transactions considered permanent in nature, are reported in accumulated other comprehensive (loss) income, a separate component of stockholders' equity. Gains and losses arising from transactions and translation of period-end balances denominated in currencies other than the functional currency are included in other expense, net.

Business Combinations: Business combinations are accounted for at fair value. Acquisition costs are expensed as incurred and recorded in selling, general and administrative expenses; previously held equity interests are valued at fair value upon the acquisition of a controlling interest; in-process research and development ("IPR&D") is recorded at fair value as an intangible asset at the acquisition date; restructuring costs associated with a business combination are expensed subsequent to the acquisition date; and changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition date affect income tax expense. Measurement period adjustments are made in the period in which the amounts are determined and the current period income effect of such adjustments will be calculated as if the adjustments had been completed as of the acquisition date. All changes that do not qualify as measurement period adjustments are also included in current period earnings. The accounting for business combinations requires estimates and judgment as to expectations for future cash flows of the acquired business, and the allocation of those cash flows to identifiable intangible assets, in determining the estimated fair value for assets acquired and liabilities assumed. The fair values assigned to tangible and intangible assets acquired and liabilities assumed, including contingent consideration, are based on management's estimates and assumptions, as well as other information compiled by management, including valuations that utilize customary valuation procedures and techniques. If the actual results differ from the estimates and judgments used in these estimates, the amounts recorded in the financial statements could result in a possible impairment of the intangible assets and goodwill, require acceleration of the amortization expense of finite-lived intangible assets, or the recognition of additional consideration which would be expensed.

Goodwill and Other Intangible Assets: The Company's intangible assets consist of (i) goodwill, which is not being amortized; (ii) indefinite lived intangibles, which consist of a trade name that is not subject to amortization; and (iii) amortizing intangibles, which consist of patents, trade names and trademarks, licenses, customer relationships, and purchased technologies, which are being amortized over their estimated useful lives.

The process of testing goodwill for impairment involves the determination of the fair value of the applicable reporting units. The test consists of a two-step process. The first step is the comparison of the fair value to the carrying value of the reporting unit to determine if the carrying value exceeds the fair value. The second step measures the amount of an impairment loss, and is only performed if the carrying value exceeds the fair value of the reporting unit. This annual impairment assessment is performed by the Company on the later of January 1 or the first day of each fiscal year. This same impairment test will be performed at other times during the course of the year, should an event occur which suggests that the recoverability of goodwill should be reconsidered. Non-amortizing intangibles are also subject to an annual impairment test. The impairment test consists of a comparison of the fair value of the non-amortizing intangible asset with its carrying amount. If the carrying amount of a non-amortizing intangible asset exceeds its fair value, an impairment loss in an amount equal to that excess is recognized. In addition, the Company evaluates the remaining useful life of its non-amortizing intangible assets at least annually to determine whether events or circumstances continue to support an indefinite useful life. If events or circumstances indicate that the useful lives of non-amortizing intangible assets are no longer indefinite, the assets will be tested for impairment. These intangible assets will then be amortized prospectively over their estimated remaining useful life and accounted for in the same manner as other intangible assets that are subject to amortization. Amortizing intangible assets are reviewed for impairment when indicators of impairment are present. When a potential impairment has been identified, forecasted undiscounted net cash flows of the operations to which the asset relates are compared to the current carrying value of the long-lived assets present in that operation. If such cash flows are less than such carrying amounts, long-lived assets, including such intangibles, are written down to their respective fair values. See Note 12 below for additional details.

Stock-Based Compensation: The Company accounts for stock-based compensation expense based on estimated grant date fair value, generally using the Black-Scholes option-pricing model. The fair value is recognized, net of estimated forfeitures, as expense in the consolidated financial statements over the requisite service period. The determination of fair value and the timing of expense using option pricing models such as the Black-Scholes model require the input of highly subjective assumptions, including the expected term and the expected price volatility of the underlying stock. The Company estimates the expected term assumption based on historical experience. In determining the Company's expected stock price volatility assumption, the Company reviews both the historical and implied volatility of the Company's common stock, with implied volatility based on the implied volatility of publicly traded options on the Company's common stock. The Company has one stock-based compensation plan from which it makes grants, which is described more fully in Note 18 below.

Marketable Securities and Investments: The cost of securities sold is based on the specific identification method. If securities are classified as available for sale, the Company records these investments at their fair values with unrealized gains and losses included in accumulated other comprehensive (loss) income. Under the cost method of accounting, equity investments in private companies are carried at cost and are adjusted for other-than-temporary declines in fair value, additional investments or distributions.

Cash and Cash Equivalents: The Company considers all highly liquid unrestricted instruments with a purchased maturity of three months or less to be cash equivalents. The carrying amount of cash equivalents approximates fair value due to the short maturities of these instruments.

Environmental Matters: The Company accrues for costs associated with the remediation of environmental pollution when it is probable that a liability has been incurred and the Company's proportionate share of the amount can be reasonably estimated. The recorded liabilities have not been discounted.

Research and Development: Research and development costs are expensed as incurred. The fair value of acquired IPR&D costs are recorded at fair value as an intangible asset at the acquisition date and amortized once the product is ready for sale or expensed if abandoned.

Restructuring Charges: In recent fiscal years, the Company has undertaken a series of restructuring actions related to the impact of acquisitions and divestitures, the alignment of its operations with its growth strategy, the integration of its business units and its productivity initiatives. In connection with these initiatives, the Company has recorded restructuring charges, as more fully described in Note 4 below. Generally, costs associated with an exit or disposal activity are recognized when the liability is incurred. Prior to recording restructuring charges for employee separation agreements, the Company notifies all employees of termination. Costs related to employee separation arrangements requiring future service beyond a specified minimum retention period are recognized over the service period. Costs related to lease terminations are recorded at the fair value of the liability based on the remaining lease rental payments, reduced by estimated sublease rentals that could be reasonably obtained for the property, at the date the Company ceases use.

Comprehensive Income: Comprehensive income is defined as net income or loss and other changes in stockholders' equity from transactions and other events from sources other than stockholders. Comprehensive income is reflected in the consolidated statements of comprehensive income.

Derivative Instruments and Hedging: Derivatives are recorded on the consolidated balance sheets at fair value. Accounting for gains or losses resulting from changes in the values of those derivatives depends on the use of the derivative instrument and whether it qualifies for hedge accounting.

For a cash flow hedge, the effective portion of the derivative's gain or loss is initially reported as a component of other comprehensive income and subsequently amortized into net earnings when the hedged exposure affects net earnings. Cash flow hedges related to anticipated transactions are designated and documented at the inception of each hedge by matching the terms of the contract to the underlying transaction. The Company classifies the cash flows from hedging transactions in the same categories as the cash flows from the respective hedged items. Once established, cash flow hedges are generally recorded in other comprehensive income, unless an anticipated transaction is no longer likely to occur, and subsequently amortized into net earnings when the hedged exposure affects net earnings. Discontinued or dedesignated cash flow hedges are immediately settled with counterparties, and the related accumulated derivative gains or losses are recognized into net earnings on the consolidated financial statements. Settled cash flow hedges related to forecasted transactions that remain probable are recorded as a component of other comprehensive (loss) income and are subsequently amortized into net earnings when the hedged exposure affects net earnings. Forward contract effectiveness for cash flow hedges is calculated by comparing the fair value of the contract to the change in value of the anticipated transaction using forward rates on a monthly basis. The Company also has entered into other foreign currency forward contracts that are not designated as hedging instruments for accounting purposes. These contracts are recorded at fair value, with the changes in fair value recognized into interest and other expense, net on the consolidated financial statements.

The Company also uses foreign currency denominated debt to hedge its investments in certain foreign subsidiaries. Realized and unrealized translation adjustments from these hedges are included in the foreign currency translation component of Accumulated Other Comprehensive Income ("AOCI"), as well as the offset translation adjustments on the underlying net assets of foreign subsidiaries. The cumulative translation gains or losses will remain in AOCI until the foreign subsidiaries are liquidated or sold.

Recently Issued Accounting Pronouncements: From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the "FASB") and are adopted by the Company as of the specified effective dates. Unless otherwise discussed, such pronouncements did not have or will not have a significant impact on the Company's consolidated financial position, results of operations and cash flows or do not apply to the Company's operations.

In January 2017, the FASB issued Accounting Standards Update No. 2017-04, *Intangibles-Goodwill and Other Topic (Topic 350), Simplifying the Test for Goodwill Impairment* ("ASU 2017-04"), which amends Topic 350 to simplify the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test. ASU 2017-04 requires that an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize the impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider the income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. The provisions of this guidance are to be applied on a prospective basis. ASU 2017-04 is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company intends to early adopt ASU 2017-04 and will apply the provisions of this standard in its interim or annual goodwill impairment tests subsequent to January 1, 2017.

In January 2017, the FASB issued Accounting Standards Update No. 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business* ("ASU 2017-01"), which amends Topic 805 to provide a screen to determine when a set of assets and liabilities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. If the screen is not met, the standard (1) requires that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) removes the evaluation of whether a market participant could replace missing elements. The standard provides a framework to assist entities in evaluating whether both an input and a substantive process are present. The standard also provides a framework that includes two sets of criteria to consider that depend on whether a set has outputs and a more stringent criteria for sets without outputs. Lastly, the standard narrows the definition of the term "output" so that the term is consistent with how outputs are described in Topic 606. The provisions of this guidance are to be applied prospectively. ASU 2017-01 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted in limited circumstances. The Company is evaluating the requirements of this guidance. The adoption is not expected to have a material impact on the Company's consolidated financial position, results of operations and cash flows.

In November 2016, the FASB issued Accounting Standards Update No. 2016-18, *Statement of Cash Flows (Topic 230), Restricted Cash* ("ASU 2016-18"), which amends Topic 230 to add or clarify guidance on the classification and presentation of restricted cash in the statement of cash flows. The standard requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The provisions of this guidance are to be applied using a retrospective transition method to each period presented. ASU 2016-18 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. The Company is evaluating the requirements of this guidance. The adoption is not expected to have a material impact on the Company's consolidated financial position, results of operations and cash flows.

In October 2016, the FASB issued Accountiug Standards Update No. 2016-16, *Income Taxes (Topic 740), Intra-entity Transfer of Assets Other than Inventory* ("ASU 2016-16"). ASU 2016-16 removes the prohibitiou in ASC 740 against the immediate recognition of the current and deferred income tax effects of intra-entity transfers of assets other than inventory. The standard requires entities to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. The provisions of this guidance are to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. ASU 2016-16 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. The Company is evaluating the requirements of this guidance and has not yet determined the impact of its adoption on the Company's consolidated financial position, results of operations and cash flows.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, *Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). ASU 2016-15 addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows under Topic 230 and other topics. The provisions of this guidance are to be applied using a retrospective transition method to each period presented, and if it is impracticable to apply the amendments retrospectively for some of the issues, ASU 2016-15 allows the amendments for those issues to be applied prospectively as of the earliest date practicable. ASU 2015-16 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. The Company is evaluating the requirements of this guidance. The adoption is not expected to have a material impact on the Company's consolidated financial position, results of operations and cash flows.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, *Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. The standard requires entities to use the expected loss impairment model and will apply to most financial assets measured at amortized cost and certain other instruments, including trade and other receivables, loans, held-to-maturity debt securities, net investments in leases and off-balance sheet credit exposures. Entities are required to estimate the lifetime "expected credit loss" for each applicable financial asset and record an allowance that, when deducted from the amortized cost basis of the financial asset, presents the net amount expected to be collected on the financial asset. The standard also amends the impairment model for available-for-sale ("AFS") debt securities and requires entities to determine whether all or a portion of the unrealized loss on an AFS debt security is a credit loss. An entity will recognize an allowance for credit losses on an AFS debt security as a contra-account to the amortized cost basis rather than as a direct reduction of the amortized cost basis of the investment. The provisions of this guidance are to be applied using a modified-retrospective approach. A prospective transition approach is required for debt securities for which an other-than-temporary impairment had been recognized before the effective date. ASU 2016-13 is effective for annual reporting periods beginning after December 15, 2019, and interim periods within those years. Early adoption is permitted for annual periods beginning after December 15, 2018, and interim periods therein. The Company is evaluating the requirements of this guidance and has not yet determined the impact of its adoption on the Company's consolidated financial position, results of operations and cash flows.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, *Compensation—Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting* ("ASU No. 2016-09"). The new standard simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory withholding requirements, as well as the related classification in the statement of cash flows. The new standard is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those years, with early adoption permitted. The standard requires an entity to recognize all excess tax benefits and tax deficiencies as income tax benefit or expense in the income statement as discrete items in the reporting period in which they occur, and such tax benefits and tax deficiencies are not included in the estimate of an entity's annual effective tax rate, applied on a prospective basis. Further, the standard eliminates the requirement to defer the recognition of excess tax benefits until the benefit is realized through a reduction to taxes payable. All excess tax benefits previously unrecognized, along with any valuation allowance, should be recognized on a modified retrospective basis as a cumulative adjustment to retained earnings as of the date of adoption. Under ASU No. 2016-09, an entity that applies the treasury stock method in calculating diluted earnings per share is

required to exclude excess tax benefits and deficiencies from the calculation of assumed proceeds since such amounts are recognized in the income statement. Excess tax benefits should also be classified as operating activities in the same manner as other cash flows related to income taxes on the statement of cash flows, as such excess tax benefits no longer represent financing activities since they are recognized in the income statement, and should be applied prospectively or retrospectively to all periods presented. The Company adopted ASU No. 2016-09 at the beginning of the first quarter of fiscal year 2016. The Company recorded a cumulative increase of $14.2 million in the beginning of the first quarter of fiscal year 2016 retained earnings with a corresponding increase in deferred tax assets related to the prior years' unrecognized excess tax benefits. Excess tax benefits related to exercised options and vested restricted stock and restricted stock units during the fiscal year 2016 have been recognized in the current period's income statement. The Company also excluded the excess tax benefits from the calculation of diluted earnings per share for fiscal year 2016. The Company applied the cash flow presentation section of the guidance on a prospective basis, and the prior period statement of cash flows was not adjusted. ASU No. 2016-09 also allows an entity to elect as an accounting policy either to continue to estimate the total number of awards for which the requisite service period will not be rendered or to account for forfeitures for service based awards as they occur. An entity that elects to account for forfeitures as they occur should apply the accounting change on a modified retrospective basis as a cumulative effect adjustment to retained earnings as of the date of adoption. The Company has elected to account for forfeitures as they occur. The adoption of this accounting policy did not have a material impact on the Company's consolidated financial position, results of operations and cash flows.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 requires organizations that lease assets to recognize assets and liabilities on the balance sheet related to the rights and obligations created by those leases, regardless of whether they are classified as finance or operating leases. Consistent with current guidance, the recognition, measurement, and presentation of expenses and cash flows arising from a lease primarily will depend on its classification as a finance or operating lease. ASU 2016-02 also requires new disclosures to help financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. The provisions of this guidance are effective for annual periods beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. ASU 2016-02 is to be applied using a modified retrospective approach. The Company is evaluating the requirements of this guidance and has not yet determined the impact of the adoption on its consolidated financial position, results of operations and cash flows.

In July 2015, the FASB issued Accounting Standards Update No. 2015-11, *Simplifying the Measurement of Inventory*. Under this new guidance, companies that use inventory measurement methods other than last-in, first-out or the retail inventory method should measure inventory at the lower of cost and net realizable value. The provisions of this guidance are to be applied prospectively and are effective for interim and annual periods beginning after December 15, 2016, with early adoption permitted. The adoption is not expected to have a material impact on the Company's consolidated financial position, results of operations and cash flows.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"). Under this new guidance, an entity should use a five-step process to recognize revenue, depicting the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires new disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Subsequent to the issuance of the standard, the FASB decided to defer the effective date for one year to annual reporting periods beginning after December 15, 2017, with early adoption permitted for annual reporting periods beginning after December 15, 2016. In May 2016, the FASB also issued Accounting Standards Update No. 2016-12, *Revenue from Contracts with Customers (Topic 606), Narrow-Scope Improvements and Practical Expedients* ("ASU 2016-12"), which amended its revenue recognition guidance in ASU 2014-09 on transition, collectibility, non-cash consideration, contract modifications and completed contracts at transition and the presentation of sales and other similar taxes collected from customers. In April 2016, the FASB also issued Accounting Standards Update No. 2016-10, *Revenue from Contracts with Customers (Topic 606), Identifying Performance Obligations and Licensing* ("ASU 2016-10"), which amended its revenue recognition guidance in ASU 2014-09 on identifying performance obligations to allow entities to disregard items that are immaterial in the context of the contract, clarify when a promised good or service is separately identifiable (i.e., distinct within the context of the contract) and allow an entity to elect to account for

the cost of shipping and handling performed after control of a good has been transferred to the customer as a fulfillment cost (i.e., an expense). ASU 2016-10 also clarifies how an entity should evaluate the nature of its promise in granting a license of intellectual property ("IP") and requires entities to classify IP in one of two categories: functional IP or symbolic IP, which will determine whether it recognizes revenue over time or at a point in time. ASU 2016-10 also address how entities should consider license renewals and restrictions and apply the exception for sales- and usage-based royalties received in exchange for licenses of IP. In March 2016, the FASB also issued Accounting Standards Update No. 2016-08, *Revenue from Contracts with Customers (Topic 606), Principal versus Agent Considerations (Reporting Revenue Gross versus Net)* ("ASU 2016-08"), which amended the principal-versus-agent implementation guidance and illustrations in ASU 2014-09. ASU 2016-08 clarifies that an entity should evaluate when it is the principal or agent for each specified good or service promised in a contract with a customer. ASU 2016-12, ASU 2016-10, ASU 2016-08 and ASU 2014-09 may be adopted either using a full retrospective approach or a modified retrospective approach. The Company is evaluating the requirements of the foregoing standards and has not yet determined the impact of their adoption on the Company's consolidated financial position, results of operations and cash flows. The Company intends to adopt these standards using the modified retrospective approach, and the Company does not intend to early adopt these standards.

While the Company is currently evaluating the impact of the new revenue standard, the Company believes the key changes in the standard that impact revenue recognition relate to the accounting for certain transactions with multiple elements or "bundled" arrangements (for example, sales of software subscriptions for which the Company does not have VSOE for maintenance and/or support) because the requirement to have VSOE for undelivered elements under current accounting standards is eliminated under the new standard. Accordingly, the Company may be required to recognize as revenue a portion of the sales price upon delivery of the software, as compared to the current requirement of recognizing the entire sales price ratably over the maintenance period.

Note 2: Business Combinations

Acquisitions in fiscal year 2016

During fiscal year 2016, the Company completed the acquisition of two businesses for a total consideration of $72.2 million in cash. The acquired businesses were Bioo Scientific Corporation, which was acquired for total consideration of $63.5 million in cash and one other business acquired for a total consideration of $8.8 million in cash. The excess of the purchase prices over the fair values of each of the acquired businesses' net assets represents cost and revenue synergies specific to the Company, as well as non-capitalizable intangible assets, such as the employee workforce acquired. As a result of the acquisitions, the Company recorded goodwill of $45.6 million, which is not tax deductible, and intangible assets of $19.9 million. The Company has reported the operations for these acquisitions within the results of the Company's Diagnostics and Discovery & Analytical Solutions segments from the acquisition dates. Identifiable definite-lived intangible assets, such as core technology, trade names and customer relationships, acquired as part of these acquisitions had a weighted average amortization period of 9.5 years.

The total purchase price for the acquisitions in fiscal year 2016 has been allocated to the estimated fair values of assets acquired and liabilities assumed as follows:

	2016 Acquisitions (In thousands)
Fair value of business combination:	
Cash payments	$ 72,497
Working capital and other adjustments	(261)
Less: cash acquired	(2,152)
Total	$ 70,084
Identifiable assets acquired and liabilities assumed:	
Current assets	$ 7,293
Property, plant and equipment	7,542
Identifiable intangible assets:	
Core technology	5,500
Trade names	570
Customer relationships	13,800
Goodwill	45,648
Deferred taxes	(8,284)
Liabilities assumed	(1,985)
Total	$ 70,084

Subsequent to January 1, 2017, the Company completed the acquisition of Tulip Diagnostics Private Limited ("Tulip"), a company based in Goa, India, for a total consideration of $125.0 million in cash, net of cash acquired, as of the closing date. The Company has a potential obligation to pay the shareholders of Tulip additional contingent consideration of up to $25.0 million that will be accounted for as compensation expense in the Company's financial statements over a two year period. The operations for this acquisition will be reported within the results of the Company's Diagnostics segment from the acquisition date.

Acquisitions in fiscal year 2015

During fiscal year 2015, the Company completed the acquisition of five businesses for a total consideration of $77.1 million in cash. The acquired businesses included Vanadis Diagnostics AB ("Vanadis"), which was acquired for total consideration of $35.1 million in cash, as further described in Note 21 below, and other acquisitions for an aggregate consideration of $42.0 million in cash. The Company has a potential obligation to pay the shareholders of Vanadis additional contingent consideration of up to $93.0 million, which at closing had an estimated fair value of $56.9 million. The excess of the purchase prices over the fair values of each of the acquired businesses' net assets represents cost and revenue synergies specific to the Company, as well as non-capitalizable intangible assets, such as the employee workforce acquired, and has been allocated to goodwill, of which $9.2 million is tax deductible. The Company has reported the operations for all of these acquisitions within the results of the Company's Diagnostics and Discovery & Analytical Solutions segments from the acquisition dates. Identifiable definite-lived intangible assets, such as core technology and trade names, acquired as part of this acquisition had a weighted average amortization period of 9 years.

The total purchase price for the acquisitions in fiscal year 2015 has been allocated to the estimated fair values of assets acquired and liabilities assumed as follows:

	2015 Acquisitions (In thousands)
Fair value of business combination:	
Cash payments	$ 75,285
Contingent consideration	56,878
Working capital and other adjustments	1,832
Less: cash acquired	(3,864)
Total	$ 130,131
Identifiable assets acquired and liabilities assumed:	
Current assets	$ 2,551
Property, plant and equipment	998
Identifiable intangible assets:	
Core technology	15,759
Trade names	200
Licenses	116
Customer relationships	3,073
IPR&D	75,700
Goodwill	53,112
Deferred taxes	(18,528)
Liabilities assumed	(2,850)
Total	$ 130,131

Acquisitions in fiscal year 2014

Acquisition of Perten Instruments Group AB. In December 2014, the Company acquired all of the outstanding stock of Perten Instruments Group AB ("Perten"). Perten is a provider of analytical instruments and services for quality control of food, grain, flour and feed. The Company expects this acquisition to enhance its industrial, environmental and safety business by expanding the Company's product offerings to the academic and industrial end markets. The Company paid the shareholders of Perten $269.9 million in cash for the stock of Perten. The excess of the purchase price over the fair value of the acquired net assets represents cost and revenue synergies specific to the Company, as well as non-capitalizable intangible assets, such as the employee workforce acquired, and has been allocated to goodwill, none of which is tax deductible. The Company has reported the operations for this acquisition within the results of the Company's Discovery & Analytical Solutions segment from the acquisition date. Identifiable definite-lived intangible assets, such as core technology, customer relationships and trade names, acquired as part of this acquisition had weighted average amortization periods of approximately 5 to 10 years.

Other acquisitions in fiscal year 2014. In addition to the Perten acquisition, the Company completed the acquisition of two businesses in fiscal year 2014 for total consideration of $17.6 million in cash and $4.3 million of assumed debt. The excess of the purchase price over the fair value of each of the acquired businesses' net assets represents cost and revenue synergies specific to the Company, as well as non-capitalizable intangible assets, such as the employee workforce acquired, and has been allocated to goodwill, none of which is tax deductible. The Company reported the operations for these acquisitions within the results of the Discovery & Analytical Solutions and Diagnostics segments from the acquisition dates.

The total purchase price for the acquisitions in fiscal year 2014 has been allocated to the estimated fair values of assets acquired and liabilities assumed as follows:

	Perten	2014 Other Acquisitions
	(In thousands)	
Fair value of business combination:		
Cash payments	$ 269,937	$ 17,898
Working capital and other adjustments	—	(294)
Less: cash acquired	(16,732)	(124)
Total	$ 253,205	$ 17,480
Identifiable assets acquired and liabilities assumed:		
Current assets	$ 32,578	$ 1,935
Property, plant and equipment	1,485	125
Other assets	—	364
Identifiable intangible assets:		
Core technology	17,000	1,705
Trade names	8,000	—
Customer relationships	87,000	6,800
IPR&D	—	1,266
Goodwill	160,776	15,518
Deferred taxes	(28,612)	(3,072)
Deferred revenue	—	(589)
Liabilities assumed	(17,422)	(2,285)
Debt assumed	(7,600)	(4,287)
Total	$ 253,205	$ 17,480

The Company does not consider the acquisitions completed during fiscal years 2016, 2015 and 2014 to be material to its consolidated results of operations; therefore, the Company is not presenting pro forma financial information of operations. During fiscal years 2016 and 2015, the Company recognized $80.7 million and $65.7 million, respectively, of revenue for Perten. The Company has determined that the presentation of the results of operations for each of the other acquisitions, from the date of acquisition, is impracticable due to the integration of the operations upon acquisition.

As of January 1, 2017, the allocations of purchase prices for acquisitions completed in fiscal years 2015 and 2014 were final. The preliminary allocations of the purchase prices for acquisitions completed in fiscal year 2016 were based upon initial valuations. The Company's estimates and assumptions underlying the initial valuations are subject to the collection of information necessary to complete its valuations within the measurement periods, which are up to one year from the respective acquisition dates. The primary areas of the preliminary purchase price allocations that are not yet finalized relate to the fair value of certain tangible and intangible assets acquired and liabilities assumed, assets and liabilities related to income taxes and related valuation allowances, and residual goodwill. The Company expects to continue to obtain information to assist in determining the fair values of the net assets acquired at the acquisition dates during the measurement periods. During the measurement periods, the Company will adjust assets or liabilities if new information is obtained about facts and circumstances that existed as of the acquisition dates that, if known, would have resulted in the recognition of those assets and liabilities as of those dates. These adjustments will be made in the periods in which the amounts are determined and the cumulative effect of such adjustments will be calculated as if the adjustments had been completed as of the acquisition dates. All changes that do not qualify as adjustments made during the measurement periods are also included in current period earnings.

During fiscal year 2016, the Company obtained information to assist in determining the fair values of certain tangible and intangible assets acquired and liabilities assumed as part of its acquisitions and adjusted its purchase price allocations. Based on

this information, for acquisitions completed during fiscal year 2015, the Company recognized an increase in deferred taxes of $1.8 million, with a corresponding increase in goodwill.

Allocations of the purchase price for acquisitions are based on estimates of the fair value of the net assets acquired and are subject to adjustment upon finalization of the purchase price allocations. The accounting for business combinations requires estimates and judgments as to expectations for future cash flows of the acquired business, and the allocation of those cash flows to identifiable intangible assets, in determining the estimated fair values for assets acquired and liabilities assumed. The fair values assigned to tangible and intangible assets acquired and liabilities assumed, including contingent consideration, are based on management's estimates and assumptions, as well as other information compiled by management, including valuations that utilize customary valuation procedures and techniques. Contingent consideration is measured at fair value at the acquisition date, based on the probability that revenue thresholds or product development milestones will be achieved during the earnout period, with changes in the fair value after the acquisition date affecting earnings to the extent it is to be settled in cash. Increases or decreases in the fair value of contingent consideration liabilities primarily result from changes in the estimated probabilities of achieving revenue thresholds or product development milestones during the earnout period.

As of January 1, 2017, the Company may have to pay contingent consideration, related to acquisitions with open contingency periods, of up to $84.6 million. As of January 1, 2017, the Company has recorded contingent consideration obligations of $63.2 million, of which $15.4 million was recorded in accrued expenses and other current liabilities, and $47.8 million was recorded in long-term liabilities. As of January 3, 2016, the Company has recorded contingent consideration obligations of $57.4 million, of which $9.4 million was recorded in accrued expenses and other current liabilities, and $48.0 million was recorded in long-term liabilities. The expected maximum earnout period for acquisitions with open contingency periods does not exceed 3 years from the respective acquisition dates, and the remaining weighted average expected earnout period at January 1, 2017 was 1.75 years. If the actual results differ from the estimates and judgments used in these fair values, the amounts recorded in the consolidated financial statements could result in a possible impairment of the intangible assets and goodwill, require acceleration of the amortization expense of definite-lived intangible assets or the recognition of additional contingent consideration which would be recognized as a component of operating expenses from continuing operations.

In connection with the purchase price allocations for acquisitions, the Company estimates the fair value of deferred revenue assumed with its acquisitions. The estimated fair value of deferred revenue is determined by the legal performance obligation at the date of acquisition, and is generally based on the nature of the activities to be performed and the related costs to be incurred after the acquisition date. The fair value of an assumed liability related to deferred revenue is estimated based on the current market cost of fulfilling the obligation, plus a normal profit margin thereon. The estimated costs to fulfill the deferred revenue are based on the historical direct costs related to providing the services. The Company does not include any costs associated with selling effort, research and development, or the related margins on these costs. In most acquisitions, profit associated with selling effort is excluded because the acquired businesses would have concluded the selling effort on the support contracts prior to the acquisition date. The estimated research and development costs are not included in the fair value determination, as these costs are not deemed to represent a legal obligation at the time of acquisition. The sum of the costs and operating income approximates, in theory, the amount that the Company would be required to pay a third-party to assume the obligation.

Total transaction costs related to acquisition and divestiture activities for fiscal years 2016, 2015 and 2014 were $1.2 million, $0.7 million and $3.1 million, respectively. These transaction costs were expensed as incurred and recorded in selling, general and administrative expenses in the Company's consolidated statements of operations.

Note 3: Disposition of Businesses and Assets

As part of the Company's continuing efforts to focus on higher growth opportunities, the Company has discontinued certain businesses. When the discontinued operations represented a strategic shift that will have a major effect on the Company's operations and financial statements, the Company has accounted for these businesses as discontinued operations and accordingly, has presented the results of operations and related cash flows as discontinued operations. Any business deemed to be a discontinued operation prior to the adoption of ASU 2014-08, *Reporting Discontinued Operations and*

Disclosures of Disposals of Components of An Entity, continues to be reported as a discontinued operation, and the results of operations and related cash flows are presented as discontinued operations for all periods presented. Any remaining assets and liabilities of these bnsinesses have been presented separately, and are reflected within assets and liabilities from discontinued operations in the accompanying condensed consolidated balance sheets as of January 1, 2017 and January 3, 2016.

The Company recorded the following pre-tax gains and losses, which have been reported as a net gain or loss on disposition of discontinued operations during the three fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Loss on disposition of microarray-based diagnostic testing laboratory	$ —	$ —	$ (90)
Gain (loss) on disposition of Technical Services business	1,753	(28)	(156)
Loss on disposition of Flnid Sciences Segment	(1,134)	—	—
Other discontinued operations	—	—	(14)
Gain (loss) on disposition of discontinued operations before income taxes	$ 619	$ (28)	$ (260)

During fiscal year 2016, the Company sold PerkinElmer Labs, Inc. for cash consideration of $20.0 million, recognizing a pre-tax gain of $7.1 million. The sale generated a capital loss for tax purposes of $7.3 million, which resulted in an income tax benefit of $2.5 million that was recognized as a discrete benefit during the second qnarter of 2016. PerkinElmer Labs, Inc. was a component of the Company's Diagnostics segment. The pre-tax gain recognized in fiscal year 2016 is included in interest and other expense, net in the condensed consolidated statement of operations. The divestiture of PerkinElmer Labs, Inc. has not been classified as a discontinued operation in this Form 10-K because the disposition does not represent a strategic shift that will have a major effect on the Company's operations and financial statements.

During fiscal year 2016, the Company entered into a letter of intent to contribute certain assets to an academic institution in the United Kingdom. The Company recognized a pre-tax loss of $1.6 million related to the write-off of assets in the second quarter of 2016 which is included in interest and other expense, net in the condensed consolidated statement of operations.

In December 2016, the Company entered into a Master Purchase and Sale Agreement (the "Agreement") with Varian Medical Systems, Inc. (the "Purchaser"), under which the Company agreed to sell to the Purchaser all of the outstanding equity interests in the Company's wholly owned indirect subsidiaries PerkinElmer Medical Holdings, Inc. and Dexela Limited, together with certain assets of the Company and its direct and indirect subsidiaries relating to the Company's business of designing, manufacturing and marketing flat panel x-ray detectors, and related software, accessories and ancillary products, to x-ray system manufacturers (the "Medical Imaging Business"), for cash consideration of approximately $276.0 million and the Purchaser's assumption of specified liabilities relating to the Medical Imaging Business (collectively, the "Transaction"). The Medical Imaging Business had been reported in the Diagnostics segment. The Agreement contemplates that the Purchaser will finance the Transaction through a debt financing and that, except as determined otherwise by the Purchaser, the closing will occur no earlier than April 2017. However, the closing of the Transaction is not conditioned upon the receipt of any such financing. The Transaction is subject to customary closing conditions, including the expiration of specified antitrust waiting periods. The Agreement contains certain termination rights of the Company and the Purchaser and provides that under specified circumstances, upon termination of the Agreement, the Purchaser will be required to pay the Company a termination fee of up to $22.1 million. The pending sale of the Medical Imaging Business represents a strategic shift that will have a major effect on the Company's operations and financial statements. Accordingly, the Company has classified the assets and liabilities related to the Medical Imaging Business as assets and liabilities of discontinued operations in the Company's consolidated balance sheets and its results of operations are classified as income from discontinued operations in the Company's consolidated statements of operations. Financial information in this report relating to fiscal years 2015 and 2014 has been retrospectively adjusted to reflect this discontinued operation.

In May 2014, the Company approved the shutdown of microarray-based diagnostic testing laboratory in the United States, which had been reported within our Diagnostics segment. The Company determined that, with the lack of adeqnate reimbursement from health care payers, the microarray-based diagnostic testing laboratory in the United States would need

significant investment in its operations to reduce costs in order to effectively compete in the market. The shutdown of the microarray-based diagnostic testing laboratory in the United States resulted in a $0.1 million net pre-tax gain primarily related to the disposal of fixed assets, which was partially offset by the sale of a building in fiscal year 2014.

In August 1999, the Company sold the assets of its Technical Service business. The Company recorded pre-tax gain (losses) of $1.8 million in fiscal year 2016, $(0.03) million in fiscal year 2015 and $(0.2) million in fiscal year 2014 for a contingency related to this business. These gain (losses) were recognized as a gain (loss) on disposition of discontinued operations before income taxes.

The summary pre-tax operating results of the discontinued operations, which include the periods prior to disposition and a $1.0 million pre-tax restructuring charge related to workforce reductions in the microarray-based diagnostic testing laboratory in the United States during fiscal year 2014, were as follows during the three fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Revenue	$ 146,217	$ 158,128	$ 168,124
Cost of revenue	95,395	97,777	100,512
Selling, general and administrative expenses	13,657	11,712	12,503
Research and development expenses	14,368	13,391	13,222
Restructuring and contract termination charges, net	568	43	1,111
Income from discontinued operations before income taxes	$ 22,229	$ 35,205	$ 40,776

The Company recorded a tax provision of $4.3 million, $11.5 million and $12.9 million on discontinued operations and dispositions in fiscal years 2016, 2015 and 2014, respectively.

The carrying amounts of the major classes of assets and liabilities included in discontinued operations as of January 1, 2017 and January 3, 2016 consisted of the following:

	January 1, 2017	January 3, 2016
	(In thousands)	
Current assets of discontinued operations:		
Accounts receivables	$ 28,400	$ 23,951
Inventories	26,977	28,542
Prepaid income taxes	425	68
Other current assets	3,183	3,771
Total current assets of discontinued operations	58,985	56,332
Property, plant and equipment	25,219	29,465
Intangible assets	3,292	5,174
Goodwill	38,794	39,286
Other assets, net	1,084	1,104
Long-term assets of discontinued operations	68,389	75,029
Total assets of discontinned operations	$ 127,374	$ 131,361
Current liabilities of discontinued operations:		
Accounts payable	$ 16,770	$ 11,746
Accrued restructuring and contract termination charges	209	48
Accrued expenses and other current liabilities	9,992	8,212
Total current liabilities of discontinued operations	26,971	20,006
Deferred income taxes	7,851	9,460
Long-term liabilities	7,109	7,657
Total long-term liabilities	14,960	17,117
Total liabilities of discontinued operations	$ 41,931	$ 37,123

The following operating and investing non-cash items from discontinued operations were as follows during the three fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Depreciation	$ 4,418	$ 4,705	$ 4,678
Amortization	1,848	1,938	1,932
Capital expenditures	1,302	1,414	2,133

Note 4: Restructuring and Contract Termination Charges, Net

The Company has undertaken a series of restructuring actions related to the impact of acquisitions and divestitures, the alignment of the Company's operations with its growth strategy, the integration of its business units and its productivity initiatives. The current portion of restructuring and contract termination charges is recorded in accrued restructuring and contract termination charges and the long-term portion of restructuring and contract termination charges is recorded in long-term liabilities. The activities associated with these plans have been reported as restructuring and contract termination charges, net, as applicable, and are included as a component of income from continuing operations.

The Company implemented a restructuring plan in the third quarter of fiscal year 2016 consisting of workforce reductions principally intended to focus resources on higher growth product lines (the "Q3 2016 Plan"). The Company implemented a restructuring plan in the second quarter of fiscal year 2016 consisting of workforce reductions principally intended to focus resources on higher growth end markets (the "Q2 2016 Plan"). The Company implemented restructuring plans in the fourth quarter of fiscal year 2015 and the second and first quarters of fiscal year 2014 consisting of workforce reductions and the

closure of excess facility space principally intended to focus resources on higher growth end markets (the "Q4 2015 Plan", "Q2 2014 Plan", and "Q1 2014 Plan", respectively). The Company implemented restructuring plans in the second quarter of fiscal year 2015 and the third quarter of fiscal year 2014 consisting of workforce reductions principally intended to realign resources to emphasize growth initiatives (the "Q2 2015 Plan" and "Q3 2014 Plan", respectively). All other previous restructuring plans were workforce reductions or the closure of excess facility space principally intended to integrate the Company's businesses in order to realign operations, reduce costs, achieve operational efficiencies and shift resources into geographic regions and end markets that are more consistent with the Company's growth strategy (the "Previous Plans").

The following table summarizes the number of employees reduced, the initial restructuring or contract termination charges by operating segment, and the dates by which payments were substantially completed, or the expected dates by which payments will be substantially completed, for restructuring actions implemented during fiscal years 2016, 2015 and 2014 in continuing operations:

	Workforce Reductions			Closure of Excess Facility			(Expected) Date Payments Substantially Completed	
	Headcount Reduction	Diagnostics	Discovery & Analytical Solutions	Diagnostics	Discovery & Analytical Solutions	Total	Severance	Excess Facility
	(In thousands, except headcount data)							
Q3 2016 Plan	22	$ 41	$ 1,779	$ —	$ —	$ 1,820	Q4 FY2017	—
Q2 2016 Plan	72	561	4,106	—	—	4,667	Q3 FY2017	—
Q4 2015 Plan	174	1,315	9,980	—	285	11,580	Q1 FY2017	Q4 FY2017
Q2 2015 Plan	95	673	5,290	—	—	5,963	Q2 FY2016	—
Q3 2014 Plan	152	2,885	10,166	—	—	13,051	Q4 FY2015	—
Q2 2014 Plan	21	235	435	—	—	670	Q2 FY2015	
Q1 2014 Plan	17	281	286	—	—	567	Q4 FY2014	—

The Company expects to make payments under the Previous Plans for remaining residual lease obligations, with terms varying in length, through fiscal year 2022.

The Company also has terminated various contractual commitments in connection with certain disposal activities and has recorded charges, to the extent applicable, for the costs of terminating these contracts before the end of their terms and the costs that will continue to be incurred for the remaining terms without economic benefit to the Company. The Company recorded additional pre-tax charges of $0.1 million, $0.1 million and $1.5 million in the Discovery & Analytical Solutions segment during fiscal years 2016, 2015 and 2014, respectively, as a result of these contract terminations.

At January 1, 2017, the Company had $10.5 million recorded for accrued restructuring and contract termination charges, of which $7.5 million was recorded in short-term accrued restructuring and $3.1 million was recorded in long-term liabilities. At January 3, 2016, the Company had $22.2 million recorded for accrued restructuring and contract termination charges, of which $17.0 million was recorded in short-term accrued restructuring and $5.1 million was recorded in long-term liabilities. The following table summarizes the Company's restructuring accrual balances and related activity by restructuring plan, as well as contract termination accrual balances and related activity, during fiscal years 2016, 2015 and 2014 in continuing operations:

	Balance at December 29, 2013	2014 Charges and Changes in Estimates, Net	2014 Amounts Paid	Balance at December 28, 2014	2015 Charges and Changes in Estimates, Net	2015 Amounts Paid	Balance at January 3, 2016	2016 Charges and Changes in Estimates, Net	2016 Amounts Paid	Balance at January 1, 2017
					(In thousands)					
Severance:										
Q3 2016 Plan	—	$ —	$ —	$ —	$ —	$ —	$ —	$ 1,820	$ (612)	$ 1,208
Q2 2016 Plan	—	—	—	—	—	—	—	4,667	(3,231)	1,436
Q4 2015 Plan[1]	—	—	—	—	11,295	(925)	10,370	(953)	(8,198)	1,219
Q2 2015 Plan[2]	—	—	—	—	5,423	(4,322)	1,101	(533)	(370)	198
Q3 2014 Plan	—	13,051	(2,992)	10,059	(3,064)	(5,460)	1,535	—	(672)	863
Q2 2014 Plan	—	670	(419)	251	(179)	(13)	59	—	—	59
Q1 2014 Plan	—	567	(475)	92	(92)	—	—	—	—	—
Facility:										
Q4 2015 Plan	—	—	—	—	285	(26)	259	—	(248)	11
Previous Plans including 2013 plans	35,200	(2,508)	(19,572)	13,120	(204)	(4,222)	8,694	35	(3,299)	5,430
Restructuring	35,200	11,780	(23,458)	23,522	13,464	(14,968)	22,018	5,036	(16,630)	10,424
Contract Termination	300	1,545	(1,541)	304	83	(255)	132	88	(103)	117
Total Restructuring and Contract Termination	$ 35,500	$ 13,325	$ (24,999)	$ 23,826	$ 13,547	$ (15,223)	$ 22,150	$ 5,124	$ (16,733)	$ 10,541

(1) During fiscal year 2016, the Company recognized pre-tax restructuring reversals of $1.0 million in the Discovery & Analytical Solutions segment related to lower than expected costs associated with workforce reductions for the Q4 2015 Plan.

(2) During fiscal year 2016, the Company recognized pre-tax restructuring reversals of $0.1 million in the Diagnostics segments and $0.5 million in the Discovery & Analytical Solutions segments related to lower than expected costs associated with workforce reductions for the Q2 2015 Plan.

Note 5: Interest and Other Expense, Net

Interest and other expense, net, consisted of the following for the fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Interest income	$ (702)	$ (673)	$ (667)
Interest expense	41,528	37,997	36,270
Gain on disposition of businesses and assets (see Note 3)	(5,562)	—	—
Other expense, net	3,734	4,795	5,536
Total interest and other expense, net	$ 38,998	$ 42,119	$ 41,139

Foreign currency transaction (gains) losses were $(1.5) million, $25.3 million and $5.5 million in fiscal years 2016, 2015 and 2014, respectively. Net losses (gains) from forward currency hedge contracts were $5.4 million, $(20.6) million and $(0.2) million in fiscal years 2016, 2015 and 2014, respectively. These amounts were included in other expense, net.

Note 6: Income Taxes

The Company regularly reviews its tax positions in each significant taxing jurisdiction in the process of evaluating its unrecognized tax benefits. The Company makes adjustments to its unrecognized tax benefits when: (i) facts and circumstances regarding a tax position change, causing a change in management's judgment regarding that tax position; (ii) a tax position is effectively settled with a tax authority at a differing amount; and/or (iii) the statute of limitations expires regarding a tax position.

The tabular reconciliation of the total amounts of unrecognized tax benefits is as follows for the fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Unrecognized tax benefits, beginning of year	$ 28,143	$ 32,342	$ 39,410
Gross increases—tax positions in prior periods	1,514	325	—
Gross decreases—tax positions in prior periods	(183)	(2,305)	(1,809)
Gross increases—current-period tax positions	3,547	—	239
Settlements	—	(441)	(1,400)
Lapse of statute of limitations	(4,109)	(1,077)	(4,129)
Foreign currency translation adjustments	695	(701)	31
Unrecognized tax benefits, end of year	$ 29,607	$ 28,143	$ 32,342

The Company classifies interest and penalties as a component of income tax expense. At January 1, 2017, the Company had accrued interest and penalties of $1.8 million and $0.4 million, respectively. At January 3, 2016, the Company had accrued interest and penalties of $2.1 million and $0.1 million, respectively. During fiscal year 2016, the Company recognized a net benefit of $0.4 million for interest and an expense of $0.3 million for penalties in its total tax provision primarily due to settlements and statutes of limitations that had lapsed. During fiscal year 2015, the Company recognized net benefits of $1.5 million for interest and $0.1 million for penalties in its total tax provision primarily due to settlements and statutes of limitations that had lapsed. During fiscal year 2014, the Company recognized benefits of $0.7 million for interest and $0.2 million for penalties in its total tax provision due to settlements and statutes of limitations that had lapsed. At January 1, 2017, the Company had gross tax effected unrecognized tax benefits of $29.6 million, of which $27.9 million, if recognized, would affect the continuing operations effective tax rate. The remaining amount, if recognized, would affect discontinued operations.

The Company believes that it is reasonably possible that approximately $4.6 million of its uncertain tax positions at January 1, 2017, including accrued interest and penalties, and net of tax benefits, may be resolved over the next twelve months as a result of lapses in applicable statutes of limitations and potential settlements. Various tax years after 2010 remain open to examination by certain jurisdictions in which the Company has significant business operations, such as Finland, Germany, Italy, Netherlands, Singapore, the United Kingdom and the United States. The tax years under examination vary by jurisdiction.

During fiscal years 2016, 2015 and 2014, the Company recorded net discrete income tax benefits of $9.6 million, $6.4 million and $7.1 million, respectively, primarily related to the recognition of excess tax benefits on stock compensation, reversals of uncertain tax position reserves, and resolution of other tax matters.

The components of income (loss) from continuing operations before income taxes were as follows for the fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
	(In thousands)		
U.S.	$ 39,689	$ (21,510)	$ (58,886)
Non-U.S.	204,379	230,317	182,754
Total	$ 244,068	$ 208,807	$ 123,868

On a U.S. income tax basis, the Company has reported significant taxable income over the three year period ended January 1, 2017. The Company has utilized tax attributes to minimize cash taxes paid on that taxable income.

The components of the provision for (benefit from) income taxes for continuing operations were as follows:

	Current Expense (Benefit)	Deferred Expense (Benefit)	Total
		(In thousands)	
Fiscal year ended January 1, 2017			
Federal	$ 14	$ 2,994	$ 3,008
State	2,143	(575)	1,568
Non-U.S.	30,754	(6,968)	23,786
Total	$ 32,911	$ (4,549)	$ 28,362
Fiscal year ended January 3, 2016			
Federal	$ (10,952)	$ (4,794)	$ (15,746)
State	2,613	(2,563)	50
Non-U.S.	37,963	(2,245)	35,718
Total	$ 29,624	$ (9,602)	$ 20,022
Fiscal year ended December 28, 2014			
Federal	$ (6,417)	$ (20,164)	$ (26,581)
State	2,373	(4,166)	(1,793)
Non-U.S.	31,878	(9,775)	22,103
Total	$ 27,834	$ (34,105)	$ (6,271)

The total provision for (benefit from) income taxes included in the consolidated financial statements is as follows for the fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Continuing operations	$ 28,362	$ 20,022	$ (6,271)
Discontinued operations	4,255	11,537	12,877
Total	$ 32,617	$ 31,559	$ 6,606

A reconciliation of income tax expense at the U.S. federal statutory income tax rate to the recorded tax provision is as follows for the fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Tax at statutory rate	$ 85,424	$ 73,082	$ 43,354
Non-U.S. rate differential, net	(52,648)	(47,994)	(34,845)
U.S. taxation of multinational operations	6,941	1,732	2,367
State income taxes, net	1,509	80	1,352
Prior year tax matters	(9,621)	(6,387)	(7,146)
Federal tax credits	(7,189)	(2,096)	(3,399)
Change in valuation allowance	(2,755)	2,593	(7,679)
Non-deductible acquisition expense	5,701	—	—
Other, net	1,000	(988)	(275)
Total	$ 28,362	$ 20,022	$ (6,271)

The variation in the Company's effective tax rate for each year is primarily a result of the recognition of earnings in foreign jurisdictions, predominantly Singapore, Finland, and China, which are taxed at rates lower than the U.S. federal statutory rate, resulting in a benefit from income taxes of $45.8 million in fiscal year 2016, $34.2 million in fiscal year 2015 and $29.1 million in fiscal year 2014. These amounts include $11.4 million in fiscal year 2016, $8.3 million in fiscal year 2015 and $7.1 million in fiscal year 2014 of benefits derived from tax holidays in China and Singapore. The effect of these benefits derived from tax holidays on basic and diluted earnings per share for fiscal year 2016 was $0.10 and $0.10, respectively, for fiscal year 2015 was $0.07 and $0.07, respectively, and for fiscal year 2014 was $0.06 and $0.06, respectively. The tax holiday in China is scheduled to expire in fiscal year 2017 and the tax holiday in Singapore is scheduled to expire in fiscal year 2018.

The tax effects of temporary differences and attributes that gave rise to deferred income tax assets and liabilities as of January 1, 2017 and January 3, 2016 were as follows:

	January 1, 2017	January 3, 2016
	(In thousands)	
Deferred tax assets:		
Inventory	$ 10,994	$ 8,231
Reserves and accruals	24,669	28,984
Accrued compensation	26,715	23,010
Net operating loss and credit carryforwards	113,415	100,336
Accrued pension	37,005	34,736
Restructuring reserve	1,954	6,362
Deferred revenue	38,113	40,065
All other, net	682	695
Total deferred tax assets	253,547	242,419
Deferred tax liabilities:		
Postretirement health benefits	(4,785)	(4,202)
Unrealized foreign exchange gain or loss	(15,730)	(782)
Depreciation and amortization	(130,176)	(128,173)
Total deferred tax liabilities	(150,691)	(133,157)
Valuation allowance	(65,640)	(67,400)
Net deferred tax assets	$ 37,216	$ 41,862

The components of net deferred tax assets as of January 1, 2017 and January 3, 2016 were recognized in the consolidated balance sheets as follows:

	January 1, 2017	January 3, 2016
	(In thousands)	
Other assets, net	$ 85,312	$ 94,035
Long-term liabilities	(48,096)	(52,173)
Total	$ 37,216	$ 41,862

At January 1, 2017, for income tax return purposes the Company had U.S. federal net operating loss carryforwards of $27.7 million, state net operating loss carryforwards of $211.9 million, foreign net operating loss carryforwards of $227.2 million, state tax credit carryforwards of $10.7 million, general business tax credit carryforwards of $33.1 million, and foreign tax credit carryforwards of $5.7 million. These are subject to expiration in years ranging from 2017 to 2035, and without expiration for certain foreign net operating loss carryforwards and certain state credit carryforwards.

Valuation allowances take into consideration limitations imposed upon the use of the tax attributes and reduce the value of such items to the likely net realizable amount. The Company regularly evaluates positive and negative evidence available to determine if valuation allowances are required or if existing valuation allowances are no longer required. Valuation allowances have been provided on state net operating loss and state tax credit carryforwards and on certain foreign tax attributes that the Company has determined are not more likely than not to be realized. The decrease in the valuation allowance in fiscal year 2016 is primarily due to a decrease in tax attributes that the Company does not expect to realize for one of its non-U.S. subsidiaries. The increase in valuation allowance of $11.9 million in fiscal year 2015 is primarily due to an increase in tax attributes that the Company does not expect to realize for two of its non-U.S. subsidiaries.

The components of net deferred tax assets (liabilities) as of January 1, 2017 and January 3, 2016 were as follows:

	January 1, 2017	January 3, 2016
	(In thousands)	
U.S.	$ 52,604	$ 63,872
Non-U.S.	(15,388)	(22,010)
Total	$ 37,216	$ 41,862

Taxes have not been provided on unremitted earnings of international subsidiaries that the Company considers indefinitely reinvested because the Company plans to keep these amounts indefinitely reinvested overseas except for instances where the Company can remit such earnings to the U.S. without an associated net tax cost. The Company's indefinite reinvestment determination is based on the future operational and capital requirements of its U.S. and non-U.S. operations. As of January 1, 2017, the amount of foreign earnings that the Company has the intent and ability to keep invested outside the U.S. indefinitely and for which no U.S. tax cost has been provided was approximately $1.1 billion. It is not practical to calculate the unrecognized deferred tax liability on those earnings.

Note 7: Earnings Per Share

Basic earnings per share was computed by dividing net income by the weighted-average number of common shares outstanding during the period less restricted unvested shares. Diluted earnings per share was computed by dividing net income by the weighted-average number of common shares outstanding plus all potentially dilutive common stock equivalents, primarily shares issuable upon the exercise of stock options using the treasury stock method. The following table reconciles the number of shares utilized in the earnings per share calculations for the fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Number of common shares—basic	109,478	112,507	112,593
Effect of dilutive securities:			
Stock options	640	621	922
Restricted stock awards	195	187	224
Number of common shares—diluted	110,313	113,315	113,739
Number of potentially dilutive securities excluded from calculation due to antidilutive impact	458	607	475

Antidilutive securities include outstanding stock options with exercise prices and average unrecognized compensation cost in excess of the average fair market value of common stock for the related period. Antidilutive options were excluded from the calculation of diluted net income per share and could become dilutive in the future.

Note 8: Accounts Receivable, Net

Accounts receivable were net of reserves for doubtful accounts of $29.2 million and $29.9 million as of January 1, 2017 and January 3, 2016, respectively.

Note 9: Inventories

Inventories as of January 1, 2017 and January 3, 2016 consisted of the following:

	January 1, 2017	January 3, 2016
	(In thousands)	
Raw materials	$ 79,189	$ 85,100
Work in progress	6,561	5,919
Finished goods	161,097	168,467
Total inventories	$ 246,847	$ 259,486

Note 10: Property, Plant and Equipment, Net

Property, plant and equipment, at cost, as of January 1, 2017 and January 3, 2016, consisted of the following:

	January 1, 2017	January 3, 2016
	(In thousands)	
Land	$ 4,250	$ 802
Building and leasehold improvements	162,780	156,035
Machinery and equipment	260,873	244,903
Total property, plant and equipment	427,903	401,740
Accumulated depreciation	(282,409)	(264,176)
Total property, plant and equipment, net	$ 145,494	$ 137,564

Depreciation expense on property, plant and equipment for the fiscal years ended January 1, 2017, January 3, 2016 and December 28, 2014 was $28.5 million, $28.7 million and $29.0 million, respectively.

Note 11: Marketable Securities and Investments

Investments as of January 1, 2017 and January 3, 2016 consisted of the following:

	January 1, 2017	January 3, 2016
	(In thousands)	
Marketable securities	$ 1,678	$ 1,586

Marketable securities include equity and fixed-income securities held to meet obligations associated with the Company's supplemental executive retirement plan and other deferred compensation plans. The Company has, accordingly, classified these securities as long-term.

The net unrealized holding gain and loss on marketable securities, net of deferred income taxes, reported as a component of other comprehensive income (loss) in the statements of stockholders' equity, were not material in fiscal years 2016 and 2015. The proceeds from the sales of securities and the related gains and losses are not material for any period presented.

Marketable securities classified as available for sale as of January 1, 2017 and January 3, 2016 consisted of the following:

	Market Value	Gross Unrealized Holding		
		Cost	Gains	(Losses)
		(In thousands)		
January 1, 2017				
Equity securities	$ 598	$ 1,077	$ —	$ (479)
Fixed-income securities	22	22	—	—
Other	1,058	1,121	—	(63)
	$ 1,678	$ 2,220	$ —	$ (542)
January 3, 2016				
Equity securities	$ 908	$ 1,299	$ —	$ (391)
Fixed-income securities	57	57	—	—
Other	621	822	—	(201)
	$ 1,586	$ 2,178	$ —	$ (592)

Note 12: Goodwill and Intangible Assets, Net

The Company tests goodwill and non-amortizing intangible assets at least annually for possible impairment. Accordingly, the Company completes the annual testing of impairment for goodwill and non-amortizing intangible assets on the later of January 1 or the first day of each fiscal year. In addition to its annual test, the Company regularly evaluates whether events or circumstances have occurred that may indicate a potential impairment of goodwill or non-amortizing intangible assets.

The process of testing goodwill for impairment involves the determination of the fair value of the applicable reporting units. The test consists of a two-step process. The first step is the comparison of the fair value to the carrying value of the reporting unit to determine if the carrying value exceeds the fair value. The second step measures the amount of an impairment loss, and is only performed if the carrying value exceeds the fair value of the reporting unit. The Company performed its annual impairment testing for its reporting units as of January 4, 2016, its annual impairment date for fiscal year 2016. The Company concluded based on the first step of the process that there was no goodwill impairment, and the fair value exceeded the carrying value by more than 20.0% for each reporting unit. The long-term terminal growth rate for the Company's reporting units was 3.0% for the fiscal year 2016 impairment analysis. The range for the discount rates for the reporting units was 10.5% to 13.2%. Keeping all other variables constant, a 10.0% change in any one of the input assumptions for the various reporting units would still allow the Company to conclude, based on the first step of the process, that there was no impairment of goodwill.

The Company has consistently employed the income approach to estimate the current fair value when testing for impairment of goodwill. A number of significant assumptions and estimates are involved in the application of the income approach to forecast operating cash flows, including markets and market share, sales volumes and prices, costs to produce, tax rates, capital spending, discount rates and working capital changes. Cash flow forecasts are based on approved business unit operating plans for the early years' cash flows and historical relationships in later years. The income approach is sensitive to changes in long-term terminal growth rates and the discount rates. The long-term terminal growth rates are consistent with the Company's historical long-term terminal growth rates, as the current economic trends are not expected to affect the long-term terminal growth rates of the Company. The Company corroborates the income approach with a market approach.

As discussed in Note 23, the Company realigned its organization into two new operating segments at the beginning of the fourth quarter of fiscal year 2016. In conjunction with the realignment of its operating segments, the Company also redefined its reporting units based on the new operating segments. Financial information in this report relating to fiscal years 2015 and 2014 has been retrospectively adjusted to reflect the changes in the Company's operating segments. The Company's segment management reviews the results of the operations one level below its operating segments. The Company has determined that the reporting units that should be used to test goodwill for impairment are environmental health excluding food, food, life

sciences and technology, informatics, OneSource, diagnostics excluding cord blood, cord blood and medical imaging. The income approach, specifically the discounted cash flow model, was used to determine the fair values of each of the reporting units in order to allocate goodwill on a relative fair value basis. As a result of the realignment, the Company reallocated goodwill of $125.8 million from its life sciences and technology reporting unit to the diagnostics excluding cord blood reporting unit based on the relative fair value, determined using the income approach, of the applied genomics business as of October 3, 2016.

As of January 2, 2017, the Company's Informatics reporting unit, which had a goodwill balance of $211.0 million, had a fair value that was less than 20% but greater than 10% more than its carrying value. Informatics is at increased risk of an impairment charge given its ongoing weakness due to a highly competitive industry. Despite the increased risk associated with this reporting unit, the Company does not believe there will be a significant change in the key estimates or assumptions driving the fair value of this reporting unit that would lead to a material impairment charge.

The Company has consistently employed the relief from royalty model to estimate the current fair value when testing for impairment of non-amortizing intangible assets. The impairment test consists of a comparison of the fair value of the non-amortizing intangible asset with its carrying amount. If the carrying amount of a non-amortizing intangible asset exceeds its fair value, an impairment loss in an amount equal to that excess is recognized. In addition, the Company evaluates the remaining useful lives of its non-amortizing intangible assets at least annually to determine whether events or circumstances continue to support an indefinite useful life. If events or circumstances indicate that the useful lives of non-amortizing intangible assets are no longer indefinite, the assets will be tested for impairment. These intangible assets will then be amortized prospectively over their estimated remaining useful lives and accounted for in the same manner as other intangible assets that are subject to amortization. The Company performed its annual impairment testing as of January 4, 2016, and concluded that there was no impairment of non-amortizing intangible assets. An assessment of the recoverability of amortizing intangible assets takes place when events have occurred that may give rise to an impairment. No such events occurred during the fiscal year 2016.

The changes in the carrying amount of goodwill for fiscal years 2016 and 2015 are as follows:

	Diagnostics	Discovery & Analytical Solutions	Consolidated
		(In thousands)	
Balance at December 28, 2014	$ 922,582	$ 1,321,547	$ 2,244,129
Foreign currency translation	(15,939)	(38,778)	(54,717)
Acquisitions, earnouts and other	33,496	13,955	47,451
Balance at January 3, 2016	940,139	1,296,724	2,236,863
Foreign currency translation	(11,873)	(16,602)	(28,475)
Acquisitions, earnouts and other	15,764	23,814	39,578
Balance at January 1, 2017	$ 944,030	$ 1,303,936	$ 2,247,966

Identifiable intangible asset balances at January 1, 2017 by category and by business segment were as follows:

	Diagnostics	Discovery & Analytical Solutions	Consolidated
		(In thousands)	
Patents	$ 11,900	$ 28,001	$ 39,901
Less: Accumulated amortization	(9,556)	(22,852)	(32,408)
Net patents	2,344	5,149	7,493
Trade names and trademarks	11,523	28,563	40,086
Less: Accumulated amortization	(8,090)	(15,927)	(24,017)
Net trade names and trademarks	3,433	12,636	16,069
Licenses	7,936	49,831	57,767
Less: Accumulated amortization	(7,762)	(38,745)	(46,507)
Net licenses	174	11,086	11,260
Core technology	70,896	233,291	304,187
Less: Accumulated amortization	(49,380)	(184,340)	(233,720)
Net core technology	21,516	48,951	70,467
Customer relationships	123,884	259,419	383,303
Less: Accumulated amortization	(93,720)	(119,342)	(213,062)
Net customer relationships	30,164	140,077	170,241
IPR&D	72,946	5,569	78,515
Less: Accumulated amortization	(960)	(3,445)	(4,405)
Net IPR&D	71,986	2,124	74,110
Net amortizable intangible assets	129,617	220,023	349,640
Non-amortizable intangible assets:			
Trade name	—	70,584	70,584
Total	$ 129,617	$ 290,607	$ 420,224

Identifiable intangible asset balances at January 3, 2016 by category and business segment were as follows:

	Diagnostics	Discovery & Analytical Solutions	Consolidated
		(In thousands)	
Patents	$ 11,900	$ 28,011	$ 39,911
Less: Accumulated amortization	(8,475)	(21,313)	(29,788)
Net patents	3,425	6,698	10,123
Trade names and trademarks	11,503	28,746	40,249
Less: Accumulated amortization	(7,002)	(13,684)	(20,686)
Net trade names and trademarks	4,501	15,062	19,563
Licenses	7,939	48,226	56,165
Less: Accumulated amortization	(6,942)	(36,029)	(42,971)
Net licenses	997	12,197	13,194
Core technology	71,821	231,004	302,825
Less: Accumulated amortization	(43,182)	(166,471)	(209,653)
Net core technology	28,639	64,533	93,172
Customer relationships	128,604	256,921	385,525
Less: Accumulated amortization	(94,222)	(93,836)	(188,058)
Net customer relationships	34,382	163,085	197,467
IPR&D	78,479	7,200	85,679
Less: Accumulated amortization	(756)	(3,389)	(4,145)
Net IPR&D	77,723	3,811	81,534
Net amortizable intangible assets	149,667	265,386	415,053
Non-amortizable intangible assets:			
Trade name	—	70,584	70,584
Total	$ 149,667	$ 335,970	$ 485,637

Total amortization expense related to definite-lived intangible assets was $71.5 million in fiscal year 2016, $76.6 million in fiscal year 2015 and $81.4 million in fiscal year 2014. Estimated amortization expense related to definite-lived intangible assets for each of the next five years is $63.1 million in fiscal year 2017, $61.2 million in fiscal year 2018, $49.8 million in fiscal year 2019, $41.1 million in fiscal year 2020, and $28.7 million in fiscal year 2021.

The Company entered into a strategic agreement in fiscal year 2012 under which it acquired certain intangible assets and received a license to certain core technology for an analytics and data discovery platform, as well as the exclusive right to distribute the platform in certain scientific research and development markets. During fiscal year 2012, the Company paid $6.8 million for net intangible assets and $25.0 million for prepaid royalties. During fiscal year 2013, the Company extended the existing agreement for an additional year. In addition, the Company entered into a new agreement to expand the distribution rights to the clinical and other related markets and acquired additional intangible assets. During fiscal year 2013, the Company paid $7.0 million for net intangible assets and $40.3 million for prepaid royalties. During fiscal year 2016, the Company extended the existing agreement for an additional 3 years and expanded the distribution rights to the related markets. During fiscal year 2016, the Company paid $6.0 million for prepaid royalties related to the extension and new agreement. During the fiscal years 2016 and 2015, the Company paid $9.4 million and $9.8 million, respectively, for additional prepaid royalties. The prepaid royalties have been recorded primarily as other long-term assets. The Company expects to pay $7.5 million of additional prepaid royalties within the next twelve months. The Company expenses royalties as revenue is recognized. These intangible assets are being amortized over their estimated useful lives. The Company has reported the amortization of these intangible assets within the results of the Company's Discovery & Analytical Solutions segment from the execution date.

Note 13: Debt

Senior Unsecured Revolving Credit Facility. On August 11, 2016, the Company terminated its previous senior unsecured revolving credit facility and entered into a new senior unsecured revolving credit facility with a five year term and an expansion of borrowing capacity from $700.0 million to $1.0 billion. The new senior unsecured revolving credit facility provides for $1.0 billion of revolving loans and has an initial maturity of August 11, 2021. As of January 1, 2017, undrawn letters of credit in the aggregate amount of $11.4 million were treated as issued and outstanding when calculating the borrowing availability under the new senior unsecured revolving credit facility. As of January 1, 2017, the Company had $988.6 million available for additional borrowing under the facility. The Company uses the new senior unsecured revolving credit facility for general corporate purposes, which may include working capital, refinancing existing indebtedness, capital expenditures, share repurchases, acquisitions and strategic alliances. The interest rates under the senior unsecured revolving credit facility are based on the Eurocurrency rate or the base rate at the time of borrowing, plus a margin. The base rate is the higher of (i) the rate of interest in effect for such day as publicly announced from time to time by JP Morgan Chase Bank, N.A. as its "prime rate," (ii) the Federal Funds rate plus 50 basis points or (iii) an adjusted one-month Libor plus 1.00%. As of January 1, 2017, the new senior unsecured revolving credit facility had no outstanding borrowings, and $4.3 million of unamortized debt issuance costs. As of January 3, 2016, the previous senior unsecured revolving credit facility had an aggregate carrying value of $479.6 million, which was net of $2.4 million of unamortized debt issuance costs. The credit agreement for the facility contains affirmative, negative and financial covenants and events of default. The financial covenants include a debt-to-capital ratio that remains applicable for so long as the Company's debt is rated as investment grade. In the event that the Company's debt is not rated as investment grade, the debt-to-capital ratio covenant is replaced with a maximum consolidated leverage ratio covenant and a minimum consolidated interest coverage ratio covenant.

5% Senior Unsecured Notes due in 2021. On October 25, 2011, the Company issued $500.0 million aggregate principal amount of senior unsecured notes due in 2021 (the "2021 Notes") in a registered public offering and received $496.9 million of net proceeds from the issuance. The 2021 Notes were issued at 99.372% of the principal amount, which resulted in a discount of $3.1 million. As of January 1, 2017, the 2021 Notes had an aggregate carrying value of $495.8 million, net of $1.7 million of unamortized original issue discount and $2.5 million of unamortized debt issuance costs. As of January 3, 2016, the 2021 Notes had an aggregate carrying value of $495.1 million, net of $2.0 million of unamortized original issue discount and $2.9 million of unamortized debt issuance costs. The 2021 Notes mature in November 2021 and bear interest at an annual rate of 5%. Interest on the 2021 Notes is payable semi-annually on May 15th and November 15th each year. Prior to August 15, 2021 (three months prior to their maturity date), the Company may redeem the 2021 Notes in whole or in part, at its option, at a redemption price equal to the greater of (i) 100% of the principal amount of the 2021 Notes to be redeemed, plus accrued and unpaid interest, or (ii) the sum of the present values of the remaining scheduled payments of principal and interest in respect to the 2021 Notes being redeemed, discounted on a semi-annual basis, at the Treasury Rate plus 45 basis points, plus accrued and unpaid interest. At any time on or after August 15, 2021 (three months prior to their maturity date), the Company may redeem the 2021 Notes, at its option, at a redemption price equal to 100% of the principal amount of the 2021 Notes to be redeemed plus accrued and unpaid interest. Upon a change of control (as defined in the indenture governing the 2021 Notes) and a contemporaneous downgrade of the 2021 Notes below investment grade, each holder of 2021 Notes will have the right to require the Company to repurchase such holder's 2021 Notes for 101% of their principal amount, plus accrued and unpaid interest.

1.875% Senior Unsecured Notes due 2026. On July 19, 2016, the Company issued €500.0 million aggregate principal amount of senior unsecured notes due in 2026 (the "2026 Notes") in a registered public offering and received approximately €492.3 million of net proceeds from the issuance. The 2026 Notes were issued at 99.118% of the principal amount, which resulted in a discount of €4.4 million. The 2026 Notes mature in July 2026 and bear interest at an annual rate of 1.875%. Interest on the 2026 Notes is payable annually on July 19th each year. The proceeds from the 2026 Notes were used to pay in full the outstanding balance of the Company's previons senior unsecured revolving credit facility. As of January 1, 2017, the 2026 Notes had an aggregate carrying value of $517.8 million, net of $4.5 million of unamortized original issue discount and $4.8 million of unamortized debt issuance costs.

Prior to April 19, 2026 (three months prior to their maturity date), the Company may redeem the 2026 Notes in whole at any time or in part from time to time, at its option, at a redemption price equal to the greater of (i) 100% of the principal amount of the 2026 Notes to be redeemed, or (ii) the sum of the present values of the remaining scheduled payments of principal and interest in respect to the 2026 Notes being redeemed, discounted on an annual basis, at the applicable Comparable Government Bond Rate (as defined in the indenture governing the 2026 Notes) plus 35 basis points; plus, in each case, accrued and unpaid interest. In addition, at any time on or after April 19, 2026 (three months prior to their maturity date), the Company may redeem the 2026 Notes, at its option, at a redemption price equal to 100% of the principal amount of the 2026 Notes due to be redeemed plus accrued and unpaid interest.

Upon a change of control (as defined in the indenture governing the 2026 Notes) and a contemporaneous downgrade of the 2026 Notes below investment grade, the Company will, in certain circumstances, make an offer to purchase the 2026 Notes at a price equal to 101% of their principal amount plus any accrued and unpaid interest.

Financing Lease Obligations. In fiscal year 2012, the Company entered into agreements with the lessors of certain buildings that the Company is currently occupying and leasing to expand those buildings. The Company provided a portion of the funds needed for the construction of the additions to the buildings, and as a result the Company was considered the owner of the buildings during the construction period. At the end of the construction period, the Company was not reimbursed by the lessors for all of the construction costs. The Company is therefore deemed to have continuing involvement and the leases qualify as financing leases under sale-leaseback accounting guidance, representing debt obligations for the Company and non-cash investing and financing activities. As a result, the Company capitalized $29.3 million in property, plant and equipment, net, representing the fair value of the buildings with a corresponding increase to debt. The Company has also capitalized $11.5 million in additional construction costs necessary to complete the renovations to the buildings, which were funded by the lessors, with a corresponding increase to debt. At January 1, 2017, the Company had $37.1 million recorded for these financing lease obligations, of which $1.2 million was recorded as short-term debt and $35.9 million was recorded as long-term debt. At January 3, 2016, the Company had $38.2 million recorded for these financing lease obligations, of which $1.1 million was recorded as short-term debt and $37.1 million was recorded as long-term debt. The buildings are being depreciated on a straight-line basis over the terms of the leases to their estimated residual values, which will equal the remaining financing obligation at the end of the lease term. At the end of the lease term, the remaining balances in property, plant and equipment, net and debt will be reversed against each other.

The following table summarizes the maturities of the Company's indebtedness as of January 1, 2017:

	Sr. Unsecured Revolving Credit Facility Maturing 2021	5.0% Sr. Notes Maturing 2021	1.875% Sr. Notes Maturing 2026	Financing Lease Obligations	Total
			(In thousands)		
2017	$ —	$ —	$ —	$ 1,172	$ 1,172
2018	—	—	—	1,367	1,367
2019	—	—	—	1,532	1,532
2020	—	—	—	1,597	1,597
2021	—	500,000	—	1,664	501,664
2022 and thereafter	—	—	527,050	29,742	556,792
Total before unamortized discount and debt issuance costs	—	500,000	527,050	37,074	1,064,124
Unamortized discount and debt issuance costs	(4,260)	(4,167)	(9,271)	—	(17,698)
Total	$ (4,260)	$ 495,833	$ 517,779	$ 37,074	$ 1,046,426

Note 14: Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of January 1, 2017 and January 3, 2016 consisted of the following:

	January 1, 2017	January 3, 2016
	(In thousands)	
Payroll and incentives	$ 61,474	$ 61,319
Employee benefits	31,039	31,979
Deferred revenue	162,987	163,006
Federal, non-U.S. and state income taxes	8,189	2,882
Other accrued operating expenses	136,011	123,148
Total accrued expenses and other current liabilities	$ 399,700	$ 382,334

Note 15: Employee Benefit Plans

Savings Plan: The Company has a 401(k) Savings Plan for the benefit of all qualified U.S. employees, with such employees receiving matching contributions in the amount equal to 100.0% of the first 5.0% of eligible compensation up to applicable Internal Revenue Service limits. Savings plan expense was $12.8 million in fiscal years 2016 and 2015, and $12.2 million in fiscal year 2014.

Pension Plans: The Company has a defined benefit pension plan covering certain U.S. employees and non-U.S. pension plans for certain non-U.S. employees. The principal U.S. defined benefit pension plan was closed to new hires effective January 31, 2001, and benefits for those employed by the Company's former Life Sciences business were frozen as of that date. Plan benefits were frozen as of March 2003 for those employed by the Company's former Analytical Instruments business and corporate employees. Plan benefits were frozen as of January 31, 2011 for all remaining employees that were still actively accruing in the plan. The plans provide benefits that are based on an employee's years of service and compensation near retirement.

Net periodic pension cost for U.S. and non-U.S. plans included the following components for fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Service cost	$ 4,337	$ 4,332	$ 4,070
Interest cost	18,638	20,696	23,475
Expected return on plan assets	(24,245)	(26,021)	(25,007)
Curtailment gain	—	(907)	—
Actuarial loss	15,890	12,953	71,700
Amortization of prior service cost	(210)	(238)	(281)
Net periodic pension cost	$ 14,410	$ 10,815	$ 73,957

During fiscal year 2014, the Company notified certain employees of its intention to terminate their employment as part of the Q3 2014 restructuring plan. During fiscal year 2015, the termination of these participants decreased the expected future service lives in excess of the curtailment limit for one of the Company's pension plans, which resulted in a curtailment gain. The Company recorded the curtailment gain of $0.8 million during fiscal year 2015. As part of the curtailment, the Company remeasured the assets and liabilities of the plan that had the curtailment based upon current discount rates and the fair value of the pension plan's assets as of the curtailment date, which resulted in an actuarial loss of $0.8 million.

The following table sets forth the changes in the funded status of the principal U.S. pension plan and the principal non-U.S. pension plans and the amounts recognized in the Company's consolidated balance sheets as of January 1, 2017 and January 3, 2016.

	January 1, 2017		January 3, 2016	
	Non-U.S.	U.S.	Non-U.S.	U.S.
	(In thousands)			
Actuarial present value of benefit obligations:				
Accumulated benefit obligations	$ 271,127	$ 300,650	$ 267,862	$ 301,416
Change in benefit obligations:				
Projected benefit obligations at beginning of year	$ 276,960	$ 301,416	$ 303,809	$ 327,632
Service cost	2,262	2,075	2,532	1,800
Interest cost	6,205	12,433	7,695	13,001
Benefits paid and plan expenses	(11,940)	(19,424)	(11,100)	(24,127)
Participants' contributions	209	—	343	—
Business divestiture	(2,955)	—	—	—
Plan curtailments	—	—	(759)	—
Plan settlements	(993)	—	(1,401)	—
Actuarial loss (gain)	38,623	4,150	131	(16,890)
Effect of exchange rate changes	(28,849)	—	(24,290)	—
Projected benefit obligations at end of year	$ 279,522	$ 300,650	$ 276,960	$ 301,416
Change in plan assets:				
Fair value of plan assets at beginning of year	$ 150,894	$ 244,693	$ 156,767	$ 256,254
Actual return on plan assets	32,581	18,548	3,745	(7,434)
Benefits paid and plan expenses	(11,940)	(19,424)	(11,100)	(24,127)
Employer's contributions	9,562	—	10,908	20,000
Participants' contributions	209	—	343	—
Plan settlements	(993)	—	(1,401)	—
Effect of exchange rate changes	(27,032)	—	(8,368)	—
Fair value of plan assets at end of year	153,281	243,817	150,894	244,693
Net liabilities recognized in the consolidated balance sheets	$ (126,241)	$ (56,833)	$ (126,066)	$ (56,723)
Net amounts recognized in the consolidated balance sheets consist of:				
Noncurrent assets	$ 12,944	$ —	$ 12,135	$ —
Current liabilities	(6,033)	—	(6,261)	—
Noncurrent liabilities	(133,152)	(56,833)	(131,940)	(56,723)
Net liabilities recognized in the consolidated balance sheets	$ (126,241)	$ (56,833)	$ (126,066)	$ (56,723)
Net amounts recognized in accumulated other comprehensive income consist of:				
Prior service cost	$ (603)	$ —	$ (932)	$ —
Actuarial assumptions as of the year-end measurement date:				
Discount rate	2.06%	4.06%	2.88%	4.25%
Rate of compensation increase	3.64%	None	3.26%	None

Actuarial assumptions used to determine net periodic pension cost during the year were as follows:

	January 1, 2017		January 3, 2016		December 28, 2014	
	Non-U.S.	U.S.	Non-U.S.	U.S.	Non-U.S.	U.S.
Discount rate	2.88%	4.25%	2.75%	4.08%	3.77%	4.77%
Rate of compensation increase	3.26%	None	3.28%	None	3.23%	None
Expected rate of return on assets	5.30%	7.25%	4.60%	7.25%	5.30%	7.25%

The following table provides a breakdown of the non-U.S. benefit obligations and fair value of assets for pension plans that have benefit obligations in excess of plan assets:

	January 1, 2017	January 3, 2016
	(In thousands)	
Pension Plans with Projected Benefit Obligations in Excess of Plan Assets		
Projected benefit obligations	$ 139,185	$ 138,201
Fair value of plan assets	—	—
Pension Plans with Accumulated Benefit Obligations in Excess of Plan Assets		
Accumulated benefit obligations	$ 136,197	$ 134,858
Fair value of plan assets	—	—

Assets of the defined benefit pension plans are primarily equity and debt securities. Asset allocations as of January 1, 2017 and January 3, 2016, and target asset allocations for fiscal year 2017 are as follows:

	Target Allocation		Percentage of Plan Assets at			
	December 31, 2017		January 1, 2017		January 3, 2016	
Asset Category	Non-U.S.	U.S.	Non-U.S.	U.S.	Non-U.S.	U.S.
Equity securities	45-55%	40-50%	48%	41%	49%	42%
Debt securities	45-55%	50-60%	51%	59%	50%	58%
Other	0-5%	0-5%	1%	—%	1%	—%
Total	100%	100%	100%	100%	100%	100%

The Company maintains target allocation percentages among various asset classes based on investment policies established for the pension plans which are designed to maximize the total rate of return (income and appreciation) after inflation within the limits of prudent risk taking, while providing for adequate near-term liquidity for benefit payments.

The Company's expected rate of return on assets assumptions are derived from management's estimates, as well as other information compiled by management, including studies that utilize customary procedures and techniques. The studies include a review of anticipated future long-term performance of individual asset classes and consideration of the appropriate asset allocation strategy given the anticipated requirements of the plans to determine the average rate of earnings expected on the funds invested to provide for the pension plans benefits. While the study gives appropriate consideration to recent fund performance and historical returns, the assumption is primarily a long-term, prospective rate.

The Company's discount rate assumptions are derived from a range of factors, including a yield curve for certain plans, composed of the rates of return on high-quality fixed-income corporate bonds available at the measurement date and the related expected duration for the obligations, and a bond matching approach for certain plans.

For the plans in the United States, the Company adopted the updated projection scale, MP-2015, that was published by the Society of Actuaries in 2015, as of January 3, 2016. The adoption of the updated projection scale resulted in a $6.8 million decrease to the projected benefit obligation as of January 3, 2016. During fiscal year 2016, the Society of Actuaries issued an updated projection scale, MP-2016, which reduced the life expectancy used to determine the projected benefit obligation. The

Company adopted MP-2016 as of January 1, 2017. The adoption of the updated projection scale resulted in a $5.5 million decrease to the projected benefit obligation at January 1, 2017. The changes to the projected benefit obligations due to the adoption of the mortality base table and projection scale are included within "Actuarial loss (gain)" in the Change in Benefit Obligations for fiscal years 2016 and 2015 above.

The target allocations for plan assets are listed in the above table. Equity securities primarily include investments in large-cap and mid-cap companies located in the United States and abroad, and equity index funds. Debt securities include corporate bonds of companies from diversified industries, high-yield bonds, and U.S. government securities. Other types of investments include investments in non-U.S. government index linked bonds, multi-strategy hedge funds and venture capital funds that follow several different strategies.

The fair values of the Company's pension plan assets as of January 1, 2017 and January 3, 2016 by asset category, classified in the three levels of inputs described in Note 21 to the consolidated financial statements are as follows:

		Fair Value Measurements at January 1, 2017 Using:		
	Total Carrying Value at January 1, 2017	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(In thousands)		
Cash	$ 6,079	$ 6,079	$ —	$ —
Equity Securities:				
U.S. large-cap	25,523	25,523	—	—
International large-cap value	28,267	28,267	—	—
U.S. small mid-cap	1,756	1,756	—	—
Emerging markets growth	12,144	12,144	—	—
Equity index funds	74,274	—	74,274	—
Domestic real estate funds	1,401	1,401	—	—
Commodity funds	6,854	6,854	—	—
Fixed income securities:				
Non-U.S. Treasury Securities	22,059	—	22,059	—
Corporate and U.S. debt instruments	133,406	35,971	97,435	—
Corporate bonds	23,906	—	23,906	—
High yield bond funds	5,636	5,636	—	—
Other types of investments:				
Multi-strategy hedge funds	23,790	—	—	23,790
Non-U.S. government index linked bonds	32,003	—	32,003	—
Total assets measured at fair value	$ 397,098	$ 123,631	$ 249,677	$ 23,790

	Total Carrying Value at January 3, 2016	Fair Value Measurements at January 3, 2016 Using: Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(In thousands)		
Cash	$ 2,890	$ 2,890	$ —	$ —
Equity Securities:				
U.S. large-cap	30,357	30,357	—	—
International large-cap value	26,686	26,686	—	—
Emerging markets growth	10,600	10,600	—	—
Equity index funds	74,974	—	74,974	—
Domestic real estate funds	2,735	2,735	—	—
Commodity funds	8,128	8,128	—	—
Fixed income securities:				
Non-U.S. Treasury Securities	21,531	—	21,531	—
Corporate and U.S. debt instruments	137,117	28,746	108,371	—
Corporate bonds	23,871	—	23,871	—
High yield bond funds	3,324	3,324	—	—
Other types of investments:				
Multi-strategy hedge funds	23,415	—	—	23,415
Venture capital funds	1	—	—	1
Non-U.S. government index linked bonds	29,958	—	29,958	—
Total assets measured at fair value	$ 395,587	$ 113,466	$ 258,705	$ 23,416

Valuation Techniques: Valuation techniques utilized need to maximize the use of observable inputs and minimize the use of unobservable inputs. There have been no changes in the methodologies utilized at January 1, 2017 compared to January 3, 2016. The following is a description of the valuation techniques utilized to measure the fair value of the assets shown in the table above.

Equity Securities: Shares of registered investment companies that are publicly traded are categorized as Level 1 assets; they are valued at quoted market prices that represent the net asset value of the fund. These instruments have active markets.

Equity index funds are mutual funds that are not publicly traded and are comprised primarily of underlying equity securities that are publicly traded on exchanges. Price quotes for the assets held by these funds are readily observable and available. Equity index funds are categorized as Level 2 assets.

Fixed Income Securities: Fixed income mutual funds that are publicly traded are valued at quoted market prices that represent the net asset value of securities held by the fund and are categorized as Level 1 assets.

Fixed income index funds that are not publicly traded are stated at net asset value as determined by the issuer of the fund based on the fair value of the underlying investments and are categorized as Level 2 assets.

Individual fixed income bonds are categorized as Level 2 assets except where sufficient quoted prices exist in active markets, in which case such securities are categorized as Level 1 assets. These securities are valued using third-party pricing services. These services may use, for example, model-based pricing methods that utilize observable market data as inputs. Broker dealer bids or quotes of securities with similar characteristics may also be used.

Other Types of Investments: Non-U.S. government index link bond funds are not publicly traded and are stated at net asset value as determined by the issuer of the fund based on the fair value of the underlying investments. Underlying investments consist of bonds in which payment of income on the principal is related to a specific price index and are categorized as Level 2 assets.

Hedge funds, private equity funds and venture capital funds are valued at fair value by using the net asset values provided by the investment managers and are updated, if necessary, using analytical procedures, appraisals, public market data and/or inquiry of the investment managers. The net asset values are determined based upon the fair values of the underlying investments in the funds. These other investments invest primarily in readily available marketable securities and allocate gains, losses, and expense to the investor based on the ownership percentage as described in the fund agreements. They are categorized as Level 3 assets.

The Company's policy is to recognize significant transfers between levels at the actual date of the event.

A reconciliation of the beginning and ending Level 3 assets for fiscal years 2016, 2015 and 2014 is as follows:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3):		
	Venture Capital Funds	Multi-strategy Hedge Funds	Total
	(In thousands)		
Balance at December 29, 2013	$ 8	$ 22,689	$ 22,697
Unrealized (losses) gains	(7)	643	636
Balance at December 28, 2014	1	23,332	23,333
Unrealized gains	—	83	83
Balance at January 3, 2016	1	23,415	23,416
Realized losses	(1)	—	(1)
Unrealized gains	—	375	375
Balance at January 1, 2017	$ —	$ 23,790	$ 23,790

With respect to plans outside of the United States, the Company expects to contribute $7.6 million in the aggregate during fiscal year 2017. During fiscal year 2016, the Company contributed $9.6 million, in the aggregate, to pension plans outside of the United States. During fiscal year 2015, the Company made contributions of $14.9 million, in the aggregate, to plans outside of the United States and $20.0 million to its defined benefit pension plan in the United States. During fiscal year 2014, the Company contributed $11.2 million, in the aggregate, to plans outside of the United States.

The following benefit payments, which reflect expected future service, as appropriate, are expected to be paid as follows:

	Non-U.S.	U.S.
	(In thousands)	
2017	$ 10,147	$ 18,406
2018	10,474	18,559
2019	10,839	18,651
2020	11,232	18,775
2021	11,749	19,103
2022-2026	62,667	96,349

The Company also sponsors a supplemental executive retirement plan to provide senior management with benefits in excess of normal pension benefits. Effective July 31, 2000, this plan was closed to new entrants. At January 1, 2017 and January 3, 2016, the projected benefit obligations were $21.8 million and $21.5 million, respectively. Assets with a fair value of $1.1 million and $0.6 million, segregated in a trust (which is included in marketable securities and investments on the consolidated balance sheets), were available to meet this obligation as of January 1, 2017 and January 3, 2016, respectively. Pension expenses and income for this plan netted to expense of $1.6 million in fiscal year 2016, income of $1.6 million in fiscal year 2015 and expense of $4.8 million in fiscal year 2014.

Postretirement Medical Plans: The Company provides healthcare benefits for eligible retired U.S. employees under a comprehensive major medical plan or under health maintenance organizations where available. Eligible U.S. employees qualify for retiree health benefits if they retire directly from the Company and have at least ten years of service. Generally, the major medical plan pays stated percentages of covered expenses after a deductible is met and takes into consideration payments by other group coverage and by Medicare. The plan requires retiree contributions under most circumstances and has provisions for cost-sharing charges. Effective January 1, 2000, this plan was closed to new hires. For employees retiring after 1991, the Company has capped its medical premium contribution based on employees' years of service. The Company funds the amount allowable under a 401(h) provision in the Company's defined benefit pension plan. Assets of the plan are primarily equity and debt securities and are available only to pay retiree health benefits.

Net periodic postretirement medical benefit (credit) cost included the following components for the fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Service cost	$ 101	$ 108	$ 95
Interest cost	142	143	155
Expected return on plan assets	(1,035)	(1,062)	(964)
Actuarial loss (gain)	(539)	971	(384)
Net periodic postretirement medical benefit (credit) cost	$ (1,331)	$ 160	$ (1,098)

The following table sets forth the changes in the postretirement medical plan's funded status and the amounts recognized in the Company's consolidated balance sheets as of January 1, 2017 and January 3, 2016.

	January 1, 2017	January 3, 2016
	(In thousands)	
Actuarial present value of benefit obligations:		
Retirees	$ 907	$ 1,033
Active employees eligible to retire	423	424
Other active employees	2,031	2,119
Accumulated benefit obligations at beginning of year	3,361	3,576
Service cost	101	108
Interest cost	142	143
Benefits paid	(145)	(158)
Actuarial gain	(329)	(308)
Change in accumulated benefit obligations during the year	(231)	(215)
Retirees	804	907
Active employees eligible to retire	379	423
Other active employees	1,948	2,031
Accumulated benefit obligations at end of year	$ 3,131	$ 3,361
Change in plan assets:		
Fair value of plan assets at beginning of year	$ 14,353	$ 14,728
Actual return on plan assets	1,100	(375)
Fair value of plan assets at end of year	$ 15,453	$ 14,353
Net assets recognized in the consolidated balance sheets	$ 12,322	$ 10,992
Net amounts recognized in the consolidated balance sheets consist of:		
Noncurrent assets	$ 12,322	$ 10,992
Net assets recognized in the consolidated balance sheets	$ 12,322	$ 10,992
Net amounts recognized in accumulated other comprehensive income consist of:		
Prior service cost	$ —	$ —
Net amounts recognized in accumulated other comprehensive income	$ —	$ —
Actuarial assumptions as of the year-end measurement date:		
Discount rate	4.11%	4.34%

Actuarial assumptions used to determine net cost during the year are as follows:

	January 1, 2017	January 3, 2016	December 28, 2014
Discount rate	4.34%	4.10%	4.77%
Expected rate of return on assets	7.25%	7.25%	7.25%

The Company maintains a master trust for plan assets related to the U.S. defined benefit plans and the U.S. postretirement medical plan. Accordingly, investment policies, target asset allocations and actual asset allocations are the same as those disclosed for the U.S. defined benefit plans.

The fair values of the Company's plan assets at January 1, 2017 and January 3, 2016 by asset category, classified in the three levels of inputs described in Note 21, are as follows:

		Fair Value Measurements at January 1, 2017 Using:		
	Total Carrying Value at January 1, 2017	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(In thousands)		
Cash	$ 319	$ 319	$ —	$ —
Equity Securities:				
U.S. large-cap	1,618	1,618	—	—
International large-cap value	1,792	1,792	—	—
U.S. small mid-cap	111	111	—	—
Emerging markets growth	770	770	—	—
Domestic real estate funds	89	89	—	—
Commodity funds	434	434	—	—
Fixed income securities:				
Corporate debt instruments	8,456	2,280	6,176	—
High yield bond funds	356	356	—	—
Other types of investments:				
Multi-strategy hedge funds	1,508	—	—	1,508
Total assets measured at fair value	$ 15,453	$ 7,769	$ 6,176	$ 1,508

		Fair Value Measurements at January 3, 2016 Using:		
	Total Carrying Value at January 3, 2016	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(In thousands)		
Cash	$ 133	$ 133	$ —	$ —
Equity Securities:				
U.S. large-cap	1,781	1,781	—	—
International large-cap value	1,566	1,566	—	—
Emerging markets growth	622	622	—	—
Domestic real estate funds	160	160	—	—
Commodity funds	477	477	—	—
Fixed income securities:				
Corporate debt instruments	8,045	1,687	6,358	—
High yield bond funds	195	195	—	—
Other types of investments:				
Multi-strategy hedge funds	1,374	—	—	1,374
Total assets measured at fair value	$ 14,353	$ 6,621	$ 6,358	$ 1,374

Valuation Techniques: Valuation techniques are the same as those disclosed for the U.S. defined benefit plans above.

A reconciliation of the beginning and ending Level 3 assets for fiscal years 2016, 2015 and 2014 is as follows:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3):
	Multi-strategy Hedge Funds
	(In thousands)
Balance at December 29, 2013	$ 1,217
Unrealized gains	124
Balance at December 28, 2014	1,341
Unrealized gains	33
Balance at January 3, 2016	1,374
Unrealized gains	134
Balance at January 1, 2017	$ 1,508

The Company does not expect to make any contributions to the postretirement medical plan during fiscal year 2017.

The following benefit payments, which reflect expected future service, as appropriate, are expected to be paid as follows:

Postretirement Medical Plan

	(In thousands)
2017	$ 152
2018	159
2019	166
2020	173
2021	184
2022-2026	1,057

Deferred Compensation Plans: During fiscal year 1998, the Company implemented a nonqualified deferred compensation plan that provides benefits payable to officers and certain key employees or their designated beneficiaries at specified future dates, or upon retirement or death. The plan was amended to eliminate deferral elections, with the exception of Company 401(k) excess contributions for eligible participants, for plan years beginning January 1, 2011. Benefit payments under the plan are funded by contributions from participants, and for certain participants, contributions by the Company. The obligations related to the deferred compensation plan totaled $0.9 million at January 1, 2017 and $1.2 million at January 3, 2016.

Note 16: Contingencies

The Company is conducting a number of environmental investigations and remedial actions at current and former locations of the Company and, along with other companies, has been named a potentially responsible party ("PRP") for certain waste disposal sites. The Company accrues for environmental issues in the accounting period that the Company's responsibility is established and when the cost can be reasonably estimated. The Company has accrued $9.9 million and $11.8 million as of January 1, 2017 and January 3, 2016, respectively, in accrued expenses and other current liabilities, which represents its management's estimate of the cost of the remediation of known environmental matters, and does not include any potential liability for related personal injury or property damage claims. During fiscal year 2014, the Company recorded a benefit of $2.3

million for cost reimbursements related to a particular site for monitoring and mitigation activities. The Company's environmental accrual is not discounted and does not reflect the recovery of any material amounts through insurance or indemnification arrangements. The cost estimates are subject to a number of variables, including the stage of the environmental investigations, the magnitude of the possible contamination, the nature of the potential remedies, possible joint and several liability, the time period over which remediation may occur, and the possible effects of changing laws and regulations. For sites where the Company has been named a PRP, management does not currently anticipate any additional liability to result from the inability of other significant named parties to contribute. The Company expects that the majority of such accrued amounts could be paid out over a period of up to ten years. As assessment and remediation activities progress at each individual site, these liabilities are reviewed and adjusted to reflect additional information as it becomes available. There have been no environmental problems to date that have had, or are expected to have, a material adverse effect on the Company's consolidated financial statements. While it is possible that a loss exceeding the amounts recorded in the consolidated financial statements may be incurred, the potential exposure is not expected to be materially different from those amounts recorded.

The Company is subject to various claims, legal proceedings and investigations covering a wide range of matters that arise in the ordinary course of its business activities. Although the Company has established accruals for potential losses that it believes are probable and reasonably estimable, in the opinion of the Company's management, based on its review of the information available at this time, the total cost of resolving these contingencies at January 1, 2017 should not have a material adverse effect on the Company's consolidated financial statements. However, each of these matters is subject to uncertainties, and it is possible that some of these matters may be resolved unfavorably to the Company.

Note 17: Warranty Reserves

The Company provides warranty protection for certain products usually for a period of one year beyond the date of sale. The majority of costs associated with warranty obligations include the replacement of parts and the time for service personnel to respond to repair and replacement requests. A warranty reserve is recorded based upon historical results, supplemented by management's expectations of future costs. Warranty reserves are included in "Accrued expenses and other current liabilities" on the consolidated balance sheets.

A summary of warranty reserve activity for the fiscal years ended January 1, 2017, January 3, 2016 and December 28, 2014 is as follows:

	(In thousands)
Balance at December 29, 2013	$ 9,643
Provision charged to income	15,995
Payments	(15,634)
Adjustments to previously provided warranties, net	73
Foreign currency translation and acquisitions	(484)
Balance at December 28, 2014	9,593
Provision charged to income	15,792
Payments	(14,936)
Adjustments to previously provided warranties, net	(146)
Foreign currency translation and acquisitions	(460)
Balance at January 3, 2016	9,843
Provision charged to income	14,901
Payments	(14,749)
Adjustments to previously provided warranties, net	(850)
Foreign currency translation and acquisitions	(133)
Balance at January 1, 2017	$ 9,012

Note 18: Stock Plans

Stock-Based Compensation:

In addition to the Company's Employee Stock Purchase Plan, the Company utilizes one stock-based compensation plan, the 2009 Incentive Plan (the "2009 Plan"). Under the 2009 Plan, 10.0 million shares of the Company's common stock are authorized for stock option grants, restricted stock awards, performance units and stock grants as part of the Company's compensation programs. In addition to shares of the Company's common stock originally authorized for issuance under the 2009 Plan, the 2009 Plan includes shares of the Company's common stock previously granted under the Amended and Restated 2001 Incentive Plan and the 2005 Incentive Plan that were canceled or forfeited without the shares being issued.

The following table summarizes total pre-tax compensation expense recognized related to the Company's stock options, restricted stock, restricted stock units, performance units and stock grants, net of estimated forfeitures, included in the Company's consolidated statements of operations for fiscal years 2016, 2015 and 2014:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Cost of product and service revenue	$ 1,031	$ 1,272	$ 1,380
Research and development expenses	902	526	484
Selling, general and administrative expenses	15,225	15,480	12,193
Total stock-based compensation expense	$ 17,158	$ 17,278	$ 14,057

The total income tax benefit recognized in the consolidated statements of operations for stock-based compensation was $10.5 million in fiscal year 2016, $5.8 million in fiscal year 2015 and $5.4 million in fiscal year 2014. Stock-based compensation costs capitalized as part of inventory were $0.3 million and $0.2 million as of January 1, 2017 and January 3, 2016, respectively. The excess tax benefit recognized from stock compensation, classified as a financing cash activity, was $2.4 million in fiscal year 2015.

Stock Options: The Company has granted options to purchase common shares at prices equal to the market price of the common shares on the date the option is granted. Conditions of vesting are determined at the time of grant. Options are generally exercisable in equal annual installments over a period of three years, and will generally expire seven years after the date of grant. Options replaced in association with business combination transactions are generally issued with the same terms of the respective plans under which they were originally issued.

The fair value of each option grant is estimated using the Black-Scholes option pricing model. The fair value is then amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Expected volatility was calculated based on the historical and implied volatility of the Company's stock. The average expected life was based on the contractual term of the option and historic exercise experience. The risk-free interest rate is based on United States Treasury zero-coupon issues with a remaining term equal to the expected life assumed at the date of grant. The Company's weighted-average assumptions used in the Black-Scholes option pricing model were as follows for the fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
Risk-free interest rate	1.7%	1.3%	1.5%
Expected dividend yield	0.6%	0.6%	0.7%
Expected lives	5 years	5 years	5 years
Expected stock volatility	25.2%	26.5%	30.9%

The following table summarizes stock option activity for the fiscal year ended January 1, 2017:

	January 1, 2017	
	Number of Shares	Weighted-Average Exercise Price
	(Shares in thousands)	
Outstanding at beginning of year	2,372	$ 33.12
Granted	607	44.79
Exercised	(576)	25.04
Canceled	(1)	12.95
Forfeited	(115)	45.50
Outstanding at end of year	2,287	$ 37.64
Exercisable at end of year	1,342	$ 32.46

The aggregate intrinsic value for stock options outstanding at January 1, 2017 was $33.4 million with a weighted-average remaining contractual term of 3.9 years. The aggregate intrinsic value for stock options exercisable at January 1, 2017 was $26.5 million with a weighted-average remaining contractual term of 2.6 years. At January 1, 2017, there were 2.3 million stock options that were vested, and expected to vest in the future, with an aggregate intrinsic value of $33.4 million and a weighted-average remaining contractual term of 3.9 years.

The weighted-average per-share grant-date fair value of options granted during fiscal years 2016, 2015 and 2014 was $10.20, $11.02, and $11.86, respectively. The total intrinsic value of options exercised during fiscal years 2016, 2015 and 2014 was $16.6 million, $25.9 million, and $22.0 million, respectively. Cash received from option exercises for fiscal years 2016, 2015 and 2014 was $14.4 million, $14.9 million, and $24.5 million, respectively. The total compensation expense recognized related to the Company's outstanding options was $4.4 million in fiscal year 2016, $4.1 million in fiscal year 2015 and $4.9 million in fiscal year 2014.

There was $5.6 million of total unrecognized compensation cost related to nonvested stock options granted as of January 1, 2017. This cost is expected to be recognized over a weighted-average period of 1.8 years.

Restricted Stock Awards: The Company has awarded shares of restricted stock and restricted stock units to certain employees and non-employee directors at no cost to them, which cannot be sold, assigned, transferred or pledged during the restriction period. The restricted stock and restricted stock units vest through the passage of time, assuming continued employment. The fair value of the award at the time of the grant is expensed on a straight line basis primarily in selling, general and administrative expenses over the vesting period, which is generally 3 years. These awards were granted under the Company's 2009 Plan. Recipients of the restricted stock have the right to vote such shares and receive dividends.

The following table summarizes restricted stock award activity for the fiscal year ended January 1, 2017:

	January 1, 2017	
	Number of Shares	Weighted-Average Grant-Date Fair Value
	(Shares in thousands)	
Nonvested at beginning of year	502	$ 42.61
Granted	296	47.60
Vested	(214)	39.23
Forfeited	(63)	45.52
Nonvested at end of year	521	$ 46.48

The fair value of restricted stock awards vested during fiscal years 2016, 2015 and 2014 was $8.4 million, $7.8 million, and $7.1 million, respectively. The total compensation expense recognized related to the restricted stock awards was $9.3 million in fiscal year 2016, $8.4 million in fiscal year 2015 and $6.8 million in fiscal year 2014.

As of January 1, 2017, there was $12.4 million of total unrecognized compensation cost, net of forfeitures, related to nonvested restricted stock awards. That cost is expected to be recognized over a weighted-average period of 1.4 years.

Performance Units: The Company's performance unit program provides a cash award based on the achievement of specific performance criteria. A target number of units are granted at the beginning of a three-year performance period. The number of units earned at the end of the performance period is determined by multiplying the number of units granted by a performance factor ranging from 0% to 200%. Awards are determined by multiplying the number of units earned by the stock price at the end of the performance period, and are paid in cash and accounted for as a liability based award. The compensation expense associated with these units is recognized over the period that the performance targets are expected to be achieved. The Company granted 72,164 performance units, 66,509 performance units, and 79,463 performance units during fiscal years 2016, 2015 and 2014, respectively. The weighted-average per-share grant-date fair value of performance units granted during fiscal years 2016, 2015 and 2014 was $42.79, $46.83, and $42.84, respectively. During fiscal years 2016, 2015 and 2014, 19,584, 8,860 and 35,954 performance units were forfeited, respectively. The total compensation expense related to performance units was $2.7 million, $4.0 million, and $1.6 million for fiscal years 2016, 2015 and 2014, respectively. As of January 1, 2017, there were 190,700 performance units outstanding subject to forfeiture, with a corresponding liability of $6.1 million recorded in accrued expenses and long-term liabilities.

Stock Awards: The Company's stock award program provides non-employee directors an annual equity award. For fiscal years 2016, 2015 and 2014 the award equaled the number of shares of the Company's common stock which has an aggregate fair market value of $100,000 on the date of the award. The stock award is prorated for non-employee directors who serve for only a portion of the year. The compensation expense associated with these stock awards is recognized when the stock award is granted. In fiscal years 2016, 2015 and 2014, each non-employee director was awarded 1,821 shares, 1,953 shares, and 2,373 shares, respectively. The Company also granted 2,672 shares to new non-employee directors during fiscal year 2016. The weighted-average per-share grant-date fair value of stock awards granted during fiscal years 2016, 2015 and 2014 was $54.58, $51.01, and $42.14, respectively. In each of fiscal years 2016, 2015 and 2014, the total compensation expense recognized related to these stock awards was $0.8 million.

Employee Stock Purchase Plan:

In April 1999, the Company's shareholders approved the 1998 Employee Stock Purchase Plan. In April 2005, the Compensation and Benefits Committee of the Board voted to amend the Employee Stock Purchase Plan, effective July 1, 2005, whereby participating employees have the right to purchase common stock at a price equal to 95% of the closing price on the last day of each six-month offering period. The number of shares which an employee may purchase, subject to certain aggregate limits, is determined by the employee's voluntary contribution, which may not exceed 10% of the employee's base compensation. During fiscal year 2016, the Company issued 49,578 shares of common stock under the Company's Employee Stock Purchase Plan at a weighted-average price of $49.67 per share. During fiscal year 2015, the Company issued 78,294 shares under this plan at a weighted-average price of $47.08 per share. During fiscal year 2014, the Company issued 60,870 shares under this plan at a weighted-average price of $41.71 per share. At January 1, 2017 there remains available for sale to employees an aggregate of 0.9 million shares of the Company's common stock out of the 5.0 million shares authorized by shareholders for issuance under this plan.

Note 19: Stockholders' Equity

Comprehensive Income:

The components of accumulated other comprehensive (loss) income consisted of the following:

	Foreign Currency Translation Adjustment, net of tax	Unrecognized Prior Service Costs, net of tax	Unrealized (Losses) Gains on Securities, net of tax	Accumulated Other Comprehensive Income (Loss)
		(In thousands)		
Balance, December 29, 2013	$ 76,283	$ 1,429	$ (121)	$ 77,591
Current year change	(52,951)	146	14	(52,791)
Balance, December 28, 2014	23,332	1,575	(107)	24,800
Current year change	(70,178)	(316)	(262)	(70,756)
Balance, January 3, 2016	(46,846)	1,259	(369)	(45,956)
Current year change	(54,077)	(860)	32	(54,905)
Balance, January 1, 2017	$ (100,923)	$ 399	$ (337)	$ (100,861)

During fiscal years 2016, 2015 and 2014, pre-tax income of $0.9 million, pre-tax expense of $0.3 million, and pre-tax income of $0.1 million, respectively, were reclassified from accumulated other comprehensive income into selling, general and administrative expenses as a component of net periodic benefit cost.

Stock Repurchases:

On October 23, 2014, the Board of Directors (the "Board") authorized the Company to repurchase up to 8.0 million shares of common stock under a stock repurchase program (the "Repurchase Program"). On July 27, 2016, the Board authorized the Company to immediately terminate the Repurchase Program and further authorized the Company to repurchase up to 8.0 million shares of common stock under a new stock repurchase program (the "New Repurchase Program"). The New Repurchase Program will expire on July 26, 2018 unless terminated earlier by the Board, and may be suspended or discontinued at any time. During the fiscal year 2016, the Company repurchased 3.2 million shares of common stock in the open market at an aggregate cost of $148.2 million, including commissions, under the Repurchase Program. No shares remain available for repurchase under the Repurchase Program due to its cancellation. As of January 1, 2017, 8.0 million shares remained available for repurchase under the New Repurchase Program.

The Board has authorized the Company to repurchase shares of common stock to satisfy minimum statutory tax withholding obligations in connection with the vesting of restricted stock awards and restricted stock unit awards granted pursuant to the Company's equity incentive plans and to satisfy obligations related to the exercise of stock options made pursuant to the Company's equity incentive plans. During fiscal year 2016, the Company repurchased 75,198 shares of common stock for this purpose at an aggregate cost of $3.6 million. During fiscal year 2015, the Company repurchased 95,129 shares of common stock for this purpose at an aggregate cost of $4.4 million. During fiscal year 2014, the Company repurchased 98,269 shares of common stock for this purpose at an aggregate cost of $4.3 million. The repurchased shares have been reflected as additional authorized but unissued shares, with the payments reflected in common stock and capital in excess of par value.

Dividends:

The Board declared a regular quarterly cash dividend of $0.07 per share in each quarter of fiscal years 2016 and 2015. At January 1, 2017, the Company has accrued $7.7 million for dividends declared on October 26, 2016 for the fourth quarter of fiscal year 2016 that was paid in February 2017. On January 27, 2017, the Company announced that the Board had declared a quarterly dividend of $0.07 per share for the first quarter of fiscal year 2017 that will be payable in May 2017. In the future, the Board may determine to reduce or eliminate the Company's common stock dividend in order to fund investments for growth, repurchase shares or conserve capital resources.

Note 20: Derivatives and Hedging Activities

The Company uses derivative instruments as part of its risk management strategy only, and includes derivatives utilized as economic hedges that are not designated as hedging instruments. By nature, all financial instruments involve market and credit risks. The Company enters into derivative instruments with major investment grade financial institutions and has policies to monitor the credit risk of those counterparties. The Company does not enter into derivative contracts for trading or other speculative purposes, nor does the Company use leveraged financial instruments. Approximately 60% of the Company's business is conducted outside of the United States, generally in foreign currencies. As a result, fluctuations in foreign currency exchange rates can increase the costs of financing, investing and operating the business.

In the ordinary course of business, the Company enters into foreign exchange contracts for periods consistent with its committed exposures to mitigate the effect of foreign currency movements on transactions denominated in foreign currencies. The intent of these economic hedges is to offset gains and losses that occur on the underlying exposures from these currencies, with gains and losses resulting from the forward currency contracts that hedge these exposures. Transactions covered by hedge contracts include intercompany and third-party receivables and payables. The contracts are primarily in European and Asian currencies, have maturities that do not exceed 12 months, have no cash requirements until maturity, and are recorded at fair value on the Company's consolidated balance sheets. The unrealized gains and losses on the Company's foreign currency contracts are recognized immediately in interest and other expense, net. The cash flows related to the settlement of these hedges are included in cash flows from operating activities within the Company's consolidated statement of cash flows.

Principal hedged currencies include the British Pound, Euro, Japanese Yen and Singapore Dollar. The Company held forward foreign exchange contracts, designated as economic hedges, with U.S. dollar equivalent notional amounts totaling $137.5 million at January 1, 2017, $127.3 million at January 3, 2016, and $95.0 million at December 28, 2014, and the fair value of these foreign currency derivative contracts was insignificant. The gains and losses realized on these foreign currency derivative contracts are not material. The duration of these contracts was generally 30 days or less during each of fiscal years 2016, 2015 and 2014.

In addition, in connection with certain intercompany loan agreements utilized to finance its acquisitions, the Company enters into forward foreign exchange contracts intended to hedge movements in foreign exchange rates prior to settlement of such intercompany loans denominated in foreign currencies. The Company records these hedges at fair value on the Company's consolidated balance sheets. The unrealized gains and losses on these hedges, as well as the gains and losses associated with the remeasurement of the intercompany loans, are recognized immediately in interest and other expense, net. The cash flows related to the settlement of these hedges are included in cash flows from financing activities within the Company's consolidated statement of cash flows.

As of January 1, 2017, the outstanding forward exchange contracts designated as economic hedges, that were intended to hedge movements in foreign exchange rates prior to the settlement of certain intercompany loan agreements included combined Euro notional amounts of €58.6 million, combined U.S. Dollar notional amounts of $8.7 million and combined Swedish Krona notional amounts of kr969.5 million. The combined Euro notional amounts of these outstanding hedges was €107.4 million as of January 3, 2016. The net gains and losses on these derivatives, combined with the gains and losses on the remeasurement of the hedged intercompany loans were not material for each of the fiscal years 2016 and 2015. The Company paid $1.9 million and received $18.7 million during the fiscal years 2016 and 2015, respectively, from the settlement of these hedges.

During fiscal year 2016, the Company entered into a series of foreign currency forward contracts with a notional amount of €492.3 million to hedge its investments in certain foreign subsidiaries. Realized and unrealized translation adjustments from these hedges were included in the foreign currency translation component of accumulated other comprehensive income ("AOCI"), which offsets the translation adjustments on the underlying net assets of foreign subsidiaries. The cumulative translation gains or losses will remain in AOCI until the foreign subsidiaries are liquidated or sold. The foreign currency forward contracts were settled during the third quarter of 2016 and the Company recorded a net realized foreign exchange gain in AOCI amounting to $1.8 million during fiscal year 2016.

During the fiscal year 2016, in connection with the issuance of the 2026 Notes, the Company designated the 2026 Notes to hedge its investments in certain foreign subsidiaries. Realized and unrealized translation adjustments from these hedges will be included in the foreign currency translation component of AOCI, which will offset translation adjustments on the underlying net assets of foreign subsidiaries. The cumulative translation gains or losses will remain in AOCI until the foreign subsidiaries are liquidated or sold. As of January 1, 2017, the total notional amount of foreign currency denominated debt designated to hedge investments in foreign subsidiaries was €495.8 million. The unrealized foreign exchange loss recorded in AOCI related to the net investment hedge was $23.8 million for the fiscal year 2016 .

The Company does not expect any material net pre-tax gains or losses to be reclassified from accumulated other comprehensive (loss) income into interest and other expense, net within the next twelve months.

Note 21: Fair Value Measurements

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash equivalents, derivatives, marketable securities and accounts receivable. The Company believes it had no significant concentrations of credit risk as of January 1, 2017.

The Company uses the market approach technique to value its financial instruments and there were no changes in valuation techniques during fiscal years 2016 and 2015. The Company's financial assets and liabilities carried at fair value are primarily comprised of marketable securities, derivative contracts used to hedge the Company's currency risk, and acquisition related contingent consideration. The Company has not elected to measure any additional financial instruments or other items at fair value.

Valuation Hierarchy: The following summarizes the three levels of inputs required to measure fair value. For Level 1 inputs, the Company utilizes quoted market prices as these instruments have active markets. For Level 2 inputs, the Company utilizes quoted market prices in markets that are not active, broker or dealer quotations, or utilizes alternative pricing sources with reasonable levels of price transparency. For Level 3 inputs, the Company utilizes unobservable inputs based on the best information available, including estimates by management primarily based on information provided by third-party fund managers, independent brokerage firms and insurance companies. A financial asset's or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible.

The following tables show the assets and liabilities carried at fair value measured on a recurring basis as of January 1, 2017 and January 3, 2016 classified in one of the three classifications described above:

		Fair Value Measurements at January 1, 2017 Using:		
	Total Carrying Value at January 1, 2017	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(In thousands)		
Marketable securities	$ 1,678	$ 1,678	$ —	$ —
Foreign exchange derivative assets	1,208	—	1,208	—
Foreign exchange derivative liabilities	(1,370)	—	(1,370)	—
Contingent consideration	(63,201)	—	—	(63,201)

	Total Carrying Value at January 3, 2016	Fair Value Measurements at January 3, 2016 Using: Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(In thousands)		
Marketable securities	$ 1,586	$ 1,586	$ —	$ —
Foreign exchange derivative assets	2,659	—	2,659	—
Foreign exchange derivative liabilities, net	(442)	—	(442)	—
Contingent consideration	(57,350)	—	—	(57,350)

Level 1 and Level 2 Valuation Techniques: The Company's Level 1 and Level 2 assets and liabilities are comprised of investments in equity and fixed-income securities as well as derivative contracts. For financial assets and liabilities that utilize Level 1 and Level 2 inputs, the Company utilizes both direct and indirect observable price quotes, including common stock price quotes, foreign exchange forward prices and bank price quotes. Below is a summary of valuation techniques for Level 1 and Level 2 financial assets and liabilities.

Marketable securities: Include equity and fixed-income securities measured at fair value using the quoted market prices in active markets at the reporting date.

Foreign exchange derivative assets and liabilities: Include foreign exchange derivative contracts that are valued using quoted forward foreign exchange prices at the reporting date. The Company's foreign exchange derivative contracts are subject to master netting arrangements that allow the Company and its counterparties to net settle amounts owed to each other. Derivative assets and liabilities that can be net settled under these arrangements have been presented in the Company's consolidated balance sheet on a net basis and are recorded in other assets. As of both January 1, 2017 and January 3, 2016, none of the master netting arrangements involved collateral.

Level 3 Valuation Techniques: The Company's Level 3 liabilities are comprised of contingent consideration related to acquisitions. For liabilities that utilize Level 3 inputs, the Company uses significant unobservable inputs. Below is a summary of valuation techniques for Level 3 liabilities.

Contingent consideration: Contingent consideration is measured at fair value at the acquisition date using projected milestone dates, discount rates, probabilities of success and projected revenues (for revenue-based considerations). Projected risk-adjusted contingent payments are discounted back to the current period using a discounted cash flow model.

During fiscal year 2015, the Company acquired all the shares of Vanadis. Under the terms of the acquisition, the initial purchase consideration was $32.0 million, net of cash and the Company will be obligated to make potential future milestone payments, based on completion of a proof of concept, regulatory approvals and product sales, of up to $93.0 million ranging from 2016 to 2019. The key assumptions used to determine the fair value of the contingent consideration included projected milestone dates of 2016 to 2019, discount rates ranging from 3.1% to 11.3%, conditional probabilities of success of each individual milestone ranging from 85% to 95% and cumulative probabilities of success for each individual milestone ranging from 53% to 90%. The fair value of the contingent consideration as of the acquisition date was estimated at $56.9 million. During the fiscal year 2016, the Company updated the fair value of the contingent consideration and recorded a liability of $63.2 million as of January 1, 2017. The key assumptions used to determine the fair value of the contingent consideration as of January 1, 2017 included projected milestone dates of 2017 to 2019, discount rates ranging from 1.9% to 8.5%, conditional probabilities of success of each individual milestone ranging from 90% to 95% and cumulative probabilities of success for each individual milestone ranging from 65.8% to 95%. A significant delay in the product development (including projected regulatory milestone) achievement date in isolation could result in a significantly lower fair value measurement; a significant acceleration in the product development (including projected regulatory milestone) achievement date in isolation would not have a material impact on the fair value measurement; a significant change in the discount rate in isolation would not have a material impact on the fair value measurement; and a significant change in the probabilities of success in isolation could result in a significant change in fair value measurement.

The fair values of contingent consideration are calculated on a quarterly basis based on a collaborative effort of the Company's regulatory, research and development, operations, finance and accounting groups, as appropriate. Potential valuation adjustments are made as additional information becomes available, including the progress towards achieving proof of concept, regulatory approvals and revenue targets as compared to initial projections, the impact of market competition and market landscape shifts from non-invasive prenatal testing products, with the impact of such adjustments being recorded in the consolidated statements of operations.

As of January 1, 2017, the Company may have to pay contingent consideration, related to acquisitions with open contingency periods, of up to $84.6 million. The expected maximum earnout period for acquisitions with open contingency periods does not exceed 3 years from the respective acquisition dates, and the remaining weighted average expected earnout period at January 1, 2017 was 1.75 years.

A reconciliation of the beginning and ending Level 3 net liabilities for contingent consideration is as follows:

	(In thousands)
Balance at December 29, 2013	$ (4,926)
Additions	—
Amounts paid and foreign currency translation	2,074
Change in fair value (included within selling, general and administrative expenses)	2,761
Balance at December 28, 2014	(91)
Additions	(57,353)
Amounts paid and foreign currency translation	113
Change in fair value (included within selling, general and administrative expenses)	(19)
Balance at January 3, 2016	(57,350)
Additions	—
Amounts paid and foreign currency translation	332
Reclassified to other current liabilities for milestone achieved	10,000
Change in fair value (included within selling, general and administrative expenses)	(16,183)
Balance at January 1, 2017	$ (63,201)

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate fair value due to the short-term maturities of these assets and liabilities. If measured at fair value, cash and cash equivalents would be classified as Level 1.

As of January 1, 2017, the Company's new senior unsecured revolving credit facility, which provides for $1.0 billion of revolving loans, had no outstanding borrowings. As of January 3, 2016, the Company's previous senior unsecured revolving credit facility had $482.0 million of borrowings outstanding, which excluded $2.4 million unamortized debt issuance costs and letters of credit. The interest rate on the Company's new senior unsecured revolving credit facility is reset at least monthly to correspond to variable rates that reflect currently available terms and conditions for similar debt. The Company had no change in credit standing during fiscal year 2016. Consequently, the borrowing value of the current year and prior year credit facilities approximate fair value and would be classified as Level 2.

The Company's 2021 Notes, with a face value of $500.0 million, had an aggregate carrying value of $495.8 million, net of $1.7 million of unamortized original issue discount and $2.5 million of unamortized debt issuance costs as of January 1, 2017. The 2021 Notes had an aggregate carrying value of $495.1 million, net of $2.0 million of unamortized original issue discount and $2.9 million of unamortized debt issuance costs as of January 3, 2016. The 2021 Notes had a fair value of $539.2 million and $518.9 million as of January 1, 2017 and January 3, 2016, respectively. The fair value of the 2021 Notes is estimated using market quotes from brokers and is based on current rates offered for similar debt.

The Company's 2026 Notes, with a face value of €500.0 million, had an aggregate carrying value of $517.8 million, net of $4.5 million of unamortized original issue discount and $4.8 million of unamortized debt issuance costs as of January 1,

2017. The 2026 Notes had a fair value of €507.5 million as of January 1, 2017. The fair value of the 2026 Notes is estimated using market quotes from brokers and is based on current rates offered for similar debt.

The Company's financing lease obligations had an aggregate carrying value of $37.1 million and $38.2 million as of January 1, 2017 and January 3, 2016, respectively. The carrying values of the Company's financing lease obligations approximated their fair value as there has been minimal change in the Company's incremental borrowing rate.

As of January 1, 2017, the 2021 Notes, 2026 Notes and financing lease obligations were classified as Level 2.

As of January 1, 2017, there has not been any significant impact to the fair value of the Company's derivative liabilities due to credit risk. Similarly, there has not been any significant adverse impact to the Company's derivative assets based on the evaluation of its counterparties' credit risks.

Note 22: Leases

The Company leases certain property and equipment under operating leases. Rental expense charged to continuing operations for fiscal years 2016, 2015 and 2014 amounted to $52.0 million, $52.4 million, and $52.8 million, respectively. Minimum rental commitments under noncancelable operating leases are as follows: $49.8 million in fiscal year 2017, $33.9 million in fiscal year 2018, $26.0 million in fiscal year 2019, $20.8 million in fiscal year 2020, $16.3 million in fiscal year 2021 and $52.1 million in fiscal year 2022 and thereafter.

On August 22, 2013, the Company sold one of its facilities located in Boston, Massachusetts for net proceeds of $47.6 million. Simultaneously with the closing of the sale of the property, the Company entered into a lease agreement to lease back the property for its continued use. The lease has an initial term of 15 years and the Company has the right to extend the term of the lease for two additional periods of ten years each. The lease is accounted for as an operating lease and at the transaction date the Company had deferred $26.5 million of gains which are being amortized in operating expenses over the initial lease term of 15 years. The Company amortized $1.8 million of the deferred gains related to the lease during each of the fiscal years 2016, 2015 and 2014. The deferred gains remaining to be amortized were $20.6 million at January 1, 2017, of which $1.8 million was recorded in accrued expenses and other current liabilities, and $18.8 million was recorded in long-term liabilities. The deferred gains remaining to be amortized were $22.3 million at January 3, 2016, of which $1.8 million was recorded in accrued expenses and other current liabilities, and $20.5 million was recorded in long-term liabilities.

Note 23: Industry Segment and Geographic Area Information

The Company discloses information about its operating segments based on the way that management organizes the segments within the Company for making operating decisions and assessing financial performance. The Company evaluates the performance of its operating segments based on revenue and operating income. Intersegment revenue and transfers are not significant. The accounting policies of the operating segments are the same as those described in Note 1.

Effective October 3, 2016, the Company realigned its businesses to better position the Company to grow in attractive end markets and expand share with the Company's core product offerings. Diagnostics became a standalone operating segment and the Company formed a new operating segment, Discovery & Analytical Solutions. The results reported for fiscal year 2016 reflect this new alignment of the Company's operating segments. Financial information in this report relating to fiscal years 2015 and 2014 has been retrospectively adjusted to reflect this change to the Company's operating segments.

The principal products and services of the Company's two operating segments are:

- *Discovery & Analytical Solutions.* Provides products and services targeted towards the environmental, industrial, food, life sciences research and laboratory services markets.
- *Diagnostics.* Develops diagnostics, tools and applications focused on clinically-oriented customers, especially within the reproductive health, emerging market diagnostics and applied genomics markets. The Diagnostics segment serves the diagnostics market.

The Company has included the expenses for its corporate headquarters, such as legal, tax, audit, human resources, information technology, and other management and compliance costs, as well as the activity related to the mark-to-market adjustment on postretirement benefit plans, as "Corporate" below. The Company has a process to allocate and recharge expenses to the reportable segments when these costs are administered or paid by the corporate headquarters based on the extent to which the segment benefited from the expenses. These amounts have been calculated in a consistent manner and are included in the Company's calculations of segment results to internally plan and assess the performance of each segment for all purposes, including determining the compensation of the business leaders for each of the Company's operating segments.

Revenue and operating income (loss) from continuing operations by operating segment are shown in the table below for the fiscal years ended:

	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Discovery & Analytical Solutions			
Product revenue	$ 934,098	$ 968,034	$ 944,446
Service revenue	578,886	560,385	539,694
Total revenue	1,512,984	1,528,419	1,484,140
Operating income from continuing operations[1]	207,487	173,668	162,074
Diagnostics			
Product revenue	462,798	427,068	428,290
Service revenue	139,735	149,336	157,450
Total revenue	602,533	576,404	585,740
Operating income from continuing operations	138,909	135,572	124,610
Corporate			
Operating loss from continuing operations[2][3]	(63,330)	(58,314)	(121,677)
Continuing Operations			
Product revenue	1,396,896	1,395,102	1,372,736
Service revenue	718,621	709,721	697,144
Total revenue	2,115,517	2,104,823	2,069,880
Operating income from continuing operations	283,066	250,926	165,007
Interest and other expense, net (see Note 5)	38,998	42,119	41,139
Income from continuing operations before income taxes	$ 244,068	$ 208,807	$ 123,868

(1) Legal costs for a particular case in the Discovery & Analytical Solutions segment were $0.8 million for fiscal year 2015.

(2) Activity related to the mark-to-market adjustment on postretirement benefit plans has been included in the Corporate operating loss from continuing operations, and in the aggregate constituted a pre-tax loss of $15.3 million in fiscal year 2016, a pre-tax loss of $12.4 million in fiscal year 2015, and pre-tax loss of $75.4 million in fiscal year 2014.

(3) Includes expenses related to litigation with Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (collectively, "Enzo"). Enzo filed a complaint in 2002 that alleged that the Company separately and together with other defendants breached distributorship and settlement agreements with Enzo, infringed Enzo's patents, engaged in unfair competition and fraud, and committed torts against Enzo by, among other things, engaging in commercial development and exploitation of Enzo's patented products and technology. The Company entered into a settlement agreement with Enzo dated June 20, 2014 and during fiscal year 2014 paid $7.0 million into a designated escrow account to resolve this matter, of which $3.7 million had been accrued in previous years and $3.3 million was recorded during fiscal year 2014. In addition, $3.4 million of expenses were incurred and recorded in preparation for the trial during fiscal year 2014.

Additional information relating to the Company's reporting segments is as follows for the three fiscal years ended January 1, 2017:

	Depreciation and Amortization Expense			Capital Expenditures		
	January 1, 2017	January 3, 2016	December 28, 2014	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)			(In thousands)	
Discovery & Analytical Solutions	$ 72,484	$ 74,177	$ 72,288	$ 21,486	$ 18,175	$ 18,234
Diagnostics	25,339	29,728	36,146	8,556	6,854	7,196
Corporate	2,149	1,459	2,031	1,660	3,189	1,722
Continuing operations	$ 99,972	$ 105,364	$ 110,465	$ 31,702	$ 28,218	$ 27,152
Discontinued operations	$ 6,266	$ 6,643	$ 6,610	$ 1,302	$ 1,414	$ 2,133

	Total Assets		
	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
Discovery & Analytical Solutions	$ 2,612,757	$ 2,546,583	$ 2,614,911
Diagnostics	1,505,381	1,459,854	1,343,110
Corporate	31,171	28,497	28,482
Current and long-term assets of discontinued operations	127,374	131,361	141,073
Total assets	$ 4,276,683	$ 4,166,295	$ 4,127,576

The following geographic area information for continuing operations includes revenue based on location of external customers for the three fiscal years ended January 1, 2017 and net long-lived assets based on physical location as of January 1, 2017 and January 3, 2016:

	Revenue		
	January 1, 2017	January 3, 2016	December 28, 2014
		(In thousands)	
U.S.	$ 842,364	$ 854,336	$ 794,568
International:			
China	336,728	296,908	257,669
United Kingdom	65,904	69,081	81,127
Germany	89,839	86,632	88,071
Italy	70,948	71,225	80,834
France	71,104	70,665	77,637
Japan	65,980	69,381	90,284
Other international	572,650	586,595	599,690
Total international	1,273,153	1,250,487	1,275,312
Total sales	$ 2,115,517	$ 2,104,823	$ 2,069,880

	Net Long-Lived Assets		
	January 1, 2017	January 3, 2016	December 28, 2014
	(In thousands)		
U.S.	$ 182,186	$ 165,827	$ 161,430
International:			
China	36,458	34,494	36,951
United Kingdom	14,638	14,244	12,155
Finland	12,295	12,203	12,758
Singapore	6,820	7,679	7,041
Netherlands	4,162	3,835	3,614
Italy	3,398	2,958	4,142
Sweden	2,645	1,247	742
Other international	12,448	10,539	12,871
Total international	92,864	87,199	90,274
Total net long-lived assets	$ 275,050	$ 253,026	$ 251,704

Note 24: Quarterly Financial Information (Unaudited)

Selected quarterly financial information is as follows for the fiscal years ended:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter[1]	Year
	(In thousands, except per share data)				
January 1, 2017					
Revenue	$ 498,016	$ 536,242	$ 514,489	$ 566,770	$ 2,115,517
Gross profit	235,086	253,554	248,550	276,163	1,013,353
Restructuring and contract termination charges, net	—	4,468	656	—	5,124
Operating income from continuing operations	60,577	66,266	75,781	80,442	283,066
Income from continuing operations before income taxes	49,491	60,873	64,518	69,186	244,068
Income from continuing operations	41,744	57,756	53,917	62,289	215,706
Income from discontinued operations and dispositions	5,722	6,101	4,210	2,560	18,593
Net income	47,466	63,857	58,127	64,849	234,299
Basic earnings per share:					
Income from continuing operations	$ 0.38	$ 0.53	$ 0.49	$ 0.57	$ 1.97
Income from discontinued operations and dispositions	0.05	0.06	0.04	0.02	0.17
Net income	0.43	0.59	0.53	0.59	2.14
Diluted earnings per share:					
Income from continuing operations	$ 0.38	$ 0.53	$ 0.49	$ 0.57	$ 1.96
Income from discontinued operations and dispnsitions	0.05	0.06	0.04	0.02	0.17
Net income	0.43	0.58	0.53	0.59	2.12
Cash dividends declared per common share	$ 0.07	$ 0.07	$ 0.07	$ 0.07	$ 0.28
January 3, 2016					
Revenue	$ 484,143	$ 525,268	$ 525,509	$ 569,903	$ 2,104,823
Gross profit	219,206	237,923	239,371	267,731	964,231
Restructuring and contract termination charges, net	—	4,910	(115)	8,752	13,547
Operating income from continuing operations	46,771	59,543	67,389	77,223	250,926
Income from continuing operations before income taxes	37,350	48,700	55,445	67,312	208,807
Income from continuing operations	33,108	43,166	49,119	63,392	188,785
Income from discontinued operations and dispositions	7,226	5,808	5,744	4,862	23,640
Net income	40,334	48,974	54,863	68,254	212,425
Basic earnings per share:					
Income from continuing operations	$ 0.29	$ 0.38	$ 0.44	$ 0.57	$ 1.68
Income from discontinued operations and dispositions	0.06	0.05	0.05	0.04	0.21
Net income	0.36	0.43	0.49	0.61	1.89
Diluted earnings per share:					
Income continuing operations	$ 0.29	$ 0.38	$ 0.43	$ 0.56	$ 1.67
Income from discontinued operations and dispositinus	0.06	0.05	0.05	0.04	0.21
Net income	0.36	0.43	0.48	0.61	1.87

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter[1]	Year
	(In thousands, except per share data)				
Cash dividends declared per common share	$ 0.07	$ 0.07	$ 0.07	$ 0.07	$ 0.28

(1) The fourth quarter of fiscal year 2016 includes a pre-tax loss of $15.3 million as a result of the mark-to-market adjustment on postretirement benefit plans. The fourth quarter of fiscal year 2015 includes a pre-tax loss of $12.4 million as a result of the mark-to-market adjustment on postretirement benefit plans. See Note 1 for a discussion of this accounting policy.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***Controls and Procedures***

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of January 1, 2017. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of January 1, 2017, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of January 1, 2017. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in the 2013 Internal Control-Integrated Framework.

Based on this assessment, our management concluded that, as of January 1, 2017, our internal control over financial reporting was effective based on those criteria.

Our registered public accounting firm has issued an attestation report on our internal control over financial reporting. This report appears below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of PerkinElmer, Inc.
Waltham, Massachusetts

We have audited the internal control over financial reporting of PerkinElmer, Inc. and subsidiaries (the "Company") as of January 1, 2017, based on criteria established in *Internal Control-- Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of January 1, 2017, based on the criteria established in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended January 1, 2017 of the Company and our report dated February 28, 2017 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts
February 28, 2017

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended January 1, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other Information***

Not applicable.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information required to be disclosed by this Item pursuant to Item 401 of Regulation S-K with respect to our executive officers is contained in Part I of this annual report on Form 10-K under the caption, "Executive Officers of the Registrant." The remaining information required to be disclosed by the Item pursuant to Item 401 and Item 407 of Regulation S-K is contained in the proxy statement for our annual meeting of stockholders to be held on April 25, 2017 under the captions "Proposal No. 1 Election of Directors" and "Information Relating to Our Board of Directors and Its Committees" and is incorporated in this annual report on Form 10-K by reference.

The information required to be disclosed by this Item pursuant to Item 405 of Regulation S-K is contained in the proxy statement for our annual meeting of stockholders to be held on April 25, 2017 under the caption "Section 16(a) Beneficial Ownership Reporting Compliance," and is incorporated in this annual report on Form 10-K by reference.

We have adopted a code of ethics, our Standards of Business Conduct, that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions. Our Standards of Business Conduct, as well as our corporate governance guidelines and the charters for the audit, compensation and benefits, nominating and corporate governance, executive and finance committees of our Board of Directors, are each accessible under the "Corporate Governance" heading of the "Investors" section of our website, http://www.perkinelmer.com. This information is also available in print to any stockholder who requests it, by writing to PerkinElmer, Inc., 940 Winter Street, Waltham, Massachusetts 02451, Attention: Investor Relations. We also intend to disclose in the same location on our website, any amendments to, or waivers from, our Standards of Business Conduct that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K.

Item 11. ***Executive Compensation***

The information required to be disclosed by this Item pursuant to Item 402 and Item 407(e) of Regulation S-K is contained in the proxy statement for our annual meeting of stockholders to be held on April 25, 2017 under the captions "Information Relating to Our Board of Directors and Its Committees—Director Compensation," "Information Relating to Our Board of Directors and Its Committees—Compensation Committee Interlocks and Insider Participation," and "Executive Compensation," and is incorporated in this annual report on Form 10-K by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required to be disclosed by this Item pursuant to Item 403 of Regulation S-K is contained in the proxy statement for our annual meeting of stockholders to be held on April 25, 2017 under the caption "Beneficial Ownership of Common Stock," and is incorporated in this annual report on Form 10-K by reference.

The information required to be disclosed by this Item pursuant to Item 201(d) of Regulation S-K is contained in the proxy statement for our annual meeting of stockholders to be held on April 25, 2017 under the caption "Executive Compensation—Equity Compensation Plan Information," and is incorporated in this annual report on Form 10-K by reference.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information required to be disclosed by this Item pursuant to Item 404 of Regulation S-K is contained in the proxy statement for our annual meeting of stockholders to be held on April 25, 2017 under the caption "Information Relating to Our Board of Directors and Its Committees—Certain Relationships and Policies on Related Party Transactions," and is incorporated in this annual report on Form 10-K by reference.

The information required to be disclosed by this Item pursuant to Item 407(a) of Regulation S-K is contained in the proxy statement for our annual meeting of stockholders to be held on April 25, 2017 under the caption "Information Relating to

Our Board of Directors and Its Committees—Determination of Independence," and is incorporated in this annual report on Form 10-K by reference.

Item 14. ***Principal Accountant Fees and Services***

The information required to be disclosed by this Item pursuant to Item 9(e) of Schedule 14A is contained in the proxy statement for our annual meeting of stockholders to be held on April 25, 2017 under the caption "Information Relating to Our Board of Directors and Its Committees—Independent Registered Public Accounting Firm Fees and Other Matters", and is incorporated in this annual report on Form 10-K by reference.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) DOCUMENTS FILED AS PART OF THIS REPORT:

1. FINANCIAL STATEMENTS

Included in Part II, Item 8:

Report of Independent Registered Public Accounting Firm

Consolidated Statements of Operations for Each of the Three Fiscal Years in the Period Ended January 1, 2017

Consolidated Statements of Comprehensive Income for Each of the Three Fiscal Years in the Period Ended January 1, 2017

Consolidated Balance Sheets as of January 1, 2017 and January 3, 2016

Consolidated Statements of Stockholders' Equity for Each of the Three Fiscal Years in the Period Ended January 1, 2017

Consolidated Statements of Cash Flows for Each of the Three Fiscal Years in the Period Ended January 1, 2017

Notes to Consolidated Financial Statements

2. FINANCIAL STATEMENT SCHEDULE

Schedule II—Valuation and Qualifying Accounts

We have omitted financial statement schedules, other than those we note above, because of the absence of conditions under which they are required, or because the required information is given in the financial statements or notes thereto.

3. EXHIBITS

Exhibit No.	Exhibit Title
2.1[(1)]	Share Purchase Agreement, dated November 21, 2014, by and among Valedo Partners Fund I AB, the Other Sellers party thereto and PerkinElmer Holding Luxembourg S.à.r.l., filed with the Commission on November 28, 2014 as Exhibit 2.1 to our current report on Form 8-K and herein incorporated by reference.
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3.1	PerkinElmer, Inc.'s Restated Articles of Organization, filed with the Commission on May 11, 2007 as Exhibit 3.1 to our quarterly report on Form 10-Q and herein incorporated by reference.
3.2	PerkinElmer, Inc.'s Amended and Restated By-laws, filed with the Commission on July 27, 2016 as Exhibit 3.2 to our current report on Form 8-K and herein incorporated by reference.
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4.3	Supplemental Indenture dated as of October 25, 2011 between PerkinElmer, Inc. and U.S. Bank National Association, filed with the Commission on October 27, 2011 as Exhibit 99.2 to our current report on Form 8-K and herein incorporated by reference.
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(3) Employment Agreement by and between Frank A. Wilson and PerkinElmer, Inc. dated as of April 28, 2009, filed with the Commission on April 30, 2009 as Exhibit 10.1 to our current report on Form 8-K and herein incorporated by reference;

(4) Form of Amendment, entered into by and between PerkinElmer, Inc. and each of the following executive officers on the dates indicated below, filed with the Commission on March 1, 2011 as Exhibit 10.4(7) to our annual report on Form 10-K and herein incorporated by reference:

Executive Officer	Date
Joel S. Goldberg	December 3, 2010
Frank A. Wilson	December 21, 2010

(5) Employment Agreement between James Corbett and PerkinElmer, Inc. dated as of February 1, 2012, filed with the Commission on May 8, 2012 as Exhibit 10.1 to our quarterly report on Form 10-Q and herein incorporated by reference.

(6) Employment Agreement between Jonathan DiVincenzo and PerkinElmer, Inc. dated as of December 2, 2013, filed with the Commission on February 25, 2014 as Exhibit 10.2(9) to our annual report on Form 10-K and herein incorporated by reference.

(7) Amended and Restated Employment Agreement between Andrew Okun and PerkinElmer, Inc. dated as of January 1, 2014, filed with the Commission on February 25, 2014 as Exhibit 10.2(10) to our annual report on Form 10-K and herein incorporated by reference.

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10.3*	PerkinElmer, Inc.'s 2009 Incentive Plan, filed with the Commission on March 12, 2014 as Appendix A to our definitive proxy statement on Schedule 14A and herein incorporated by reference.
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10.7*	PerkinElmer, Inc.'s Performance Unit Program Description, filed with the Commission on February 6, 2009 as Exhibit 10.10 to our annual report on Form 10-K and herein incorporated by reference.
10.8*	PerkinElmer, Inc. 1998 Employee Stock Purchase Plan as Amended and Restated on December 10, 2009, filed with the Commission on March 1, 2010 as Exhibit 10.15 to our annual report on Form 10-K and herein incorporated by reference.
10.9*	Form of Stock Option Agreement given by PerkinElmer, Inc. to its chief executive officer for use under the 2009 Incentive Plan, filed with the Commission on April 28, 2009 as Exhibit 10.2 to our current report on Form 8-K and herein incorporated by reference.
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10.13*	Form of Restricted Stock Agreement with performance-based vesting for use under the 2009 Incentive Plan, filed with the Commission on April 28, 2009 as Exhibit 10.6 to our current report on Form 8-K and herein incorporated by reference.
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10.15*	Form of Restricted Stock Unit Agreement with performance-based vesting for use under the 2009 Incentive Plan, filed with the Commission on April 28, 2009 as Exhibit 10.8 to our current report on Form 8-K and herein incorporated by reference.
10.16*	Form of Restricted Stock Agreement with time-based vesting for use under the 2009 Incentive Plan, filed with the Commission on May 10, 2011 as Exhibit 10.2 to our quarterly report on Form 10-Q and herein incorporated by reference.

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10.17*	Form of Stock Option Agreement for use under the 2009 Incentive Plan, filed with the Commission on May 10, 2011 as Exhibit 10.3 to our quarterly report on Form 10-Q and herein incorporated by reference.
10.18*	Form of Restricted Stock Unit Agreement given by PerkinElmer, Inc. to its non-employee directors for use under the 2009 Incentive Plan, filed with the Commission on February 24, 2015 as Exhibit 10.25 to our annual report on Form 10-K and herein incorporated by reference.
10.19*	Form of 162(m)-compliant Restricted Stock Agreement with single-trigger acceleration for use under the 2009 Incentive Plan, attached hereto as Exhibit 10.19.
10.20*	Form of 162(m)-compliant Restricted Stock Agreement with double-trigger acceleration for use under the 2009 Incentive Plan, attached hereto as Exhibit 10.20.
10.21*	Form of 162(m)-compliant Restricted Stock Unit Agreement with single-trigger acceleration for use under the 2009 Incentive Plan, attached hereto as Exhibit 10.21.
10.22*	Form of 162(m)-compliant Restricted Stock Unit Agreement with double-trigger acceleration for use under the 2009 Incentive Plan, attached hereto as Exhibit 10.22.
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10.25*	PerkinElmer, Inc.'s Amended and Restated Performance Incentive Plan (Executive Officers), filed with the Commission on February 25, 2014 as Exhibit 10.37 to our annual report on Form 10-K and herein incorporated by reference.
12.1	Statement regarding computation of ratio of earnings to fixed charges, attached hereto as Exhibit 12.1.
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23	Consent of Independent Registered Public Accounting Firm, attached hereto as Exhibit 23.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, attached hereto as Exhibit 31.1.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, attached hereto as Exhibit 31.2.
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101.INS	XBRL Instance Document.
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101.DEF	XBRL Definition Linkbase Document.
101.LAB	XBRL Labels Linkbase Document.
101.PRE	XBRL Presentation Linkbase Document.

(1) The exhibits and schedules to this agreement have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The registrant agrees to furnish copies of any of such exhibits or schedules to the SEC upon request.

* Management contract or compensation plan or arrangement required to be filed as an exhibit pursuant to Item 15(b) of Form 10-K.

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language):

(i) Consolidated Statements of Operations for each of the three years in the period ended January 1, 2017, (ii) Consolidated Balance Sheets as of January 1, 2017 and January 3, 2016, (iii) Consolidated Statements of Comprehensive Income for each of the three years in the period ended January 1, 2017, (iv) Consolidated Statements of Stockholders' Equity for each of the three years in the period ended January 1, 2017, (v) Consolidated Statements of Cash Flows for each of the three years in the period ended January 1, 2017, (vi) Notes to Consolidated Financial Statements, and (vii) Financial Schedule of Valuation and Qualifying Accounts.

SCHEDULE II

PERKINELMER, INC. AND SUBSIDIARIES

VALUATION AND QUALIFYING ACCOUNTS
For the Three Years Ended January 1, 2017

Description	Balance at Beginning of Year	Provisions	Charges/ Write-offs	Other[1]	Balance at End of Year
			(In thousands)		
Reserve for doubtful accounts:					
Year ended December 28, 2014	$ 28,143	$ 9,447	$ (4,125)	$ (608)	$ 32,857
Year ended January 3, 2016	32,857	3,564	(5,709)	(846)	29,866
Year ended January 1, 2017	29,866	5,346	(5,499)	(501)	29,212

(1) Other amounts primarily relate to the impact of acquisitions, discontinued operations and foreign exchange movements.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PERKINELMER, INC.

	Signature	Title	Date
By:	/S/ ROBERT F. FRIEL Robert F. Friel	Chairman, Chief Executive Officer and President (Principal Executive Officer)	February 28, 2017
By:	/S/ FRANK A. WILSON Frank A. Wilson	Sr. Vice President and Chief Financial Officer (Principal Financial Officer)	February 28, 2017
By:	/S/ ANDREW OKUN Andrew Okun	Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 28, 2017

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of PerkinElmer, Inc., hereby severally constitute Robert F. Friel and Frank A. Wilson, and each of them singly, our true and lawful attorneys with full power to them, and each of them singly, to sign for us and in our names, in the capacities indicated below, this Annual Report on Form 10-K and any and all amendments to said Annual Report on Form 10-K, and generally to do all such things in our name and behalf in our capacities as officers and directors to enable PerkinElmer, Inc. to comply with the provisions of the Securities Exchange Act of 1934, and all requirements of the Securities and Exchange Commission, hereby ratifying and confirming signed by our said attorneys, and any and all amendments thereto.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

	Signature	Title	Date
By:	/S/ ROBERT F. FRIEL Robert F. Friel	Chairman, Chief Executive Officer and President (Principal Executive Officer)	February 28, 2017
By:	/S/ FRANK A. WILSON Frank A. Wilson	Sr. Vice President and Chief Financial Officer (Principal Financial Officer)	February 28, 2017
By:	/S/ ANDREW OKUN Andrew Okun	Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 28, 2017
By:	/S/ PETER BARRETT Peter Barrett	Director	February 28, 2017
By:	/S/ SAMUEL R. CHAPIN Samuel R. Chapin	Director	February 28, 2017
By:	/S/ SYLVIE GRÉGOIRE, PharmD Sylvie Grégoire, PharmD	Director	February 28, 2017
By:	/S/ NICHOLAS A. LOPARDO Nicholas A. Lopardo	Director	February 28, 2017
By:	/S/ ALEXIS P. MICHAS Alexis P. Michas	Director	February 28, 2017
By:	/S/ VICKI L. SATO, PhD Vicki L. Sato, PhD	Director	February 28, 2017
By:	/S/ KENTON J. SICCHITANO Kenton J. Sicchitano	Director	February 28, 2017
By:	/S/ PATRICK J. SULLIVAN Patrick J. Sullivan	Director	February 28, 2017
By:	/S/ FRANK WITNEY, PhD Frank Witney, PhD	Director	February 28, 2017

EXHIBIT INDEX

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Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language):

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USE OF NON-GAAP FINANCIAL MEASURES

In addition to financial measures prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), this Annual Report also contains non-GAAP financial measures. Management believes that, in order to more fully understand our short-term and long-term financial and operational needs, investors may wish to consider the impact of certain non-cash, non-recurring or other items, which result from facts and circumstances that vary in frequency and impact on continuing operations. Accordingly, we present non-GAAP financial measures as a supplement to the financial measures we present in accordance with GAAP. These non-GAAP financial measures provide management with additional means to understand and evaluate the operating results and trends in our ongoing business by adjusting for certain non-cash expenses and other items that management believes might otherwise make comparisons of our ongoing business with prior periods more difficult, obscure trends in ongoing operations, or reduce management's ability to make useful forecasts. Management believes these non-GAAP financial measures provide additional means of evaluating period-over-period operating performance. In addition, management understands that some investors and financial analysts find this information helpful in analyzing our financial and operational performance and comparing this performance to our peers and competitors.

The non-GAAP financial measures that we disclose are not meant to be considered superior to, or a substitute for, our financial measures prepared in accordance with GAAP. There are material limitations associated with non-GAAP financial measures because they exclude charges that have an effect on our reported results and, therefore, should not be relied upon as the sole financial measures by which to evaluate our financial results. Management compensates and believes that investors should compensate for these limitations by viewing the non-GAAP financial measures in conjunction with the GAAP financial measures. In addition, the non-GAAP financial measures included in this Annual Report may be different from, and therefore may not be comparable to, similar measures used by other companies.

Each of the non-GAAP financial measures that we disclose is also used by our management to evaluate our operating performance, communicate our financial results to our Board of Directors, benchmark our results against our historical performance and the performance of our peers, evaluate investment opportunities including acquisitions and discontinued operations, and determine the bonus payments for senior management and employees.

RECONCILIATION OF NON-GAAP FINANCIAL MEASURES

This Annual Report contains the non-GAAP financial measures of adjusted earnings per share, adjusted revenue, adjusted operating margins, and free cash flow. A tabular reconciliation of these non-GAAP financial measures to the most comparable GAAP financial measures is set forth here.

ADJUSTED EARNINGS PER SHARE (EPS)[1]	**FY16**	**FY15**
GAAP EPS	$ 2.12	$ 1.87
Discontinued operations	0.17	0.21
GAAP EPS from continuing operations	**$ 1.96**	**$ 1.67**
Amortization of intangible assets	0.65	0.68
Purchase accounting adjustments	0.16	0.07
Significant litigation matter	—	0.01
Acquisition and divestiture-related expenses	0.01	0.01
Disposition of businesses and assets	(0.05)	—
Mark-to-market on post-retirement benefits	0.14	0.11
Restructuring and contract termination charges	0.05	0.12
Tax on above items	(0.31)	(0.33)
Adjusted EPS	**$ 2.60**	**$ 2.33**

ADJUSTED REVENUE AND OPERATING INCOME (in millions)[1]	**FY16**	**FY15**
GAAP revenue	$2,116	$2,105
Purchase accounting adjustments	1	1
Adjusted revenue	**$2,116**	**$2,106**
GAAP operating income	283	251
Intangibles amortization	71	77
Purchase accounting adjustments	17	8
Acquisition and divestiture-related expenses	1	1
Significant litigation matter	—	1
Mark-to-market on post-retirement benefits	15	12
Restructuring and contract termination charges	5	14
Adjusted Operating Income	**$ 394**	**$ 363**
Adjusted OP%	*18.6%*	*17.2%*

FREE CASH FLOW (in millions)	**FY16**	**FY15**
Net cash provided by operating activities	$ 351	$ 287
Less: capital expenditures (including discontined operations)	(33)	(30)
Free cash flow	**$ 318**	**$ 257**

(1) amounts may not add due to rounding

CORPORATE HEADQUARTERS
PerkinElmer, Inc.
940 Winter Street
Waltham, MA 02451 USA
Phone: (781) 663-6900
Fax: (781) 663-6052
www.perkinelmer.com

Information requests from security analysts and other members of the financial community can be directed to Investor Relations.

ANNUAL MEETING
The Annual Meeting of PerkinElmer, Inc. shareholders will be held at 8:00 A.M. on Tuesday, April 25, 2017, at the PerkinElmer Headquarters, 940 Winter Street, Waltham, Massachusetts. A formal meeting notice, an Annual Report, a Proxy Statement and a form of Proxy will be furnished to each shareholder as of the record date of February 27, 2017.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
Deloitte & Touche LLP
200 Berkeley Street
Boston, MA 02116

SHAREHOLDER SERVICES
PerkinElmer shareholder records are maintained by its transfer agent, Computershare. Inquiries relating to shareholder records, stock transfer, changes of ownership, changes of address, dividend payments, dividend reinvestment, direct deposit of quarterly dividends and consolidation of accounts should be addressed to:

Regular mail
Computershare, Inc.
P.O. Box 30170
College Station, TX 77842
www.computershare.com

Overnight delivery
Computershare, Inc.
211 Quality Circle, Suite 210
College Station, TX 77845

Shareholders may also call 1-877-711-4098 (U.S.) or 1-201-680-6578 (non-U.S.). For the hearing impaired (TTY/TDD), call 1-800-231-5469 (U.S.) or 1-201-680-6610 (non-U.S.).

STOCK EXCHANGE INFORMATION
PerkinElmer, Inc., common stock is listed and traded on the New York Stock Exchange.
Ticker symbol: PKI

INVESTOR RELATIONS INFORMATION LINE
The Company's quarterly earnings results are available through the PerkinElmer Investor Relations Information Line. Shareholders can receive current corporate information, such as dividend data, recent earnings and press release information. The toll-free number is 1-877-PKI-NYSE.

PERKINELMER STANDARDS OF BUSINESS CONDUCT
PerkinElmer is fully committed to conducting business with our customers, shareholders, and employees in accordance with high moral and ethical principles, and in compliance with applicable law. As part of this commitment, PerkinElmer provides Business Conduct training and its Standards of Business Conduct to all employees, who are expected to follow the spirit as well as the letter of the law. At PerkinElmer, we place a high priority on managing our business in an ethical manner in order to maintain our established reputation for integrity and dependability.

FACTORS AFFECTING FUTURE PERFORMANCE
This document contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements in this document that relate to prospective events or developments are deemed to be forward-looking statements. Words such as "believes," "intends," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions, and references to guidance, are intended to identify forward-looking statements about the expected future business and financial performance of PerkinElmer.

Forward-looking statements are based on management's current expectations and assumptions, which are inherently subject to uncertainties, risks and changes in circumstances that are difficult to predict. Actual outcomes and results may differ materially from these expectations and assumptions due to changes in political, economic, business, financial, competitive, market, regulatory and other factors. Refer to our enclosed Annual Report on Form 10-K, under the caption "Item 1A. Risk Factors," for more information. We undertake no obligation to publicly update or review any forward-looking information, whether as a result of new information, future developments or otherwise.

FORM 10-K
This Annual Report to Shareholders includes a copy of our Annual Report on Form 10-K for the fiscal year ended January 1, 2017, excluding exhibits, as filed with the Securities and Exchange Commission and available through our Web site at www.perkinelmer.com. We will, upon written request and payment of an appropriate processing fee, provide our shareholders with copies of the exhibits to our Annual Report on Form 10-K. Please address your request to PerkinElmer, Inc., 940 Winter Street, Waltham, Massachusetts 02451, Attention: Investor Relations.

PerkinElmer Genetics, Inc.

Response to

Request for Proposal (RFP) #5710Z1

Newborn Screening Laboratory Testing Services

ORIGINAL - COST PROPOSAL

PRICING SUMMARY

VII. COST PROPOSAL REQUIREMENTS

This section describes the requirements to be addressed by bidders in preparing the State's Cost Sheet. The bidder must use the State's Cost Sheet. The bidder should submit the State's Cost Sheet in accordance with Section I Submission of Proposal.

THE STATE'S COST SHEET AND ANY OTHER COST DOCUMENT SUBMITTED WITH THE PROPOSAL SHALL NOT BE CONSIDERED CONFIDENTIAL OR PROPRIETARY AND IS CONSIDERED A PUBLIC RECORD IN THE STATE OF NEBRASKA AND WILL BE POSTED TO A PUBLIC WEBSITE.

A. PRICING SUMMARY

Specimen testing cost for the screening panel as described in this RFP including Pompe, MPS-I and X-ALD **$60.50** + $10 /infant screened fee = Total amount per infant billed upon completion of initial specimen testing: **$70.50**. All requested repeat specimens shall be tested without billing to the submitter.

Specimen testing cost for the screening panel as described in this RFP including Pompe, MPS-I and X-ALD if they are adopted via regulation: **$60.50** + $20/infant screened fee = Total amount per infant billed upon completion of initial specimen testing: **$80.50**. All requested repeat specimens shall be tested without billing to the submitter.

The State reserves the right to review all aspects of cost for reasonableness and to request clarification of any proposal where the cost component shows significant and unsupported deviation from industry standards or in areas where detailed pricing is required.

B. PRICES

Prices quoted shall be net, including transportation and delivery charges fully prepaid by the bidder, F.O.B. destination named in the RFP. No additional charges will be allowed for packing, packages, or partial delivery costs. When an arithmetic error has been made in the extended total, the unit price will govern.

C. ALTERNATIVE PRICING

Alternative pricing is also being requested for the addition of any testing for conditions not listed in this RFP. The alternative pricing will not be part of the evaluation of this Request for Proposal.

For any optional scope of work/additional tests for conditions/diseases beyond those required in this RFP, a separate cost proposal should be submitted. Additional costs should be listed individually for each test, and if part of a multi-plex assay a single cost for the group of conditions should also be listed.

Specimen testing cost for optional test/disease of:_____ $_____
Specimen testing cost for optional test/disease of:_____ $_____
Specimen testing cost for optional test/disease of:_____ $_____
Specimen testing cost for optional test/disease of:_____ $_____
Specimen testing cost for optional test/disease of:_____ $_____

Single Specimen testing cost $_____ for multiplex testing for optional diseases of: _____,
_____.

PerkinElmer Genetics, Inc.

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Request for Proposal (RFP) #5710Z1

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ORIGINAL - COST PROPOSAL

ALTERNATIVE PRICING

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PRICING SUMMARY

Specimen testing cost for the screening panel as described in this RFP including Pompe, MPS-I and X-ALD _____ + $10 /infant screened fee = Total amount per infant billed upon completion of initial specimen testing: $_____. All requested repeat specimens shall be tested without billing to the submitter.

Specimen testing cost for the screening panel as described in this RFP including Pompe, MPS-I and X-ALD if they are adopted via regulation: _____ + $20/infant screened fee = Total amount per infant billed upon completion of initial specimen testing: $_____. All requested repeat specimens shall be tested without billing to the submitter.

The State reserves the right to review all aspects of cost for reasonableness and to request clarification of any proposal where the cost component shows significant and unsupported deviation from industry standards or in areas where detailed pricing is required.

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For any optional scope of work/additional tests for conditions/diseases beyond those required in this RFP, a separate cost proposal should be submitted. Additional costs should be listed individually for each test, and if part of a multi-plex assay a single cost for the group of conditions should also be listed.

Specimen testing cost for optional test/disease of: **sequencing any gene associated with the Nebraska Newborn Screening panel $650.00**
Specimen testing cost for optional test/disease of:_____ $_____
Specimen testing cost for optional test/disease of:_____ $_____
Specimen testing cost for optional test/disease of:_____ $_____
Specimen testing cost for optional test/disease of:_____ $_____

Single Specimen testing cost $_____ for multiplex testing for optional diseases of: _____, _____.

ADDENDUM ONE, QUESTIONS and ANSWERS

Date: December 4, 2017

To: All Bidders

From: Michelle Thompson/Annette Walton, Buyers
AS Materiel State Purchasing

RE: Addendum for Request for Proposal Number RFP 5710 Z1
to be opened January 8, 2018, at 2:00 P.M. Central Time

Questions and Answers

Following are the questions submitted and answers provided for the above mentioned Request for Proposal. The questions and answers are to be considered as part of the Request for Proposal. It is the Bidder's responsibility to check the State Purchasing Bureau website for all addenda or amendments.

Question Number	RFP Section Reference	RFP Page Number	Question	State Response
1.	I E Notification of Intent to Bid	2	There is a conflict between E and Form B on page 42. Is it permissible to submit the Notification of Intent to Bid (Form B) via email?	Yes, Form B may be submitted by e-mail to as/materielpurchasing@nebraska.gov.
2.	I E Notification of Intent to Bid	2	By what date will the final list of vendors who submitted a Notification of Intent to Bid be posted on the website?	Per the Schedule of Events, the last day to submit the Notification of Intent to Bid is Friday, December 22, 2017. The State will post the list of vendors on Tuesday, December 26, 2017.
3.	I E Notification of Intent to Bid	2	If a vendor does not submit a "Notification of Intent to Bid Form" but submits a proposal, will the vendor's proposal be evaluated?	Yes, if the vendor does not submit a Notification of Intent to Bid Form and submits a proposal response, the proposal response will be evaluated. The Notification of Intent to Bid Form is optional.
4.	II E Change Orders	9	What does "corrections of any deliverable, service or work" mean?	If the Contractor delivers a defective product which is a requirement of the contract, it is the Contractors responsibility to correct the defect at no additional cost to the State.
5.	II E Change Orders	9	What does "forfeiture of the contract" mean?	If the State changes the contract, the Contractor cannot claim that the State made a change and as a result, the contractor stops performing under the contract.

6.	III F Ownership of Information and Data/Deliverables	17	Will the "deliverables" be defined?	See section V. U. Deliverables. The deliverables will be defined in the contract by a combination of the RFP requirements and the response to the RFP.
7.	V C 11 Hemoglobinopathies	25	Please clarify the sequencing preferred comment. Will sequencing be considered 3rd tier after IEF and point mutation by the State? On which IEF results does the State want sequencing performed?	Sequencing would be required as a 3rd tier test upon request (and is not required routinely) for clarification of suspected alpha-globin or unidentified variants. As such cost to provide this service is not expected in the cost proposal for routine screening. Bidders who can offer this as part of the routine screening should state in the proposal response.
8.	VII A Cost Proposal Requirements	40	The first 2 paragraphs contain different information. Please describe the difference in the infant screened fee and why the first paragraph does not have the phrase "if they are adopted via regulation".	Since the publication of this RFP it has been determined that Pompe, MPS-I and X-ALD will be implemented July 1, 2018 due to statutory requirement, regardless of whether regulation revisions are made or not. So the phrase "if they are adopted via regulation" is no longer applicable to the three diseases. The difference between the pricing summary in the first paragraph is the $10 fee, vs. the 2nd paragraph the $20 fee. The $20 fee will only go into effect if regulations are revised.
9.	General question	5710 Z1	Is Nebraska open to a different model to provide this service, one that would modify many of the requirements of the RFP? [redacted] would consider a lab to lab model where Nebraska would be responsible for distributing the cards, collecting them from each hospital, entering and monitoring demographics, etc. Nebraska would send the card to [redacted] and [redacted] would send Nebraska back results, and Nebraska would be responsible for distribution to each hospital.	No. All proposals must follow the requirements of the RFP.
10.	General Question	5710 Z1	Please confirm the RFP due date. Is it 12/22 or	The optional Form B, Notification of Intent to Bid Form is due on December

			1/8?	22, 2017. The Proposal opening is January 8, 2018 at 2:00 PM Central Time. If submitting a proposal response, the State must receive the proposal response before January 8, 2018 at 2:00 PM Central Time.
11.	PROCURMENT PROCEDURE Section F	5710 Z1 2	Please verify that a bidder has the right to not extend if the State does not agree to the discussed pricing increases.	Please see Section II. Terms and Conditions, R. Early Termination.
12.	PROJECT DESCRIPTION AND SCOPE OF WORK Section A	5710 Z1 23	Can you please clarify the requirements of this provision: The contractor will provide the NNSP with access to an electronic database fulfilling all requirements of this RFP. (A Project overview).	The electronic database must fulfill all requirements in section V.G. Data Systems Requirements, including the documentation requirements in V.F. Reporting and V.H. Data System Future Enhancement.
13.	PROJECT DESCRIPTION AND SCOPE OF WORK Section D	5710 Z1 27	What are the requirements for tracking under this provision: The laboratory must document tracking of which filter paper specimen collection devices were provided to which birthing hospital/facility and communicate this information to the NNSP as requested. (D. Filter paper).	Maintain a record of which filter papers (by serial number) were distributed to which birthing facility.
14.	PROJECT DESCRIPTION AND SCOPE OF WORK Section D	5710 Z1 27	Can contractor require site pay for filter paper card upfront? Provision:The contractor will distribute supplies of the filter paper collection devices to all Nebraska birthing facility submitters. (D. Filter paper).	No. The RFP only allows charges to submitters on a per-infant-screened basis, not per-filter paper submitted or distributed. See V.D. Filter Paper paragraph 1. All costs to provide the services described in this RFP should be considered when determining the per-infant screened cost proposal.
15.	PROJECT DESCRIPTION AND SCOPE OF WORK Section J	5710 Z1 39	Can contractor take over current courier and delivery network? Is that network and operation functioning? Question assumes current provider is subcontracting this work (J. Subcontractors).	It is the contractor's responsibility to establish an effective courier and delivery network. See Section V.E. Specimen Shipping. The bidder should provide a response that best meets the requirements of this RFP.

This addendum will become part of the proposal and should be acknowledged with the Request for Proposal.

State of Nebraska State Purchasing Bureau
REQUEST FOR PROPOSAL FOR CONTRACTUAL SERVICES

RETURN TO:
State Purchasing Bureau
1526 K Street, Suite 130
Lincoln, NE 68508
Phone: (402) 471-6500

SOLICITATION NUMBER	RELEASE DATE
RFP 5710 Z1	October 26, 2017
OPENING DATE AND TIME	**PROCUREMENT CONTACT**
January 8, 2018 2:00 p.m. Central Time	Michelle Thompson / Annette Walton

PLEASE READ CAREFULLY!

SCOPE OF SERVICE

The State of Nebraska (State), Department of Administrative Services (DAS), Materiel Division, State Purchasing Bureau (SPB), is issuing this Request for Proposal (RFP) Number 5710 Z1 for the purpose of selecting a qualified Bidder to provide Newborn Screening Laboratory Testing Services. A more detailed description can be found in Section V. The resulting contract may not be an exclusive contract as the State reserves the right to contract for the same or similar services from other sources now or in the future.

The term of the contract will be two (2) years commencing upon execution of the contract beginning July 1, 2018. The Contract includes the option to renew for four (4) additional two (2) year periods upon mutual agreement of the Parties. The State reserves the right to extend the period of this contract beyond the termination date when mutually agreeable to the Parties.

ALL INFORMATION PERTINENT TO THIS REQUEST FOR PROPOSAL CAN BE FOUND ON THE INTERNET AT: **http://das.nebraska.gov/materiel/purchasing.html**.

IMPORTANT NOTICE: Pursuant to Neb. Rev. Stat. § 84-602.02, State contracts in effect as of January 1, 2014, and contracts entered into thereafter, must be posted to a public website. The resulting contract, the RFP, and the successful bidder's proposal or response will be posted to a public website managed by DAS, which can be found at http://statecontracts.nebraska.gov.

In addition and in furtherance of the State's public records Statute (Neb. Rev. Stat. § 84-712 et seq.), all proposals or responses received regarding this RFP will be posted to the State Purchasing Bureau public website.

These postings will include the entire proposal or response. Bidders must request that proprietary information be excluded from the posting. The bidder must identify the proprietary information, mark the proprietary information according to state law, and submit the proprietary information in a separate container or envelope marked conspicuously in black ink with the words "PROPRIETARY INFORMATION". The bidder must submit a detailed written document showing that the release of the proprietary information would give a business advantage to named business competitor(s) and explain how the named business competitor(s) will gain an actual business advantage by disclosure of information. The mere assertion that information is proprietary or that a speculative business advantage might be gained is not sufficient. (See Attorney General Opinion No. 92068, April 27, 1992) THE BIDDER MAY NOT ASSERT THAT THE ENTIRE PROPOSAL IS PROPRIETARY. COST PROPOSALS WILL NOT BE CONSIDERED PROPRIETARY AND ARE A PUBLIC RECORD IN THE STATE OF NEBRASKA. The State will then determine, in its discretion, if the interests served by nondisclosure outweighs any public purpose served by disclosure. (See Neb. Rev. Stat. § 84-712.05(3)) The Bidder will be notified of the agency's decision. Absent a State determination that information is proprietary, the State will consider all information a public record subject to release regardless of any assertion that the information is proprietary.

If the agency determines it is required to release proprietary information, the bidder will be informed. It will be the bidder's responsibility to defend the bidder's asserted interest in non-disclosure.

To facilitate such public postings, with the exception of proprietary information, the State of Nebraska reserves a royalty-free, nonexclusive, and irrevocable right to copy, reproduce, publish, post to a website, or otherwise use any contract, proposal, or response to this RFP for any purpose, and to authorize others to use the documents. Any individual or entity awarded a contract, or who submits a proposal or response to this RFP, specifically waives any copyright or other protection the contract, proposal, or response to the RFP may have; and, acknowledges that they have the ability and authority to enter into such waiver. This reservation and waiver is a prerequisite for submitting a proposal or response to this RFP, and award of a contract. Failure to agree to the reservation and waiver will result in the proposal or response to the RFP being found non-responsive and rejected.

Any entity awarded a contract or submitting a proposal or response to the RFP agrees not to sue, file a claim, or make a demand of any kind, and will indemnify and hold harmless the State and its employees, volunteers, agents, and its elected and appointed officials from and against any and all claims, liens, demands, damages, liability, actions, causes of action, losses, judgments, costs, and expenses of every nature, including investigation costs and expenses, settlement costs, and attorney fees and expenses, sustained or asserted against the State, arising out of, resulting from, or attributable to the posting of the contract or the proposals and responses to the RFP, awards, and other documents.

TABLE OF CONTENTS

GLOSSARY OF TERMS

Acceptance Test Procedure: Benchmarks and other performance criteria, developed by the State of Nebraska or other sources of testing standards, for measuring the effectiveness of products or services and the means used for testing such performance.

Addendum: Something to be added or deleted to an existing document; a supplement.

After Receipt of Order (ARO): After Receipt of Order

Agency: Any state agency, board, or commission other than the University of Nebraska, the Nebraska State colleges, the courts, the Legislature, or any other office or agency established by the Constitution of Nebraska.

Agent/Representative: A person authorized to act on behalf of another.

Amend: To alter or change by adding, subtracting, or substituting.

Amendment: A written correction or alteration to a document.

Appropriation: Legislative authorization to expend public funds for a specific purpose. Money set apart for a specific use.

Award: All purchases, leases, or contracts which are based on competitive proposals will be awarded according to the provisions in the RFP. The State reserves the right to reject any or all proposals, wholly or in part, or to award to multiple bidders in whole or in part. The State reserves the right to waive any deviations or errors that are not material, do not invalidate the legitimacy of the proposal, and do not improve the bidder's competitive position. All awards will be made in a manner deemed in the best interest of the State.

Best and Final Offer (BAFO): In a competitive bid, the final offer submitted which contains the bidder's (vendor's) most favorable terms for price.

Bid/Proposal: The offer submitted by a vendor in a response to a written solicitation.

Bid Bond: An insurance agreement, accompanied by a monetary commitment, by which a third party (the surety) accepts liability and guarantees that the vendor will not withdraw the bid.

Bidder: A vendor who submits an offer bid in response to a written solicitation.

Business: Any corporation, partnership, individual, sole proprietorship, joint-stock company, joint venture, or any other private legal entity.

Business Day: Any weekday, except State-recognized holidays.

Calendar Day: Every day shown on the calendar including Saturdays, Sundays, and State/Federal holidays.

Cancellation: To call off or revoke a purchase order without expectation of conducting or performing it at a later time.

Central Processing Unit (CPU): Any computer or computer system that is used by the State to store, process, or retrieve data or perform other functions using Operating Systems and applications software.

Change Order: Document that provides amendments to an executed purchase order or contract.

Collusion: An agreement or cooperation between two or more persons or entities to accomplish a fraudulent, deceitful, or unlawful purpose.

Commodities: Any equipment, material, supply or goods; anything movable or tangible that is provided or sold.

Commodities Description: Detailed descriptions of the items to be purchased; may include information necessary to obtain the desired quality, type, color, size, shape, or special characteristics necessary to perform the work intended to produce the desired results.

Competition: The effort or action of two or more commercial interests to obtain the same business from third parties.

Confidential Information: Unless otherwise defined below, "Confidential Information" shall also mean proprietary trade secrets, academic and scientific research work which is in progress and unpublished, and other information which if released would give advantage to business competitors and serve no public purpose (see Neb. Rev. Stat. §84-712.05(3)). In

accordance with Nebraska Attorney General Opinions 92068 and 97033, proof that information is proprietary requires identification of specific, named competitor(s) who would be advantaged by release of the information and the specific advantage the competitor(s) would receive.

Contract: An agreement between two or more parties creating obligations that are enforceable or otherwise recognizable at law; the writing that sets forth such an agreement.

Contract Administration: The management of the contract which includes and is not limited to; contract signing, contract amendments and any necessary legal actions.

Contract Award: Occurs upon execution of the State document titled "Service Contract Award" by the proper authority.

Contract Management: The management of day to day activities at the agency which includes and is not limited to ensuring deliverables are received, specifications are met, handling meetings and making payments to the Contractor.

Contract Period: The duration of the contract.

Contractor: Any individual or entity having a contract to furnish commodities or services.

Cooperative Purchasing: The combining of requirements of two or more political entities to obtain advantages of volume purchases, reduction in administrative expenses or other public benefits.

Copyright: A property right in an original work of authorship fixed in any tangible medium of expression, giving the holder the exclusive right to reproduce, adapt and distribute the work.

Critical Program Error: Any Program Error, whether or not known to the State, which prohibits or significantly impairs use of the Licensed Software as set forth in the documentation and intended in the contract.

Customer Service: The process of ensuring customer satisfaction by providing assistance and advice on those products or services provided by the Contractor.

Default: The omission or failure to perform a contractual duty.

Deviation: Any proposed change(s) or alteration(s) to either the terms and conditions or deliverables within the scope of the written solicitation or contract.

Evaluation: The process of examining an offer after opening to determine the vendor's responsibility, responsiveness to requirements, and to ascertain other characteristics of the offer that relate to determination of the successful award.

Evaluation Committee: Committee(s) appointed by the requesting agency that advises and assists the procuring office in the evaluation of bids/proposals (offers made in response to written solicitations).

Extension: Continuance of a contract for a specified duration upon the agreement of the parties beyond the original Contract Period. Not to be confused with "Renewal Period".

Free on Board (F.O.B.) Destination: The delivery charges are included in the quoted price and prepaid by the vendor. Vendor is responsible for all claims associated with damages during delivery of product.

Free on Board (F.O.B.) Point of Origin: The delivery charges are not included in the quoted price and are the responsibility of the agency. Agency is responsible for all claims associated with damages during delivery of product.

Foreign Corporation: A foreign corporation that was organized and chartered under the laws of another state, government, or country.

Installation Date: The date when the procedures described in "Installation by Contractor", and "Installation by State", as found in the RFP, or contract, are completed.

Interested Party: A person, acting in their personal capacity, or an entity entering into a contract or other agreement creating a legal interest therein.

Late Bid/Proposal: An offer received after the Opening Date and Time.

Licensed Software Documentation: The user manuals and any other materials in any form or medium customarily provided by the Contractor to the users of the Licensed Software which will provide the State with sufficient information to operate, diagnose, and maintain the Licensed Software properly, safely, and efficiently.

Mandatory/Must: Required, compulsory, or obligatory.

May: Discretionary, permitted; used to express possibility.

Module (see System): A collection of routines and data structures that perform a specific function of software.

Must: See Mandatory/ Must and Shall/Will/Must.

National Institute for Governmental Purchasing (NIGP): National Institute of Governmental Purchasing – Source used for assignment of universal commodity codes to goods and services.

Newborn Screening Advisory Committee: Nebraska based Advisory Committee charged with advising the Nebraska Department of Health and Human Services Newborn Screening Program on policy and technical provisions.

Open Market Purchase: Authorization may be given to an agency to purchase items above direct purchase authority due to the unique nature, price, quantity, location of the using agency, or time limitations by the AS Materiel Division, State Purchasing Bureau.

Opening Date and Time: Specified date and time for the public opening of received, labeled, and sealed formal proposals.

Operating System: The control program in a computer that provides the interface to the computer hardware and peripheral devices, and the usage and allocation of memory resources, processor resources, input/output resources, and security resources.

Outsourcing: The contracting out of a business process which an organization may have previously performed internally or has a new need for, to an independent organization from which the process is purchased back.

Payroll & Financial Center (PFC): Electronic procurement system of record.

Performance Bond: An insurance agreement, accompanied by a monetary commitment, by which a third party (the surety) accepts liability and guarantees that the Contractor fulfills any and all obligations under the contract.

Platform: A specific hardware and Operating System combination that is different from other hardware and Operating System combinations to the extent that a different version of the Licensed Software product is required to execute properly in the environment established by such hardware and Operating System combination.

Point of Contact (POC): The person designated to receive communications and to communicate.

Pre-Bid/Pre-Proposal Conference: A meeting scheduled for the purpose of clarifying a written solicitation and related expectations.

Product: Something that is distributed commercially for use or consumption and that is usually (1) tangible personal property, (2) the result of fabrication or processing, and (3) an item that has passed through a chain of commercial distribution before ultimate use or consumption.

Program Error: Code in Licensed Software which produces unintended results or actions, or which produces results or actions other than those described in the specifications. A program error includes, without limitation, any Critical Program Error.

Program Set: The group of programs and products, including the Licensed Software specified in the RFP, plus any additional programs and products licensed by the State under the contract for use by the State.

Project: The total scheme, program, or method worked out for the accomplishment of an objective, including all documentation, commodities, and services to be provided under the contract.

Proposal: See Bid/Proposal.

Proprietary Information: Proprietary information is defined as trade secrets, academic and scientific research work which is in progress and unpublished, and other information which if released would give advantage to business competitors and serves no public purpose (see Neb. Rev. Stat. § 84-712.05(3)). In accordance with Attorney General Opinions 92068 and 97033, proof that information is proprietary requires identification of specific named competitor(s) advantaged by release of the information and the demonstrated advantage the named competitor(s) would gain by the release of information.

Protest/Grievance: A complaint about a governmental action or decision related to a RFP or resultant contract, brought by

a vendor who has timely submitted a bid response in connection with the award in question, to AS Materiel Division or another designated agency with the intention of achieving a remedial result.

Public Proposal Opening: The process of opening correctly submitted offers at the time and place specified in the written solicitation and in the presence of anyone who wished to attend.

Recommended Hardware Configuration: The data processing hardware (including all terminals, auxiliary storage, communication, and other peripheral devices) to the extent utilized by the State as recommended by the Contractor.

Release Date: The date of public release of the written solicitation to seek offers.

Renewal Period: Optional contract periods subsequent to the original Contract Period for a specified duration with previously agreed to terms and conditions. Not to be confused with Extension.

Request for Information (RFI): A general invitation to vendors requesting information for a potential future solicitation. The RFI is typically used as a research and information gathering tool for preparation of a solicitation.

Request for Proposal (RFP): A written solicitation utilized for obtaining competitive offers.

Responsible Bidder: A bidder who has the capability in all respects to perform fully and lawfully all requirements with integrity and reliability to assure good faith performance.

Responsive Bidder: A bidder who has submitted a bid which conforms to all requirements of the solicitation document.

Shall/Will/Must: An order/command; mandatory.

Should: Expected; suggested, but not necessarily mandatory.

Software License: Legal instrument with or without printed material that governs the use or redistribution of licensed software.

Sole Source – Commodity: When an item is available from only one source due to the unique nature of the requirement, its supplier, or market conditions.

Sole Source – Services: A service of such a unique nature that the vendor selected is clearly and justifiably the only practical source to provide the service. Determination that the vendor selected is justifiably the sole source is based on either the uniqueness of the service or sole availability at the location required.

Specifications: The detailed statement, especially of the measurements, quality, materials, and functional characteristics, or other items to be provided under a contract.

Statutory: These clauses are controlled by state law and are not subject to negotiation.

Subcontractor: Individual or entity with whom the contractor enters a contract to perform a portion of the work awarded to the contractor.

System (see Module): Any collection or aggregation of two (2) or more Modules that is designed to function, or is represented by the Contractor as functioning or being capable of functioning, as an entity.

Termination: Occurs when either Party, pursuant to a power created by agreement or law, puts an end to the contract prior to the stated expiration date. All obligations which are still executory on both sides are discharged but any right based on prior breach or performance survives.

Third Party: Any person or entity, including but not limited to fiduciaries, shareholders, owners, officers, managers, employees, legally disinterested persons, and sub-contractors or agents, and their employees. It shall not include any entity or person who is an interested Party to the contract or agreement.

Trade Secret: Information, including, but not limited to, a drawing, formula, pattern, compilation, program, device, method, technique, code, or process that (a) derives independent economic value, actual or potential, from not being known to, and not being ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy (see Neb. Rev. Stat. §87-502(4)).

Trademark: A word, phrase, logo, or other graphic symbol used by a manufacturer or vendor to distinguish its product from those of others, registered with the U.S. Patent and Trademark Office.

Upgrade: Any change that improves or alters the basic function of a product or service.

Vendor: An individual or entity lawfully conducting business in the State of Nebraska, or licensed to do so, who seeks to provide goods or services under the terms of a written solicitation.

Vendor Performance Report: A report issued to the Contractor by State Purchasing Bureau when products or services delivered or performed fail to meet the terms of the purchase order, contract, and/or specifications, as reported to State Purchasing Bureau by the agency. The State Purchasing Bureau shall contact the Contractor regarding any such report. The vendor performance report will become a part of the permanent record for the Contractor. The State may require vendor to cure. Two such reports may be cause for immediate termination.

Will: See Shall/Will/Must

Work Day: See Business Day.

ACRONYMS

3-MCC: 3-Methylcrotonyl CoA Carboxylase Deficiency. A disease of organic acid metabolism.

ANSI: American National Standard Institute

ASA: Argininosuccinic Acidemia. A disease of amino acid metabolism.

BIO: Biotinidase Deficiency. A metabolic disease of vitamin metabolism.

BKT: Beta Ketothiolase Deficiency. A disease of organic acid metabolism.

CAH: Congential Adrenal Hyperplasia. An endocrine system disease.

CAP: College of Ameican Pathology

CDC: Centers for Disease Control and Prevention. Federal agency providing proficiency and quality control services for newborn screening testing laboratories.

CF: Cystic Fibrosis. A genetic disease affecting function of chloride channel receptors.

CIT: Citrullinema Type I. A disease of amino acid metabolism

CLIA: Clinical Laboratory Improvement Act. Federal law governing clinical laboratories.

CLSI: Clinical Laboratory Standards Institute. Organization providing globally applicable professional laboratory standards and guidelines.

CPH: Congenital Primary Hypothryoidism. An endocrine system disease.

CUD: Carnitine Uptake Defect. A disease of fatty acid oxidation

EIA: Enzyme immunoassay. A laboratory test method.

FDA: Federal Food and Drug Administration. Federal agency governing medical devices.

GAL: Galactosemia. An enzymopathy affecting galactose metabolism.

GA I: Glutaric Acidemia Type I. A disases of amino acid metabolism.

HCY: Homocystinuria. A disease of amino acid metabolism.

HGB: Hemoglobinopathies. A group of diseases affecting hemoglobin function.

HMG: 3-Hydroxy 3-Methylglutaric Aciduria. A disease of organic acid metabolism.

HL7: Installation Health Level Seven standards developed by one of American National Standards Institute (ANSI) standards development organizations. The specifications in these standards include a messaging standard that enables disparate healthcare applications to exchange key sets of clinical and administrative data electronically.

HPLC: High Pressure Liquid Chromatography. A test method.

IVA: Isovaleric Acidemia: A disease of organic acid metabolism.

LCHAD: Long Chain Hydroxyacyl CoA Dehydrogenase Deficiency. A disease of fatty acid metabolism.

LDT: Laboratory developed tests

LOINC: Logical Observation Identifiers Names and Codes. A universal code system for identifying laboratory and clinical observations used in electronic messaging.

MCAD: Medium Chain Acyl CoA Dehydrogenase Deficiency. A disease of fatty acid metabolism.

MCD: Multiple carboxylase deficiency. A disease of organic acid metabolism.

MMA (Mutase): Methylmalonic acidemia (Mutase). A disease of organic acid metabolism.

MMA (Cbl A & B): Methylmalonic acidemia (Cobalamin A and B). Diseases of organic acid metabolism.

MPS I: Mucopolysaccharidosis. A lysosomal storage disease.

MS/MS: Tandem Mass Spectrometry. A multi-plex laboratory test method.

MSUD: Maple Syrup Urine Disease. A disease of amino acid metabolism.

NNSP: Nebraska Newborn Screening Program. Program within the Nebraska Department of Health and Human Services responsible for managing newborn screening requirements of Neb.Rev.Stat.§§71-519 -71-524.

PA: Propionic Acidemia: A disease of amino acid metabolism.

PD: Pompe Disease. A lysosomal storage disease.

PKU: Phenylketonuria. A disease of amino acid metabolism.

PCR: Polymerase chain reaction. A laboratory test method.

RIA: Radio-immunoassay. A laboratory test method.

SCID: Severe Combined Immune Deficiency. A group of immunodeficiencies due to insufficient T-cell production.

TFP: Tri-functional Protein Deficiency: A disease of fatty acid metabolism.

TYR: Tyrosinemia. A disease of amino acid metabolism.

VLCAD: Very Long Chain Acyl CoA Dehydrogenase Deficiency. A disease of fatty acid metabolism.

X-ALD: X-linked Adrenoleukodystrophy. A peroxisomal storage disease.

I. PROCUREMENT PROCEDURE

A. GENERAL INFORMATION

The RFP is designed to solicit proposals from qualified Bidders who will be responsible for providing Newborn Screening Laboratory Testing Services at a competitive and reasonable cost.

Proposals shall conform to all instructions, conditions, and requirements included in the RFP. Prospective bidders are expected to carefully examine all documents, schedules, and requirements in this RFP, and respond to each requirement in the format prescribed. Proposals may be found non-responsive if they do not conform to the RFP.

B. PROCURING OFFICE AND COMMUNICATION WITH STATE STAFF AND EVALUATORS

Procurement responsibilities related to this RFP reside with the State Purchasing Bureau. The point of contact (POC) for the procurement is as follows:

Name: Michelle Thompson / Annette Walton
Agency: State Purchasing Bureau
Address: 1526 K Street, Suite 130
Lincoln, NE 68508
Telephone: 402-471-6500
E-Mail: as.materielpurchasing@nebraska.gov

From the date the RFP is issued until the Intent to Award is issued, communication from the Bidder is limited to the POC listed above. After the Intent to Award is issued, the Bidder may communicate with individuals the State has designated as responsible for negotiating the contract on behalf of the State. No member of the State Government, employee of the State, or member of the Evaluation Committee is empowered to make binding statements regarding this RFP. The POC will issue any clarifications or opinions regarding this RFP in writing. Only the buyer can modify the RFP, answer questions, render opinions, and only the SPB or awarding agency can award a contract. Bidders shall not have any communication with, or attempt to communicate or influence any evaluator involved in this RFP.

The following exceptions to these restrictions are permitted:

1. Contact made pursuant to pre-existing contracts or obligations;
2. Contact required by the schedule of events or an event scheduled later by the RFP POC; and
3. Contact required for negotiation and execution of the final contract.

The State reserves the right to reject a bidder's proposal, withdraw an Intent to Award, or terminate a contract if the State determines there has been a violation of these procurement procedures.

C. SCHEDULE OF EVENTS

The State expects to adhere to the procurement schedule shown below, but all dates are approximate and subject to change.

	ACTIVITY	DATE/TIME
1.	Release RFP	October 26, 2017
2.	Last day to submit written questions	November 16, 2017
3.	State responds to written questions through RFP "Addendum" and/or "Amendment" to be posted to the Internet at: http://das.nebraska.gov/materiel/purchasing.html	December 4, 2017
4.	Last day to submit "Notification of Intent To Bid"	December 22, 2017
5.	Proposal opening Location: State Purchasing Bureau 1526 K Street, Suite 130 Lincoln, NE 68508	January 8, 2018 2:00 PM Central Time
6.	Review for conformance to RFP requirements	January 10, 2018
7.	Evaluation period	January 11 - 31, 2018
8.	"Oral Interviews/Presentations and/or Demonstrations" (if required)	February 12, 2018
9.	Post "Intent to Award" to Internet at: http://das.nebraska.gov/materiel/purchasing.html	February 26, 2018
10.	Contract finalization period	February 26, 2018 – March 26, 2018
11.	Contract award	March 26, 2018
12.	Contractor start date	July 1, 2018

D. WRITTEN QUESTIONS AND ANSWERS

Questions regarding the meaning or interpretation of any RFP provision must be submitted in writing to the State Purchasing Bureau and clearly marked "RFP Number 5710 Z1; Newborn Screening Laboratory Testing Services Questions". The POC is not obligated to respond to questions that are received late per the Schedule of Events.

Bidders should present, as questions, any assumptions upon which the Bidder's proposal is or might be developed. Proposals will be evaluated without consideration of any known or unknown assumptions of a bidder. The contract will not incorporate any known or unknown assumptions of a bidder.

It is preferred that questions be sent via e-mail to as.materielpurchasing@nebraska.gov, but may be delivered by hand or by U.S. Mail. It is recommended that Bidders submit questions using the following format.

RFP Section Reference	RFP Page Number	Question

Written answers will be posted at http://das.nebraska.gov/materiel/purchasing.html per the Schedule of Events.

E. NOTIFICATION OF INTENT TO BID

Bidders who intend to bid should complete a "Notification of Intent to Bid Form" (see Form B) and deliver the form by hand or U.S. mail to the POC for the RFP per the Schedule of Events. A list of vendors who submitted a Notification of Intent to Bid will be posted on the Internet at http://das.nebraska.gov/materiel/purchasing.html.

F. PRICES

Prices submitted on the cost proposal form shall remain fixed for the initial two (2) years of the contract. Any annual request for a price increase subsequent to the initial two (2) year term of the contract shall not exceed two and a half (2.5%) of the previous Contract period. Increases will be cumulative across the remaining periods of the contract. Requests for an increase must be submitted in writing to the State Purchasing Bureau a minimum of 120 days prior to the end of the current contract period. Documentation may be required by the State to support the price increase. Documentation may include market analysis data verifying increased personnel costs to sustain quality and remain competitive as well as the documentation verifying actual personnel costs, increased cost for essential supplies or equipment or increased costs for subcontractor's such as specimen shipping services or specimen destruction services

The State reserves the right to deny any requested price increase. No price increases are to be billed to any State Agencies prior to written amendment of the contract by the parties.

G. SECRETARY OF STATE/TAX COMMISSIONER REGISTRATION REQUIREMENTS (Statutory)

All bidders must be authorized to transact business in the State of Nebraska and comply with all Nebraska Secretary of State Registration requirements. The bidder who is the recipient of an Intent to Award will be required to certify that it has complied and produce a true and exact copy of its current (within ninety (90) calendar days of the intent to award) Certificate or Letter of Good Standing, or in the case of a sole proprietorship, provide written documentation of sole proprietorship and complete the United States Citizenship Attestation Form, available on the Department of Administrative Services website at http://das.nebraska.gov/materiel/purchasing.html. This must be accomplished prior to execution of the contract.

H. ETHICS IN PUBLIC CONTRACTING

The State reserves the right to reject bids, withdraw an intent to award or award, or terminate a contract if a bidder commits or has committed ethical violations, which include, but are not limited to:

1. Offering or giving, directly or indirectly, a bribe, fee, commission, compensation, gift, gratuity, or anything of value to any person or entity in an attempt to influence the bidding process;
2. Utilize the services of lobbyists, attorneys, political activists, or consultants to influence or subvert the bidding process;
3. Being considered for, presently being, or becoming debarred, suspended, ineligible, or excluded from contracting with any state or federal entity:
4. Submitting a proposal on behalf of another Party or entity; and
5. Collude with any person or entity to influence the bidding process, submit sham proposals, preclude bidding, fix pricing or costs, create an unfair advantage, subvert the bid, or prejudice the State.

The Bidder shall include this clause in any subcontract entered into for the exclusive purpose of performing this contract.

Bidder shall have an affirmative duty to report any violations of this clause by the Bidder throughout the bidding process, and throughout the term of this contract for the successful Bidder and their subcontractors.

I. DEVIATIONS FROM THE REQUEST FOR PROPOSAL

The requirements contained in the RFP become a part of the terms and conditions of the contract resulting from this RFP. Any deviations from the RFP in Sections II through VI must be clearly defined by the bidder in its proposal and, if accepted by the State, will become part of the contract. Any specifically defined deviations must not be in conflict with the basic nature of the RFP, requirements, or applicable state or federal laws or statutes. "Deviation", for the purposes of this RFP, means any proposed changes or alterations to either the contractual language or deliverables within the scope of this RFP. The State discourages deviations and reserves the right to reject proposed deviations.

J. SUBMISSION OF PROPOSALS

Bidders should submit one proposal marked on the first page: "ORIGINAL". If multiple proposals are submitted, the State will retain one copy marked "ORIGINAL" and destroy the other copies. The Bidder is solely responsible for any variance between the copies submitted. Proposal responses should include the completed Form A, "Bidder Contact Sheet". Proposals must reference the RFP number and be sent to the specified address. Please note that the address label should appear as specified in Section I B. on the face of each container or bidder's bid response packet. If a recipient phone number is required for delivery purposes, 402-471-6500 should be used. The RFP number should be included in all correspondence.

Emphasis should be concentrated on conformance to the RFP instructions, responsiveness to requirements, completeness, and clarity of content. If the bidder's proposal is presented in such a fashion that makes evaluation difficult or overly time consuming the State reserves the right to reject the proposal as non-conforming.

By signing the "Request for Proposal for Contractual Services" form, the bidder guarantees compliance with the provisions stated in this RFP.

The State shall not incur any liability for any costs incurred by bidders in replying to this RFP, in the demonstrations and/or oral presentations, or in any other activity related to bidding on this RFP.

The Technical and Cost Proposals should be packaged separately (loose-leaf binders are preferred) on standard 8 ½" by 11" paper, except that charts, diagrams and the like may be on fold-outs which, when folded, fit into the 8 ½" by 11" format. Pages may be consecutively numbered for the entire proposal, or may be numbered consecutively within sections. Figures and tables should be numbered and referenced in the text by that number. They should be placed as close as possible to the referencing text. The Technical Proposal should not contain any reference to dollar amounts. However, information such as data concerning labor hours and categories, materials, subcontracts and so forth, shall be considered in the Technical Proposal so that the bidder's understanding of the scope of work may be evaluated. The Technical Proposal shall disclose the bidder's technical approach in as much detail as possible, including, but not limited to, the information required by the Technical Proposal instructions.

K. BID PREPARATION COSTS

The State shall not incur any liability for any costs incurred by Bidders in replying to this RFP, including any activity related to bidding on this RFP.

L. FAILURE TO COMPLY WITH REQUEST FOR PROPOSAL

Violation of the terms and conditions contained in this RFP or any resultant contract, at any time before or after the award, shall be grounds for action by the State which may include, but is not limited to, the following:

1. Rejection of a bidder's proposal;
2. Withdrawal of the Intent to Award;
3. Withdrawal of the Award;
4. Termination of the resulting contract;
5. Legal action; and
6. Suspension of the bidder from further bidding with the State for the period of time relative to the seriousness of the violation, such period to be within the sole discretion of the State.

M. BID CORRECTIONS

A bidder may correct a mistake in a bid prior to the time of opening by giving written notice to the State of intent to withdraw the bid for modification or to withdraw the bid completely. Changes in a bid after opening are acceptable only if the change is made to correct a minor error that does not affect price, quantity, quality, delivery, or contractual conditions. In case of a mathematical error in extension of price, unit price shall govern.

N. LATE PROPOSALS

Proposals received after the time and date of the proposal opening will be considered late proposals. Late proposals will be returned unopened, if requested by the bidder and at bidder's expense. The State is not responsible for proposals that are late or lost regardless of cause or fault.

O. PROPOSAL OPENING

The opening of proposals will be public and the bidders will be announced. Proposals **WILL NOT** be available for viewing by those present at the proposal opening. Vendors may contact the State to schedule an appointment for viewing proposals after the Intent to Award has been posted to the website. Once proposals are opened, they become the property of the State of Nebraska and will not be returned.

P. REQUEST FOR PROPOSAL/PROPOSAL REQUIREMENTS

The proposals will first be examined to determine if all requirements listed below have been addressed and whether further evaluation is warranted. Proposals not meeting the requirements may be rejected as non-responsive. The requirements are:

1. Original Request for Proposal for Contractual Services form signed using an indelible method;
2. Clarity and responsiveness of the proposal;
3. Completed Corporate Overview;
4. Completed Sections II through VI;
5. Completed Technical Approach; and
6. Completed State Cost Proposal Template.

Q. EVALUATION COMMITTEE

Proposals are evaluated by members of an Evaluation Committee(s). The Evaluation Committee(s) will consist of individuals selected at the discretion of the State. Names of the members of the Evaluation Committee(s) will not be published prior to the intent to award.

Any contact, attempted contact, or attempt to influence an evaluator that is involved with this RFP may result in the rejection of this proposal and further administrative actions.

R. EVALUATION OF PROPOSALS

All proposals that are responsive to the RFP will be evaluated. Each evaluation category will have a maximum point potential. The State will conduct a fair, impartial, and comprehensive evaluation of all proposals in accordance with the criteria set forth below. Areas that will be addressed and scored during the evaluation include:

1. Corporate Overview should include but is not limited to:
   - **a.** the ability, capacity, and skill of the bidder to deliver and implement the system or project that meets the requirements of the RFP;
   - **b.** the character, integrity, reputation, judgment, experience, and efficiency of the bidder;
   - **c.** whether the bidder can perform the contract within the specified time frame;
   - **d.** the quality of bidder performance on prior contracts;
   - **e.** such other information that may be secured and that has a bearing on the decision to award the contract;

2. Technical Approach; and,
3. Cost Proposal.

Neb. Rev. Stat. §73-107 allows for a preference for a resident disabled veteran or business located in a designated enterprise zone. When a state contract is to be awarded to the lowest responsible bidder, a resident disabled veteran or a business located in a designated enterprise zone under the Enterprise Zone Act shall be allowed a preference over any other resident or nonresident bidder, if all other factors are equal.

Resident disabled veterans means any person (a) who resides in the State of Nebraska, who served in the United States Armed Forces, including any reserve component or the National Guard, who was discharged or otherwise separated with a characterization of honorable or general (under honorable conditions), and who possesses a disability rating letter issued by the United States Department of Veterans Affairs establishing a service-connected disability or a disability determination from the United States Department of Defense and (b)(i) who owns and controls a business or, in the case of a publicly owned business, more than fifty percent of the stock is owned by one or more persons described in subdivision (a) of this subsection and (ii) the management and daily business operations of the business are controlled by one or more persons described in subdivision(a) of this subsection. Any contract entered into without compliance with this section shall be null and void.

Therefore, if a resident disabled veteran or business located in a designated enterprise zone submits a proposal in accordance with Neb. Rev. Stat. §73-107 and has so indicated on the RFP cover page under "Bidder must complete the following" requesting priority/preference to be considered in the award of this contract, the following will need to be submitted by the vendor within ten (10) business days of request:

1. Documentation from the United States Armed Forces confirming service;

2. Documentation of discharge or otherwise separated characterization of honorable or general (under honorable conditions);
3. Disability rating letter issued by the United States Department of Veterans Affairs establishing a service-connected disability or a disability determination from the United States Department of Defense; and
4. Documentation which shows ownership and control of a business or, in the case of a publicly owned business, more than fifty percent of the stock is owned by one or more persons described in subdivision (a) of this subsection; and the management and daily business operations of the business are controlled by one or more persons described in subdivision (a) of this subsection.

Failure to submit the requested documentation within ten (10) business days of notice will disqualify the bidder from consideration of the preference.

Evaluation criteria weighting will be released with the RFP.

S. ORAL INTERVIEWS/PRESENTATIONS AND/OR DEMONSTRATIONS

The State may determine after the completion of the Technical and Cost Proposal evaluation that oral interviews/presentations and/or demonstrations are required. Every bidder may not be given an opportunity to interview/present and/or give demonstrations; the State reserves the right, in its discretion, to select only the top scoring bidders to present/give oral interviews. The scores from the oral interviews/presentations and/or demonstrations will be added to the scores from the Technical and Cost Proposals. The presentation process will allow the bidders to demonstrate their proposal offering, explaining and/or clarifying any unusual or significant elements related to their proposals. Bidders' key personnel, identified in their proposal, may be requested to participate in a structured interview to determine their understanding of the requirements of this proposal, their authority and reporting relationships within their firm, and their management style and philosophy. Only representatives of the State and the presenting bidder will be permitted to attend the oral interviews/presentations and/or demonstrations. A written copy or summary of the presentation, and demonstrative information (such as briefing charts, et cetera) may be offered by the bidder, but the State reserves the right to refuse or not consider the offered materials. Bidders shall not be allowed to alter or amend their proposals.

Once the oral interviews/presentations and/or demonstrations have been completed, the State reserves the right to make an award without any further discussion with the bidders regarding the proposals received.

Any cost incidental to the oral interviews/presentations and/or demonstrations shall be borne entirely by the bidder and will not be compensated by the State.

T. BEST AND FINAL OFFER

If best and final offers (BAFO) are requested by the State and submitted by the bidder, they will be evaluated (using the stated BAFO criteria), scored, and ranked by the Evaluation Committee. The State reserves the right to conduct more than one Best and Final Offer. The award will then be granted to the highest scoring bidder. However, a bidder should provide its best offer in its original proposal. Bidders should not expect that the State will request a best and final offer.

U. REFERENCE AND CREDIT CHECKS

The State reserves the right to conduct and consider reference and credit checks. The State reserves the right to use third parties to conduct reference and credit checks. By submitting a proposal in response to this RFP, the bidder grants to the State the right to contact or arrange a visit in person with any or all of the bidder's clients. Reference and credit checks may be grounds to reject a proposal, withdraw an intent to award, or rescind the award of a contract.

V. AWARD

The State reserves the right to evaluate proposals and award contracts in a manner utilizing criteria selected at the State's discretion and in the State's best interest. After evaluation of the proposals, or at any point in the RFP process, the State of Nebraska may take one or more of the following actions:

1. Amend the RFP;
2. Extend the time of or establish a new proposal opening time;
3. Waive deviations or errors in the State's RFP process and in bidder proposals that are not material, do not compromise the RFP process or a bidder's proposal, and do not improve a bidder's competitive position;
4. Accept or reject a portion of or all of a proposal;
5. Accept or reject all proposals;
6. Withdraw the RFP;
7. Elect to rebid the RFP;
8. Award single lines or multiple lines to one or more bidders; or,
9. Award one or more all-inclusive contracts.

The RFP does not commit the State to award a contract. Once intent to award decision has been determined, it will be posted to the Internet at:
http://das.nebraska.gov/materiel/purchasing.html

Grievance and protest procedure is available on the Internet at:
http://das.nebraska.gov/materiel/purchasing.html

Any protests must be filed by a bidder within ten (10) business days after the intent to award decision is posted to the Internet.

II. TERMS AND CONDITIONS

Bidders should complete Sections II through VI as part of their proposal. Bidder is expected to read the Terms and Conditions and should initial either accept, reject, or reject and provide alternative language for each clause. The bidder should also provide an explanation of why the bidder rejected the clause or rejected the clause and provided alternate language. By signing the RFP, bidder is agreeing to be legally bound by all the accepted terms and conditions, and any proposed alternative terms and conditions submitted with the proposal. The State reserves the right to negotiate rejected or proposed alternative language. If the State and bidder fail to agree on the final Terms and Conditions, the State reserves the right to reject the proposal. The State of Nebraska is soliciting proposals in response to this RFP. The State of Nebraska reserves the right to reject proposals that attempt to substitute the bidder's commercial contracts and/or documents for this RFP.

The bidders should submit with their proposal any license, user agreement, service level agreement, or similar documents that the bidder wants incorporated in the Contract. The State will not consider incorporation of any document not submitted with the bidder's proposal as the document will not have been included in the evaluation process. These documents shall be subject to negotiation and will be incorporated as addendums if agreed to by the Parties.

If a conflict or ambiguity arises after the Addendum to Contract Award have been negotiated and agreed to, the Addendum to Contract Award shall be interpreted as follows:

1. If only one Party has a particular clause then that clause shall control;
2. If both Parties have a similar clause, but the clauses do not conflict, the clauses shall be read together;
3. If both Parties have a similar clause, but the clauses conflict, the State's clause shall control.

A. GENERAL

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contract resulting from this RFP shall incorporate the following documents:

1. Request for Proposal and Addenda;
2. Amendments to the RFP;
3. Questions and Answers;
4. Contractor's proposal (RFP and properly submitted documents);
5. The executed Contract and Addendum One to Contract, if applicable ; and,
6. Amendments/Addendums to the Contract.

These documents constitute the entirety of the contract.

Unless otherwise specifically stated in a future contract amendment, in case of any conflict between the incorporated documents, the documents shall govern in the following order of preference with number one (1) receiving preference over all other documents and with each lower numbered document having preference over any higher numbered document: 1) Amendment to the executed Contract with the most recent dated amendment having the highest priority, 2) executed Contract and any attached Addenda, 3) Amendments to RFP and any Questions and Answers, 4) the original RFP document and any Addenda, and 5) the Contractor's submitted Proposal.

Any ambiguity or conflict in the contract discovered after its execution, not otherwise addressed herein, shall be resolved in accordance with the rules of contract interpretation as established in the State of Nebraska.

B. NOTIFICATION

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Contractor and State shall identify the contract manager who shall serve as the point of contact for the executed contract.

Communications regarding the executed contract shall be in writing and shall be deemed to have been given if delivered personally or mailed, by U.S. Mail, postage prepaid, return receipt requested, to the parties at their respective addresses set forth below, or at such other addresses as may be specified in writing by either of the parties. All notices, requests, or communications shall be deemed effective upon personal delivery or three (3) calendar days following deposit in the mail.

Vendor Contract Manager	Julie Luedtke
Vendor	Department of Health and Human Services
Vendor Street Address	301 Centennial Mall South, PO Box 95026
Vendor City, State, Zip	Lincoln, NE 68508-5026

C. GOVERNING LAW (Statutory)

Notwithstanding any other provision of this contract, or any amendment or addendum(s) entered into contemporaneously or at a later time, the parties understand and agree that, (1) the State of Nebraska is a sovereign state and its authority to contract is therefore subject to limitation by the State's Constitution, statutes, common law, and regulation; (2) this contract will be interpreted and enforced under the laws of the State of Nebraska; (3) any action to enforce the provisions of this agreement must be brought in the State of Nebraska per state law; (4) the person signing this contract on behalf of the State of Nebraska does not have the authority to waive the State's sovereign immunity, statutes, common law, or regulations; (5) the indemnity, limitation of liability, remedy, and other similar provisions of the final contract, if any, are entered into subject to the State's Constitution, statutes, common law, regulations, and sovereign immunity; and, (6) all terms and conditions of the final contract, including but not limited to the clauses concerning third party use, licenses, warranties, limitations of liability, governing law and venue, usage verification, indemnity, liability, remedy or other similar provisions of the final contract are entered into specifically subject to the State's Constitution, statutes, common law, regulations, and sovereign immunity.

The Parties must comply with all applicable local, state and federal laws, ordinances, rules, orders, and regulations.

D. BEGINNING OF WORK

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The bidder shall not commence any billable work until a valid contract has been fully executed by the State and the successful Contractor. The Contractor will be notified in writing when work may begin.

E. CHANGE ORDERS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The State and the Contractor, upon the written agreement, may make changes to the contract within the general scope of the RFP. Changes may involve specifications, the quantity of work, or such other items as the State may find necessary, desirable or required by State Statute or Regulation. Corrections of any deliverable, service, or work required pursuant to the contract shall not be deemed a change. The Contractor may not claim forfeiture of the contract by reasons of such changes.

The Contractor shall prepare a written description of the work required due to the change and an itemized cost sheet for the change. Changes in work and the amount of compensation to be paid to the Contractor shall be determined in accordance with applicable unit prices if any, a pro-rated value, or through negotiations. The State shall not incur a price increase for changes that should have been included in the Contractor's proposal, were foreseeable, or result from difficulties with or failure of the Contractor's proposal or performance.

No change shall be implemented by the Contractor until approved by the State, and the Contract is amended to reflect the change and associated costs, if any. If there is a dispute regarding the cost, but both parties agree that immediate implementation is necessary, the change may be implemented, and cost negotiations may continue with both Parties retaining all remedies under the contract and law.

F. NOTICE OF POTENTIAL CONTRACTOR BREACH

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

If Contractor breaches the contract or anticipates breaching the contract, the Contractor shall immediately give written notice to the State. The notice shall explain the breach or potential breach, a proposed cure, and may include a request for a waiver of the breach if so desired. The State may, in its discretion, temporarily or permanently waive the breach. By granting a waiver, the State does not forfeit any rights or remedies to which the State is entitled by law or equity, or pursuant to the provisions of the contract. Failure to give immediate notice, however, may be grounds for denial of any request for a waiver of a breach.

G. BREACH

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Either Party may terminate the contract, in whole or in part, if the other Party breaches its duty to perform its obligations under the contract in a timely and proper manner. Termination requires written notice of default and a thirty (30) calendar day (or longer at the non-breaching Party's discretion considering the gravity and nature of the default) cure period. Said notice shall be delivered by Certified Mail, Return Receipt Requested, or in person with proof of delivery. Allowing time to cure a failure or breach of contract does not waive the right to immediately terminate the contract for the same or different contract breach which may occur at a different time. In case of default of the Contractor, the State may contract the service from other sources and hold the Contractor responsible for any excess cost occasioned thereby.

The State's failure to make payment shall not be a breach, and the Contractor shall retain all available statutory remedies and protections.

H. NON-WAIVER OF BREACH

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The acceptance of late performance with or without objection or reservation by a Party shall not waive any rights of the Party nor constitute a waiver of the requirement of timely performance of any obligations remaining to be performed.

I. SEVERABILITY

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

If any term or condition of the contract is declared by a court of competent jurisdiction to be illegal or in conflict with any law, the validity of the remaining terms and conditions shall not be affected, and the rights and obligations of the parties shall be construed and enforced as if the contract did not contain the provision held to be invalid or illegal.

J. INDEMNIFICATION

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

1. GENERAL

The Contractor agrees to defend, indemnify, and hold harmless the State and its employees, volunteers, agents, and its elected and appointed officials ("the indemnified parties") from and against any and all third party claims, liens, demands, damages, liability, actions, causes of action, losses, judgments, costs, and expenses of every nature, including investigation costs and expenses, settlement costs, and attorney fees and expenses ("the claims"), sustained or asserted against the State for personal injury, death, or property loss or damage, arising out of, resulting from, or attributable to the willful misconduct, negligence, error, or omission of the Contractor, its employees, Subcontractors, consultants, representatives, and agents, resulting from this contract, except to the extent such Contractor liability is attenuated by any action of the State which directly and proximately contributed to the claims.

2. INTELLECTUAL PROPERTY

The Contractor agrees it will, at its sole cost and expense, defend, indemnify, and hold harmless the indemnified parties from and against any and all claims, to the extent such claims arise out of, result from, or are attributable to, the actual or alleged infringement or misappropriation of any patent, copyright, trade secret, trademark, or confidential information of any third party by the Contractor or its employees, Subcontractors, consultants, representatives, and agents; provided, however, the State gives the Contractor prompt notice in writing of the claim. The Contractor may not settle any infringement claim that will affect the State's use of the Licensed Software without the State's prior written consent, which consent may be withheld for any reason.

If a judgment or settlement is obtained or reasonably anticipated against the State's use of any intellectual property for which the Contractor has indemnified the State, the Contractor shall, at the Contractor's sole cost and expense, promptly modify the item or items which were determined to be infringing, acquire a license or licenses on the State's behalf to provide the necessary rights to the State to eliminate the infringement, or provide the State with a non-infringing substitute that provides the State the same functionality. At the State's election, the actual or anticipated judgment may be treated as a breach of warranty by the Contractor, and the State may receive the remedies provided under this RFP.

3. PERSONNEL

The Contractor shall, at its expense, indemnify and hold harmless the indemnified parties from and against any claim with respect to withholding taxes, worker's compensation, employee benefits, or any other claim, demand, liability, damage, or loss of any nature relating to any of the personnel, including subcontractor's and their employees, provided by the Contractor.

4. SELF-INSURANCE

The State of Nebraska is self-insured for any loss and purchases excess insurance coverage pursuant to Neb. Rev. Stat. § 81-8,239.01 (Reissue 2008). If there is a presumed loss under the provisions of this agreement, Contractor may file a claim with the Office of Risk Management pursuant to Neb. Rev. Stat. §§ 81-8,829 – 81-8,306 for review by the State Claims Board. The State retains all rights and immunities under the State Miscellaneous (Section 81-8,294), Tort (Section 81-8,209), and Contract Claim Acts (Section 81-8,302), as outlined in Neb. Rev. Stat. § 81-8,209 et seq. and under any other provisions of law and accepts liability under this agreement to the extent provided by law.

5. The Parties acknowledge that Attorney General for the State of Nebraska is required by statute to represent the legal interests of the State, and that any provision of this indemnity clause is subject to the statutory authority of the Attorney General.

K. ATTORNEY'S FEES

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

In the event of any litigation, appeal, or other legal action to enforce any provision of the contract, the Parties agree to pay all expenses of such action, as permitted by law and if order by the court, including attorney's fees and costs, if the other Party prevails.

L. PERFORMANCE BOND

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor will be required to supply a bond executed by a corporation authorized to contract surety in the State of Nebraska, payable to the State of Nebraska, which shall be valid for the life of the contract to include any renewal and/or extension periods. The amount of the bond must be $100,000.00. The bond will guarantee that the Contractor will faithfully perform all requirements, terms and conditions of the contract. Failure to comply shall be grounds for forfeiture of the bond as liquidated damages. Amount of forfeiture will be determined by the agency based on loss to the State. The bond will be returned when the service has been satisfactorily completed as solely determined by the State, after termination or expiration of the contract.

M. ASSIGNMENT, SALE, OR MERGER

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Either Party may assign the contract upon mutual written agreement of the other Party. Such agreement shall not be unreasonably withheld.

The Contractor retains the right to enter into a sale, merger, acquisition, internal reorganization, or similar transaction involving Contractor's business. Contractor agrees to cooperate with the State in executing amendments to the contract to allow for the transaction. If a third party or entity is involved in the transaction, the Contractor will remain responsible for performance of the contract until such time as the person or entity involved in the transaction agrees in writing to be contractually bound by this contract and perform all obligations of the contract.

N. CONTRACTING WITH OTHER NEBRASKA POLITICAL SUB-DIVISIONS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor may, but shall not be required to, allow agencies, as defined in Neb. Rev. Stat. §81-145, to use this contract. The terms and conditions, including price, of the contract may not be amended. The State shall not be contractually obligated or liable for any contract entered into pursuant to this clause. A listing of Nebraska political subdivisions may be found at the website of the Nebraska Auditor of Public Accounts.

O. FORCE MAJEURE

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Neither Party shall be liable for any costs or damages, or for default resulting from its inability to perform any of its obligations under the contract due to a natural or manmade event outside the control and not the fault of the affected Party ("Force Majeure Event"). The Party so affected shall immediately make a written request for relief to the other Party, and shall have the burden of proof to justify the request. The other Party may grant the relief requested; relief may not be unreasonably withheld. Labor disputes with the impacted Party's own employees will not be considered a Force Majeure Event.

P. CONFIDENTIALITY

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

All materials and information provided by the Parties or acquired by a Party on behalf of the other Party shall be regarded as confidential information. All materials and information provided or acquired shall be handled in accordance with federal and state law, and ethical standards. Should said confidentiality be breached by a Party, the Party shall notify the other Party immediately of said breach and take immediate corrective action.

It is incumbent upon the Parties to inform their officers and employees of the penalties for improper disclosure imposed by the Privacy Act of 1974, 5 U.S.C. 552a. Specifically, 5 U.S.C. 552a (i)(1), which is made applicable by 5 U.S.C. 552a (m)(1), provides that any officer or employee, who by virtue of his/her employment or official position has possession of or access to agency records which contain individually identifiable information, the disclosure of which is prohibited by the Privacy Act or regulations established thereunder, and who knowing that disclosure of the specific material is prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000.

Q. OFFICE OF PUBLIC COUNSEL (Statutory)

If it provides, under the terms of this contract and on behalf of the State of Nebraska, health and human services to individuals; service delivery; service coordination; or case management, Contractor shall submit to the jurisdiction of the Office of Public Counsel, pursuant to Neb. Rev. Stat. §§ 81-8,240 et seq. This section shall survive the termination of this contract.

R. EARLY TERMINATION

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contract may be terminated as follows:

1. The State and the Contractor, by mutual written agreement, may terminate the contract at any time.

2. The State, in its sole discretion, may terminate the contract for any reason upon thirty (30) calendar day's written notice to the Contractor. Such termination shall not relieve the Contractor of warranty or other service obligations incurred under the terms of the contract. In the event of termination the Contractor shall be entitled to payment, determined on a pro rata basis, for products or services satisfactorily performed or provided.

3. The State may terminate the contract immediately for the following reasons:

- **a.** if directed to do so by statute;
- **b.** Contractor has made an assignment for the benefit of creditors, has admitted in writing its inability to pay debts as they mature, or has ceased operating in the normal course of business;
- **c.** a trustee or receiver of the Contractor or of any substantial part of the Contractor's assets has been appointed by a court;
- **d.** fraud, misappropriation, embezzlement, malfeasance, misfeasance, or illegal conduct pertaining to performance under the contract by its Contractor, its employees, officers, directors, or shareholders;
- **e.** an involuntary proceeding has been commenced by any Party against the Contractor under any one of the chapters of Title 11 of the United States Code and (i) the proceeding has been pending for at least sixty (60) calendar days; or (ii) the Contractor has consented, either expressly or by operation of law, to the entry of an order for relief; or (iii) the Contractor has been decreed or adjudged a debtor;
- **f.** a voluntary petition has been filed by the Contractor under any of the chapters of Title 11 of the United States Code;
- **g.** Contractor intentionally discloses confidential information;
- **h.** Contractor has or announces it will discontinue support of the deliverable; and,
- **i.** In the event funding is no longer available.

S. CONTRACT CLOSEOUT

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Upon contract closeout for any reason the Contractor shall within 30 days, unless stated otherwise herein:

1. Transfer all completed or partially completed deliverables to the State;
2. Transfer ownership and title to all completed or partially completed deliverables to the State;
3. Return to the State all information and data, unless the Contractor is permitted to keep the information or data by contract or rule of law. Contractor may retain one copy of any information or data as required to comply with applicable work product documentation standards or as are automatically retained in the course of Contractor's routine back up procedures;
4. Cooperate with any successor Contactor, person or entity in the assumption of any or all of the obligations of this contract;
5. Cooperate with any successor Contactor, person or entity with the transfer of information or data related to this contract;
6. Return or vacate any state owned real or personal property; and,
7. Return all data in a mutually acceptable format and manner.

Nothing in this Section should be construed to require the Contractor to surrender intellectual property, real or personal property, or information or data owned by the Contractor for which the State has no legal claim.

III. CONTRACTOR DUTIES

A. INDEPENDENT CONTRACTOR / OBLIGATIONS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

It is agreed that the Contractor is an independent contractor and that nothing contained herein is intended or should be construed as creating or establishing a relationship of employment, agency, or a partnership.

The Contractor is solely responsible for fulfilling the contract. The Contractor or the Contractor's representative shall be the sole point of contact regarding all contractual matters.

The Contractor shall secure, at its own expense, all personnel required to perform the services under the contract. The personnel the Contractor uses to fulfill the contract shall have no contractual or other legal relationship with the State; they shall not be considered employees of the State and shall not be entitled to any compensation, rights or benefits from the State, including but not limited to, tenure rights, medical and hospital care, sick and vacation leave, severance pay, or retirement benefits.

By-name personnel commitments made in the Contractor's proposal shall not be changed without the prior written approval of the State. Replacement of these personnel, if approved by the State, shall be with personnel of equal or greater ability and qualifications.

All personnel assigned by the Contractor to the contract shall be employees of the Contractor or a subcontractor, and shall be fully qualified to perform the work required herein. Personnel employed by the Contractor or a subcontractor to fulfill the terms of the contract shall remain under the sole direction and control of the Contractor or the subcontractor respectively.

With respect to its employees, the Contractor agrees to be solely responsible for the following:

1. Any and all pay, benefits, and employment taxes and/or other payroll withholding;
2. Any and all vehicles used by the Contractor's employees, including all insurance required by state law;
3. Damages incurred by Contractor's employees within the scope of their duties under the contract;
4. Maintaining Workers' Compensation and health insurance that complies with state and federal law and submitting any reports on such insurance to the extent required by governing law; and
5. Determining the hours to be worked and the duties to be performed by the Contractor's employees.
6. All claims on behalf of any person arising out of employment or alleged employment (including without limit claims of discrimination alleged against the Contractor, its officers, agents, or subcontractors or subcontractor's employees)

If the Contractor intends to utilize any subcontractor, the subcontractor's level of effort, tasks, and time allocation should be clearly defined in the bidder's proposal. The Contractor shall agree that it will not utilize any subcontractors not specifically included in its proposal in the performance of the contract without the prior written authorization of the State.

The State reserves the right to require the Contractor to reassign or remove from the project any Contractor or subcontractor employee.

Contractor shall insure that the terms and conditions contained in any contract with a subcontractor does not conflict with the terms and conditions of this contract.

The Contractor shall include a similar provision, for the protection of the State, in the contract with any Subcontractor engaged to perform work on this contract.

B. EMPLOYEE WORK ELIGIBILITY STATUS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor is required and hereby agrees to use a federal immigration verification system to determine the work eligibility status of employees physically performing services within the State of Nebraska. A federal immigration verification system means the electronic verification of the work authorization program authorized by the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, 8 U.S.C. 1324a, known as the E-Verify Program, or an equivalent federal program designated by the United States Department of Homeland Security or other federal agency authorized to verify the work eligibility status of an employee.

If the Contractor is an individual or sole proprietorship, the following applies:

1. The Contractor must complete the United States Citizenship Attestation Form, available on the Department of Administrative Services website at http://das.nebraska.gov/materiel/purchasing.html

The completed United States Attestation Form should be submitted with the RFP response.

2. If the Contractor indicates on such attestation form that he or she is a qualified alien, the Contractor agrees to provide the US Citizenship and Immigration Services documentation required to verify the Contractor's lawful presence in the United States using the Systematic Alien Verification for Entitlements (SAVE) Program.

3. The Contractor understands and agrees that lawful presence in the United States is required and the Contractor may be disqualified or the contract terminated if such lawful presence cannot be verified as required by Neb. Rev. Stat. §4-108.

C. COMPLIANCE WITH CIVIL RIGHTS LAWS AND EQUAL OPPORTUNITY EMPLOYMENT / NONDISCRIMINATION (Statutory)

The Contractor shall comply with all applicable local, state, and federal statutes and regulations regarding civil rights laws and equal opportunity employment. The Nebraska Fair Employment Practice Act prohibits Contractors of the State of Nebraska, and their Subcontractors, from discriminating against any employee or applicant for employment, with respect to hire, tenure, terms, conditions, compensation, or privileges of employment because of race, color, religion, sex, disability, marital status, or national origin (Neb. Rev. Stat. §48-1101 to 48-1125). The Contractor guarantees compliance with the Nebraska Fair Employment Practice Act, and breach of this provision shall be regarded as a material breach of contract. The Contractor shall insert a similar provision in all Subcontracts for services to be covered by any contract resulting from this RFP.

D. COOPERATION WITH OTHER CONTRACTORS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Contractor may be required to work with or in close proximity to other contractors or individuals that may be working on same or different projects. The Contractor shall agree to cooperate with such other contractors or individuals, and shall not commit or permit any act which may interfere with the performance of work by any other contractor or individual. Contractor is not required to compromise Contractor's intellectual property or proprietary information unless expressly required to do so by this contract.

E. PERMITS, REGULATIONS, LAWS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contract price shall include the cost of all royalties, licenses, permits, and approvals, whether arising from patents, trademarks, copyrights or otherwise, that are in any way involved in the contract. The Contractor shall obtain and pay for all royalties, licenses, and permits, and approvals necessary for the execution of the contract. The Contractor must guarantee that it has the full legal right to the materials, supplies, equipment, software, and other items used to execute this contract.

F. OWNERSHIP OF INFORMATION AND DATA / DELIVERABLES

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The State shall have the unlimited right to publish, duplicate, use, and disclose all information and data developed or obtained by the Contractor on behalf of the State pursuant to this contract.

The State shall own and hold exclusive title to any deliverable developed as a result of this contract. Contractor shall have no ownership interest or title, and shall not patent, license, or copyright, duplicate, transfer, sell, or exchange, the design, specifications, concept, or deliverable.

G. INSURANCE REQUIREMENTS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor shall throughout the term of the contract maintain insurance as specified herein and provide the State a current Certificate of Insurance/Acord Form (COI) verifying the coverage. The Contractor shall not commence work on the contract until the insurance is in place. If Contractor subcontracts any portion of the Contract the Contractor must, throughout the term of the contract, either:

1. Provide equivalent insurance for each subcontractor and provide a COI verifying the coverage for the subcontractor;

2. Require each subcontractor to have equivalent insurance and provide written notice to the State that the Contractor has verified that each subcontractor has the required coverage; or,

3. Provide the State with copies of each subcontractor's Certificate of Insurance evidencing the required coverage.

The Contractor shall not allow any Subcontractor to commence work until the Subcontractor has equivalent insurance. The failure of the State to require a COI, or the failure of the Contractor to provide a COI or require subcontractor insurance shall not limit, relieve, or decrease the liability of the Contractor hereunder.

In the event that any policy written on a claims-made basis terminates or is canceled during the term of the contract or within one (1) years of termination or expiration of the contract, the contractor shall obtain an extended discovery or reporting period, or a new insurance policy, providing coverage required by this contract for the term of the contract and one (1) years following termination or expiration of the contract.

If by the terms of any insurance a mandatory deductible is required, or if the Contractor elects to increase the mandatory deductible amount, the Contractor shall be responsible for payment of the amount of the deductible in the event of a paid claim.

Notwithstanding any other clause in this Contract, the State may recover up to the liability limits of the insurance policies required herein.

1. WORKERS' COMPENSATION INSURANCE

The Contractor shall take out and maintain during the life of this contract the statutory Workers' Compensation and Employer's Liability Insurance for all of the contactors' employees to be engaged in work on the project under this contract and, in case any such work is sublet, the Contractor shall require the Subcontractor similarly to provide Worker's Compensation and Employer's Liability Insurance for all of the Subcontractor's employees to be engaged in such work. This policy shall be written to meet the statutory requirements for the state in which the work is to be performed, including Occupational Disease. **The policy shall include a waiver of subrogation in favor of the State. The COI shall contain the mandatory COI subrogation waiver language found hereinafter**. The amounts of such insurance shall not be less than the limits stated hereinafter. For employees working in the State of Nebraska, the policy must be written by an entity authorized by the State of Nebraska Department of Insurance to write Workers' Compensation and Employer's Liability Insurance for Nebraska employees.

2. COMMERCIAL GENERAL LIABILITY INSURANCE AND COMMERCIAL AUTOMOBILE LIABILITY INSURANCE

The Contractor shall take out and maintain during the life of this contract such Commercial General Liability Insurance and Commercial Automobile Liability Insurance as shall protect Contractor and any Subcontractor performing work covered by this contract from claims for damages for bodily injury, including death, as well as from claims for property damage, which may arise from operations under this contract, whether such operation be by the Contractor or by any Subcontractor or by anyone directly or indirectly employed by either of them, and the amounts of such insurance shall not be less than limits stated hereinafter.

The Commercial General Liability Insurance shall be written on an **occurrence basis**, and provide Premises/Operations, Products/Completed Operations, Independent Contractors, Personal Injury, and Contractual Liability coverage. **The policy shall include the State, and others as required by the contract documents, as Additional Insured(s). This policy shall be primary, and any insurance or self-insurance carried by the State shall be considered secondary and non-contributory**. **The COI shall contain the mandatory COI liability waiver language found hereinafter.** The Commercial Automobile Liability Insurance shall be written to cover all Owned, Non-owned, and Hired vehicles.

REQUIRED INSURANCE COVERAGE (The contractor shall obtain and maintain during the life of this contract Medical Malpractice and verify that medical providers shall, at the time of award, be qualified and shall, for the duration of the contract, remain qualified under the Nebraska Hospital-Medical Liability Act. By submitting a proposal, bidders certify that they are so qualified. Such qualification will be confirmed with the Nebraska Department of Insurance. Any disqualification from the fund may result in disqualification of the bidder or immediate termination of an awarded contract.)	
COMMERCIAL GENERAL LIABILITY	
General Aggregate	$2,000,000
Products/Completed Operations Aggregate	$2,000,000
Personal/Advertising Injury	$1,000,000 per occurrence
Bodily Injury/Property Damage	$1,000,000 per occurrence
Medical Payments	$10,000 any one person
Damage to Rented Premises (Fire)	$300,000 each occurrence
Contractual	Included
Independent Contractors	Included
If higher limits are required, the Umbrella/Excess Liability limits are allowed to satisfy the higher limit.	
WORKER'S COMPENSATION	
Employers Liability Limits	$500K/$500K/$500K
Statutory Limits- All States	Statutory - State of Nebraska
Voluntary Compensation	Statutory
COMMERCIAL AUTOMOBILE LIABILITY	
Bodily Injury/Property Damage	$1,000,000 combined single limit
Include All Owned, Hired & Non-Owned Automobile liability	Included
Motor Carrier Act Endorsement	Where Applicable
UMBRELLA/EXCESS LIABILITY	
Over Primary Insurance	$5,000,000 per occurrence
PROFESSIONAL LIABILITY	
Professional liability (Medical Malpractice)	Limits consistent with Nebraska Medical Malpractice Cap
Qualification Under Nebraska Excess Fund	
CYBER LIABILITY	
Breach of Privacy, Security Breach, Denial of Service, Remediation, Fines and Penalties	$3,000,000
MANDATORY COI SUBROGATION WAIVER LANGUAGE	
"Workers' Compensation policy shall include a waiver of subrogation in favor of the State of Nebraska."	
MANDATORY COI LIABILITY WAIVER LANGUAGE	
"Commercial General Liability & Commercial Automobile Liability policies shall name the State of Nebraska as an Additional Insured and the policies shall be primary and any insurance or self-insurance carried by the State shall be considered secondary and non-contributory as additionally insured."	

If the mandatory COI subrogation waiver language or mandatory COI liability waiver language on the COI states that the waiver is subject to, condition upon, or otherwise limit by the insurance policy, a copy of the relevant sections of the policy must be submitted with the COI so the State can review the limitations imposed by the insurance policy.

3. EVIDENCE OF COVERAGE

The Contractor shall furnish the Contract Manager, with a certificate of insurance coverage complying with the above requirements prior to beginning work at:

Newborn Screening Program Manager
Nebraska Department of Health and Human Services
Attn: Julie Luedtke
301 Centennial Mall South, PO Box 95026
Lincoln, NE 68508-5026

These certificates or the cover sheet shall reference the RFP number, and the certificates shall include the name of the company, policy numbers, effective dates, dates of expiration, and amounts and types of coverage afforded. If the State is damaged by the failure of the Contractor to maintain such insurance, then the Contractor shall be responsible for all reasonable costs properly attributable thereto.

Reasonable notice of cancellation of any required insurance policy must be submitted to the contract manager as listed above when issued and a new coverage binder shall be submitted immediately to ensure no break in coverage.

4. DEVIATIONS

The insurance requirements are subject to limited negotiation. Negotiation typically includes, but is not necessarily limited to, the correct type of coverage, necessity for Workers' Compensation, and the type of automobile coverage carried by the Contractor.

H. ANTITRUST

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor hereby assigns to the State any and all claims for overcharges as to goods and/or services provided in connection with this contract resulting from antitrust violations which arise under antitrust laws of the United States and the antitrust laws of the State.

I. CONFLICT OF INTEREST

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

By submitting a proposal, bidder certifies that there does not now exist a relationship between the bidder and any person or entity which is or gives the appearance of a conflict of interest related to this RFP or project.

The bidder certifies that it shall not take any action or acquire any interest, either directly or indirectly, which will conflict in any manner or degree with the performance of its services hereunder or which creates an actual or an appearance of conflict of interest.

The bidder certifies that it will not knowingly employ any individual known by bidder to have a conflict of interest.

The Parties shall not knowingly, for a period of two years after execution of the contract, recruit or employ any employee or agent of the other Party who has worked on the RFP or project, or who had any influence on decisions affecting the RFP or project.

J. ADVERTISING

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor agrees not to refer to the contract award in advertising in such a manner as to state or imply that the company or its services are endorsed or preferred by the State. Any publicity releases pertaining to the project shall not be issued without prior written approval from the State.

K. NEBRASKA TECHNOLOGY ACCESS STANDARDS (Statutory)

Contractor shall review the Nebraska Technology Access Standards, found at http://nitc.nebraska.gov/standards/2-201.html and ensure that products and/or services provided under the contract are in compliance or will comply with the applicable standards to the greatest degree possible. In the event such standards change during the Contractor's performance, the State may create an amendment to the contract to request the contract comply with the changed standard at a cost mutually acceptable to the parties.

L. DISASTER RECOVERY/BACK UP PLAN

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The Contractor shall have a disaster recovery and back-up plan, of which a copy should be provided upon request to the State, which includes, but is not limited to equipment, personnel, facilities, and transportation, in order to continue services as specified under the specifications in the contract in the event of a disaster.

M. DRUG POLICY

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Contractor certifies it maintains a drug free work place environment to ensure worker safety and workplace integrity. Contractor agrees to provide a copy of its drug free workplace policy at any time upon request by the State.

IV. PAYMENT

A. INSPECTION AND APPROVAL

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Final inspection and approval of all work required under the contract shall be performed by the designated State officials.

The State and/or its authorized representatives shall have the right to enter any premises where the Contractor or Subcontractor duties under the contract are being performed, and to inspect, monitor or otherwise evaluate the work being performed. All inspections and evaluations shall be at reasonable times and in a manner that will not unreasonably delay work.

B. PAYMENT

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Payee shall pay the laboratory according to Section VII. Cost Proposal Requirements.

C. RIGHT TO AUDIT (First Paragraph is Statutory)

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The State shall have the right to audit the Contractor's performance of this contract upon a 30 days' written notice. Contractor shall utilize generally accepted accounting principles, and shall maintain the accounting records, and other records and information relevant to the contract (Information) to enable the State to audit the contract. The State may audit and the Contractor shall maintain, the Information during the term of the contract and for a period of five (5) years after the completion of this contract or until all issues or litigation are resolved, whichever is later. The Contractor shall make the Information available to the State at Contractor's place of business or a location acceptable to both Parties during normal business hours. If this is not practical or the Contractor so elects, the Contractor may provide electronic or paper copies of the Information. The State reserves the right to examine, make copies of, and take notes on any Information relevant to this contract, regardless of the form or the Information, how it is stored, or who possesses the Information. Under no circumstance will the Contractor be required to create or maintain documents not kept in the ordinary course of contractor's business operations, nor will contractor be required to disclose any information, including but not limited to product cost data, which is confidential or proprietary to contractor.

V. PROJECT DESCRIPTION AND SCOPE OF WORK

The bidder should provide the following information in response to this RFP.

A. PROJECT OVERVIEW

In order to comply with Neb. Rev. Stat. §§71-519 through 71-524 and 181 NAC 2, the Department of Health and Human Services, Nebraska Newborn Screening Program (NNSP) is issuing this RFP to conduct laboratory testing for the detection of a core set of treatable, inherited disorders of newborns. The State is offering this Request for Proposal (RFP) for exclusive rights to conduct the screening of Nebraska newborns for diseases specified in 181 NAC 2; it is not the purchaser of the services. The contractor will bill/invoice specimen submitters for the per-infant screened administrative fee specified in 181 NAC 2, subsection 010, plus the per-infant-screened fee for the lab testing services as agreed to in this contract. The per-infant screened administrative fee shall be forwarded monthly to the NNSP. If at any time during the term of the contract, the fee would be adjusted via statute or regulation, the contractor will adjust their billing and remittances accordingly. The NNSP may consider the addition of tests for other disorders during the contract period, so bidders shall identify other tests available or in development, methodologies available, laboratory experience with these other tests, and their costs. Cost proposals should be based on the testing and reporting of approximately 24,000 initial filter paper cards for all conditions, approximately 3,000 specimens from neonatal intensive care units and others collected at less than 24 hours for all but six conditions (See specifications under Section V.C.) and 3,500 repeat specimens for the full newborn screening panel annually and approximately 1000 repeat specimens for one or two conditions*, filter paper collection kits, 24 hour transportation costs associated with the delivery of specimens, data management, technical assistance and clinical consultation. Technical assistance and clinical consultation may be provided in person, by phone, fax, e-mail or U.S. mail. The contractor will provide the NNSP with access to an electronic database fulfilling all requirements of this RFP.

This RFP is intended to contract with a single laboratory to complete all of the testing for all required newborn screening tests per Neb.Rev.Stat.§71-523. **Proposals that include subcontracting part of the testing to another laboratory will be rejected.**

*Numbers of anticipated initial and repeat specimens subject to variation due to changes in numbers of births, performance of assays, and agreed-upon screening protocols.

B. PROJECT ENVIRONMENT

The NNSP is responsible for administering regulations governing newborn screening in Nebraska, contracting for newborn screening laboratory testing services, performing follow-up and tracking of all newborns to ensure appropriate screening has occurred, development and distribution of patient education materials, development and provision of provider education, administration of system for distribution of and access to metabolic foods and metabolic formula, and monitoring of the system to ensure quality.

The newborn screening blood tests required by Neb.Rev.Stat.§71-519 and by regulations 181 NAC 2 are to detect the endocrinopathies, hemoglobinopathies, immunodeficiencies, pulmonary conditions, lysosomal storage diseases and peroxisomal storage diseases and a group of metabolic diseases of amino acid, fatty acid, vitamin and organic acid metabolism, that may be detected from the acylcarnitine and amino acid profiles of tandem mass spectrometry including and in addition to: Argininosuccinic Acidemia (ASA), Beta-ketothiolase Deficiency (Mitochondrial Acetoacetyl-CoA Thiolase Deficiency or 3-Ketothiolase Deficiency, BKT), Biotinidase Deficiency (BIO), Carnitine Uptake Defect (CUD), Citrullinemia (CIT), Congenital Adrenal Hyperplasia CAH), Congenital Primary Hypothyroidism (CPH), Cystic Fibrosis (CF), Galactosemia (GALT), Glutaric Acidemia type 1 (GA1), Hemoglobinopathies (F, A, S & C), Homocystinuria (HCY), Isovaleric Acidemia (IVA), Long-Chain Hydroxyacyl-CoA Dehydrogenase Deficiency (3-Hydroxy Long Chain Acyl-CoA Dehydrogenase Deficiency or LCHAD), Maple Syrup Urine Disease (MSUD), Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCAD), Methylmalonic Acidemia (mutase deficiency or MMA), Methylmalonic acidemia (Cbl A, B), Multiple Carboxylase Deficiency (MCD), Phenylketonuria (PKU), Propionic Acidemia (PA or PROP), Tyrosinemia (TYR), Severe Combined Immune Deficiency (SCID), Trifunctional Protein Deficiency (TFP), Very Long-Chain Acyl Co-A Dehydrogenase Deficiency (VLCAD), 3-Hydroxy 3 Methyl Glutaric Aciduria (HMG), 3-Methylcrotonyl-CoA Carboxylase Deficiency (3-MCC), and if adopted via proposed regulation revisions, Mucopolysaccharidosis Type I (MPS-I), Pompe Disease (PD) and X-linked Adrenoleukodystrophy (X-ALD).

All of the required newborn screening tests are conducted under a contract with a laboratory.

Nebraska has approximately 27,000 plus births per year from a fluctuating number of between 59-64 birthing hospitals and facilities across the approximately 77,000 square-mile state. In addition, approximately 100 births per year are out-of-hospital or home births, whose screening specimens may be submitted by hospitals, home nurse visitation agencies, local/county/district or regional public health agencies, or private practitioner's offices.

Approximately two-thirds of all Nebraska births each year occur in the eastern one-third of the State. (See Appendix A for hospital births from 2016). Yearly average births per hospital range from 1 to 5,200. In the past 10 years (2007-2017), newborn screening has identified 370 infants with disorders for a 10 year annual incident rate of 1:506 births screened.

Using information reported via phone, fax and electronically from the laboratory, the NNSP program follow-up personnel perform short term follow-up to the point of diagnosis, or entry into clinical management/monitoring, or when a suspected diagnosis is ruled out. The NNSP staff utilize data from the laboratory data system to perform quality assurance oversight of laboratory and birthing facility performance. Electronic reporting via secure web portal and via bidirectional HL7 interface is available for the NNSP and hospitals. Approximately 66% of births occur in hospitals that have the electronic interface.

C. OVERVIEW OF THE REQUIREMENTS

This section provides an overview of the requirements for the newborn screening contractor for the Nebraska Newborn Screening Laboratory Services. Also provided is a general description of the testing requirements, telecommunications needs, consultation, documentation, and technical support. Because Technical Requirements are integral to the provision of the Project Requirements, most are embedded in this section.

The Contractor shall comply with the requirements in Neb.Rev.Stat. §71-519 and Regulations Title 181, NAC 2.

The contractor will analyze blood specimens submitted by the birth hospitals and other designees from the State of Nebraska. The State estimates that biochemical and molecular tests will likely be run on approximately 33,000 samples annually. These tests include:

Targeted Conditions and Laboratory Testing

The bidder must provide a response to C.1 through C.32 in the following table. Diseases to be screened are specified in C.1 through C.30. Other testing specifications are indicated in Appendix F, Newborn Screening Matrix. The bidder must provide responses to requirements C.33 through C.43 as indicated in Appendix F.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

1. Argininosuccinic acidemia (ASA). Currently screened using proprietary interpretation method of tandem mass spectrometry.

2. Beta-ketothiolase Deficiency (Mitochondrial Acetoacetyl-CoA Thiolase Deficiency or 3-ketothiolase Deficiency or BKT). Currently screened using proprietary interpretation method of tandem mass spectrometry.

3. Biotinidase deficiency (BIO): Currently, the sample is tested by an assay which yields a quantitative, numerical result for conversion of a labeled conjugated biotin substrate to a measureable colored product. The numerical value obtained representing the enzymatic activity of biotinidase is reported with the clinically significant cut-off. Two sets of cut-offs are utilized, lesser elevations are reported as inconclusive and repeat tests are requested. Reflex testing on DNA is conducted on all positive initial screens and all inconclusive repeat screens. Significant elevations are reported as positive screens and confirmatory testing is recommended. Semi-quantitative methods incorporating fluoroscopic measure may be acceptable with sufficient documentation of validity, sensitivity/specificity.

4. Carnitine Uptake Defect (CUD): Currently screened using proprietary interpretation method of tandem mass spectrometry.

5. Citrullinemia (CIT): Currently screened using proprietary interpretation method of tandem mass spectrometry.

6. Congenital Adrenal Hyperplasia (CAH): Currently screening test is Steroid 17-alpha hydroxy progesterone (17-OHP) using an FDA approved non-isotopic imunoassay for 17-OHP. A subset of specimens with elevated 17-OHP adjusted by birth weight reflex to an extracted 17-OHP assay. Lesser elevations of 17-

OHP and extracted OHP are reported as inconclusive and repeat specimens are requested. Significant elevations of 17-OHP for term babies are reported out as positive. Significant elevations of 17-OHP for low birth weight babies in the critical cut-off range are reported as preliminary Positive, pending the extracted results.

7. Congenital Primary Hypothyroidism (CPH): Thyroxine (T4) and Thyroid stimulating hormone (TSH) by radioimmunoassay (RIA) or preferably enzyme immunoassay (EIA) for congenital primary hypothyroidism. Currently the lowest 10% of T4's reflex to TSH. TSH's greater than 20 are reported as presumptive positive.

8. Cystic Fibrosis (CF): A combination IRT/DNA screen is currently used. Initial Immunoreactive trypsinogen results in the top 1.2% of the run reflex to DNA for the ΔF508 mutation. If no ΔF508 is found the test result is reported as inconclusive and a repeat specimen is requested. If one copy of ΔF508 is present, the specimen is reflexed again to a 39 mutation + 4 polymorphism panel. Whether one or two mutations, the infant is recommended for referral to an Accredited CF Center. If the inconclusives on repeat continue to be elevated, they reflex at that point to the 39 mutation + 4 polymorphisms panel. Whether zero, one or two mutations, the infant is recommended for referral to an Accredited CF Center at that point. Specimens collected at day of life 12 or later have a cut-off of 80 ng/mL instead of the 1.2%, but elevations would follow the same reflex pattern. Specimens from babies with reported meconium ileus or bowel obstruction are screening using the DNA panel.

9. Galactosemia (GAL): Currently Total galactose and uridyl transferase (UT) are assayed on all specimens. Percent Galactose-1-phosphate (Gal-1-P) is reported for all samples with total galactose elevated. Specimens with galactose results < 15 mg/dl are reported as normal. Specimens with galactose levels >15 mg/dl to < 30 mg/dl are reported as inconclusive. Specimens with galactose levels > 30 mg/dl are reported as positive. Repeats with gal ≥20 are positive. All samples with UT > 40μMol are reported as normal. Samples with UT < 40 μMol will be reported as positive and will reflex to DNA mutations.

10. Glutaric Acidemia type 1 (GAI): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious of GA-I reflex to DNA mutations. Repeat screening results that continue to be abnormal reflex to DNA mutations.

11. Hemoglobinopathies: Isoelectric focusing is currently done to detect hemoglobins F, A, S, C, D, E, O-Arab, Barts and other variant hemoglobins greater than A. When variant hemoglobin appears greater than hemoglobin A, the test reflexes to check for the presence of selected beta thalassemia mutations. Barts Hemoglobin, and Hemoglobin E are important to the Nebraska population to identify clinically significant thalassemias. Screening results indicating a possible clinically significant Hemoglobinopathy reflex to DNA mutations for S, C, D, E and O-Arab. Preference for sequencing of Hgb. Barts as a reflex test.

12. Homocystinuria (HCY): Currently screened using proprietary interpretation method of tandem mass spectrometry.

13. Isovaleric Acidemia (IVA): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for IVA reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

14. Long-chain Hydroxyacyl-CoA Dehydrogenase Deficiency (3-Hydroxy Long Chain Acyl-CoA Dehydrogenase Deficiency or LCHAD): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for LCHAD reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

15. Maple Syrup Urine Disease (MSUD): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for MSUD reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

16. Medium Chain Acyl Co-A Dehydrogenase Deficiency (MCAD): Currently screened using proprietary interpretation method of Tandem Mass Spectrometry analysis. Screening results highly suspicious for MCAD reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

17. Methylmalonic Acidemia (Mutase Deficiency): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for MMA reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

18. Methylmalonic Acidemia (Cbl. A, B): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for MMA reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

19. *****Muccopolysaccharidosis Type I (MPS-I): Primary screen may be MS/MS or Digital Microfluidics. For repeat screens that continue to be out of range reflex testing of DNA sequencing is preferred *** To be added effective July 1, 2018**.

20. Multiple Carboxylase Deficiency: Currently screened using proprietary interpretation method of tandem mass spectrometry.

21. Phenylketonuria (PKU): Currently screened using proprietary interpretation method of tandem mass spectrometry.

22. *****Pompe Disease (PD): Primary screen may be MS/MS or Digital Microfluidics. For repeat screens that continue to be out of range reflex testing of DNA sequencing is preferred. *** To be added effective July 1, 2018.**

23. Propionic (PA): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for PA reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

24. Severe Combined Immune Deficiency (SCID): To be screened using PCR to identify copy numbers of TRECS (T-Cell Receptor Excision Circles), with Beta- Actin reflex testing to verify amplification of DNA.).

25. Tri-Functional Protein Deficiency (TFP): Currently screened using proprietary interpretation method of tandem mass spectrometry.

26. Tyrosinemia (TYR): Currently screened using proprietary interpretation method of tandem mass spectrometry and includes analysis of succinylacetone (SUAC).

27. Very Long Chain Acyl-CoA Dehydrogenase Deficiency (VLCAD): Currently screened using proprietary interpretation method of tandem mass spectrometry.

28. *****X-linked Adrenoleukodystophy (X-ALD): Primary screen via FIA-MS/MS, reflex to HPLC for out of range screen results. For repeat screens that continue to be out of range reflex testing of DNA sequencing is preferred. *** To be added effective July 1, 2018.**

29. 3-Hydroxy 3-Methyl Glutaric Aciduria (HMG): Currently screened using proprietary interpretation method of tandem mass spectrometry.

30. 3-Methylcrotonyl-CoA Carboxylase Deficiency (3-MCC): Currently screened using proprietary interpretation method of tandem mass spectrometry. Screening results highly suspicious for 3-MCC reflex to DNA mutations, repeat screening results that continue to be abnormal reflex to DNA mutations.

31. All specimens collected at less than 24 hours of age are tested for all conditions except CAH, CPH, and CF. When MPS-I, PD and X-ALD are added these will be excluded from testing on specimens collected at < 24 hours of age. All initial specimens collected at > 24 hours of age are tested for all conditions. All repeat specimens collected at > 24 hours of age and collected due to the initial specimen being less than 24 hours at collection will be tested for all conditions exceot for SCID and BIO if prior results were normal. All repeat specimens collected due to the initial specimen being unsatisfactory will be tested for only those conditions not able to be tested on the former unsatisfactory specimen. All repeat specimens collected due to a prior inconclusive screening result will be tested for the condition found inconclusive. All repeat specimens collected due to being a required 28 day or discharge specimen for newborns < 2000 grams admitted to the NICU, will be tested for CAH and CPH and any analyte for which a prior abnormal result was reported. All of the above requested repeats shall be tested at no additional charge and so costs shall be considered and included in the per-infant testing fee when determining the total bid.

32. Any proposed changes during the course of the contract to screening methods, cut-offs, normal reference ranges, or algorithms must be mutually agreed upon between the laboratory and the State. For changes proposed by the laboratory, scientific rationale supporting the proposal must be made available by the laboratory to the NNSP and representatives of its Newborn Screening Advisory Committee for consideration.

D. FILTER PAPER

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contractor will purchase the Nebraska Newborn Screening Program Collection and Reporting Form (See Appendix E) filter paper collection devices, as required for the collection and identification of the blood specimens and for providing the necessary clinical information. The laboratory may recover the cost of the filter paper in its single fee per infant screened charge to hospitals. The contractor will distribute supplies of the filter paper collection devices to all Nebraska birthing facility submitters.

The laboratory must document tracking of which filter paper specimen collection devices were provided to which birthing hospital/facility and communicate this information to the NNSP as requested. All costs associated with this transport shall be incurred by the laboratory and incorporated into the per-infant screened laboratory charges. The bidder must pro-actively work with submitters to reduce the risk of expired filter paper being used to collect dried blood spot specimens.

Residual dried blood spots will be stored at a facility that provides security, confidentiality, stability of temperature and humidity (refrigerated in sealed bags of low gas permeability) and retrievability for 90 days. Within 30 days following the 90 day period left over filter paper blood spots shall be disposed of in a manner that ensures confidentiality. No filter paper blood spots can be used for research without the explicit consent of the newborn's parent/legal guardian, and approval by an Institutional Review Board (IRB) and approval by the Department of Health and Human Services Chief Medical Officer. Documentation of the storage, use and disposal of the residual dried blood spots shall be in compliance with 181 NAC 2. Documentation of the storage, use and disposal of the residual dried blood spots shall be made available to the NNSP upon request at no additional charge. Destruction manifests or other documentation demonstrating compliance with disposal requirements in 181 NAC 2 must be made available to the NNSP upon request.

The NNSP has a procedure for the retrieval of residual dried blood spots for use by the patient's physician for clinical diagnostic testing purposes. The laboratory will accommodate up to 100 requests for residual blood spot specimens per year to be retrieved and returned to the patient's physician with appropriately signed documentation of parent/guardian release and physician request at no additional charge.

E. SPECIMAN SHIPPING

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contractor will arrange for daily courier pick-up service at designated locations within each Nebraska birthing hospital and birthing facility (See Appendix A for the list of facilities) for next day delivery to the screening laboratory and provide for tracking of such specimens (with exceptions for weekend and holiday days when no transport service is available). A minimum of five (5) day a week pick up and overnight delivery is expected for all birthing hospitals/facilities. Six (6) day a week pick-up including Saturdays shall be provided for all hospitals where a commercial courier or shipper is available to provide that service in their community. Saturday delivery to the laboratory shall be provided for specimens shipped Fridays. For hospitals that do not have specimens to be transported daily (hospitals with few births), the contractor does not have to ensure daily pick-up. However, the contractor shall ensure procedures are in place to courier these infrequent specimens within 24 hours of collection (with exceptions for weekend and holiday days when no transport service is available). The contractor will provide to the NNSP a list of facilities with the name of their associated courier identified, daily and weekend order-by and pick up times. The contractor shall also monitor the courier service for performance and timeliness and communicate to the NNSP within 48 hours of identifying any delays or exceptions.

F. REPORTING

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contractor will report all results to the NNSP according to these technical requirements. The laboratory reports newborn screening results needing follow-up via telephone to the NNSP, the newborn's physician or designee, and the submitter (facility submitting the specimen) as soon as the results are available including afterhours weekdays, weekends and holidays. Exceptions to after normal business hours reporting include specimens collected at less than 24 hours of age, unsatisfactory specimens, transfused specimens, specimens with multiple amino acid elevations indicating likely hyperalimentation, non-clinically significant hemoglobinopathy abnormalities, positive and inconclusive Cystic Fibrosis results and inconclusive biotinidase (likely partial or carrier) deficiency results. Weekend after-hours reporting is also not conducted for SCID, Pompe, X-ALD and MPS-I. The laboratory also faxes all reports that are phoned, during weekday working hours, to the physician, submitter & NNSP.

All initial repeat and confirmatory test results must be reported to the NNSP and submitters or made available electronically within 24 hours of test completion.

The laboratory test results report format and explanatory comments will be determined, as mutually agreed upon by the laboratory and the NNSP. The laboratory test results report format will include identification for each disorder screened by tandem mass spectrometry (MS/MS) and any other multiplex method; the name of the condition screened, the analyte or test name, the numerical value when available for quantitative or semi-quantitative assays, the unit of measure, other values such as the alpha description for hemoglobinopathies, a relative interpretation (WNL for within normal limits), and identify the cut-off or reference range (expected normal) for each analyte. Comments must be agreed to by the NNSP, and should identify for which condition the screening test abnormality is "inconclusive" or "preliminary positive" or "positive" and recommended next steps (e.g. repeat dried blood spot filter paper specimen or confirmatory testing, and or referral to pediatric sub specialist). Laboratory report comments relative to specimens drawn early, unsatisfactory specimens, transfused specimens, and specimens collected post-hyperalimentation must also be developed in collaboration with and agreed to by the NNSP.

For conditions screened by MS/MS the laboratory report will list a result for the acylcarnitine profile and the amino acid profile as WNL, abnormal or positive, and "see comment". Comments for MS/MS will describe which analytes are abnormal, the degree to which they are abnormal, provide the numerical value of the screening result and expected (normal) reference value or range, using the same unit of measure, as well as any ratios applied by the laboratory. It will provide an interpretation that at a minimum distinguishes between results which urgently require confirmatory testing and/or referral to a pediatric sub specialist, vs. those which require repeat testing via dried blood spot filter paper specimens. A list of conditions screened by MS/MS at the laboratory will also be listed separately on the laboratory report.

Any proposed changes to laboratory report format, content or language must be mutually agreed upon in writing between the laboratory and the NNSP before such changes are implemented.

Complete MS/MS screening profile results including specific analyte values and ratios will be provided by the laboratory to the NNSP upon request for all babies that are confirmed positive.

The contractor will report every "positive" and/or abnormal screening result immediately via phone and in writing to the Nebraska Newborn Screening Program (NNSP), the submitter and the physician identified on the filter paper collection device (and alternate physician when discovered that the physician on the filter paper collection device is no longer seeing the baby). This notification is expected whenever the results become available on a 24 hour, seven day a week basis regardless of time. The written notification (fax) may be sent the following business day when the results are first available and reported on the weekend or after hours. After normal business hours reporting exceptions are positive, abnormal or inconclusive results for BIO, CF, Hgb's, SCID, PD, MPS-I and X-ALD which are only required to be phoned to the NNSP, submitter and physician via phone, and in writing, during normal business hours .

The contractor will report immediately via phone and in writing to the NNSP, the submitter and the physician every abnormal screening result that is "inconclusive" or in need of a repeat dried blood spot specimen only, on a 24 hour, seven day a week basis. These following exceptions need only be reported within twenty-four (24) hours and

during normal business hours Monday through Friday: results indicating possible hyperalimentation (multiple amino acids elevated), specimens collected post transfusion, specimens collected too early at < 24 hours of age, unsatisfactory specimens, abnormal hemoglobinopathy results not expected to be clinically significant to the newborn; specimens that are considered abnormal (AF) or unreliable because of transfusion, and any abnormal results for BIO, CF, MPS-I, PD, and X-ALD. Specimens with substantially abnormal or clinically significant results on a post transfusion result still require notification after normal working hours and on weekends. Depending on the screening algorithm proposed by the laboratory other abnormalities may be included in the "Monday through Friday" only expected reporting period, if mutually agreed upon by the NNSP. Unsatisfactory specimens must be reported by phone to the submitter and physician within 24 hours of when they are determined to be unsatisfactory, and in writing to the NNSP and submitter within 24 hours of this determination.

The contractor will document communication with submitters and physicians regarding unsatisfactory specimens, drawn early specimens, presumptive positive, inconclusive or abnormal, initial or repeat specimen screening results, confirmatory test results conducted by the laboratory, and reporting of laboratory errors. Laboratory (testing and reporting) errors shall be reported to the NNSP, physician and submitter within 24 hours of discovery of each error.

G. DATA SYSTEM REQUIREMENTS

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

All demographic information required on the NNSP collection and reporting form (See Appendix E) filter paper collection device must be entered into an electronic database the day the forms are received. The database system must have unlimited availability during each 24 hour period for data transmission and data access, with the exception for routine technical maintenance of the database system. The electronic data system must ensure standard SSL (Secure Sockets Layer) 128-bit encryption necessary for transmission of data, or other security measures of equal or higher quality.

Demographic information must be entered the day the specimen is received, and test result information must be entered within 24 hours of completion of the tests. The system will allow secure remote access for tracking of all Nebraska newborn's specimens. It will also be used by the NNSP to generate reports and letters. All newborn laboratory test and result data shall be kept in the computerized record system accessible to the laboratory performing the services for a period no less than 25 years from the date of the test, and to the NNSP for a period no less than 29 years from the date of the test.

Timely and accurate data entry is required to facilitate the NNSP follow-up component which will contact the primary care physician with recommendations on all abnormal screening results, unsatisfactory, drawn early, and post-transfusion specimens and which will maintain follow-up until adequate specimens are submitted, diagnosis is ruled out, or diagnosis of the infant is confirmed and the infant is in treatment or according to NNSP written procedures that the infant is determined lost to follow-up.

Data entry errors shall be reported by phone to the NNSP within 24 hours of discovery of such error.

Electronically transmit or allow electronic access to test results and other data via a secure connection. All electronic transmissions of data must meet all State and Federal security requirements including those in the Bureau of Information Services Security Manual and Health Information Portability and Accountability Act (HIPAA) and regulations and be compatible with provisions of the Health Information Technology for Economic and Clinical Health (HITECH Act). The laboratory IT personnel will provide training to the Nebraska Newborn Screening Program Manager and follow-up personnel on how to use the applications.
The contractor shall support a comprehensive data export from the laboratory data in comma delimited format for an upload to an SQL server maintained by the Department of Administrative Services Office of the Chief Information Officer. The data shall be uploaded weekly and include all data including comments-field content.

The bidder's capacity to export comma delimited text files compliant with Health Level Seven (HL7) standards to the Nebraska Department of Health and Human Services so that the data can be integrated into tables in the Nebraska Vital Records electronic registration system or other database system. The export files will need to maintain the referential integrity of the data and be exported to a Nebraska FTP (file transfer protocol) site.

A computerized system shall be maintained and updated to allow remote access by or transmission to the NNSP to the database containing all the information from the Nebraska Newborn Screening Program Collection and Reporting form on Nebraska specimens including: the date and time each sample was collected, date each sample was received from the specimen submitter, the date the laboratory tests were completed; the date results of the laboratory analyses were reported to or made available for access by the NNSP; the status of laboratory analysis (e.g. in progress, completed, or not done and reason why), results and other actions. This system will allow the NNSP to search for information, and report results of laboratory analysis on individual specimens to hospitals, and to the physician of record upon request. This does not eliminate the requirement for written reports of all test results to be provided by the laboratory to the submitter. Written reports to the submitter may be in electronic format for incorporation into each hospital/submitter's electronic medical records or printed in hard copy. The electronic data system must be HL7 compliant and capable of interfacing with hospital laboratory information systems or other health information exchanges in Nebraska to facilitate adoption of electronic medical records by providers.

The data system must produce reports of tests missing, unsatisfactory specimens, drawn early, transfused specimens, Inconclusive cystic fibrosis, newborns with meconium ileus or other bowel obstruction, out of hospital births, presumptive positives and confirmed positives that are necessary for follow-up and tracking. The data system also must produce reports of low T4's with low TSH's for information purposes only (not for required physician reporting). See appendix D for a complete listing of required reports.

The data system must also produce quality assurance reports necessary for monitoring of turnaround times, missing demographic information from the filter paper cards, statistical averages including mean, median, quarterly percentiles of all lab results producing a quantitative value, age at collection, and hospital QA reports comparing hospital numbers with State averages and percentiles of performance on multiple measures (see Appendix E). The NNSP can access a database of scanned images of dried blood spot filter paper devices received at the laboratory. The laboratory performs daily monitoring using a UPS electronic tracking report to identify any specimen shipments not received by 4 days from shipment. The laboratory follows up with the submitter and if necessary the shipper, the day an exception is identified. Exceptions are reported to the NNSP program manager, and a weekly report is routinely submitted.

All initial, repeat and confirmatory test results must be reported to the NNSP or made available electronically within 24 hours of test completion. A mechanism must be specified for the NNSP to enter/edit data or have data entered on confirmatory test results obtained from other laboratories or physicians/health care providers. Confirmatory tests used to aid in diagnosis may be done at various laboratories within and outside of Nebraska and may or may not be completed at the laboratory. When these are not done at the screening laboratory the NNSP follow-up program in the Department of Health and Human Services will track and monitor and so must have the capacity to enter these results into the Nebraska data.

The electronic data system must have the capacity to produce template letters populated with patient and health care practitioner demographic information, and test results for all abnormal screen results, as well as second request letters and letters for specimens collected too early, unsatisfactory specimens, transfused specimens and any other results requiring follow-up.

The contractor must implement a procedure to identify and merge/eliminate duplicate records. Specifically, when multiple (two or more) records on the same infant are identified when the infant has more than one specimen, there must be a mechanism to merge these into one record.

The data system must have the capacity to close a record when confirmed negative, confirmed positive or determined lost to follow-up so these records do not remain on a "pending" report. The data system must also have the capacity to remove inconclusive abnormal results from reports as closed.

The data system must be able to generate ad-hoc reports for quality assurance on variable date ranges and variable data elements.

Other reports will need to be developed to differentiate and analyze data for NICU admissions vs other newborns screened from the regular nursery vs home births.
Other reports will need to be developed to function for follow-up and tracking and for quality assurance upon the implementation of screening for new disorders screened.

H. DATA SYSTEM FUTURE ENHANCEMENT

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The data system must enable the NNSP to attach and save as part of individual patient records, electronic documents of follow-up activities (letters, faxes, reports in scanned or other Microsoft Office readable format). This data capacity must be available by the end of the first year of the contract.

By the end of the first 2 year period of the contract, a mechanism will be developed for "closing" follow-up action on patient records to enable the pending action to be dropped from the active worksheet reports, while retaining the record in open status for any other pending/needed follow-up actions.

I. SPECIALISTS

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contractor shall maintain a listing of qualified specialists in pediatric endocrine, metabolic, hemoglobin disorders, immunodeficiencies, lysosomal storage diseases, pulmonology, molecular genetics and a laboratory specialist who have agreed to provide medical consultation to the laboratory. This medical consultation may be related to establishing and monitoring screening test algorithms, and test performance, interpretation of screening test results, and recommendations for further evaluation.

J. CONFIDENTIALITY AND ASSURANCES

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Strict confidentiality of medical information will be maintained in all stages of testing and reporting, and shall be consistent with all applicable federal and state laws.

The contractor agrees to comply with all Nebraska statutes and regulations relative to newborn screening, the quality assurance measures (See Appendix D), and applicable clinical and newborn screening laboratory regulations and standards and other applicable standards, including but not limited to Clinical & Laboratory Standards Institute (CLSI) standards, Clinical Laboratory Improvement Act (CLIA) requirements, College of Pathology (CAP) requirements, and participation in Centers for Disease Control and Prevention's (CDC) Newborn Screening Proficiency Testing Program. The contractor agrees to provide copies of performance reports from their laboratory's participation in the CDC proficiency testing, and copies of certificates from CLIA and CAP reviews.

K. CONSULTATION

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Provide consultation and education to the NNSP and others, upon request of the NNSP, and as needs are identified by the contracting laboratory, on:

1. Screening for all of the conditions required in the contract, to the NNSP and Nebraska Newborn Screening Technical Advisory Committee. Such consultation may be provided via writing, phone, and teleconference and includes specific results interpretation, and in general regarding the technology.

2. Accessing the laboratory results database.

Any problematic trends identified by the contracting lab with specimen collection, transport, testing, reporting or other communication problems.

L. DISASTER PREPAREDNESS

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contractor must have disaster response plans to provide laboratory testing of the newborn screening specimens in the event of emergency, man-made or natural disaster or other event causing a delay of 24 hours or more in testing, requiring specimens to be tested at another location until such time as the bidding laboratory is able to resume testing. The response plan must include written agreements with other laboratories, and shall specify responsibilities of each laboratory involved, for specimen transportation, testing and notification of the submitter, physician and NNSP of results. Bidders should reference NCCLS (CLSI) document X4-R Planning for Challenges to a Clinical Laboratory Operations Disaster. By signing the Request for Proposal for Contractual Services form, bidder guarantees compliance with the Emergency/Disaster Preparedness Agreement in Appendix C, of this proposal.

Testing delays (e.g. due to assay problems, equipment breakdown, reagent problems) of greater than 24 hours beyond the laboratory's standard operating procedures will be reported by phone to the NNSP once recognized. Plans to alleviate the delay should also be reported (e.g. new replacement parts or reagent ordered.

M. BILLING AND REMITTANCE OF FEES

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

The contractor must have procedures for billing submitters/hospitals will include a single fee per infant screened. The single fee per infant screened may cover the costs associated with the specimen collection kit, specimen transportation to the laboratory, testing, analysis, interpretation and consultation, reporting of results by phone, electronically and in writing, quality assurance and other documentation reporting requirements, and must include

the per infant screened administrative fee. It shall be charged only once per infant screened whether or not one screen is sufficient or repeat screens are requested.

Requested repeat specimens will not be billed. Procedures must address how repeat specimens requested due to abnormal screening results, inconclusive screening results, transfused specimens, specimens collected at < 24 hours, unsatisfactory specimens and for NICU admissions < 2000 grams the 28-day/discharge specimens will be handled to assure no additional charges to the hospital or submitter are made for these.

The contractor must submit the monthly remittance of the per infant screened administrative fee specified in 181 NAC 2 to the NNSP.

N. WORK PLAN

The work plan shall address how the bidder will collaborate with the NNSP to plan for July 1, 2018 implementation, of all contract project and technical requirements, the plan for sustaining compliance with all requirements, and the plan for implementing any proposed new conditions testing. The work plan will also describe how capacity to meet all contract requirements will be maintained in the event the bidder's specimen volume processed annually should increase by more than five percent (5%).

O. TECHNICAL REQUIREMENTS

The bidder should provide the following information in response to this RFP.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	NOTES/COMMENTS:

Technical requirements are embedded in Section V.C Project Requirements as they are integral to the project requirements, and to avoid redundancy in the RFP and responses solicited. The technical requirements cover the following areas:

1. Distribution and tracking of filter paper blood specimen collection kits;
2. Rapid transport for specimens from the birthing hospitals/facilities to the laboratory;
3. Accurate and timely laboratory testing and analysis;
4. Accurate and timely communication of results;
5. Accurate, timely and comprehensive electronic reporting of data (demographic and test results, follow-up and quality assurance reports);
6. Collection and remittance of the per infant screened administrative fees to the State (Or amount specified in 181 NAC 2 Section 010 as promulgated;
7. Participation in quality assurance programs and reporting of quality assurance data; and,
8. Back-up laboratory testing assurances in the event of an emergency, disaster or other hazard preventing testing at the contracted laboratory.

The contract resulting from this RFP will be a fixed price per patient screened for providing newborn screening testing, specimen collection kits/shipment, data provision, technical assistance, clinical consultation and education to the NNSP.

P. LABORATORY PRACTICES

Explain laboratory policies and procedures that are or will be in place to address MMWR Recommendations and Reports "Using Tandem Mass Spectrometry for Metabolic Disease Screening Among Newborns," (April 13, 2001/Vol. 50/No. RR-3), and where there are variations from the recommended practices, explain why. Address this technical requirement for each of:

1. Standard and Sample Preparation

- **a.** Sample preparation technique validation
- **b.** Quality of reagents, buffers and solvents
- **c.** Validation of methods
- **d.** Use of internal standards for analysis, and where not available validation of other isotopes
- **e.** Validation of dilutions of commercial standards or in-house preparations
- **f.** Documentation of validation of
- **g.** standards and quality control preparations
- **h.** Safety recommendations, universal precautions, personal protective gear and environmental

controls that are required.

i. Good laboratory and measurement practices to be followed

2. Instrument

a. Manufacturer's guidelines for power requirements, exhaust specifications, laboratory gas purity and pressure, and laboratory environment

b. Additional peripheral equipment for MS/MS and sample preparation equipment

c. Qualification and quantity recommendations for MS/MS operators

d. Manager and supervisor of MS/MS operations experience

e. Backup plan for instrument down time

f. Calibration procedures and scales

g. Daily instrument check solution

3. Reducing Instrument-to-Instrument Variability

a. Definition of minimum sensitivity threshold, and concentration calculations using ion ratios.

4. Quality Control

a. Quality control specimens, (which are used, concentrations of these, how used)

b. Use of reagent blank

c. Monitoring of daily patient mean or median for each analyte

d. Routine maintenance schedule

e. Participation in external quality-control and proficiency testing program(s).

f. Quality control protocol for determining run validity. Specify how each assay's performance is monitored. What quality control rules are used? What remedial action is taken if a run fails? What assurances are made that specimens are repeated if a run fails and what assurances are made that no data is reported from the bad run.

5. Interpreting MS/MS Data and Reporting Results

a. Description of how cut-off levels are/will be determined using statistical measurements in consultation with metabolic disease specialists and / or CLIR data analysis software.

b. How the laboratory has/will establish the cut-off values at which concentrations greater than "x" require immediate reporting and follow-up.

c. If the laboratory has/will establish ratios of different analytes for certain conditions screened by MS/MS, provide a rationale of why, and for which analytes, and what procedures are recommended for initial reporting, follow-up, consultation, confirmation and diagnosis.

d. If the laboratory has/will establish separate cut-offs dependent on age at time of specimen collection e.g. greater than seven (7) days of age, rational of why, and for which analytes, and what procedures are recommended for initial reporting, follow-up, consultation, confirmation and diagnosis.

e. How the laboratory will report MS/MS results. If reports for MS/MS screening do not list values for all analytes, they must explicitly document for which disorders screened, results were normal. Written reports for all abnormal results must include the quantitative result of the abnormal metabolites, the normal reference range and or normal ratios, a detailed interpretation of the results, including an overview of the results' significance, possible differential diagnoses, recommendations for additional biochemical testing and confirmatory studies, and name and phone number of a laboratory representative available if the NNSP, newborn's physician, or Nebraska pediatric specialist has additional questions.

f. Specify hardware, operating systems, internet connectivity, and all software and technical support specifications necessary for the NNSP to successfully access or receive transmission of the laboratory's electronic database specific for Nebraska's newborn screening results and reports. Include for any export files a description of the file format. Explain assurances that the hardware and operating systems are secure.

g. Describe how the bidder will address accommodations for any future needs to make changes to the data collected and entered into the data system.

h. Describe current compatibility or plans to become compliant with HL7 coding requirements if not already compliant and how consultation will be provided to the NNSP in the event data is requested for an electronic download or interface with a State Health Information Exchange, and or State DHHS system (currently possible link/interface with the vital records data system) and to hospital/submitter's for download or interface with their LIMS systems.

i. Describe current compatibility or plans to ensure all patient specific data derived from the filter paper form and generated from testing and follow-up (including contact/comments) for all Nebraska babies screened, are/will be made available for upload or export to the Department of Health and Human Services for long-term data storage.

Q. PROJECT PLANNING AND MANAGEMENT

Bidder to describe the project planning process identifying who is/will be responsible for managing each step of the project plan. Provide a time line by which each component will be completed in order to fully implement the contract by the contract start date.

R. EVALUATE CURRENT PROJECT ENVIRONMENT

Bidder to describe any necessary changes or additions to the Bidder's current project environment that will need to take place in order to add the workload of the Nebraska specimens and other requirements of this RFP.

S. PERFORM IMPLEMENTATION

Bidder to identify resources (infrastructure of personnel, facilities, equipment, written procedures, ongoing staff development etc.) that will be committed to the project to ensure successful implementation.

T. PROVIDE POST IMPLEMENTATION SUPPORT

Bidder to identify resources that will be maintained in order to continue implementation of the contract. Demonstrated commitment to ongoing support must be evident.

U. DELIVERABLES

1. Purchase, distribute and track filter paper collection kits to all birthing hospitals/facilities in Nebraska.

2. Provide courier service for all birthing hospitals/facilities in Nebraska to transport newborn screening specimens from the birthing hospital/facility to the contractor's laboratory within 24 hours of pick-up (possibly excluding weekend/holiday days when no commercial transport service is available).

3. Laboratory testing in accordance with Neb. Rev. Stat. §§71-519 through 524 and regulations, including but not limited to 181 NAC 2, and in accordance with the contract resulting from this RFP on all specimens received.

4. Phone and written reporting of screening test results and acceptability of specimens (drawn early, unsatisfactory or transfused) as required in Nebraska regulations, including but not limited to 181 NAC 2 to the NNSP, submitter, and newborn's physician.

5. Timely electronic entry of all data required on the NNSP Collection and Reporting form (See Appendix E), and 24 hour access to this data by the NNSP, including follow-up and quality assurance report features specified in this RFP.

6. Consultation provided to NNSP, Nebraska's Newborn Screening Advisory Committee, primary care physicians and pediatric specialists in Nebraska.

7. Provision of quality assurance reports and provision of access to data for the NNSP to complete additional quality assurance reports as required in the contract resulting from this RFP.

8. Collection from hospitals, and remittance of the $10 per infant screened administrative fee.

9. Storage, disposal and retrieval of residual dried blood spots as specified in this RFP.

V. PAYMENT SCHEDULE

This is an exclusive contract to provide newborn screening testing services for all newborns born in the State of Nebraska and is not purchased by the State of Nebraska. Invoices for testing services are to be provided to specimen submitters.

The per-infant screened fee money (currently $10.00) shall be submitted monthly by the bidder awarded this contract, to the NNSP within 45 days following the end of each calendar month for which billing was submitted. (For example fees for specimens tested in January, billed and collected, shall be submitted to the NNSP by March 17.)

VI. PROPOSAL INSTRUCTIONS

This section documents the requirements that should be met by bidders in preparing the Technical and Cost Proposal. Bidders should identify the subdivisions of "Project Description and Scope of Work" clearly in their proposals; failure to do so may result in disqualification. Failure to respond to a specific requirement may be the basis for elimination from consideration during the State's comparative evaluation.

Proposals are due by the date and time shown in the Schedule of Events. Content requirements for the Technical and Cost Proposal are presented separately in the following subdivisions; format and order:

A. PROPOSAL SUBMISSION

1. REQUEST FOR PROPOSAL FORM

By signing the "RFP for Contractual Services" form, the bidder guarantees compliance with the provisions stated in this RFP, agrees to the Terms and Conditions stated in this RFP unless otherwise agreed to, and certifies bidder maintains a drug free work place environment.

The RFP for Contractual Services form must be signed using an indelible method (not electronically) and returned per the schedule of events in order to be considered for an award.

Sealed proposals must be received in the State Purchasing Bureau by the date and time of the proposal opening per the Schedule of Events. No late proposals will be accepted. No electronic, e-mail, fax, voice, or telephone proposals will be accepted.

It is the responsibility of the bidder to check the website for all information relevant to this solicitation to include addenda and/or amendments issued prior to the opening date. Website address is as follows: http://das.nebraska.gov/materiel/purchasing.html

Further, Sections II through VII must be completed and returned with the proposal response.

2. CORPORATE OVERVIEW

The Corporate Overview section of the Technical Proposal should consist of the following subdivisions:

a. BIDDER IDENTIFICATION AND INFORMATION

The bidder should provide the full company or corporate name, address of the company's headquarters, entity organization (corporation, partnership, proprietorship), state in which the bidder is incorporated or otherwise organized to do business, year in which the bidder first organized to do business and whether the name and form of organization has changed since first organized.

b. FINANCIAL STATEMENTS

The bidder should provide financial statements applicable to the firm. If publicly held, the bidder should provide a copy of the corporation's most recent audited financial reports and statements, and the name, address, and telephone number of the fiscally responsible representative of the bidder's financial or banking organization.

If the bidder is not a publicly held corporation, either the reports and statements required of a publicly held corporation, or a description of the organization, including size, longevity, client base, areas of specialization and expertise, and any other pertinent information, should be submitted in such a manner that proposal evaluators may reasonably formulate a determination about the stability and financial strength of the organization. Additionally, a non-publicly held firm should provide a banking reference.

The bidder must disclose any and all judgments, pending or expected litigation, or other real or potential financial reversals, which might materially affect the viability or stability of the organization, or state that no such condition is known to exist.

The State may elect to use a third party to conduct credit checks as part of the corporate overview evaluation.

c. CHANGE OF OWNERSHIP

If any change in ownership or control of the company is anticipated during the twelve (12) months following the proposal due date, the bidder should describe the circumstances of such change and indicate when the change will likely occur. Any change of ownership to an awarded vendor(s) will require notification to the State.

d. OFFICE LOCATION

The bidder's office location responsible for performance pursuant to an award of a contract with the State of Nebraska should be identified.

e. RELATIONSHIPS WITH THE STATE

The bidder should describe any dealings with the State over the previous five (5) years. If the organization, its predecessor, or any Party named in the bidder's proposal response has contracted with the State, the bidder should identify the contract number(s) and/or any other information available to identify such contract(s). If no such contracts exist, so declare.

f. BIDDER'S EMPLOYEE RELATIONS TO STATE

If any Party named in the bidder's proposal response is or was an employee of the State within the past five (5) months, identify the individual(s) by name, State agency with whom employed, job title or position held with the State, and separation date. If no such relationship exists or has existed, so declare.

If any employee of any agency of the State of Nebraska is employed by the bidder or is a Subcontractor to the bidder, as of the due date for proposal submission, identify all such persons by name, position held with the bidder, and position held with the State (including job title and agency). Describe the responsibilities of such persons within the proposing organization. If, after review of this information by the State, it is determined that a conflict of interest exists or may exist, the bidder may be disqualified from further consideration in this proposal. If no such relationship exists, so declare.

g. CONTRACT PERFORMANCE

If the bidder or any proposed Subcontractor has had a contract terminated for default during the past five (5) years, all such instances must be described as required below. Termination for default is defined as a notice to stop performance delivery due to the bidder's non-performance or poor performance, and the issue was either not litigated due to inaction on the part of the bidder or litigated and such litigation determined the bidder to be in default.

It is mandatory that the bidder submit full details of all termination for default experienced during the past five (5) years, including the other Party's name, address, and telephone number. The response to this section must present the bidder's position on the matter. The State will evaluate the facts and will score the bidder's proposal accordingly. If no such termination for default has been experienced by the bidder in the past five (5) years, so declare.

If at any time during the past five (5) years, the bidder has had a contract terminated for convenience, non-performance, non-allocation of funds, or any other reason, describe fully all circumstances surrounding such termination, including the name and address of the other contracting Party.

h. SUMMARY OF BIDDER'S CORPORATE EXPERIENCE

The bidder should provide a summary matrix listing the bidder's previous projects similar to this RFP in size, scope, and complexity. The State will use no more than three (3) narrative project descriptions submitted by the bidder during its evaluation of the proposal.

The bidder should address the following:

i. Provide narrative descriptions to highlight the similarities between the bidder's experience and this RFP. These descriptions should include:

- **a)** The time period of the project;
- **b)** The scheduled and actual completion dates;
- **c)** The Contractor's responsibilities;
- **d)** For reference purposes, a customer name (including the name of a contact person, a current telephone number, a facsimile number, and e-mail address); and
- **e)** Each project description should identify whether the work was performed as the prime Contractor or as a Subcontractor. If a bidder performed as the prime Contractor, the description should provide the originally scheduled completion date and budget, as well as the actual (or currently planned) completion date and actual (or currently planned) budget.

ii. Contractor and Subcontractor(s) experience should be listed separately. Narrative descriptions submitted for Subcontractors should be specifically identified as

Subcontractor projects.

iii. If the work was performed as a Subcontractor, the narrative description should identify the same information as requested for the Contractors above. In addition, Subcontractors should identify what share of contract costs, project responsibilities, and time period were performed as a Subcontractor.

Bidders shall provide a summary that lists their previous work similar to the services as requested in this RFP, in size, scope and complexity. Responses should describe the bidder's qualifications, experience and capacity relative to these specific areas:

i. Overall ability to perform the newborn screening.
ii. A listing of laboratory instrumentation, methods, backup capabilities (Describe the methodology used to test for each disorder).
iii. List all analytical instruments available for this project, their age and support agreements (including repair histories and average time for repair), current workload with these instruments, and backup capabilities.
iv. Experience with all newborn screening tests, technology and methodologies proposed to be utilized including Tandem Mass Spectrometry and molecular testing. Describe specific experience (amount and type) with this methodology and other methodologies associated with population based newborn screening for each relevant key staff person. (Years of experience in performing each type of screening test and estimated volume).
v. Number of tests currently performed each year for each disorder listed above in section V.C.
vi. Describe the organization's current licensures, accreditations and certifications. (Provide copies of relevant paperwork).
vii. Availability of qualified and experienced personnel, facilities, general environment and resources for the proposed services.
viii. Familiarity and experience consulting with the medical community relative to conditions included in the core newborn screening panel.
ix. Information management systems.
x. Current analytical workload, turnaround time (in-lab and collection to completion), and capacity to add Nebraska's specimens to existing workload.
xi. Clinical consultation experience for metabolic, endocrine, hemoglobin, pulmonologic and immunologic, lysosomal and peroxisomal disorders.
xii. If sub-specialists are under contract to provide such consultation for the laboratory, identify the scope of the contract, and availability/accessibility of consultants to the NNSP.
xiii. Outline a transition plan that, if awarded the contract, would be implemented to ensure a smooth transition by July 1, 2018. Plan should include communication paths with NNSP staff and DHHS information technology staff, and methods.
xiv. Ability to offer full service to Nebraska by July 1, 2018.
xv. Adequacy of plans for the administration of the program.

Describe the number and qualifications of professional and technical staff in each area: specimen processing/accessioning, biochemistry, MS/MS, DNA testing, data entry, data/information systems management and all management staff, Specify for all key professional staff their roles and responsibilities. Identify numbers and qualifications of staff maintained for laboratory operations by area, e.g. specimen accessioning/processing, data entry, testing (by area), reporting, initial notifications, filter paper management, etc.)

i. SUMMARY OF BIDDER'S PROPOSED PERSONNEL/MANAGEMENT APPROACH

The bidder should present a detailed description of its proposed approach to the management of the project.

The bidder should identify the specific professionals who will work on the State's project if their company is awarded the contract resulting from this RFP. The names and titles of the team proposed for assignment to the State project should be identified in full, with a description of the team leadership, interface and support functions, and reporting relationships. The primary work assigned to each person should also be identified.

The bidder should provide resumes for all personnel proposed by the bidder to work on the project. The State will consider the resumes as a key indicator of the bidder's understanding of the skill mixes required to carry out the requirements of the RFP in addition to assessing the experience of specific individuals.

Resumes should not be longer than three (3) pages. Resumes should include, at a minimum, academic background and degrees, professional certifications, understanding of the process, and at least three (3) references (name, address, and telephone number) who can attest to the competence and skill level of the individual. Any changes in proposed personnel shall only be implemented after written approval from the State.

j. SUBCONTRACTORS

If the bidder intends to Subcontract any part of its performance hereunder, the bidder should provide:

i. name, address, and telephone number of the Subcontractor(s);
ii. specific tasks for each Subcontractor(s);
iii. percentage of performance hours intended for each Subcontract; and
iv. total percentage of Subcontractor(s) performance hours.

As provided herein, no part of the laboratory testing shall be subcontracted except as required to implement an emergency disaster plan.

3. TECHNICAL APPROACH

The technical approach section of the Technical Proposal should consist of the following subsections:

a. Understanding of the project requirements;
b. Proposed development approach;
c. Technical considerations;
d. Detailed project work plan; and
e. Deliverables and due dates.

VII. COST PROPOSAL REQUIREMENTS

This section describes the requirements to be addressed by bidders in preparing the State's Cost Sheet. The bidder must use the State's Cost Sheet. The bidder should submit the State's Cost Sheet in accordance with Section I Submission of Proposal.

THE STATE'S COST SHEET AND ANY OTHER COST DOCUMENT SUBMITTED WITH THE PROPOSAL SHALL NOT BE CONSIDERED CONFIDENTIAL OR PROPRIETARY AND IS CONSIDERED A PUBLIC RECORD IN THE STATE OF NEBRASKA AND WILL BE POSTED TO A PUBLIC WEBSITE.

A. PRICING SUMMARY

Specimen testing cost for the screening panel as described in this RFP including Pompe, MPS-I and X-ALD _____ + $10 /infant screened fee = Total amount per infant billed upon completion of initial specimen testing: $_____. All requested repeat specimens shall be tested without billing to the submitter.

Specimen testing cost for the screening panel as described in this RFP including Pompe, MPS-I and X-ALD if they are adopted via regulation: _____ + $20/infant screened fee = Total amount per infant billed upon completion of initial specimen testing: $_____. All requested repeat specimens shall be tested without billing to the submitter.

The State reserves the right to review all aspects of cost for reasonableness and to request clarification of any proposal where the cost component shows significant and unsupported deviation from industry standards or in areas where detailed pricing is required.

B. PRICES

Prices quoted shall be net, including transportation and delivery charges fully prepaid by the bidder, F.O.B. destination named in the RFP. No additional charges will be allowed for packing, packages, or partial delivery costs. When an arithmetic error has been made in the extended total, the unit price will govern.

C. ALTERNATIVE PRICING

Alternative pricing is also being requested for the addition of any testing for conditions not listed in this RFP. The alternative pricing will not be part of the evaluation of this Request for Proposal.

For any optional scope of work/additional tests for conditions/diseases beyond those required in this RFP, a separate cost proposal should be submitted. Additional costs should be listed individually for each test, and if part of a multi-plex assay a single cost for the group of conditions should also be listed.

Specimen testing cost for optional test/disease of:_____ $_____
Specimen testing cost for optional test/disease of:_____ $_____
Specimen testing cost for optional test/disease of:_____ $_____
Specimen testing cost for optional test/disease of:_____ $_____
Specimen testing cost for optional test/disease of:_____ $_____

Single Specimen testing cost $_____ for multiplex testing for optional diseases of: _____, _____.

Form A
Bidder Contact Sheet
Request for Proposal Number 5710Z1

Form A should be completed and submitted with each response to this RFP. This is intended to provide the State with information on the bidder's name and address, and the specific person(s) who are responsible for preparation of the bidder's response.

Preparation of Response Contact Information	
Bidder Name:	
Bidder Address:	
Contact Person & Title:	
E-mail Address:	
Telephone Number (Office):	
Telephone Number (Cellular):	
Fax Number:	

Each bidder should also designate a specific contact person who will be responsible for responding to the State if any clarifications of the bidder's response should become necessary. This will also be the person who the State contacts to set up a presentation/demonstration, if required.

Communication with the State Contact Information	
Bidder Name:	
Bidder Address:	
Contact Person & Title:	
E-mail Address:	
Telephone Number (Office):	
Telephone Number (Cellular):	
Fax Number:	

Form B
Notification of Intent to Bid
Request for Proposal Number 5710 Z1

Bidder Name:	
Bidder Address:	
Contact Person:	
E-mail Address:	
Telephone Number:	
Fax Number:	

The "Notification of Intent to Bid" form should be submitted to the State Purchasing Bureau via e-mail (as.materielpurchasing@nebraska.gov), hand delivered or US Mail by the date shown in the Schedule of Events.

REQUEST FOR PROPOSAL FOR CONTRACTUAL SERVICES FORM

BIDDER MUST COMPLETE THE FOLLOWING

By signing this Request for Proposal for Contractual Services form, the bidder guarantees compliance with the procedures stated in this Request for Proposal, and agrees to the terms and conditions unless otherwise indicated in writing and certifies that bidder maintains a drug free work place.

Per Nebraska's Transparency in Government Procurement Act, Neb. Rev Stat § 73-603 DAS is required to collect statistical information regarding the number of contracts awarded to Nebraska Contractors. This information is for statistical purposes only and will not be considered for contract award purposes.

_____ NEBRASKA CONTRACTOR AFFIDAVIT: Bidder hereby attests that bidder is a Nebraska Contractor. "Nebraska Contractor" shall mean any bidder who has maintained a bona fide place of business and at least one employee within this state for at least the six (6) months immediately preceding the posting date of this RFP.

_____I hereby certify that I am a Resident disabled veteran or business located in a designated enterprise zone in accordance with Neb. Rev. Stat. § 73-107 and wish to have preference, if applicable, considered in the award of this contract.

_____ I hereby certify that I am a blind person licensed by the Commission for the Blind & Visually Impaired in accordance with Neb. Rev. Stat. §71-8611 and wish to have preference considered in the award of this contract.

FORM MUST BE SIGNED USING AN INDELIBLE METHOD (NOT ELECTRONICALLY)

FIRM:	
COMPLETE ADDRESS:	
TELEPHONE NUMBER:	
FAX NUMBER:	
DATE:	
SIGNATURE:	
TYPED NAME & TITLE OF SIGNER:	

APPENDIX A
Nebraska Births 2016
Request for Proposal 5710 Z1

	Count	City/Town
Annie Jeffrey Memorial County Health Center	19	Osceola
Antelope Memorial Hospital	11	Neligh
Avera St. Anthony's Hospital	174	O'Neil
Beatrice Community Hospital & Health Center	219	Beatrice
Boone County Health Center	95	Albion
Box Butte General Hospital	93	Alliance
Brodstone Memorial Hospital	36	Superior
Bryan Medical Center East	3173	Lincoln
Butler County Health Care Center	65	David City
Cambridge Memorial Hospital (Tri-Valley)	58	Cambridge
Chadron Community Hospital	139	Chadron
Chase County Community Hospital	15	Imperial
Cherry County Hospital	115	Valentine
CHI Health Bergan Mercy	3769	Omaha
CHI Health Creighton University Medical Center	414	Omaha
CHI Health Good Samaritan	1043	Kearney
CHI Health Immanuel	485	Omaha
CHI Health Lakeside	990	Omaha
CHI Health Schuyler	1	Schuyler
CHI Health St. Elizabeth	1664	Lincoln
CHI Health St. Francis	937	Grand Island
CHI Health St. Mary's	149	Nebraska City
Children's Hospital & Medical Center	9	Omaha
Columbus Community Hospital	615	Columbus
Community Hospital	128	McCook
Community Medical Center, Inc.	43	Falls City
Cozad Community Health Systems	51	Cozad
Crete Area Medical Center	68	Crete
Faith Regional Health Services	852	Norfolk
Fillmore County Hospital	33	Geneva
Fremont Health Medical Center	344	Fremont
Gordon Memorial Hospital District *	1	Gordon
Gothenburg Health	51	Gothenburg
Gothenburg Memorial Hospital	31	Gothenburg
Great Plains Health	552	North Platte
Harlan County Health System *	1	Alma
Henderson Health Care Services, Inc.	29	Henderson
Howard County Medical Center	37	St. Paul

Jefferson Community Health Center	17	Fairbury
Jennie M. Melham Memorial Medical Center	59	Broken Bow
Johnson County Hospital *	1	Tecumseh
Lexington Regional Health Center	140	Lexington
Mary Lanning Healthcare	938	Hastings
Memorial Community Hospital	61	Blair
Memorial Hospital-Aurora	36	Aurora
Memorial Hospital-Seward	65	Seward
Methodist Women's Hospital	5220	Omaha
Nebraska Medicine	1728	Omaha
Nebraska Medicine-Bellevue	703	Bellevue
Nemaha County Hospital *	1	Auburn
Ogallala Community Hospital	64	Ogallala
Pender Community Hospital	85	Pender
Perkins County Community Hospital	79	Grant
Phelps Memorial Health Center	130	Holdrege
Providence Medical Center	59	Wayne
Regional West Medical Center	758	Scottsbluff
Sidney Regional Medical Center	97	Sidney
St. Francis Memorial Hospital	57	Westpoint
Thayer County Health Services	32	Hebron
The Midwife's Place (no longer birthing in 2017)	94	Bellevue
Winnebago IHS Hospital	5	Macy
York General Hospital	78	York
Home Births	91	
Other-non Facility	6	
	27113	

* not "birthing facilities", emergency births, The Good Birth Place (Opening in 2017)

APPENDIX B
Table of Test Results
Request for Proposal 5710 Z1

Tables to be completed by bidder and submitted with Proposal

Numbers for 2016:

Identify #'s in a footnote for any inconclusive screen results that required more than one repeat specimen to be collected and tested in order to resolve/define the case.

Condition/ Analyte	# Screened	# **Inconclusive** (or borderline) on screen *	# Confirmed/ Diagnosed Positive	# Confirmed or repeated Negative	Inconclusive Rate
Argininosuccinic acidemia (Arg)					
BIO					
CAH (17-OHP)					
CF (IRT/DNA)					
CIT (Cit)					
CPH (T4/TSH)					
CUD(low C0)					
GA-I (C5DC or C10-OH, or C8 + C10)					
GAL (Gal/GALT)					
HCY (Met & Homocy)					
Hgb's S, SC, Thal's					
HMG (C5:OH, C6:DC w/ C5:OH)					
IVA (C5, C6-DC, w/ C5-OH)					
LCHAD (C16-OH, or C18:10OH with others)					
MSUD (Val, Leu, and/or Isoleucine)					
MCAD (C8, or C8 with others)					
MMA (C3, C3:C2, C3:C16)					
MMA cbl A, B (C3, C3:C3OH, C4DC, Met)					
MPS-I (IDUA)					
MCD (C3 or C5OH)					
PKU (Phe, Phe/Tyr)					
PD (GAA)					
PA (C3,C3:C2, C3:C16)					
SCID (TRECS)					
Tyr (Tyr)					
TFP C16-OH, C18:1-OH with C16-OH)					
VLCAD (C14, C14:1, C14:2, & C14:1/C12:1)					
X-ALD (C26.OLC)					
3-MCC (C5:OH or C5:1 w/ C5:OH)					
Other MS/MS findings					

*Positive results include all abnormal results. Most often these results indicate the need for a repeat newborn screen and less frequently confirmatory/diagnostic testing.

Totals for 2016

Condition/ Analyte	# Screened	# **Positive** on screen	# Confirmed/ Diagnosed Positive	# Confirmed Negative	Presumptive Positive Rate
Argininosuccinic acidemia (Arg)					
BIO					
CAH (17-OHP)					
CF (IRT/DNA)					
CIT (Cit)					
CPH (T4/TSH)					
CUD(low C0)					
GA-I (C5DC or C10-OH, or C8 + C10)					
GAL (Gal/GALT)					
HCY (Met & Homocy)					
Hgb's S, SC, Thal's					
HMG (C5:OH, C6:DC w/ C5:OH)					
IVA (C5, C6-DC, w/ C5-OH)					
LCHAD (C16-OH, or C18:10OH with others)					
MSUD (Val, Leu, and/or Isoleucine)					
MCAD (C8, or C8 with others)					
MMA (C3, C3:C2, C3:C16)					
MMA cbl A, B (C3, C3:C3OH, C4DC, Met)					
MPS-I (IDUA)					
MCD (C3 or C5OH)					
PKU (Phe, Phe/Tyr)					
PD (GAA)					
PA (C3,C3:C2, C3:C16)					
SCID (TRECS)					
Tyr (Tyr)					
TFP C16-OH, C18:1-OH with C16-OH)					
VLCAD (C14, C14:1, C14:2, & C14:1/C12:1)					
X-ALD (C26.0)					
3-MCC (C5:OH or C5:1 w/ C5:OH)					
Other MS/MS findings					

Unsatisfactory / Rejected Specimens
(Numerator: Total # unsatisfactory specimens 2016: _____
(Denominator: Total # initial specimens tested in 2016:_____

Reason specimen unsatisfactory / rejected	Number
Quantity not sufficient	
Blood spots not soaked through	
Specimen scratched or abraded	
Specimen not dry before mailing	
Oversaturated	
Diluted, discolored or contaminated	
Serum rings	
Clotted or layered	
Exposed to heat or humidity	
Expired filter paper:	
Other:	
Other:	
Other:	

Appendix C

Emergency/Disaster Preparedness & Proprietary Information

Request for Proposal Number 5710 Z1

In accordance with the federal CON-PLAN for newborn screening, the laboratory will:

1. Establish back up testing methods or plans
2. Obtain documentation that manufacturer or supplier has:

    a. Adequate forward stocking established
    b. Alternate transportation plans established

3. Ensure contracts hold manufacturer or supplier responsible when materials are not delivered as scheduled including:

    a. Cost of alternate testing instruments, materials, or outsourced testing;
    b. Cost of staff time to implement alternate testing
    c. Liability for litigation caused by delay in reporting abnormal test results

The laboratory agrees to provide one copy to the Nebraska Newborn Screening Program of their emergency or disaster preparedness plan. Any updates/revisions to the plan over the course of the contract shall also be provided in writing to the Nebraska Newborn Screening Program, within 30 days of making the update or revision.

The laboratory assures they have and agrees to provide one copy to the Nebraska Newborn Screening Program, of each Memorandum of Agreement (MOA) understanding (MOU), or Contract with each laboratory with which they have such an agreement to provide newborn screening testing services as a back-up in the event of an emergency or disaster that prevents the laboratory from providing newborn screening laboratory testing services for greater than 24 hours. Agreements must be in place such that once laboratory testing is interrupted for 24 hours, the back-up laboratory will take over testing within the next 48-72 hour period unless laboratory testing services will be resumed within the following 48-72 hour period. MOU/MOA/Contracts must specify which entity is responsible for what tasks (e.g. where specimens shall be shipped and how, who will enter data, how access to data will be shared, which entity will report out abnormal screen results via phone and in writing, etc.) and identify the flow of chain of custody of the specimens, and the flow of information for results to be made available to the Nebraska Newborn Screening Program, submitters and physicians. The MOU/MOA/Contracts must also specify how and where specimens will be maintained and destroyed, or released with proper authorization for diagnostic testing or IRB approved public health research. If awarded this contract for testing Nebraska newborn screening specimens, the back-up/emergency MOU/MOA/Contracts must be in force for the entirety of the Nebraska testing contract.

Appendix D

Reports

Request for Proposal Number 5710 Z1

FOLLOW-UP REPORTS

The following reports used for follow-up and monitoring can be run entering any date range. Descriptions of the type of data are provided. The date the report is run is also printed on each report. These reports are run daily and the capacity to close records is in the data system, such that once closed, the cases come off the report. All reports can be exported and saved in Excel® or PDF. All reports can be run using variably defined date ranges.

A desirable feature of a bidder's response will identify that a case can be closed on an infant for one reason yet remain open on other pending worklists as needed for other abnormalities or reasons for active follow-up to continue.

ABNORMAL HEMOGLOBINOPATHIES REPORT
Report lists every pending abnormal hemoglobinopathy screen, until closed by the State program (includes AF even though may be within normal limits for the age of the newborn/infant). Data fields include filter paper #, last name, first name, birth date/time, birth place, city of birth, test result abnormal, hemoglobin type and age in days.

INCONCLUSIVE CYSTIC FIBROSIS REPORT
Report lists every pending inconclusive CF screen, until closed by the State program. Data fields include last name, first name, birth date, filter paper #, birth place, city of birth, test result value, inconclusive result, and age in days.

MECONIUM ILEUS
Report lists every pending newborn with Meconium Ileus or other bowel obstructed identified, until closed by the State Program. Data fields include last name, first name, birth date, filter paper #, birth place, city of birth, test result inconclusive, result value, and age in days.

TESTS DRAWN TOO EARLY
Report lists every specimen collected at less than 24 hours of age, until closed by the State Program. Reports are listed in order by hospital. Data fields include city, place of birth, last name, first name, birth date filter paper # and which results were inconclusive.

UNSATISFACTORY SPECIMENS
Report lists every specimen determined to be unsatisfactory for testing, and which tests were unable to be completed, and the reason each specimen was determined to be unsatisfactory. Names come off list when the State Program closes the record. Fields include last name, first name, birth date and tie, filter paper #, disorders not screened, and reason unsatisfactory.

PRESUMPTIVE POSITIVE TESTS
Report lists every specimen presumptive positive on screening, and identifies for which condition it is positive. Names come off list when the State Program closes the record.
Fields include: Last name, First name, Birth Date and time, Filter Paper #, Birth Place, City of birth, which test result was abnormal, the result and age in days at the time report is run.

ABNORMAL MS/MS REPORT
Report lists every specimen deemed abnormal on screening, and identifies for which condition it is out of range. Names come off list when the State Program closes the record. Data fields include last name, first name birth date, filter paper # birth place, the test result that was abnormal, which profile and the age in days at the time the report is run.

ABNORMAL LSD'S REPORT (New in 2018) *(other relevant fields that would be useful?)*
Report lists every specimen determined to be out of range requiring repeat or confirmatory testing for GAA (Pompe) and IDUA (MPS-I). Data fields include last name, first name, birth date, filter paper #, birth place, abnormal analyte (GAA or IDUA), and result interpretation (INC or POS).

ABNORMAL X-ALD REPORT (New in2018) *(other relevant fields that would be useful?)*
Report lists every specimen determined to be out of range requiring repeat or confirmatory testing for C26:0. Data fields include last name, first name, birth date, filter paper #, birth place, C26:0 value and any relevant ratios, and result interpretation (INC or POS).

TSH VALUES >=20
Report lists all specimens with TSH's greater than or equal to 20. Names come off list when the State Program closes the record. Data fields include last name, first name, birth date, filter paper # birth place, city of birth the TSH value, and age in days at time the report is run.

INCONCLUSIVE 17-OHP REPORT
Report lists every specimen determined to be inconclusive - in need of repeat screen. Lists all babies with meconium ileus reported on the filter paper card or reported with meconimum ileus after submitting the filter paper card. Report is sorted by birth date and alpha last name. Date fields are last name, first name, birth date and time, filter paper #, IRT outcome (interpretation), and DNA results.

SCID INCONCLUSIVE TESTS REPORT
Report lists all babies with inconclusive SCID results requiring repeat screening. Data fields include last name, first name, birth date, filter paper number, birth place, city of birth, test result inconclusive, result and age in days when the report is run.

MONITORING, FOLLOW-UP and REPORTING

The following reports used for monitoring, follow-up and reporting are run routinely e.g. once a week, every two weeks, monthly or quarterly:

OUT OF HOSPITAL REPORT
This report includes specimens based on date of collection not date of birth. Report of all babies screened not born in hospitals (home, auto, etc.). The data fields are last name, first name, birth date, filter paper number, specimen collection date, submitter and the age at collection.

LOST TO FOLLOW-UP REPORT
List of all babies, the State program has designated/closed as "lost to follow-up." Data fields include city, birthplace, birth date/time, last name first name and lost to follow-up date.

MONTHLY MATCH REPORT (Text delimited data) (Run every 2 weeks)
List of all babies for whom a screening specimen has been received and tested. Data is exported by the NNSP in an Excel® format and merged with exported data from the birth certificate registry to identify any newborns that did not get a screen. Data is sorted by birth place, and city, and data fields includes newborn ID (number assigned by lab), last name, first name date and time of birth, mother's last name, mothers first name, and hospital code number identifier. This report export works with older data/older version of software.

TESTS DRAWN TOO EARLY WITH REPEATS
List of all babies for whom a screening specimen was collected at < 24 hours and if a repeat was collected identifies the repeat filter paper number. Sorted by place of birth. Data fields include city, place of birth, last name, first name, birth date and time, initial filter paper number, and repeat filter paper number.

DATA ARCHIVE MATCH REPORT
Report used to random check on a quarterly basis the completeness of specimen data in data archive. Data fields include filter paper number, PS_ID, accession number, collection date and lab received date.

INFANTS SCREENING RESULTS
Report used to ensure back-up paper copy of all results available for long term storage. (Variable date range). Includes all results for every baby by birth date during the date range of the report, includes actual result and interpretation (e.g. WNL= within normal limits, inc= inconclusive, pos= positive). Data fields include birth date and time, birth facility, submitter city, last name, first name, date/time collected 170OHP value, 17 OHP extracted value, AA result interpretation, AC result interpretation, BIO result interpretation and value, GAL result interpretation and value, Gal/BEU (GALT) result interpretation and value, Hemoglobin result, IRT result interpretation and value, T4 result interpretation and value, TSH result interpretation and value, TREC results interpretation.. The new report will need to include GAA, IDUA and C26:0 results interpretations and values when screening for MPS-I, Pompe, and X-ALD begins.

QUALITY ASSURANCE REPORTS

The following reports used for monitoring, follow-up and reporting are run routinely e.g. once a week, every two weeks, monthly or quarterly quality assurance reports

AVG. MIN. MAX. REPORT
Report is run on varying date ranges providing the average, minimum and maximum turnaround times from birth to specimen collection, collection to receipt in the laboratory, receipt to release of results from the laboratory, and total birth to release

times. Specific data lists the filter paper number birth date and time, collection date and time, receipt date and time, release date and time, and the associated time in days for each of the four measured parameters.

BATCHING TRACKING REPORT
This report is run weekly to provide monitoring feedback to hospitals, request investigation and develop plans to prevent recurrence of delayed or batched specimen handling in hospital and via shipping. It can be run on varying date ranges and is listed with facility data together identifying all specimens received on dates with any specimen equal to or greater than three days between collection and receipt at the laboratory. The information provided includes the baby's last name, filter paper serial number, medical record number, birth date and time, day of the week specimen was collected, date and time of collection, date and time of receipt and days/hours (in hundredths, e.g. 3.456 days) between collection and receipt times. This level of detail is provided to hospitals when a reasonable explanation for delays is not apparent to the program. Report can be exported to spreadsheet format so that individual facility information can be sent to them.

DRAWN EARLY STATS REPORT
Report used to periodically review the numbers and % of drawn early specimens received for various birth weight groupings and gestational ages. Broken down by hospital, provides the number and percent of drawn early specimens for < 2000 g babies, 2000g-<2500g, 2500g-<3000g, 3000g to < 3500 g, and ≥3500 g babies. Also for < 34 weeks gestation, 34-<36 weeks gestation, 36-< 40 weeks gestation, and ≥ 40 weeks gestation.

GREATER THAN 48 HOUR COLLECTION
Report run weekly to monitor late collection of initial specimens. Lists specimens collected at greater than 48 hours of age, in order by hospital (alphabetical). Data fields include baby's last name, filter paper number, medical record number, birth date and time, collection date and time, age in hours at time of collection, and name of submitter (facility). Specifics are reviewed to determine if other explanation such as out of hospital birth, data entry error or actually a repeat specimen not an initial specimen can rule out hospital error. Report can be exported to spreadsheet format so that individual facility information can be sent to them for investigation, correction or development of plan to prevent recurrence.

HOSPITAL QA REPORT
This report shows hospital or submitter performance by quarter over time of their average turnaround times for birth to report of results, birth to specimen collection, specimen collection to receipt at the laboratory, receipt to report out of results. Listed alphabetically by hospital.

INFANTS AGE COLLECTION REPORT
This report shows the total # of births and the number and percent of initial specimens collected between 6-12 hours of age, 12-24 hours of age, < 24 hours of age on day 1, day 2, day 3, day 4, day 5, day 6, day 7, greater than 7 days and those for whom time of collection was unknown.

QUARTERLY HOSPITAL REPORT
This report is run quarterly and provided to each submitter. It identifies the number of initial and repeat specimens submitted and provides the following measures with benchmarks, the statewide performance and the facility's performance:

a. Initial specimens collected at > 48 hours (%)
b. Unsatisfactory specimens (%)
c. Average time birth to collection (units of days, e.g. 1.23)
d. Percent non-NICU initial specimens collected @ 24-48 hours (%)
e. Average time collect to receipt (units of days, e.g. 1.34)
f. Percent received within 3 days from collection (%)
g. Percent received within 2 days from collection (%)
h. Percent received within 1 day of collection (%)
i. Average time receipt to result reported for all specimens (units of days e.g.1.45)
j. Average time collect to result reported for all specimens (units of days e.g. 4.22)
k. Percent of all specimens' results released 4 days from collection (%)
l. Percent of all specimens' results released 5 days from collection (%)
m. Percent of all specimens' results released 6 days from collection (%)
n. Percent of all specimens' results released > 6 days from collection (%)
o. Average age birth to result for all initial specimens (unit of days e.g. 4.57)
p. Percent of results released within 5 days of age (%)
q. Percent of results released within 7 days of age (%)
r. Percent of results released after 7 days of age (%)
s. Number of presumptive positive results for non-time critical conditions released by 7 days of age (#, e.g. 2 out of 4)
t. Number of presumptive positive results for time critical conditions released by 5 days of age (# e.g. 0 out of 2) *
u. Percent of presumptive positive results for time critical conditions released by 5 (%)*

*Time critical conditions as defined by the Advisory Committee on Heritable Diseases in Newborns and Children

The report also includes identification of the filter paper number, baby's last name, date of birth, collector's initials, date collected, reason unsatisfactory and tests unable to be completed for all unsatisfactory specimens during the period.

Graph's showing three years of data of the state benchmark, state performance and facilities performance are also included for these measures:

a. Unsatisfactory specimen rate
b. Average times birth to collection for initial specimens
c. Average times collection to receipt at the lab
d. Average times collection to results released for all specimens
e. Average times birth to results released for initial specimens
f. Percent of non-NICU initial specimens collected at 24-48 hours of age
g. Percent of specimens received < 3 days from collection
h. Percent of all results released by 7 days of age

INITIAL BIOTINIDASE DEFICIENCY AVERAGE VALUE REPORT
This report provides the number of initial screens for the enzyme measured, total of values, mean average value, variance, standard deviation, median, mode, minimum, maximum and 25^{th} and 75^{th} percentile values. It also lists any specimens during the reporting period reported to be positive identifying only the result and if applicable the DNA result.

INITIAL CAH AVERAGE VALUE REPORT
This report provides the number of initial screens for both the CAH and extracted CAH, total of values, mean average value, variance, standard deviation, median, mode, minimum, maximum and 25^{th} and 75^{th} percentile values. It also lists any specimens during the reporting period reported to be positive identifying only the result and if applicable the DNA result.

INITIAL CF AVERAGE VALUE REPORT
This report provides the number of initial screens for the IRT, total of values, mean average value, variance, standard deviation, median, mode, minimum, maximum and 25^{th} and 75^{th} percentile values.

INITIAL GALACTOSEMIA AVERAGE VALUE REPORT
This report provides the number of initial screen for galactose and GALT, total of values, mean average value, variance, standard deviation, median, mode, minimum, maximum and 25^{th} and 75^{th} percentile values. It also lists any specimens during the reporting period reported to be positive identifying only the result.

INITIAL T_4 AVERAGE VALUE REPORT
This report provides the number of initial screens for thyroxine (T_4), total of values, mean average value, variance, standard deviation, median, mode, minimum, maximum and 25^{th} and 75^{th} percentile values. It also lists any specimens during the reporting period reported to be positive identifying only the result for T_4 and thyroid stimulating hormone (TSH).

INITIAL TSH AVERAGE VALUE REPORT
This report provides the number of initial screens, total of values, mean average value, variance, standard deviation, median, mode, minimum, maximum and 25^{th} and 75^{th} percentile values. It also lists any specimens during the reporting period reported to be positive identifying only the TSH result.

PKU MONITORS REPORT
This report provides data for the Nebraska metabolic clinic dietician of all patients who submit their routine phenylalanine blood monitoring reports to the screening laboratory. (Testing of which is not covered under this contract, but reporting is),

NEWSTEPS 360 REPORTS
Multiple reports are available, and must be flexible to change with the expectations of the Newborn Screening Technical Assistance and Education Program (NewSTEPS) collecting state data for national dissemination to inform the federal Advisory Committee on Heritable Diseases in Newborns and Children. The number and percent of specimens are reported on 75 to 100 measures associated with timeliness for initial and subsequent specimens, categorized as time critical positives, critical/non-time sensitive positives, and all results. Data provides numbers and percent of specimens in monthly timeframes for birth to collection, collection to receipt, receipt to result and birth to result. The report requests the data for collection to receipt to be reported in days, but the Nebraska program also requires the data to reflect actual time from collection to receipt for enhanced accuracy. This data must be made available in comma delimited format in order for the NewSTEPS organization to upload the data. No individually identifying information is provided.

APPENDIX E

Collection and Reporting Form

Request for Proposal 5710 Z1

COLLECTION AND REPORTING FORM – NEBRASKA NEWBORN SCREENING PROGRAM

Birth Date____/____/____ Time ____:____ (Military)
Collection Date____/____/____ Time ____:____ (Military)
Collector's Initials_____ Gestational Age:_____
Birth Weight_____
NICU Admit ☐ Yes ☐ No
If Yes, is this specimen: ☐ Initial specimen ☐ 48-72° repeat
☐ Other repeat ☐ 28 day/ discharge repeat for a < 2000 gram birth
Has baby EVER been transfused ☐ Yes ☐ No
If Yes, Date last transfused:___/____/____Time____:____(Military)
Baby receiving TPN ☐ Yes ☐ No
If yes, was it interrupted 3 hours before taking this specimen
☐ Yes ☐ No
Baby has Meconium Ileus or other bowel obstruction ☐ Yes ☐ No
Baby on Antibiotics ☐ Yes ☐ No

Baby's last name

First name *Middle*

Patient Record Number

Place of Birth
Home birth ☐ Yes ☐ No Sex ☐ M ☐ F ☐ Unknown

Mother's last name

First name *Middle*

Address

City *State* *ZIP*
Mother's Phone_(_____)_____-_____
Mother's DOB____/____/____

NEBRASKA Serial No.

Name of Submitter/Facility

City, State (if other than NE)

Name of Ordering Physician

_(_____)_____-_____
Ordering Physician's Phone

Name of Physician following baby post –discharge

_(_____)_____-_____
Post-discharge Physician's Phone

-Allow to air dry horizontally at least 3 hours
-Do not let blood spots touch anything before they are dry
-Ship within 24 hours (when transport available

SHIP TO:

Newborn Screening Laboratory Logo and Address

Date Received

Nebraska Collection and Reporting Form (Care Form) **Serial No.**

Date Reported

Appendix F
Newborn Screening Matrix
RFP # 5710 Z1

RFP Section Number	Requirement	Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	Notes/Comments:
V.C.33	For each condition screened, the instrumentation, method, screening algorithm or cut-offs must be clearly described. Flow-chart/algorithms to illustrate the test result reporting criteria are encouraged, but should not be considered an adequate replacement for a narrative, detailed description. The methods used must follow presently accepted good laboratory practice and be compliant with FDA, and CLIA regulations, and if available FDA approved products should be used. FDA cleared products are acceptable. Methods should have been routinely used by newborn screening programs for at least one (1) year and their performance documentation exists in Quality Control reports from CDC. For proprietary information, the proposal must provide a general overview, and assurance that written protocols, interpretation criteria and screening algorithms will be provided in writing to the NNSP within 30 days following contract award date. Bidders must complete Appendix B.	Complete **attached table below** for response to this requirement. **			

V.C.34	For which disorders within these classifications, beyond those listed in Section V.C.1 - 30, their laboratory can reliably detect via tandem mass spectrometry or other multiplex testing and describe the informative markers evaluated and cut-offs or screening algorithms used to determine the need for additional follow up. The table in Appendix B must be completed identifying for each condition or analyte screened the number of specimens screened, number of abnormal screens reported out, and the number of confirmed conditions associated with that screen during the prior 2 year period. If the current method/algorithm has been used for less than 2 years, the available data described above, since using that method/algorithm.	Complete **Appendix B** for response to this requirement			
V.C.35	If any of this required information is proprietary, the following applies: By virtue of submitting a proposal the bidder agrees that if awarded the contract, the proprietary information will be provided to the NNSP within 30 days following contract award date.				
V.C.36	Data for the laboratory regarding the false positive rate per year for each of the tests performed, (see tables in Appendix B), the percent of filter paper blood specimens identified as unsatisfactory and the reasons for rejection, the turn-around time from specimen receipt to reporting of results. Data for the laboratory regarding the false negative rate, explanations for errors and remedial actions. (Complete tables in Appendix B) and return with bidder's proposal response.	Complete **Appendix B** for response to this requirement			

V.C.37	For each analytical methodology and instrument used, available methods for backup/confirmation. (e.g. Beuter and Baluda back-up for Biotinidase testing if primary testing instrument were to be unavailable).	Complete **attached table below** for response to this requirement. **			
V.C.38	If not already described in Section V.C.1-30, specify any 2nd tier or reflex testing (E.g. a different test with a new punch from the same sample) proposed as part of the screen. If DNA is used as a 2nd tier or reflex test, specify which mutations or polymorphisms are tested for or if sequencing is proposed. The Department of Health and Human Services reserves the right to determine if sequencing will be allowed as part of the screening algorithm for any condition screened. (Include in response to B).				
V.C.39	For which type of results (e.g. unsatisfactory specimens, inconclusive or preliminary positive test results for "x" condition) a repeat dried blood spot filter paper specimen would be requested (vs. confirmatory serum, plasma or other test). Requested repeats for specimens collected at less than 24 hours, that are unsatisfactory, collected post transfusion, required due to infant's birthweights being less than 2000 grams, are indeterminate because of multiple elevations of amino acids indicating hyperalimentation, or requested because of inconclusive findings shall not be charged for separately.				

V.C.40	Describe any other newborn screening and confirmatory tests not described in Section V.C .1-30, available in bidder's laboratory; including for screening tests, the estimated incidence of the disorder and the observed incidence in bidder's laboratory. Include the false positive and false negative rate per year for each of these additional screening tests. Provide a separate schedule of costs for the addition of these tests. The schedule should list the additional cost for each individual test, and if available, the cost for groups of tests (e.g. multiplex format) for similar disorders.				
V.C.41	Available, state of the art methodologies that may be currently used under research protocols or as a pilot. If it is the bidders intent to make this available to the NNSP, the test(s) should be detailed in regard to instrumentation, analytical staff, oversight, experience, backup, and ability to provide clinical consultation regarding the interpretation of new testing data.				
V.C.42	Individually, list all analytical instruments available for this project, specifying if leased or owned, their age and support agreements (including repair histories, and average time for repair), current workload with these instruments, back up capabilities (such as duplicate instruments) and the laboratory's capacity to add the workload from the Nebraska newborns to be screened. Instrument replacement plans for aging equipment should also be described.				
V.C.43	Other conditions may be detected by the acylcarnitine and amino acid profiles of tandem mass spectrometry beyond those included in the list from Section V.C.1-30. The bidder shall list other conditions that may be able to be detected by the proposed screening protocol.				

Appendix F
Newborn Screening Matrix
RFP # 5710 Z1

****Complete this table for response to V.C.33 and V.C.37.**

Condition Screened	Instrumentation *V.C.33*	Method *V.C.33*	Screening algorithm *V.C.33*	Cutoffs *V.C.33*	Flow Chart attached? *V.C.33*	Narrative description of algorithm *V.C.33*	Back up Methodology and instrument used in the event of equipment failure by the primary method. *V.C.37*
Argininosuccinic acidemia (ASA)							
BIO							
CAH (17-OHP)							
CF (IRT/DNA)							
CIT (Cit)							
CPH (T4/TSH)							
CUD(low C0)							
GA-I (C5DC or C10-OH, or C8 + C10)							
GAL (Gal/GALT)							
HCY (Met & Homocy)							
Hgb's S, SC, Thal's							
HMG (C5:OH, C6:DC w/ C5:OH)							
IVA (C5, C6-DC, w/ C5-OH)							
LCHAD (C16-OH, or C18:10OH with others)							
MSUD (Val, Leu, and/or Isoleucine)							
MCAD (C8, or C8 with others)							
MMA (C3, C3:C2, C3:C16)							

MMA cbl A, B (C3, C3:C3OH, C4DC, Met)							
MPS-I (IDUA)							
MCD (C3 or C5OH)							
PKU (Phe, Phe/Tyr)							
PD (GAA)							
PA (C3,C3:C2, C3:C16)							
SCID (TRECS)							
Tyr (Tyr)							
TFP C16-OH, C18:1-OH with C16-OH)							
VLCAD (C14, C14:1, C14:2, & C14:1/C12:1)							
X-ALD (C26.OLC)							
3-MCC (C5:OH or C5:1 w/ C5:OH)							
Other MS/MS findings							
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