

**State of Nebraska (State Purchasing Bureau)
REQUEST FOR PROPOSAL FOR
CONTRACTUAL SERVICES FORM**

RETURN TO:
State Purchasing Bureau
301 Centennial Mall South, 1st Fl
Lincoln, Nebraska 68508
OR
P.O. Box 94847
Lincoln, Nebraska 68509-4847
Phone: 402-471-2401
Fax: 402-471-2089

SOLICITATION NUMBER	RELEASE DATE
RFP 4229Z1	February 7, 2013
OPENING DATE AND TIME	PROCUREMENT CONTACT
March 15, 2013 2:00 p.m. Central Time	Ruth Gray / Michelle Musick

This form is part of the specification package and must be signed and returned, along with proposal documents, by the opening date and time specified.

PLEASE READ CAREFULLY!

SCOPE OF SERVICE

The State of Nebraska, Administrative Services (AS), Materiel Division, Purchasing Bureau, is issuing this Request for Proposal, RFP Number 4229Z1 for the purpose of selecting a qualified contractor for the right to provide Newborn Screening Laboratory Testing Services.

Written questions are due no later than February 19, 2013, and should be submitted via e-mail to matpurch.dasmat@nebraska.gov. Written questions may also be sent by facsimile to (402) 471-2089.

Bidder should submit one (1) original and five (5) copies of the entire proposal. In the event of any inconsistencies among the proposals, the language contained in the original proposal shall govern. Proposals must be submitted by the proposal due date and time.

PROPOSALS MUST MEET THE REQUIREMENTS OUTLINED IN THIS REQUEST FOR PROPOSAL TO BE CONSIDERED VALID. PROPOSALS WILL BE REJECTED IF NOT IN COMPLIANCE WITH THESE REQUIREMENTS.

1. Sealed proposals must be received in State Purchasing by the date and time of proposal opening indicated above. No late proposals will be accepted. No electronic, e-mail, fax, voice, or telephone proposals will be accepted.
2. This form "REQUEST FOR PROPOSAL FOR CONTRACTUAL SERVICES" MUST be manually signed, in ink, and returned by the proposal opening date and time along with bidder's proposal and any other requirements as specified in the Request for Proposal in order to be considered for an award.
3. 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://www.das.state.ne.us/materiel/purchasing/>
4. It is understood by the parties that in the State of Nebraska's opinion, any limitation on the contractor's liability is unconstitutional under the Nebraska State Constitution, Article XIII, Section 3, and that any limitation of liability shall not be binding on the State of Nebraska despite inclusion of such language in documents supplied with the contractor's bid or in the final contract.

BIDDER MUST COMPLETE THE FOLLOWING

By signing this Request For Proposal For Contractual Services form, the bidder guarantees compliance with the provisions stated in this Request for Proposal, agrees to the terms and conditions (see Section III) and certifies bidder maintains a drug free work place environment.

FIRM: _____

COMPLETE ADDRESS: _____

TELEPHONE NUMBER: _____ FAX NUMBER: _____

SIGNATURE: _____ DATE: _____

TYPED NAME & TITLE OF SIGNER: _____

TABLE OF CONTENTS

REQUEST FOR PROPOSAL FOR CONTRACTUAL SERVICES FORM	i
TABLE OF CONTENTS	ii
GLOSSARY OF TERMS	v
I. SCOPE OF THE REQUEST FOR PROPOSAL	1
A. SCHEDULE OF EVENTS	1
II. PROCUREMENT PROCEDURES	2
A. PROCURING OFFICE AND CONTACT PERSON	2
B. GENERAL INFORMATION	2
C. COMMUNICATION WITH STATE STAFF	2
D. WRITTEN QUESTIONS AND ANSWERS	3
E. ORAL INTERVIEWS/PRESENTATIONS AND/OR DEMONSTRATIONS	3
F. SUBMISSION OF PROPOSALS	4
G. PROPOSAL OPENING	4
H. LATE PROPOSALS	4
I. REJECTION OF PROPOSALS	5
J. EVALUATION OF PROPOSALS	5
K. EVALUATION COMMITTEE	5
L. MANDATORY REQUIREMENTS	5
M. REFERENCE CHECKS	6
N. SECRETARY OF STATE/TAX COMMISSIONER REGISTRATION REQUIREMENTS	6
O. VIOLATION OF TERMS AND CONDITIONS	6
III. TERMS AND CONDITIONS	7
A. GENERAL	7
B. AWARD	7
C. COMPLIANCE WITH CIVIL RIGHTS LAWS AND EQUAL OPPORTUNITY EMPLOYMENT / NONDISCRIMINATION	8
D. PERMITS, REGULATIONS, LAWS	8
E. OWNERSHIP OF INFORMATION AND DATA	8
F. INSURANCE REQUIREMENTS	8
G. COOPERATION WITH OTHER CONTRACTORS	10
H. INDEPENDENT CONTRACTOR	10
I. CONTRACTOR RESPONSIBILITY	11
J. CONTRACTOR PERSONNEL	11
K. STATE OF NEBRASKA PERSONNEL RECRUITMENT PROHIBITION	12
L. CONFLICT OF INTEREST	12
M. PROPOSAL PREPARATION COSTS	12
N. ERRORS AND OMISSIONS	12
O. BEGINNING OF WORK	12
P. ASSIGNMENT BY THE STATE	12
Q. ASSIGNMENT BY THE CONTRACTOR	12
R. DEVIATIONS FROM THE REQUEST FOR PROPOSAL	12
S. GOVERNING LAW	13

T.	ATTORNEY'S FEES	13
U.	ADVERTISING	13
V.	STATE PROPERTY	13
W.	SITE RULES AND REGULATIONS.....	13
X.	NOTIFICATION	13
Y.	EARLY TERMINATION	14
Z.	FUNDING OUT CLAUSE OR LOSS OF APPROPRIATIONS	15
AA.	BREACH BY CONTRACTOR.....	15
BB.	ASSURANCES BEFORE BREACH	15
CC.	PERFORMANCE BOND	15
DD.	FORCE MAJEURE.....	15
EE.	PAYMENT	16
FF.	AUDIT REQUIREMENTS.....	16
GG.	TAXES	16
HH.	INSPECTION AND APPROVAL.....	16
II.	CHANGES IN SCOPE/CHANGE ORDERS	16
JJ.	SEVERABILITY.....	17
KK.	CONFIDENTIALITY.....	17
LL.	PROPRIETARY INFORMATION	17
MM.	CERTIFICATION OF INDEPENDENT PRICE DETERMINATION/COLLUSIVE BIDDING	18
NN.	PRICES.....	18
OO.	BEST AND FINAL OFFER	19
PP.	ETHICS IN PUBLIC CONTRACTING	19
QQ.	INDEMNIFICATION.....	19
RR.	NEBRASKA TECHNOLOGY ACCESS STANDARDS.....	20
SS.	ANTITRUST	20
TT.	DISASTER RECOVERY/BACK UP PLAN.....	20
UU.	TIME IS OF THE ESSENCE	21
VV.	RECYCLING	21
WW.	DRUG POLICY.....	21
XX.	NEW EMPLOYEE WORK ELIGIBILITY STATUS.....	21
YY.	CERTIFICATION REGARDING DEBARMENT, SUSPENSION AND INELIGIBILITY.....	21
ZZ.	PUBLIC COUNSEL	22
IV.	PROJECT DESCRIPTION AND SCOPE OF WORK.....	23
A.	PROJECT OVERVIEW	23
B.	PROJECT ENVIRONMENT	23
C.	PROJECT REQUIREMENTS.....	26
D.	PROJECT REQUIREMENTS TO BE ADDRESSED IN TECHNICAL APPROACH OF PROPOSAL RESPONSE	32
E.	THE BIDDER'S PROPOSAL RESPONSE MUST ADDRESS THE FOLLOWING:	32
F.	BUSINESS REQUIREMENTS TO BE ADDRESSED IN PROPOSAL RESPONSE.....	42
G.	TECHNICAL REQUIREMENTS TO BE ADDRESSED IN THE PROPOSAL RESPONSE.....	43
H.	PROJECT PLANNING AND MANAGEMENT	45
I.	EVALUATE CURRENT PROJECT ENVIRONMENT.....	45
J.	PERFORM IMPLEMENTATION.....	46
K.	PROVIDE POST IMPLEMENTATION SUPPORT	46
L.	DELIVERABLES	46

V. PROPOSAL INSTRUCTIONS 47

- A. TECHNICAL PROPOSAL..... 47**
- B. COST PROPOSAL REQUIREMENTS 51**
- C. PAYMENT SCHEDULE..... 52**

Form A Bidder Contact Sheet..... 53

Appendix A Nebraska Births 2011..... 54

Appendix B Current Regulations, Title 181, NAC 2..... 56

Attachment 2 Collection and Reporting (CARE) Form – Nebraska Newborn Screening Program 75

Attachment 3 Newborn Transfer Form Nebraska Newborn Screening Program 76

Appendix C Table of Test Results 77

Appendix D Emergency/Disaster Preparedness & Proprietary Information..... 80

Appendix E Follow-up/Monitoring and Quality Assurance Reports 81

Appendix F Screening Algorithms and Reporting Procedures..... 92

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 added or deleted.

Agency: Any state agency, board, or commission other than the University of Nebraska, the Nebraska State colleges, the courts, the Legislature, or any officer or agency established by the Constitution of Nebraska.

Agent: A person authorized by a superior or organization to act on their behalf.

Amend: To alter or change by adding, subtracting, or substituting. A contract can be amended only by the parties participating in the contract. A written contract can only be amended in writing.

Amendment: Written correction or alteration.

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 Request for Proposal. 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): A second-stage bid in a public procurement for services.

Bid: The executed document submitted by a bidder in response to a Request for Proposal.

Bid Bond: A bond given by a surety on behalf of the bidder to ensure that the bidder will enter into the contract as bid and is retained by the State from the date of the bid opening to the date of contract signing.

Bidder: Any person or entity submitting a competitive bid response to a solicitation.

Business: Any corporation, partnership, individual, sole proprietorship, joint-stock company, joint venture, or any other private legal entity.

Business Day: Any weekday, excepting public holidays.

CAP: College of American Pathology.

CDC: Center for Disease Control and Prevention.

CLIA: Clinical Laboratory Improvement Act.

CLSI: Clinical and Laboratory Standards Institute.

Calendar Day: Every day shown on the calendar; Saturdays, Sundays and State/Federal holidays included. Not to be confused with “Work Day”.

Collusion: A secret agreement or cooperation between two or more persons or entities to accomplish a fraudulent, deceitful or unlawful purpose.

Competition: The process by which two or more vendors vie to secure the business of a purchaser by offering the most favorable terms as to price, quality, delivery and/or service.

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 provide.

Confirmatory Testing: A test done on a new specimen in response to a positive screening result. Depending on the positive screen result, the confirmatory specimen recommended may be whole blood, serum, other fluid or tissue, and the test method is often quantitative or semi-quantitative and different from that used for the screen.

Contract: An agreement between two or more persons to perform a specific act or acts.

Contract Administration: The Management of various facets of contracts to assure that the contractors total performance is in accordance with the contractual commitments and obligations to the purchaser are fulfilled.

Contract Management: Includes reviewing and approving of changes, executing renewals, handling disciplinary actions, adding additional users, and any other form of action that could change the contract.

Contractor: Any person or entity that supplies goods and/or services.

Conversion Period: A period of time not to exceed six (6) months, during which the State converts to a new Operating System under “Conversion” as per this RFP.

Copyright: A grant to a writer/artist that recognizes sole authorship/creation of a work and protects the creator’s interest(s) therein.

Core Panel of Conditions Screened: Refer to Appendix B, Title 181, NAC 2, Regulations Governing Screening of Infants for Metabolic Diseases, 2-002 Definitions.

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.

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.

DHHS: Department of Health and Human Services

Default: The omission or failure to perform a contractual duty.

Deviation: Any proposed change(s) or alteration(s) to either the contractual language or deliverables within the scope of this Request for Proposal.

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.

EIA: Enzyme Immunoassay.

Evaluation Committee: A committee (or committees) appointed by the requesting agency that advises and assists the procuring office in the evaluation of proposals.

Evaluation of Proposal: The process of examining a proposal after opening to determine the bidder's responsibility, responsiveness to requirements, and to ascertain other characteristics of the proposal that relate to determination of the successful bidder.

Extension: A provision, or exercise of a provision, of a contract that allows a continuance of the contract (at the option of the State of Nebraska) for an additional time according to contract conditions. Not to be confused with "Renewals."

FDA: Federal Food & Drug Administration.

HL7: 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.

HPLC: High Pressure Liquid Chromatography.

Inconclusive Screen Result: A newborn screening test result that is out of range of the normal expected results. Usually associated with a recommendation for a repeat dried blood spot filter paper specimen collection and testing rather than confirmatory/diagnostic testing.

F.O.B. Destination: Free on Board. The delivery charges have been included in the quoted price and prepaid by the vendor. Vendor is responsible for all claims associated with damages during delivery of product.

Foreign Corporation: A foreign corporation is a corporation that was formed (i.e. incorporated) in another state but transacting business in Nebraska pursuant to a certificate of authority issued by the Nebraska Secretary of State.

Installation Date: The date when the procedures described in "Installation by Contractor, and Installation by State", as found in the RFP, are completed.

Late Proposal: A proposal received at the place specified in the solicitation after the date and time designated for all proposals to be received.

Licensed Software: Any and all software and documentation by which the State acquires or is granted any rights under the contract.

LOINC: Logical Observation Identifiers Names and Codes. A universal code system for identifying laboratory and clinical observations.

MMWR: Morbidity and Mortality Weekly Report.

MS/MS: Tandem Mass Spectrometry.

Mandatory: Required, compulsory or obligatory.

May: Denotes discretion.

Module: A collection of routines and data structures that perform a specific function of the Licensed Software.

Must: Denotes the imperative, required, compulsory or obligatory.

NNSP: Nebraska Newborn Screening Program

Opening Date: Specified date and time for the public opening of received, labeled and sealed formal proposals. Not to be confused with "Release Date".

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: Acquiring computing or related services from a source outside of the State of Nebraska which may include programming and/or executing the State's Licensed Software on the State's CPU's, programming, and/or executing the State's programs and Licensed Software on the contractor's CPU's or any mix thereof.

Outsourcing Company: A company that provides Outsourcing Services under contract to the State.

Performance Bond: A bond given by a surety on behalf of the contractor to ensure the timely and proper (in sole estimation of the State) performance of a 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.

Pre-Proposal Conference: A meeting scheduled for the purpose of providing clarification regarding a Request for Proposal and related expectations.

Product: A module, a system, or any other software-related item provided by the contractor to the State.

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 of all software, documentation, and services to be provided by the contractor under this contract.

Proposal: The executed document submitted by a bidder in response to a Request for 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 serve 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) who would be advantaged by release of the information and the specific advantage the competitor(s) would receive.

Protest: A complaint about a governmental action or decision related to a Request for Proposal or the resultant contract, brought by a prospective bidder, a bidder, a contractor, or other interested party to AS Materiel Division or another designated agency with the intention of achieving a remedial result.

Public Proposal Opening: The process of opening proposals, conducted at the time and place specified in the Request for Proposal, and in the presence of anyone who wishes to attend.

RIA: Radio-immunoassay.

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.

Reflex Test: or 2nd Tier Test: A test done following an abnormal result, using a different assay to measure or evaluate an analyte done on another punch from the same/original blood spot specimen. Usually intended to clarify or validate the result of the initial test result used to screen for a condition and/or to reduce the number of false positive screening results.

Repeat Test: A test done on a newly collected dried blood spot specimen. Usually done in response to an inconclusive screening result, unsatisfactory specimen, transfused specimen, or specimen collected too early.

Release Date: Date of release of the Request for Proposal to the public for submission of proposal responses. Not to be confused with "Opening Date".

Renewal: Continuance of a contract for an additional term after a formal signing by the parties.

Representative: Includes an agent, an officer of a corporation or association, a trustee, executor or administrator of an estate, or any other person legally empowered to act for another.

Request for Proposal (RFP): All documents, whether attached or incorporated by reference, utilized for soliciting competitive proposals.

Responsible Bidder: A bidder who has the capability in all respects to perform fully all requirements with integrity and reliability to assure good faith performance.

Responsive Bidder: A bidder who has submitted a bid which conforms in all respects to the solicitation document.

Shall: Denotes the imperative, required, compulsory or obligatory.

Should: Indicates an expectation.

Solicitation: The process of notifying prospective bidders or offerors that the State of Nebraska wishes to receive proposals for furnishing services. The process may consist of public advertising, posting notices, or mailing Request for Proposals and/or Request for Proposal announcement letter to prospective bidders, or all of these.

Solicitation Document: Request for Proposal.

Specifications: The information provided by or on behalf of the contractor that fully describes the capabilities and functionality of the Licensed Software as set forth in any material provided by the contractor, including the documentation and User's Manuals described herein.

System: 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. All obligations which are still executory on both sides are discharged but any right based on prior breach or performance survives.

Trademark: A distinguishing sign, symbol, mark, word, or arrangement of words in the form of a label or other indication, that is adopted and used by a manufacturer or distributor to designate its particular goods and which no other person has the legal right to use.

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, 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)).

Upgrade: Any improvement or change in the Software that improves or alters its basic function.

Vendor: An actual or potential contractor; a contractor.

Will: Denotes the imperative, required, compulsory or obligatory.

I. SCOPE OF THE REQUEST FOR PROPOSAL

The State of Nebraska, Administrative Services (AS), Materiel Division, Purchasing Bureau (hereafter known as State Purchasing Bureau), is issuing this Request for Proposal, RFP Number 4229Z1 for the purpose of selecting a qualified contractor for the right to provide newborn screening laboratory testing services.

A contract resulting from this Request for Proposal will be issued for a period of two (2) years and two (2) months effective from date of contract award through June 30, 2015, with the option to renew for three (3) additional one (1) year periods as mutually agreed upon by all parties.

ALL INFORMATION PERTINENT TO THIS REQUEST FOR PROPOSAL CAN BE FOUND ON THE INTERNET AT: <http://www.das.state.ne.us/materiel/purchasing/rfp.htm>

A. SCHEDULE OF EVENTS

The State expects to adhere to the tentative procurement schedule shown below. It should be noted, however, that some dates are approximate and subject to change.

ACTIVITY		DATE/TIME
1.	Release Request for Proposal	February 7, 2013
2.	Last day to submit written questions	February 19, 2013
3.	State responds to written questions through Request for Proposal "Addendum" and/or "Amendment" to be posted to the Internet at: http://www.das.state.ne.us/materiel/purchasing/rfp.htm	March 1, 2013
4.	Proposal opening Location: Nebraska State Office Building State Purchasing Bureau 301 Centennial Mall South, Mall Level Lincoln, NE 68508	March 15, 2013 2:00 PM Central Time
5.	Review for conformance of mandatory requirements	March 15, 2013
6.	Evaluation period	March 18, 2013 through March 29, 2013
7.	"Oral Interviews/Presentations and/or Demonstrations" (if required)	To Be Determined
8.	Post "Letter of Intent to Contract" to Internet at: http://www.das.state.ne.us/materiel/purchasing/rfp.htm	April 3, 2013
9.	Performance bond submission	April 15, 2013
10.	Contract award	April 30, 2013
11.	Contractor start date	July 1, 2013

II. PROCUREMENT PROCEDURES

A. PROCURING OFFICE AND CONTACT PERSON

Procurement responsibilities related to this Request for Proposal reside with the State Purchasing Bureau. The point of contact for the procurement is as follows:

Name: Ruth Gray / Michelle Musick
Agency: State Purchasing Bureau
Address: 301 Centennial Mall South, Mall Level
Lincoln, NE 68508

OR

Address: P.O. Box 94847
Lincoln, NE 68509
Telephone: 402-471-2401
Facsimile: 402-471-2089
E-Mail: matpurch.dasmat@nebraska.gov

B. GENERAL INFORMATION

The Request for Proposal is designed to solicit proposals from qualified vendors for the right to provide and who will be responsible for providing newborn screening laboratory testing services at a competitive and reasonable cost. Proposals that do not conform to the mandatory items as indicated in the Request for Proposal will not be considered.

Proposals shall conform to all instructions, conditions, and requirements included in the Request for Proposal. Prospective bidders are expected to carefully examine all documentation, schedules and requirements stipulated in this Request for Proposal, and respond to each requirement in the format prescribed.

A fixed-price contract will be awarded as a result of this proposal. In addition to the provisions of this Request for Proposal and the awarded proposal, which shall be incorporated by reference in the contract, any additional clauses or provisions required by the terms and conditions will be included as an amendment to the contract.

C. COMMUNICATION WITH STATE STAFF

From the date the Request for Proposal is issued until a determination is announced regarding the selection of the contractor, contact regarding this project between potential contractors and individuals employed by the State is restricted to only written communication with the staff designated above as the point of contact for this Request for Proposal.

Once a contractor is preliminarily selected, as documented in the intent to contract, that contractor is restricted from communicating with State staff until a contract is signed. Violation of this condition may be considered sufficient cause to reject a contractor's proposal and/or selection irrespective of any other condition.

The following exceptions to these restrictions are permitted:

1. written communication with the person(s) designated as the point(s) of contact for this Request for Proposal or procurement;
2. contacts made pursuant to any pre-existing contracts or obligations; and

3. State-requested presentations, key personnel interviews, clarification sessions or discussions to finalize a contract.

Violations of these conditions may be considered sufficient cause to reject a bidder's proposal and/or selection irrespective of any other condition. No individual member of the State, employee of the State, or member of the Evaluation Committee is empowered to make binding statements regarding this Request for Proposal. The buyer will issue any clarifications or opinions regarding this Request for Proposal in writing.

D. WRITTEN QUESTIONS AND ANSWERS

Any explanation desired by a bidder regarding the meaning or interpretation of any Request for Proposal provision must be submitted in writing to the State Purchasing Bureau and clearly marked "RFP Number 4229Z1; Newborn Screening Laboratory Testing Services Questions". It is preferred that questions be sent via e-mail to matpurch.dasmat@nebraska.gov. Questions may also be sent by facsimile to 402-471-2089, but must include a cover sheet clearly indicating that the transmission is to the attention of Ruth Gray / Michelle Musick, showing the total number of pages transmitted, and clearly marked "RFP Number 4229Z1; Newborn Screening Laboratory Testing Services Questions".

Written answers will be provided through an addendum to be posted on the Internet at <http://www.das.state.ne.us/materiel/purchasing/rfp.htm> on or before the date shown in the Schedule of Events.

E. ORAL INTERVIEWS/PRESENTATIONS AND/OR DEMONSTRATIONS

The Evaluation Committee(s) may conclude after the completion of the Technical and Cost Proposal evaluation that oral interviews/presentations and/or demonstrations are required in order to determine the successful bidder. All bidders may not have an opportunity to interview/present and/or give demonstrations; the State reserves the right to select only the top scoring bidders to present/give oral interviews in its sole discretion. 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 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. Bidders shall not be allowed to alter or amend their proposals. Only representatives of the State and the presenting bidders will be permitted to attend the oral interviews/presentations and/or demonstrations.

Once the oral interviews/presentations and/or demonstrations have been completed the State reserves the right to make a contract award without any further discussion with the bidders regarding the proposals received.

Detailed notes of oral interviews/presentations and/or demonstrations may be recorded and supplemental information (such as briefing charts, et cetera) may be accepted; however, such supplemental information shall not be considered an amendment to a bidders' proposal. Additional written information gathered in this manner shall not constitute replacement of proposal contents.

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.

F. SUBMISSION OF PROPOSALS

The following describes the requirements related to proposal submission, proposal handling and review by the State.

To facilitate the proposal evaluation process, one (1) original, clearly identified as such, and five (5) copies of the entire proposal should be submitted. The copy marked "original" shall take precedence over any other copies, should there be a discrepancy. Proposals must be submitted by the proposal due date and time. A separate sheet must be provided that clearly states which sections have been submitted as proprietary or have copyrighted materials. All proprietary information the bidder wishes the State to withhold must be submitted in accordance with the instructions outlined in Section III, Proprietary Information. Proposal responses should include the completed Form A, Bidder Contact Sheet. Proposals must reference the request for proposal number and be sent to the specified address. Container(s) utilized for original documents should be clearly marked "ORIGINAL DOCUMENTS". Please note that the address label should appear as specified in Section II part A on the face of each container or bidder's bid response packet. Rejected late proposals will be returned to the bidder unopened, if requested, at bidder's expense. If a recipient phone number is required for delivery purposes, 402-471-2401 should be used. The request for proposal number must be included in all correspondence.

Emphasis should be concentrated on conformance to the Request for Proposal 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, it is likely that points will be lost in the evaluation process. Elaborate and lengthy proposals are neither necessary nor desired.

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 must 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 must 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.

G. PROPOSAL OPENING

The sealed proposals will be publicly opened and the bidding entities announced on the date, time and location shown in the Schedule of Events. Proposals will be available for viewing by those present after the proposal opening. Vendors may also contact the State to schedule an appointment for viewing proposals after the opening date.

H. LATE PROPOSALS

Proposals received after the time and date of the proposal opening will be considered late proposals. Rejected late proposals will be returned to the bidder unopened, if requested, at bidder's expense. The State is not responsible for proposals that are late or lost due to mail service inadequacies, traffic or any other reason(s).

I. REJECTION OF PROPOSALS

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.

J. EVALUATION OF PROPOSALS

All responses to this Request for Proposal which fulfill all mandatory requirements will be evaluated. Each category will have a maximum possible 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. Executive Summary;
2. Corporate Overview shall 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 Request for Proposal;
 - 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;
3. Technical Approach; and
4. Cost Proposal.

Evaluation criteria will become public information at the time of the Request for Proposal opening. Evaluation criteria and a list of respondents will be posted to the State Purchasing Bureau website at <http://www.das.state.ne.us/materiel/purchasing/rfp.htm> Evaluation criteria will not be released prior to the proposal opening.

K. EVALUATION COMMITTEE

Proposals will be independently evaluated by members of the Evaluation Committee(s). The committee(s) will consist of staff with the appropriate expertise to conduct such proposal evaluations. Names of the members of the Evaluation Committee(s) will not become public information.

Prior to award, bidders are advised that only the point of contact indicated on the front cover of this Request For Proposal For Contractual Services Form can clarify issues or render any opinion regarding this Request for Proposal. No individual member of the State, employee of the State or member of the Evaluation Committee(s) is empowered to make binding statements regarding this Request for Proposal.

L. MANDATORY REQUIREMENTS

The proposals will first be examined to determine if all mandatory requirements listed below have been addressed to warrant further evaluation. Proposals not meeting mandatory requirements will be excluded from further evaluation. The mandatory requirement items are as follows:

1. Signed, in ink, Request For Proposal For Contractual Services form;

2. Executive Summary;
3. Corporate Overview;
4. Technical Approach; and
5. Cost Proposal.

M. REFERENCE CHECKS

The State reserves the right to check any reference(s), regardless of the source of the reference information, including but not limited to, those that are identified by the company in the proposal, those indicated through the explicitly specified contacts, those that are identified during the review of the proposal, or those that result from communication with other entities involved with similar projects.

Information to be requested and evaluated from references may include, but is not limited to, some or all of the following: project description and background, job performed, functional and technical abilities, communication skills and timeliness, cost and schedule estimates and accuracy, problems (poor quality deliverables, contract disputes, work stoppages, et cetera), overall performance, and whether or not the reference would rehire the firm or individual. Only top scoring bidders may receive reference checks and negative references may eliminate bidders from consideration for award.

N. SECRETARY OF STATE/TAX COMMISSIONER REGISTRATION REQUIREMENTS

All bidders are expected to comply with any statutory registration requirements. It is the responsibility of the bidder who is the recipient of an Intent to Award to comply with any statutory registration requirements pertaining to types of business entities (e.g. a foreign or Nebraska corporation, non-resident contractor, limited partnership, or other type of business entity). The bidder who is the recipient of Intent to Award will be required to certify that it has so complied and produce a true and exact copy of its registration certificate, or, in the case registration is not required, to provide the reason as to why none is required. This must be accomplished prior to the award of contract.

O. VIOLATION OF TERMS AND CONDITIONS

Violation of the terms and conditions contained in this Request for Proposal 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. 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.

III. TERMS AND CONDITIONS

By signing the "Request For Proposal For Contractual Services" form, the bidder guarantees compliance with the provisions stated in this Request for Proposal, agrees to the terms and conditions and certifies bidder maintains a drug free work place environment.

Bidders are expected to closely read the Terms and Conditions and provide a binding signature of intent to comply with the Terms and Conditions; provided, however, a bidder may indicate any exceptions to the Terms and Conditions by (1) clearly identifying the term or condition by subsection, (2) including an explanation for the bidder's inability to comply with such term or condition which includes a statement recommending terms and conditions the bidder would find acceptable. Rejection in whole or in part of the Terms and Conditions may be cause for rejection of a bidder's proposal.

A. GENERAL

Accept
& Initial

The contract resulting from this Request for Proposal shall incorporate the following documents:

1. the signed Request For Proposal form;
2. the original Request for Proposal document;
3. any Request for Proposal addenda and/or amendments to include questions and answers;
4. the contractor's proposal;
5. any contract amendments, in order of significance; and
6. contract award.

Unless otherwise specifically stated in a 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) the contract award, 2) contract amendments with the latest dated amendment having the highest priority, 3) Request for Proposal addenda and/or amendments with the latest dated amendment having the highest priority, 4) the original Request for Proposal, 5) the signed Request For Proposal form, 6) the contractor's proposal.

Any ambiguity in any provision of this contract which shall be discovered after its execution shall be resolved in accordance with the rules of contract interpretation as established in the State of Nebraska.

Once proposals are opened they become the property of the State of Nebraska and will not be returned.

B. AWARD

Accept
& Initial

All purchases, leases, or contracts which are based on competitive proposals will be awarded according to the provisions in the Request for Proposal. 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, and at its discretion, may withdraw or amend the Request for Proposal at any time. 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. The Request for Proposal does not commit the State to award a contract. If, in the opinion of the State, revisions or amendments will require substantive changes in proposals, the due date may be extended.

By submitting a proposal in response to this Request for Proposal, 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.

Once an intent to award decision has been determined, it will be posted to the Internet at: <http://www.das.state.ne.us/materiel/purchasing/rfp.htm>

Grievance and protest procedure is available on the Internet at: <http://www.das.state.ne.us/materiel/purchasing/agencyervicesprocurementmanual/ProtestGrievanceProcedureForServices.doc>

Any protests must be filed by a vendor within ten (10) calendar days after the intent to award decision is posted to the Internet.

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

Accept
& Initial

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 or privileges of employment because of race, color, religion, sex, disability, 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 Request for Proposal.

D. PERMITS, REGULATIONS, LAWS

Accept
& Initial

The contractor shall procure and pay for all permits, licenses and approvals necessary for the execution of the contract. The contractor shall comply with all applicable local, state, and federal laws, ordinances, rules, orders and regulations.

E. OWNERSHIP OF INFORMATION AND DATA

Accept
& Initial

The State of Nebraska shall have the unlimited right to publish, duplicate, use and disclose all information and data developed or derived by the contractor pursuant to this contract.

The contractor must guarantee that it has the full legal right to the materials, supplies, equipment, and other rights or titles (e.g. rights to licenses transfer or assign deliverables) necessary to execute this contract. The contract price shall, without exception, include compensation for all royalties and costs arising from patents, trademarks and copyrights that are in any way involved in the contract. It shall be the responsibility of the contractor to pay for all royalties and costs, and the State must be held harmless from any such claims.

F. INSURANCE REQUIREMENTS

Accept
& Initial

The contractor shall not commence work under this contract until he or she has obtained all the insurance required hereunder and such insurance has been approved by the State. If contractor will be utilizing any subcontractors, the contractor is responsible for obtaining the certificate(s) of insurance required herein under from any and all subcontractor(s). Contractor is also responsible for ensuring subcontractor(s) maintain the insurance required until completion of the contract requirements. The contractor shall not allow any subcontractor to commence work on his or her subcontract until all similar insurance required of the

or services required by the contractor under the contract shall have no contractual relationship with the State; they shall not be considered employees of the State.

All claims on behalf of any person arising out of employment or alleged employment (including without limit claims of discrimination against the contractor, its officers or its agents) shall in no way be the responsibility of the State. The contractor will hold the State harmless from any and all such claims. Such personnel or other persons shall not require nor be entitled to any compensation, rights or benefits from the State including without limit, tenure rights, medical and hospital care, sick and vacation leave, severance pay or retirement benefits.

I. CONTRACTOR RESPONSIBILITY

Accept
& Initial

The contractor is solely responsible for fulfilling the contract, with responsibility for all services offered and products to be delivered as stated in the Request for Proposal, the contractor's proposal, and the resulting contract. The contractor shall be the sole point of contact regarding all contractual matters.

If the contractor intends to utilize any subcontractors' services, the subcontractors' level of effort, tasks and time allocation must be clearly defined in the contractor'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. Following execution of the contract, the contractor shall proceed diligently with all services and shall perform such services with qualified personnel in accordance with the contract.

J. CONTRACTOR PERSONNEL

Accept
& Initial

The contractor warrants that all persons assigned to the project shall be employees of the contractor or specified subcontractors, and shall be fully qualified to perform the work required herein. Personnel employed by the contractor to fulfill the terms of the contract shall remain under the sole direction and control of the contractor. The contractor shall include a similar provision in any contract with any subcontractor selected to perform work on the project.

Personnel commitments made in the contractor's proposal shall not be changed without the prior written approval of the State. Replacement of key personnel, if approved by the State, shall be with personnel of equal or greater ability and qualifications.

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

In respect to its employees, the contractor agrees to be responsible for the following:

1. any and all 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 and submitting any reports on such insurance to the extent required by governing State law; and
5. determining the hours to be worked and the duties to be performed by the contractor's employees.

Notice of cancellation of any required insurance policy must be submitted to the State when issued and a new coverage binder shall be submitted immediately to ensure no break in coverage.

K. STATE OF NEBRASKA PERSONNEL RECRUITMENT PROHIBITION

Accept
& Initial

The contractor shall not, at any time, recruit or employ any State employee or agent who has worked on the Request for Proposal or project, or who had any influence on decisions affecting the Request for Proposal or project.

L. CONFLICT OF INTEREST

Accept
& Initial

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

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

M. PROPOSAL PREPARATION COSTS

Accept
& Initial

The State shall not incur any liability for any costs incurred by bidders in replying to this Request for Proposal, in the demonstrations, or oral presentations, or in any other activity related to bidding on this Request for Proposal.

N. ERRORS AND OMISSIONS

Accept
& Initial

The bidder shall not take advantage of any errors and/or omissions in this Request for Proposal or resulting contract. The bidder must promptly notify the State of any errors and/or omissions that are discovered.

O. BEGINNING OF WORK

Accept
& Initial

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.

P. ASSIGNMENT BY THE STATE

Accept
& Initial

The State shall have the right to assign or transfer the contract or any of its interests herein to any agency, board, commission, or political subdivision of the State of Nebraska. There shall be no charge to the State for any assignment hereunder.

Q. ASSIGNMENT BY THE CONTRACTOR

Accept
& Initial

The contractor may not assign, voluntarily or involuntarily, the contract or any of its rights or obligations hereunder (including without limitation rights and duties of performance) to any third party, without the prior written consent of the State, which will not be unreasonably withheld.

R. DEVIATIONS FROM THE REQUEST FOR PROPOSAL

Accept
& Initial

The requirements contained in the Request for Proposal become a part of the terms and conditions of the contract resulting from this Request for Proposal. Any deviations from the Request for Proposal 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 Request for Proposal or mandatory requirements. "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.

S. GOVERNING LAW

Accept
& Initial

The contract shall be governed in all respects by the laws and statutes of the State of Nebraska. Any legal proceedings against the State of Nebraska regarding this Request for Proposal or any resultant contract shall be brought in the State of Nebraska administrative or judicial forums as defined by State law. The contractor must be in compliance with all Nebraska statutory and regulatory law.

T. ATTORNEY'S FEES

Accept
& Initial

In the event of any litigation, appeal or other legal action to enforce any provision of the contract, the contractor agrees to pay all expenses of such action, as permitted by law, including attorney's fees and costs, if the State is the prevailing party.

U. ADVERTISING

Accept
& Initial

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. News releases pertaining to the project shall not be issued without prior written approval from the State.

V. STATE PROPERTY

Accept
& Initial

The contractor shall be responsible for the proper care and custody of any State-owned property which is furnished for the contractor's use during the performance of the contract. The contractor shall reimburse the State for any loss or damage of such property, normal wear and tear is expected.

W. SITE RULES AND REGULATIONS

Accept
& Initial

The contractor shall use its best efforts to ensure that its employees, agents and subcontractors comply with site rules and regulations while on State premises. If the contractor must perform on-site work outside of the daily operational hours set forth by the State, it must make arrangements with the State to ensure access to the facility and the equipment has been arranged. No additional payment will be made by the State on the basis of lack of access, unless the State fails to provide access as agreed to between the State and the contractor.

X. NOTIFICATION

Accept
& Initial

During the bid process, all communication between the State and a bidder shall be between the bidder's representative clearly noted in its proposal and the buyer noted in Section II, A. Procuring Office and Contact Person of this RFP. After the award of the contract, all notices under the contract shall be deemed duly given upon delivery to the staff designated as the point of contact for this Request for Proposal, in person, or upon delivery by U.S. Mail, facsimile, or e-mail. Each bidder should provide in its proposal the name, title and complete address of its designee to receive notices.

1. Except as otherwise expressly specified herein, all notices, requests or other communications 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 above, 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) days following deposit in the mail.

2. Whenever the contractor encounters any difficulty which is delaying or threatens to delay its timely performance under the contract, the contractor shall immediately give notice thereof in writing to the State reciting all relevant information with respect thereto. Such notice shall not in any way constitute a basis for an extension of the delivery schedule or be construed as a waiver by the State of any of its rights or remedies to which it is entitled by law or equity or pursuant to the provisions of the contract. Failure to give such notice, however, may be grounds for denial of any request for an extension of the delivery schedule because of such delay.

Either party may change its address for notification purposes by giving notice of the change, and setting forth the new address and an effective date.

For the duration of the contract, all communication between contractor and the State regarding the contract shall take place between the contractor and individuals specified by the State in writing. Communication about the contract between contractor and individuals not designated as points of contact by the State is strictly forbidden.

Y. EARLY TERMINATION

The contract may be terminated as follows:

Accept
& Initial

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 30 days 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 cancellation 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) 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;

- i. second or subsequent documented "vendor performance report" form deemed acceptable by the State Purchasing Bureau.

Z. FUNDING OUT CLAUSE OR LOSS OF APPROPRIATIONS

Accept
& Initial

The State may terminate the contract, in whole or in part, in the event funding is no longer available. The State's obligation to pay amounts due for fiscal years following the current fiscal year is contingent upon legislative appropriation of funds for the contract. Should said funds not be appropriated, the State may terminate the contract with respect to those payments for the fiscal years for which such funds are not appropriated. The State will give the contractor written notice thirty (30) days prior to the effective date of any termination, and advise the contractor of the location (address and room number) of any related equipment. All obligations of the State to make payments after the termination date will cease and all interest of the State in any related equipment will terminate. The contractor 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 contractor be paid for a loss of anticipated profit.

AA. BREACH BY CONTRACTOR

Accept
& Initial

The State may terminate the contract, in whole or in part, if the contractor fails to perform its obligations under the contract in a timely and proper manner. The State may, by providing a written notice of default to the contractor, allow the contractor to cure a failure or breach of contract within a period of thirty (30) days (or longer at State's discretion considering the gravity and nature of the default). Said notice shall be delivered by Certified Mail, Return Receipt Requested or in person with proof of delivery. Allowing the contractor time to cure a failure or breach of contract does not waive the State's 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.

BB. ASSURANCES BEFORE BREACH

Accept
& Initial

If any document or deliverable required pursuant to the contract does not fulfill the requirements of the Request for Proposal/resulting contract, upon written notice from the State, the contractor shall deliver assurances in the form of additional contractor resources at no additional cost to the project in order to complete the deliverable, and to ensure that other project schedules will not be adversely affected.

CC. PERFORMANCE BOND

Accept
& Initial

The selected contractor will be required to supply a certified check or 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 certified check or bond must be \$100,000. The check or bond will guarantee that the selected contractor will faithfully perform all requirements, terms and conditions of the contract. Failure to comply shall be grounds for forfeiture of the check or bond as liquidated damages. Amount of forfeiture will be determined by the agency based on loss to the State. The bond or certified check will be returned when the service has been satisfactorily completed as solely determined by the State, after termination or expiration of the contract.

DD. FORCE MAJEURE

Accept
& Initial

Neither party shall be liable for any costs or damages resulting from its inability to perform any of its obligations under the contract due to a natural disaster, or other

similar event outside the control and not the fault of the affected party (“Force Majeure Event”). A Force Majeure Event shall not constitute a breach of the contract. The party so affected shall immediately give notice to the other party of the Force Majeure Event. The State may grant relief from performance of the contract if the contractor is prevented from performance by a Force Majeure Event. The burden of proof for the need for such relief shall rest upon the contractor. To obtain release based on a Force Majeure Event, the contractor shall file a written request for such relief with the State Purchasing Bureau. Labor disputes with the impacted party’s own employees will not be considered a Force Majeure Event and will not suspend performance requirements under the contract.

EE. PAYMENT

Accept
& Initial

The State hereby agrees, in consideration of the covenants and agreements specified to be kept and performed by the Contractor, to provide exclusive rights to the Contractor to provide the newborn screening laboratory services for all occurrent births in Nebraska, and for the Contractor to collect fees for this testing from the specimen submitters.

FF. AUDIT REQUIREMENTS

Accept
& Initial

All contractor books, records and documents relating to work performed or monies received under the contract shall be subject to audit at any reasonable time upon the provision of reasonable notice by the State. These records shall be maintained for a period of five (5) full years from the date of final payment, or until all issues related to an audit, litigation or other action are resolved, whichever is longer. All records shall be maintained in accordance with generally accepted accounting principles.

In addition to, and in no way in limitation of any obligation in the contract, the contractor shall agree that it will be held liable for any State audit exceptions, and shall return to the State all payments made under the contract for which an exception has been taken or which has been disallowed because of such an exception. The contractor agrees to correct immediately any material weakness or condition reported to the State in the course of an audit.

GG. TAXES

Accept
& Initial

The State is not required to pay taxes of any kind and assumes no such liability as a result of this solicitation. Any property tax payable on the contractor's equipment which may be installed in a state-owned facility is the responsibility of the contractor.

HH. INSPECTION AND APPROVAL

Accept
& Initial

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.

II. CHANGES IN SCOPE/CHANGE ORDERS

Accept
& Initial

The State may, at any time with written notice to the contractor, make changes within the general scope of the contract. Changes in scope shall only be conducted with the written approval of the State’s designee as so defined by the State from time to time.

(The State retains the right to employ the services of a third party to perform any change order(s)).

The State may, at any time work is in progress, by written order, make alterations in the terms of work as shown in the specifications, require the performance of extra work, decrease the quantity of work, or make such other changes as the State may find necessary or desirable. The contractor shall not claim forfeiture of contract by reasons of such changes by the State. Changes in work and the amount of compensation to be paid to the contractor for any extra work so ordered shall be determined in accordance with the applicable unit prices of the contractor's proposal.

Corrections of any deliverable services or performance of work required pursuant to the contract shall not be deemed a modification requiring a change order.

JJ. SEVERABILITY

Accept
& Initial

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 particular provision held to be invalid.

KK. CONFIDENTIALITY

Accept
& Initial

All materials and information provided by the State or acquired by the contractor on behalf of the State shall be regarded as confidential information. All materials and information provided by the State or acquired by the contractor on behalf of the State shall be handled in accordance with Federal and State Law, and ethical standards. The contractor must ensure the confidentiality of such materials or information. Should said confidentiality be breached by a contractor; contractor shall notify the State immediately of said breach and take immediate corrective action.

It is incumbent upon the contractor to inform its 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 to contractors by 5 U.S.C. 552a (m)(1), provides that any officer or employee of a contractor, 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.

LL. PROPRIETARY INFORMATION

Accept
& Initial

Data contained in the proposal and all documentation provided therein, become the property of the State of Nebraska and the data becomes public information upon opening the proposal. If the bidder wishes to have any information withheld from the public, such information must fall within the definition of proprietary information contained within Nebraska's public record statutes. All proprietary information the bidder wishes the State to withhold must be submitted in a sealed package, which is separate from the remainder of the proposal. The separate package must be clearly marked PROPRIETARY on the outside of the package. Bidders may not mark their entire

Request for Proposal as proprietary. Bidder's cost proposals may not be marked as proprietary information. Failure of the bidder to follow the instructions for submitting proprietary and copyrighted information may result in the information being viewed by other bidders and the public. 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 serve no public purpose (see Neb. Rev. Stat. §84-712.05(3)). In accordance with Attorney General Opinions 92068 and 97033, bidders submitting information as proprietary may be required to prove specific, named competitor(s) who would be advantaged by release of the information and the specific advantage the competitor(s) would receive. Although every effort will be made to withhold information that is properly submitted as proprietary and meets the State's definition of proprietary information, the State is under no obligation to maintain the confidentiality of proprietary information and accepts no liability for the release of such information.

MM. CERTIFICATION OF INDEPENDENT PRICE DETERMINATION/COLLUSIVE BIDDING

Accept
& Initial

By submission of this proposal, the bidder certifies, that he or she is the party making the foregoing proposal that the proposal is not made in the interest of, or on behalf of, any undisclosed person, partnership, company, association, organization, or corporation; that the proposal is genuine and not collusive or sham; that the bidder has not directly or indirectly induced or solicited any other bidder to put in a false or sham proposal, and has not directly or indirectly colluded, conspired, connived, or agreed with any bidder or anyone else to put in a sham proposal, or that anyone shall refrain from bidding; that the bidder has not in any manner, directly or indirectly, sought by agreement, communication, or conference with anyone to fix the proposal price of the bidder or any other bidder, or to fix any overhead, profit, or cost element of the proposal price, or of that of any other bidder, or to secure any advantage against the public body awarding the contract of anyone interested in the proposed contract; that all statements contained in the proposal are true; and further that the bidder has not, directly or indirectly, submitted his or her proposal price or any breakdown thereof, or the contents thereof, or divulged information or data relative thereto, or paid, and will not pay, any fee to any corporation, partnership, company association, organization, proposal depository, or to any member or agent thereof to effectuate a collusive or sham proposal.

NN. PRICES

Accept
& Initial

All prices, costs, terms and conditions outlined in the proposal shall remain fixed and valid commencing on the opening date of the proposal until an award is made (and for bidder receiving award prices shall remain as bid for the duration of the contract unless otherwise so stated in the contract) or the Request for Proposal is cancelled.

Contractor represents and warrants that all prices for services, now or subsequently specified are as low as and no higher than prices which the contractor has charged or intends to charge customers other than the State for the same or similar products and services of the same or equivalent quantity and quality for delivery or performance during the same periods of time. If, during the term of the contract, the contractor shall reduce any and/or all prices charged to any customers other than the State for the same or similar products or services specified herein, the contractor shall make an equal or equivalent reduction in corresponding prices for said specified products or services.

Contractor also represents and warrants that all prices set forth in the contract and all prices in addition, which the contractor may charge under the terms of the contract, do not and will not violate any existing federal, state or municipal law or regulations concerning price discrimination and/or price fixing. Contractor agrees to hold the State harmless from any such violation. Prices quoted shall not be subject to increase throughout the contract period unless specifically allowed by these specifications.

OO. BEST AND FINAL OFFER

Accept
& Initial

The State will compile the final scores for all parts of each proposal. The award may be granted to the highest scoring responsive and responsible bidder. Alternatively, the highest scoring bidder or bidders may be requested to submit best and final offers. If best and final offers are requested by the State and submitted by the bidder, they will be evaluated (using the stated criteria), scored and ranked by the Evaluation Committee. 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.

PP. ETHICS IN PUBLIC CONTRACTING

Accept
& Initial

No bidder shall pay or offer to pay, either directly or indirectly, any fee, commission compensation, gift, gratuity, or anything of value to any State officer, legislator or employee based on the understanding that the receiving person's vote, actions or judgment will be influenced thereby. No bidder shall give any item of value to any employee of the State Purchasing Bureau.

Bidders shall be prohibited from utilizing the services of lobbyists, attorneys, political activists, or consultants to secure the contract. It is the intent of this provision to assure that the prohibition of state contact during the procurement process is not subverted through the use of lobbyists, attorneys, political activists, or consultants. It is the intent of the State that the process of evaluation of proposals and award of the contract be completed without external influence. It is not the intent of this section to prohibit bidders from seeking professional advice, for example consulting legal counsel, regarding terms and conditions of this Request for Proposal or the format or content of their proposal.

If the bidder is found to be in non-compliance with this section of the Request for Proposal, they may forfeit the contract if awarded to them or be disqualified from the selection process.

QQ. INDEMNIFICATION

Accept
& Initial

1. GENERAL

The contractor agrees to defend, indemnify, hold, and save harmless the State and its employees, volunteers, agents, and its elected and appointed officials ("the indemnified parties") 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 ("the claims"), sustained or asserted against the State, 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, 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 provided by the contractor.

RR. NEBRASKA TECHNOLOGY ACCESS STANDARDS

Contractor shall review the Nebraska Technology Access Standards, found at http://www.nitc.nebraska.gov/standards/accessibility/accessibility_standards.pdf and ensure that products and/or services provided under the contract comply with the applicable standards. In the event such standards change during the contractor's performance, the State may create an amendment to the contract to request that contract comply with the changed standard at a cost mutually acceptable to the parties.

Accept
& Initial

SS. ANTITRUST

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.

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& Initial

TT. DISASTER RECOVERY/BACK UP PLAN

The contractor shall have a disaster recovery and back-up plan, of which a copy should be provided to the State, which includes, but is not limited to equipment, supplies,

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personnel, facilities, communications and transportation, in order to continue services as specified under these specifications in the event of a disaster. Reference Appendix D

UU. TIME IS OF THE ESSENCE

Accept
& Initial

Time is of the essence in this contract. The acceptance of late performance with or without objection or reservation by the State shall not waive any rights of the State nor constitute a waiver of the requirement of timely performance of any obligations on the part of the contractor remaining to be performed.

VV. RECYCLING

Accept
& Initial

Preference will be given to items which are manufactured or produced from recycled material or which can be readily reused or recycled after their normal use as per state statute (Neb. Rev. Stat. §81-15, 159).

WW. DRUG POLICY

Accept
& Initial

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.

XX. NEW EMPLOYEE WORK ELIGIBILITY STATUS

Accept
& Initial

The Contractor is required and hereby agrees to use a federal immigration verification system to determine the work eligibility status of new 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 a newly hired 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 www.das.state.ne.us.
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.

YY. CERTIFICATION REGARDING DEBARMENT, SUSPENSION AND INELIGIBILITY

Accept
& Initial

The contractor, by signature to this RFP, certifies that the contractor is not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any federal department or agency from participating in transactions (debarred). The contractor also agrees to include the above requirements in any and all

subcontracts into which it enters. The contractor shall immediately notify the Department if, during the term of this contract, contractor becomes debarred. The Department may immediately terminate this contract by providing contractor written notice if contractor becomes debarred during the term of this contract.

ZZ. PUBLIC COUNSEL

In the event Contractor provides health and human services to individuals on behalf of DHHS under the terms of this contract, Contractor shall submit to the jurisdiction of the Public Counsel under NEB. REV. STAT. §§ 81-8,240 through 81-8,254 with respect to the provision of services under this contract. This provision shall not apply to contracts between DHHS and long-term care facilities subject to the jurisdiction of the state long-term care ombudsman pursuant to the Long-Term Care Ombudsman Act. This provision shall survive termination of the contract.

Accept
& Initial

IV. PROJECT DESCRIPTION AND SCOPE OF WORK

A. PROJECT OVERVIEW

In order to comply with Neb. Rev. Stat. §§71-519 through 71-524 and Title 181, NAC 2 Regulations Governing Screening of Infants for Metabolic Disorders, 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 Title 181, NAC 2, and is not the purchaser of the services. The contractor will bill/invoice specimen submitters for the per-infant screened fee as agreed to in the contract awarded as a result of this RFP, plus the \$10 per infant screened administrative fee. The \$10 per infant screened administrative fee shall be forwarded monthly to the Department of Health and Human Services, Nebraska Newborn Screening Program. If at any time during the term of the contract, the fee would be adjusted via statutory authority, the contractor will adjust their billing and remittances accordingly. The Department of Health and Human Services, Nebraska Newborn Screening Program may consider the addition of tests for other disorders during the contract period so bidders are asked to identify other tests available, methodologies available, laboratory experience with these other tests, and their costs. Cost proposals should be based on the testing of approximately 24,000 initial filter paper cards for all conditions except congenital primary hypothyroidism, congenital adrenal hyperplasia and cystic fibrosis, and approximately 3500 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, and 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. Proposals that include subcontracting part of the testing to another laboratory will not be accepted.

*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 Nebraska Newborn Screening Program (NNSP) is administered within the Lifespan Health Services Unit, Section of Community Health, Division of Public Health, in the Nebraska Department of Health and Human Services located at 301 Centennial Mall South, Lincoln, Nebraska. The NNSP is responsible for regulations governing newborn screening in Nebraska, 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 assure quality.

The newborn screening blood tests required in Statute and regulation are to detect the endocrinopathies, hemoglobinopathies, pulmonary conditions, 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), 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, Severe Combined Immune Deficiency (SCID).

Currently all of the required newborn screening tests are conducted at PerkinElmer Genetics Inc. Screening Laboratory.

Specimens are currently shipped overnight via UPS or Federal express Monday through Friday from all birthing hospitals, and include Saturday pick-up at hospitals with 400 or more births per year. Delivery to the laboratory is Monday through Saturday (the Saturday delivery check-box must be marked on the mailer).

Nebraska has approximately 26,000 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 2011). Yearly average births per hospital range from 1 to 3,000. In the past 10 years (2002-2011), newborn screening has identified 370 infants with disorders for a 10 year annual incident rate of 1:1,035 births screened. During this time, the following newborns were identified with these conditions:

1 argininosuccinic aciduria, 7 biotinidase deficiency, 32 partial biotinidase, 6 congenital adrenal hyperplasia, 1 cah due to 11 hydroxylase deficiency, 104 congenital primary hypothyroidism, 17 other hypothyroidism, 55 cystic fibrosis, 1 cf related metabolic syndrome, 2 galactosemia, 7 duarte galactosemia, 24 sickle cell disease, 5 hemoglobin c disease, 16 sickle hemoglobin c disease, 3 hemoglobin e disease, 2 beta thalassemia major, 1 sickle beta thalassemia, 1 hereditary persistence of fetal hemoglobin, 1 isovaleric acidemia, 15 transient tyrosinemias (treated), 1 tyrosinemia type II, 12 PKU, 16 hyperphenylalaninemia, 1 argininosuccinic acidemia, 1 hypermethioninemia, 1 long chain acyl-coA dehydrogenase deficiency, 16 medium chain acyl-coA dehydrogenase

deficiency, 3 short chain acyl-coA dehydrogenase deficiency, 2 very long chain acyl-coA dehydrogenase deficiency, 5 methylmalonic aciduria, 6 3- methylcrotonyl carboxylase deficiency, 1 homocystinuria, 1 carnitine deficiency due to maternal GA1, 2 glutaric acidemia type 1, 1 isobutyryl carboxylase deficiency.

PerkinElmer Genetics Inc. Screening Laboratory enters demographic and test result data daily Monday through Friday. The NNSP accesses this data via secure internet server on a 24 hour 7 day a week basis. A weekly download from the laboratory data is done to an SQL server maintained by the Department of Health and Human Services.

As part of the emergency preparedness plan, a back-up follow-up system is in place via secure internet connection to the laboratory data system using off-site laptops and wireless internet connections.

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. The laboratory also faxes all reports that are phoned, during weekday working hours.

The data system can 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 produces reports of low T4's with low TSH's for information purposes only.

The data system can 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 (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.

The NNSP facilitates consultation and referral between the newborn's primary care physician and/or newborn's parents and the appropriate pediatric sub-specialist. Two primary pediatric metabolists and two back-up pediatric metabolists are available through the University of Nebraska Medical Center (UNMC) and Children's Hospital metabolic clinics in Omaha. Pediatric endocrinology services are provided by one (1) primary and two (2) back up specialists at UNMC and Children's Hospital. Pediatric

hematology services are provided by groups of pediatric hematologists at UNMC and Children's hospital. Cystic Fibrosis services are available at the Accredited CF Center at UNMC and Children's Hospital in Omaha. A referral team for follow-up on SCID is coordinated by a pediatric hematologist, and includes a pediatric immunologist and pathologist. Genetics and Medically Handicapped Children's satellite clinics scheduled periodically across Nebraska also are available to serve families. A Pediatrician/geneticist is also available in Lincoln. Telemedicine services have expanded to reach every hospital in the State so the rural or somewhat remote areas can more readily access sub-specialty services as well.

C. PROJECT REQUIREMENTS

1. 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.

The contractor will analyze blood specimens, submitted by the birth hospitals and other designees from the State of Nebraska. Biochemical tests will be run on approximately 28,500 samples annually. These tests include:

a. CORE CONDITIONS

- i.** Argininosuccinic acidemia (ASA). Currently screened using proprietary interpretation method of tandem mass spectrometry.
- ii.** Beta-ketothiolase Deficiency (Mitochondrial Acetoacetyl-CoA Thiolase Deficiency or 3-ketothiolase Deficiency or BKT). Currently screened using proprietary interpretation method of tandem mass spectrometry.
- iii.** Biotinidase deficiency (BIO): 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 Positive screens reflex to DNA.
- iv.** Carnitine Uptake Defect (CUD): Currently screened using proprietary interpretation method of tandem mass spectrometry.
- v.** Citrullinemia (CIT): Currently screened using proprietary interpretation method of tandem mass spectrometry.

- vi. Congenital Adrenal Hyperplasia (CAH): Steroid 17-alpha hydroxy progesterone (17-OHP) using an FDA approved non-isotopic immunoassay 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.
- vii. 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.
- viii. Cystic Fibrosis (CF): A combination IRT/DNA screen is used. Initial Immunoreactive trypsinogen results in the top 1.2% of the run reflex to DNA for the $\Delta F508$ mutation. If no $\Delta F508$ is found the test result is reported as inconclusive and repeat specimen requested. If one copy of $\Delta F508$ is present, the specimen is reflexed again to a 39 + 4 mutation panel. Whether one or two mutations, the infant is recommended for referral to Accredited CF Center. If the inconclusives on repeat continue to be elevated, they reflex at that point to the 36 + 4 mutation panel. Whether zero, one or two mutations, the infant is recommended for referral to 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.
- ix. Galactosemia (GAL): 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. All samples with UT > 40 μ Mol are reported as normal. Samples with UT < 40 μ Mol will be reported as positive and will reflex to DNA.
- x. 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. Repeat screening results that continue to be abnormal reflex to DNA.
- xi. Hemoglobinopathies: Isoelectric focusing to detect hemoglobins F, A, S, C, D, E, O-Arab, Barts and other variant hemoglobins greater than A. When variant hemoglobin is 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.

- xii.** Homocystinuria (HCY): Currently screened using proprietary interpretation method of tandem mass spectrometry.
- xiii.** Isovaleric Acidemia (IVA): Currently screened using proprietary interpretation method of tandem mass spectrometry.
- xiv.** 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.
- xv.** Maple Syrup Urine Disease (MSUD): Currently screened using proprietary interpretation method of tandem mass spectrometry.
- xvi.** Medium Chain Acyl Co-A Dehydrogenase Deficiency (MCAD): Tandem Mass Spectrometry analysis. Screening results highly suspicious for MCAD reflex to DNA, repeat screening results that continue to be abnormal reflex to DNA.
- xvii.** Methylmalonic Acidemia (Mutase Deficiency): Currently screened using proprietary interpretation method of tandem mass spectrometry.
- xviii.** Methylmalonic Acidemia (Cbl. A, B): Currently screened using proprietary interpretation method of tandem mass spectrometry.
- xix.** Multiple Carboxylase Deficiency: Currently screened using proprietary interpretation method of tandem mass spectrometry.
- xx.** Phenylketonuria (PKU): Currently screened using proprietary interpretation method of tandem mass spectrometry.
- xxi.** Propionic (PA): Currently screened using proprietary interpretation method of tandem mass spectrometry.
- xxii.** 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.) To begin upon adoption of regulations.
- xxiii.** Tri-Functional Protein Deficiency (TFP): Currently screened using proprietary interpretation method of tandem mass spectrometry.
- xxiv.** Tyrosinemia (TYR): Currently screened using proprietary interpretation method of tandem mass spectrometry and includes analysis of succinylacetone (SUAC).
- xxv.** Very Long Chain Acyl-CoA Dehydrogenase Deficiency (VLCAD): Currently screened using proprietary interpretation method of tandem mass spectrometry.
- xxvi.** 3-Hydroxy 3-Methyl Glutaric Aciduria (HMG): Currently screened using proprietary interpretation method of tandem mass spectrometry.
- xxvii.** 3-Methylcrotonyl-CoA Carboxylase Deficiency (3-MCC): Currently screened using proprietary interpretation method of tandem mass spectrometry.

All specimens collected at less than 24 hours are tested for all conditions except CAH, CPH and CF. All initial specimens collected at > 24 hours of life are tested for all conditions. All repeats > 24 hours of life and collected due to the initial specimen being less than 24 hours at collection will be tested for all conditions. All repeats 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 repeats collected due to a prior inconclusive screening result will be tested for the condition found inconclusive. All repeats collected due to being the 28 day or discharge specimen for newborns < 2000 grams admitted to the NICU, will be tested for all conditions on the screening panel. All of the above requested repeats shall be repeated at no additional charge and so costs shall be considered and included in the per infant testing fee when determining the total bid.

By signing this Request for Proposal for Contractual Services form bidder guarantees compliance with the requirements in Appendix F.

2. The regulations require all infants born in the state of Nebraska must be tested for the 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 the diseases listed at Number 1 above.
3. The contractor will purchase the Nebraska Newborn Screening Program Collection and Reporting Form 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.
4. 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) for next day delivery to the contractor's 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 with 400 or more births per year where a commercial courier is available to provide that service. Saturday delivery to the laboratory shall be provided for specimens shipped Fridays. The contractor shall also monitor the courier service for performance and timeliness. 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).
5. The contractor will report all results to the NNSP according to the Project Requirements Section IV, E. 3 of this RFP. Adherence to strict turnaround times is critical.
6. A computerized system shall be maintained and updated to allow remote access by or transmission to the Nebraska Newborn Screening Program 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 Nebraska Newborn Screening Program; 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 Nebraska Newborn Screening Program 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.

7. 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 Nebraska Newborn Screening Program 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 Nebraska Newborn Screening Program for a period no less than 29 years from the date of the test.
8. Timeliness and accuracy of data entry, and accessibility is critical for 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 maintain follow-up until adequate specimens are submitted, diagnosis is ruled out, or diagnosis is confirmed and the infant is in treatment or according to NNSP written procedures the infant is determined lost to follow-up.
9. 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 Protection and Portability Assurance 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 Program Manager and Follow-up personnel on how to use the applications.
10. The laboratory shall maintain a listing of qualified specialists in pediatric endocrine, metabolic, hemoglobin disorders, immunodeficiencies, 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.

11. Strict confidentiality of medical information will be maintained in all stages of testing and reporting.
12. 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 (See regulations, Appendix B). 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 Title 181, NAC 2 Regulations Governing Screening of Infants for Metabolic Diseases. Documentation of the storage, use and disposal of the residual dried blood spots shall be made available to the Nebraska Newborn Screening Program upon request at no additional charge.

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 proposal should describe how 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.

13. Provide consultation and education to the Nebraska Newborn Screening Program staff and others, upon request of the NNSP, and as needs are identified by the contracting laboratory, on:
 - a. 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.
 - b. Accessing the laboratory results database.
 - c. Any problematic trends identified by the contracting lab with specimen collection, transport, testing, reporting or other communication problems.
14. Compliance with all Nebraska statutes and regulations relative to newborn screening (Appendix B), the quality assurance measures (Appendix E), and applicable clinical and newborn screening laboratory standards (e.g. Clinical & Laboratory Standards Institute (CLSI), CLIA, Association of Public Health Laboratories-APHL, Association of State and Territorial Public Health Laboratory Directors-ASTPHLD, and MMWR Recommendations and Reports "Using Tandem Mass Spectrometry for Metabolic Disease Screening Among Newborns", April 13, 2001/Vol. 50/No. RR-3).

D. PROJECT REQUIREMENTS TO BE ADDRESSED IN TECHNICAL APPROACH OF PROPOSAL RESPONSE

The Department of Health and Human Services, Nebraska Newborn Screening Program desires to enter into a contract with a single laboratory to conduct all of the newborn screening laboratory tests for all Nebraska births. The selected contractor must comply with Title 181, NAC 2 Regulations Governing Screening of Infants for Metabolic Diseases. (See Appendix B) The selected contractor will be responsible for supplying filter paper test kits, laboratory testing, results and interpretation for the detection of a core set of treatable, inherited disorders of newborns and complete data. The Department of Health and Human Services, Nebraska Newborn Screening Program intends to contract with a laboratory, to include but is not limited to the following:

1. rapid transport for specimens from the birthing hospitals/facilities to the laboratory;
2. accurate and timely laboratory testing and analysis;
3. accurate and timely communication of results;
4. accurate, timely and comprehensive electronic reporting of data (demographic and test results, follow-up and quality assurance reports);
5. collection and remittance of the \$10 per infant screened fees to the State;
6. participation in quality assurance programs and reporting of quality assurance data; and,
7. 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 Nebraska Newborn Screening Program.

E. THE BIDDER'S PROPOSAL RESPONSE MUST ADDRESS THE FOLLOWING:

Describe work-flow procedures including specifying the employee by title/position responsible for implementing, those responsible for supervising, and those responsible for managing (if other than the supervisor) each component of the work necessary to complete the following:

1. SPECIMEN KIT SUPPLY AND TRANSPORT

(Note: See regulations Appendix B and Sample filter paper collection device Attachment 2 of Appendix B).

The bidder's proposal response must describe:

- a. How the bidder will provide the Nebraska Newborn Screening Program Collection and Reporting form, filter paper specimen collection kits to hospitals/birthing facilities for the collection of blood specimens and necessary demographic information. Filter paper must be purchased by the laboratory. The laboratory must ship filter paper supplies to Nebraska birthing facilities. The laboratory must describe methods to document tracking of which filter paper specimen collection devices were provided to which birthing hospital/facility and communicating this

information to the NNSP. All costs associated with this transport shall be incurred by the laboratory and incorporated into the per-infant screened laboratory charges. The bidder must describe how they will pro-actively work with submitters to reduce the risk of expired filter paper being used to collect dried blood spot specimens.

- b.** How shipment of specimens from the birth hospitals to the laboratory will be handled, including tracking of specimens. Include if applicable, the name of the courier service, or how one or more will be selected. The method and any applicable subcontractor arrangements that will be in place to ensure rapid transport for specimens from the birthing hospitals/facilities to the laboratory. Include descriptions of how the laboratory will monitor the performance of the shipping/courier company(s) used for transporting Nebraska specimens, and how this quality assurance information specific to Nebraska specimen transport will be communicated with the NNSP. 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) for next day delivery to the contractor's 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 with 400 or more births per year where a commercial courier is available to provide that service. Saturday delivery to the laboratory shall be provided for specimens shipped Fridays. The contractor shall also monitor the courier service for performance and timeliness. 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).
- c.** How all costs associated with this specimen transport will be incurred by the laboratory and incorporated into the per-infant screened laboratory charges that will be billed to the specimen submitter.
- d.** Methods to minimize the possible effects of irradiation, heat and humidity or moisture on the specimens must be described as well as specifications for specimen handling and envelopes or containers used to transport the specimens.
- e.** Specimen transport methods that enable hospitals to send specimens within 24 hours after collection with exceptions for weekend and holiday days if no transport system is available. Holidays during which no transport is available must be identified. The proposal must describe a method that discourages batching (sending specimens collected over a several day period all at one time).

2. LABORATORY TESTING AND ANALYSIS

The bidder's proposal response must describe or provide (as appropriate to the question):

- a. How laboratory testing on dried-blood spot specimens will be performed for each of the core set of conditions listed in this RFP. 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 C, and respond to E and F. However, data supporting the sensitivity and specificity of these methods must be provided as part of the proposal as well.

The contractor shall describe which disorders within these classifications, beyond those listed above, 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 C must be completed identifying for each condition/ analyte screened the # of specimens screened, # of abnormal screens reported out, and the # of confirmed conditions associated with that screen.

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 Nebraska Newborn Screening Program within 30 days following contract award date.

The contractor will provide a description of other screening tests available in their laboratory (beyond those required in this RFP) including estimated incidence of the disorder and a description of the laboratory's experience in using the test relative to how long the test has been used, # of specimens tested, # of abnormal results, # of confirmed diagnoses.

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 Advisory Committee for consideration. All changes must be made in writing through an amendment to the contract prior to the institution of changes.

- b.** Data for the laboratory regarding the false positive rate per year for each of the tests performed, (see tables in Appendix C), 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 C) and return with bidder's proposal response.
- c.** Specifically, each analytical methodology and instrument used and description of available methods for method/backup/confirmation. (e.g. Beuter and Baluda back-up for Biotinidase testing if primary testing instrument were to be unavailable).
- d.** Specifically any 2nd tier or reflex testing proposed as part of the screen. (E.g. DNA mutations on a new punch from the initial sample for elevated Immunoreactive Trypsinogen CF results.) If DNA is used as a 2nd tier or reflex test, specify which mutations or polymorphisms are tested. (Include in response to Appendix F).
- e.** Specifically, for which type of results (e.g. unsatisfactory specimens, inconclusive or borderline test results for "x" condition) a repeat dried blood spot filter paper specimen would be requested (vs. confirmatory serum, plasma or other). Requested repeats for specimens collected at less than 24 hours, that are unsatisfactory, collected post transfusion, are indeterminant because of multiple elevations of amino acids indicating hyperalimentation, or requested because of inconclusive findings shall not be charged for separately.
- f.** Disaster response plans to provide laboratory testing of the newborn screening specimens in the event of emergency, 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. If the response plan includes written agreements with other laboratories, it 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 D, of this proposal.
- g.** The other newborn screening and confirmatory tests 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. See V. B, Cost Proposal Requirements.

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.

- h.** Individually, 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, 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.
- i.** The laboratory's policy on testing vs. rejecting specimens that are determined unsatisfactory - (e.g. when there is not enough blood to test the full panel, identify the priority for which diseases get tested). The laboratory's policy on testing vs. rejecting specimens that are drawn too early (less than 24 hours of age), (e.g. test all but CAH, CPH and CF and request a specimen to screen for CAH, CPH, CF and amino acidopathies). The laboratory's policy on testing specimens collected post-transfusion. Explain if these policies differ from the Nebraska policies, how the laboratory will adjust their operating practices to be able to consistently implement the Nebraska policy.

3. COMMUNICATION / DATA

Provide documentation of protocols describing how the bidder will assure that reporting will meet the following standards. For electronic documentation/reporting protocols, describe security measures that will ensure compliance with HIPAA standards for transmission to or access to data to the NNSP, submitters/hospitals, and if appropriate physicians/health care practitioners.

- a.** All demographic information required on the NNSP CARE form (filter paper collection device, Attachment 2 of regulations, Appendix B) 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.

- b. 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 bidding laboratory. When these are not done at the bidding 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.

Written reports of all initial, repeat and confirmatory test (normal and abnormal) results conducted by the contracted laboratory must be sent to the submitter within 24 hours of test completion. The contractor should describe and provide an example of a written lab result report.

- c. The laboratory report format and explanatory comments will be determined, as mutually agreed upon by the laboratory and the Nebraska Newborn Screening Program. The Laboratory report format will include identification for each disorder screened by tandem mass spectrometry (MS/MS); 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 normal reference range for each analyte. Comments must be agreed to by the Nebraska Newborn Screening Program, and should identify for which condition the abnormality is “inconclusive” or “presumptive 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 Nebraska Newborn Screening Program.

For conditions screened by MS/MS the laboratory report will list a result for the acylcarnitine profile and the amino acid profile as WNL or “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 Nebraska Newborn Screening Program 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.

- d. The laboratory will report every “positive” and/or abnormal screening result immediately via phone and in writing to the Nebraska Newborn Screening Program, 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. 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.
- e. The laboratory will report immediately via phone and in writing to the Nebraska Newborn Screening Program, 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 exceptions need only be reported within twenty-four (24) hours 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 cystic fibrosis. 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 Nebraska Newborn Screening Program. 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.
- f. The electronic data system must have the capacity to “flag” and report on specimens drawn early (less than 24 hours of age), unsatisfactory specimens, presumptive positive specimens, specimens collected post transfusion, and tests missing. This capacity must exist upon entry of the data via a validation procedure or some other automatic response from the database application.

- g.** The electronic data system must have the capacity to produce template letters populated with patient and health care practitioner demographic information as well as 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.
- h.** Describe the procedure to identify and merge/eliminate duplicate records. Specifically, how are multiple (two or more) records on the same infant identified when the infant has more than one specimen, and what is the mechanism to merge these into one record.
- i.** Data entry errors shall be reported by phone to the NNSP within 24 hours of discovery of such errors.
- j.** Quality assurance reports will be provided to the NNSP or available for the NNSP to produce from the data system, within 10 days following the end of each quarter (July-Sept, Oct-Dec, Jan-March, April-June). These reports shall include statistical values for initial screening results for all diseases screened for which a quantitative value is obtained. Statistical values include the mean, median, mode, standard deviation, p. value, and the 25th and 75th quartile (range). (See Appendix E)

Other reports required to be provided that are essential for follow-up (See Appendix E):

- i.** Number of newborns screened (initial specimens only)
- ii.** Newborns drawn early
- iii.** Newborns with unsatisfactory specimens and reasons why
- iv.** Newborns collected post-transfusion
- v.** Newborns reported with meconium ileus or other bowel obstruction
- vi.** Newborns suspected or known to have received hyperalimentation
- vii.** Newborns with inconclusive (abnormal but not positive) results
- viii.** Number presumptive positive for each disease screened
- ix.** Number confirmed positive for each disease screened (when known)
- x.** Number confirmed negative for each disease screened (when known)

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.

Other reports required to be provided that are essential for quality assurance: (See Appendix E):

- i. Age at time of collection for initial specimens
 - ii. Turnaround time (TAT) for initial galactosemia results for each submitter shall include: minimum, maximum, mean, median, mode
 - iii. TAT for initial galactosemia results for each submitter from birth to collection, collection to receipt at the laboratory, laboratory receipt to test completion/results availability.
 - iv. Quarterly hospital quality assurance reports comparing individual hospital numbers and mean averages to Statewide numbers and mean averages for the measures of:
 - a) Newborns born in the facilities
 - b) Initial newborn specimens submitted
 - c) Total specimens
 - d) Unsatisfactory specimens
 - e) Specimens drawn early(< 24 hours)
 - f) Initial specimens collected post-transfusion
 - g) Average turn-around time from birth to report
 - h) Average time from birth to collection
 - i) Average time from collection to receipt by the laboratory
 - j) Average time from receipt to report
 - k) Total average time from birth to report
 - v. Capacity for generating ad-hoc reports for quality assurance on variable date ranges and variable data elements.
 - vi. 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 after the new filter paper form with NICU demographics is fully implemented/distributed. New reports shall be operational within 6 months after distribution of the new filter paper to all Nebraska facilities that have neonatal intensive care units. The new filter paper shall be distributed within 4 months of promulgation the regulation revisions that adopt the new filter paper format.
 - vii. Other reports will need to be developed to function for follow-up and tracking and for quality assurance upon the implementation of screening for SCID when the regulation revisions are adopted.
- k.** 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 site.
- l.** Copies of quarterly proficiency testing results from participation in the Centers for Disease Control and Prevention's proficiency testing program shall be made available to the NNSP within 30 days of receipt of such reports by the laboratory. Any errors in classification or results grossly

out of the norm must have documentation of corrective action taken and be shared with the NNSP.

- m. Copies of any CLIA (Clinical Lab Improvement Assessment) and CAP (College of American Pathologists) reports or other professional or licensing reviews of the laboratory shall be provided to the NNSP within 30 days of receipt of such reports by the laboratory.
- n. Copies of any CLIA and CAP certifications shall be submitted with the response to the RFP, and copies of all renewals shall be submitted to the NNSP within 30 days of receipt of those.
- o. A copy of the laboratory's policies and procedures relevant to newborn screening and confirmatory testing shall be provided to the NNSP within 30 days following the contract date of award. A copy of all relevant updates to the policies and procedures must be provided to the NNSP prior to the effective date of the update.
- p. How the laboratory will document communication with submitters and physicians regarding unsatisfactory specimens, drawn early specimens, presumptive positive 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.
- q. How, 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).

4. BILLING/REMITTANCE OF FEES

- a. The laboratory must describe procedures for the billing of submitters/hospitals to include a single fee per infant screened. The single fee per infant screened shall 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, as well as the \$10 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.
- b. 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.

- c. The laboratory must describe procedures for the monthly remittance of the \$10 per infant screened administrative fee to the Nebraska Department of Health and Human Services, NNSP.

5. STAFFING

- a. 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.)

F. BUSINESS REQUIREMENTS TO BE ADDRESSED IN PROPOSAL RESPONSE

1. BIDDER'S QUALIFICATIONS, EXPERIENCE AND CAPACITY

Bidder's shall provide a summary that lists their previous work similar to the services as requested in this RFP, in size, scope and complexity. Bidder's response to this section should satisfy the requirements in Section V. A. 7. h. of this RFP. Responses should describe the bidder's qualifications, experience and capacity relative to these specific areas:

- a. Overall ability to perform the newborn screening.
- b. Laboratory instrumentation, methods, backup capabilities (Describe the methodology used to test for each disorder).
- c. 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.
- d. 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).
- e. Number of tests currently performed each year for each disorder listed in the core testing requirements in this RFP.
- f. Describe the organization's current licensures, accreditations and certifications. (Provide copies of relevant paperwork).
- g. Availability of qualified and experienced personnel, facilities, general environment and resources for the proposed services.
- h. Familiarity and experience consulting with the medical community relative to conditions included in the core newborn screening panel.
- i. Information management systems.

Bidder shall describe their capacity in terms of qualifications, experience and resources dedicated to addressing the following elements:

- a. Current analytical workload, turnaround time (in-lab and collection to completion), and capacity to add Nebraska's specimens to existing workload.
- b. Clinical consultation experience for metabolic, endocrine, hemoglobin, pulmonologic and immunologic disorders.
- c. 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 Nebraska Newborn Screening Program.
- d. Outline a transition plan that, if awarded the contract, would be implemented to ensure a smooth transition by July 1, 2013. Plan should include communication paths with NNSP staff and DHHS information technology staff, and methods.
- e. Ability to offer full service to Nebraska by July 1, 2013.
- f. Adequacy of plans for the administration of the program.

G. TECHNICAL REQUIREMENTS TO BE ADDRESSED IN THE PROPOSAL RESPONSE

1. Explain laboratory policies and procedures that are/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:

a. STANDARD AND SAMPLE PREPARATION

- i. Sample preparation technique validation
 - a) Quality of reagents, buffers and solvents
 - b) Validation of methods
 - c) Use of internal standards for analysis, and where not available validation of other isotopes
 - d) Validation of dilutions of commercial standards or in-house preparations
 - e) Documentation of validation of internal standards and quality-control preparations
 - f) Safety recommendations, universal precautions, personal protective gear and environmental controls that are required.
 - g) Good laboratory and measurement practices to be followed

b. INSTRUMENT RESOURCES AND CALIBRATION

- 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

h. REDUCING INSTRUMENT-TO-INSTRUMENT VARIABILITY

- i. Definition of minimum sensitivity threshold, and concentration calculations using ion ratios.

i. QUALITY CONTROL

- i. Quality control specimens, (which are used, concentrations of these, how used)
- ii. Use of reagent blank
- iii. Monitoring of daily patient mean or median for each analyte
- iv. Routine maintenance schedule
- v. Participation in external quality-control and proficiency testing program(s).
- vi. 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.

j. INTERPRETING MS/MS DATA AND REPORTING RESULTS

- i. Description of how cut-off levels are/will be determined using statistical measurements in consultation with metabolic disease specialists.
- ii. How the laboratory has/will establish the cut-off values at which concentrations greater than "x" require immediate reporting and follow-up.
- iii. 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.
- iv. 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, rationale of why, and for which analytes, and what procedures are recommended for initial reporting, follow-up, consultation, confirmation and diagnosis.

- v. 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.
- vi. 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.
- vii. Describe how the contractor will address accommodations for any future needs to make changes to the data collected and entered into the data system.
- viii. Describe current compatibility or plans to become compliant with HL7 coding requirements 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.
- ix. 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.

H. PROJECT PLANNING AND MANAGEMENT

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 July 1, 2013.

I. EVALUATE CURRENT PROJECT ENVIRONMENT

Describe the contractor's current environment for carrying out the project, and any necessary changes or additions that will need to take place in order to add the workload of the Nebraska specimens and other requirements of this RFP.

J. PERFORM IMPLEMENTATION

Identify resources (infrastructure of personnel, facilities, equipment, written procedures, ongoing staff development etc.) that will be committed to the project to ensure successful implementation.

K. PROVIDE POST IMPLEMENTATION SUPPORT

Identify resources that will be maintained in order to continue implementation of the contract. Demonstrated commitment to ongoing support must be evident.

L. DELIVERABLES

1. Purchase, distribute and track filter paper collection kits to all birthing hospitals/facilities in Nebraska.
2. 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 Nebraska regulations Title 181, NAC 2 and as agreed upon in the contract resulting from this RFP on all specimens received, for the core panel of diseases.
4. Phone and written reporting of screening test results and acceptability of specimens (drawn early, unsatisfactory or transfused) as required in Nebraska regulations Title 181, NAC 2 to the NNSP, submitter, and newborn's physician.
5. Timely electronic entry of all data required on Nebraska's Newborn Screening Program Collection and Reporting form, 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 Technical 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 to the Nebraska Department of Health and Human Services, NNSP of the \$10 per infant screened administrative fee.
9. Storage, disposal and retrieval of residual dried blood spots as specified in this RFP.

V. PROPOSAL INSTRUCTIONS

This section documents the mandatory requirements that must 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:

A. TECHNICAL PROPOSAL

The Technical Proposal shall consist of four (4) sections:

1. The SIGNED, in ink, "State of Nebraska Request for Proposal for Contractual Services" form;
2. Executive Summary;
3. Corporate Overview; and
4. Technical Approach to the Project Requirements in Section IV including responses to Appendices C, E and F.

1. REQUEST FOR PROPOSAL FORM

By signing the "Request for Proposal For Contractual Services" form, the bidder guarantees compliance with the provisions stated in this Request for Proposal, agrees to the Terms and Conditions stated in this Request for Proposal and certifies they maintain a drug free work place.

The Request for Proposal for Contractual Services form must be signed in ink and returned by the stated date and time in order to be considered for an award.

2. EXECUTIVE SUMMARY

The Executive Summary shall condense and highlight the contents of the solution being proposed by the bidder in such a way as to provide the Evaluation Committee with a broad understanding of the Contractor's Technical Proposal.

Bidders must present their understanding of the problems being addressed by implementing a new system, the objectives and intended results of the project, and the scope of work. Bidders shall summarize how their Technical Proposal meets the requirements of the Request for Proposal, and why they are best qualified to perform the work required herein.

3. CORPORATE OVERVIEW

The Corporate Overview section of the Technical Proposal must consist of the following subdivisions:

a. BIDDER IDENTIFICATION AND INFORMATION

The bidder must 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, whether the name and form of organization has changed since first organized, and Federal Employer Identification Number and/or Social Security Number.

b. FINANCIAL STATEMENTS

The bidder must provide financial statements applicable to the firm. If publicly held, the bidder must 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 must 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 must 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.

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 must 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 must be identified.

e. RELATIONSHIPS WITH THE STATE

The bidder shall 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 shall 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 twelve (12) 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 which termination occurred before completion of all obligations under the initial Contract provisions, describe fully all such termination including the name and address of the other contracting party, and the circumstances surrounding the termination. If no such early termination has occurred, so declare.

h. SUMMARY OF BIDDER'S CORPORATE EXPERIENCE

The bidder shall provide a summary matrix listing the bidder's previous projects similar to this Request for Proposal 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 must address the following:

- i. Bidder must provide narrative descriptions to highlight the similarities between their experience and this Request for Proposal. These descriptions must 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 shall identify whether the work was performed as the prime Contractor or as a subcontractor. If a bidder performed as the prime Contractor, the description must 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 must be listed separately. Narrative descriptions submitted for subcontractors must be specifically identified as subcontractor projects.
 - iii. If the work was performed as a subcontractor, the narrative description shall identify the same information as requested for the Contractors above. In addition, subcontractors shall identify what share of Contract costs, project responsibilities, and time period were performed as a subcontractor.

i. SUMMARY OF BIDDER'S PROPOSED PERSONNEL/MANAGEMENT APPROACH

The bidder must present a detailed description of its proposed approach to the management of the project.

The bidder must identify the specific professionals who will work on the State's project if their company is awarded the Contract resulting from this Request for Proposal. The names and titles of the team proposed for assignment to the State project shall 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 shall 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 Request for Proposal in addition to assessing the experience of specific individuals.

Resumes must not be longer than three (3) pages. Resumes shall 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.

j. SUBCONTRACTORS

This RFP is intended to contract with a single laboratory to complete all of the testing for all required newborn screening tests. Proposals that include subcontracting part of the testing to another laboratory will not be accepted. If the bidder intends to subcontract any other part of its performance hereunder, the bidder must 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.

4. TECHNICAL APPROACH

The technical approach section of the Technical Proposal must consist of the following subsections.

- a. Understanding of the Project Requirements;
- b. Proposed Development Approach;
- c. Technical Considerations; including responses to Appendices C, E, and F; and
- d. Deliverables.

B. COST PROPOSAL REQUIREMENTS

This section describes the requirements to be addressed by bidders in preparing the Cost Proposal. The bidder must submit the Cost Proposal in a section of the proposal that is separate section or is packaged separately as specified in this RFP from the Technical Proposal section.

The component costs of the fixed price proposal for providing the services set forth in the Request for Proposal must be provided by submitting forms substantially equivalent to those described below.

1. PRICING SUMMARY

This summary shall present the total fixed price to perform all of the requirements of the Request for Proposal. The bidder must include details in the Cost Proposal supporting any and all costs. These details must include, at a minimum, detailed descriptions and/or specifications of the goods and/or services to be provided, quantities, and timing and unit costs, if applicable.

The State reserves the right to review all aspects of the Cost Proposal 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.

- 2. Prices quoted shall be net, including transportation and delivery charges fully prepaid by the bidder, F.O.B. destination named in the Request for Proposal. 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. PAYMENT SCHEDULE

This is a contract of exclusivity 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 of \$10 per infant shall be submitted monthly to the Nebraska Newborn Screening Program 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.)

The Cost Proposal shall identify:

Specimen testing cost for the screening panel as described in this RFP without SCID: _____ + \$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 SCID if it is adopted via regulation: _____ \$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.

Alternative pricing is also being requested for the addition of any testing for conditions not listed in this RFP. Additional costs should be listed individually for each condition, unless part of a multi-plex assay in which case a single cost for the group of conditions should be listed. The alternative pricing will not be part of the evaluation of this Request for Proposal.

Form A

Bidder Contact Sheet

Request for Proposal Number 4229Z1

Form A should be completed and submitted with each response to this Request for Proposal. 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 shall 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:	

Appendix A

Nebraska Births 2011

Request for Proposal Number 4229Z1

NEBRASKA BIRTHS, 2011	
HOSPITAL	Births
TOTAL	26095
ALBION, BOONE COUNTY HEALTH CENTER	92
ALLIANCE, BOX BUTTE GENERAL HOSPITAL	75
AURORA, MEMORIAL HOSPITAL	53
BEATRICE COMMUNITY HOSPITAL & HEALTH CENTER	149
BELLEVUE MEDICAL CENTER	621
BELLEVUE, THE MIDWIFE'S PLACE	3
BENKELMAN, DUNDY COUNTY HOSPITAL	10
BLAIR, MEMORIAL COMMUNITY HOSPITAL	74
BROKEN BOW, JENNIE M. MELHAM MEMORAL MEDICAL CENTER	74
CAMBRIDGE MEMORIAL HOSPITAL	46
CHADRON COMMUNITY HOSPITAL	129
COLUMBUS COMMUNITY HOSPITAL	564
COZAD COMMUNITY HEALTH SYSTEMS	31
CRETE AREA MEDICAL CENTER	91
DAVID CITY, BUTLER COUNTY HEALTH CARE CENTER	88
FAIRBURY, JEFFERSON COMMUNITY HEALTH CENTER	33
FALLS CITY, COMMUNITY MEDICAL CENTER, INC.	61
FREMONT AREA MEDICAL CENTER	327
GENEVA, FILLMORE COUNTY HOSPITAL	32
GOTHENBURG MEMORIAL HOSPITAL	24
GRAND ISLAND, SAINT FRANCIS MEDICAL CENTER	912
GRANT, PERKINS COUNTY COMMUNITY HOSPITAL	45
HASTINGS, MARY LANNING MEMORIAL HOSPITAL	733
HEBRON, THAYER COUNTY HEALTH SERVICES	33
HENDERSON HEALTH CARE SERVICES, INC.	17
HOLDREGE, PHELPS MEMORIAL HEALTH CENTER	115
IMPERIAL, CHASE COUNTY COMMUNITY HOSPITAL	26
KEARNEY, GOOD SAMARITAN HEALTH SYSTEMS	995
LEXINGTON, REGIONAL HEALTH CENTER	56
LEXINGTON, TRI-COUNTY AREA HOSPITAL	116
LINCOLN, BRYAN LGH MEDICAL CENTER EAST	2511
LINCOLN, ST. ELIZABETH REGIONAL MEDICAL CENTER	2233
MCCOOK, COMMUNITY HOSPITAL	132
NEBRASKA CITY, ST. MARY'S COMMUNITY HOSPITAL	133

NEBRASKA NON-HOSPITAL BIRTHS	107
NELIGH, ANTELOPE MEMORIAL HOSPITAL	21
NEMAHA COUNTY HOSPITAL	1
NORFOLK, FAITH REGIONAL HEALTH SERVICES	928
NORTH PLATTE, GREAT PLAINS REGIONAL MEDICAL CENTER	567
O'NEILL, AVERA ST. ANTHONY'S HOSPITAL	165
OGALLALA COMMUNITY HOSPITAL	80
OMAHA, ALEGENT HEALTH BERGAN MERCY MEDICAL CENTER	3465
OMAHA, ALEGENT HEALTH IMMANUEL MEDICAL CENTER	577
OMAHA, ALEGENT HEALTH LAKESIDE HOSPITAL	1160
OMAHA, CREIGHTON UNIVERSITY MEDICAL CENTER	1133
OMAHA, METHODIST WOMEN'S HOSPITAL	3500
OMAHA, NEBRASKA MEDICAL CENTER-CLARKSON	446
OMAHA, NEBRASKA MEDICAL CENTER-UNIVERSITY	1463
OMAHA, NEBRASKA METHODIST HOSPITAL	1
ORD, VALLEY COUNTY HOSPITAL	1
OSCEOLA, ANNIE JEFFREY MEMORIAL COUNTY HEALTH CENTER	21
PAPILLION, ALEGENT HEALTH MIDLANDS HOSPITAL	314
PENDER COMMUNITY HOSPITAL	57
SCHUYLER, ALEGENT HEALTH-MEMORIAL HOSPITAL	61
SCOTTSBLUFF, REGIONAL WEST MEDICAL CENTER	795
SEWARD, MEMORIAL HOSPITAL	108
SIDNEY, MEMORIAL HEALTH CENTER	62
ST. PAUL, HOWARD COUNTY MEDICAL CENTER	46
SUPERIOR, BRODSTONE MEMORIAL HOSPITAL	47
TECUMSEH, JOHNSON COUNTY HOSPITAL	25
VALENTINE, CHERRY COUNTY HOSPITAL	95
WAYNE, PROVIDENCE MEDICAL CENTER	39
WEST POINT, ST. FRANCIS MEMORIAL HOSPITAL	59
YORK GENERAL HOSPITAL	117

(Plus in 2012 a new provider/submitter was added, "The Midwife's Place" with 108 births in 2012)

Appendix B

Current Regulations, Title 181, NAC 2

Request for Proposal Number 4229Z1

EFFECTIVE 7/2/11 NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 2 SCREENING OF INFANTS FOR METABOLIC DISEASES

2-001 SCOPE: These regulations implement the law governing screening of infants for metabolic diseases, Neb. Rev. Stat. §§ 71-519 to 71-524. These regulations define terms; state the requirements for screening for metabolic diseases; specify the diseases for which tests are required; specify the time periods for performance and reporting of results of the tests by physicians, hospitals, laboratories, and births not attended by a physician; and prescribe the mechanism for determining tests, test methods and techniques, and such reports and reporting procedures as are necessary to implement the law.

2-002 DEFINITIONS: As used in these regulations, unless the context otherwise requires:

Argininosuccinic Acidemia (ASA) means a disorder of amino acid metabolism in which an enzyme defect in the urea cycle results in elevated ammonia and citrulline. If not identified and left untreated, infants develop failure to thrive, seizures, lethargy and coma, and later onset of mental retardation.

Beta-ketothiolase Deficiency (also known as Mitochondrial Acetoacetyl-CoA Thiolase Deficiency or 3-Ketothiolase deficiency or BKT) means a disorder of organic acid metabolism in which an enzyme defect results in the accumulation of isoleucine and related metabolites. If not identified and left untreated, metabolic crisis may occur with coma or death, mental retardation, cardiac abnormalities and other physical problems.

Biotinidase Deficiency (BIOT) means a metabolic disease that results in an inability to recycle and conserve the vitamin biotin which, if not identified and left untreated, may lead to mental retardation, seizures, hearing loss, and dermatitis.

Carnitine Uptake Defect (CUD) means a disorder of fatty acid metabolism in which there is a defect in the transport of carnitine into the tissues. This prevents fatty acid metabolism and limits energy production. If not identified and left untreated, patients develop cardiomyopathy, fasting hypoglycemia and muscle disease. (Carnitine Uptake Defect might not be detected during the immediate newborn period.)

Citrullinemia (CIT) means a disorder of amino acid metabolism in which an enzyme defect in the urea cycle results in hyperammonemia and elevated citrulline. If not identified and left untreated, infants develop failure to thrive, vomiting, seizures, lethargy, coma and later onset of mental retardation.

Confirmatory Test means a test or a panel of tests performed following a presumptive positive screening test which provides additional, more specific diagnostic information concerning the existence or non-existence of diseases screened for.

Congenital Adrenal Hyperplasia (CAH) means a genetic disorder which results in the adrenal glands producing too little or no cortisol, insufficient aldosterone, and too much androgen. If not identified and left untreated, this can result in classical salt-losing CAH or an adrenal crisis that can result in sudden death.

Congenital Primary Hypothyroidism (CPH) means a disease characterized by a congenital deficiency or absence of thyroid hormone (thyroxine) which, if not identified and left untreated, may lead to mental and growth retardation.

Cutoff Value means a value on a screening test for a specific metabolic disease which gives a high degree of probability that all newborns with a greater or lower value, depending on the test method, will not have the metabolic disease.

Cystic Fibrosis (CF) means a genetic disorder in which mutations alter the structure, function, or production of a transmembrane chloride channel protein which in turn can affect the function of the lungs, upper respiratory tract, gastrointestinal tract, pancreas, liver, sweat glands, and genitourinary tract. Early diagnosis and treatment results in improved outcomes for affected patients.

Department means the Department of Health and Human Services of the State of Nebraska.

Galactosemia (GALT) means a disease of galactose metabolism which, if not identified and left untreated, may lead to failure to thrive, vomiting, liver disease, cataracts, and mental retardation.

Glutaric Acidemia type I (GAI) means a disorder of organic acid metabolism in which an enzyme defect results in increased glutaric acid and its metabolites. If not identified and left untreated children develop metabolic acidosis, failure to thrive, mental retardation and sudden onset of seizures, spasticity and movement problems.

Hemoglobinopathies (Hb SS, Hb S/βTh, Hb S/C) means a group of genetic disorders characterized by production of abnormal hemoglobin which may cause clinical disease including anemia or oxygen carrying difficulties.

Homocystinuria (HCY) means a disorder of amino acid metabolism in which an enzyme defect results in increased methionine and homocystine. If not identified and left untreated, children can develop mental retardation, vision problems, skeletal abnormalities and strokes.

Hospital means any facility defined under Neb. Rev. Stat. § 71-2017.01(2).

Isovaleric Acidemia (IVA) means a disorder of amino acid metabolism in which an enzyme defect results in elevations of leucine and isovaleric acid. If not identified and left untreated, it can cause failure to thrive, metabolic acidosis, dehydration, hyperammonemia, and hypoglycemia.

Laboratory means a facility for the biological, microbiological, serological, chemical, immunological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Long-chain Hydroxyacyl-CoA Dehydrogenase Deficiency (also known as 3-Hydroxy Long-chain Acyl-CoA Dehydrogenase Deficiency or LCHAD) means a disorder of fatty acid metabolism in which an enzyme defect results in metabolic derangement during periods of prolonged fasting. If not identified and left untreated, it can result in failure to thrive, hypoglycemia, liver disease, cardiomyopathy and possibly death.

Maple Syrup Urine Disease (MSUD) means a disorder of amino acid metabolism in which an enzyme defect allows leucine, isoleucine and valine to accumulate to toxic levels. If not identified and left untreated, it can progress to mental retardation, failure to thrive, seizures, coma, cerebral edema and possibly death.

Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCAD) means a disorder of fatty acid metabolism that results in an inability to metabolize medium-chain fatty acids which, if not identified and left untreated, under conditions of fasting may lead to hypoglycemia, seizures, developmental disability and/or sudden death.

Methylmalonic Acidemia (Mutase Deficiency or MUT or MMA) means a disorder of amino acid metabolism in which various related enzyme defects result in increased methylmalonic acid. If not identified and left untreated, it can result in failure to thrive, metabolic acidosis, dehydration, hyperammonemia, hypoglycemia, mental retardation and possibly death.

Methylmalonic Acidemia (Cbl A and B) means a disorder of vitamin B12 (cobalamin) and amino acid metabolism in which an enzyme defect results in increased methylmalonic acid and homocystine. If not identified and left untreated, it can result in failure to thrive, metabolic acidosis, seizures, anemia, mental retardation and possibly death.

Multiple Carboxylase Deficiency (MCD) means a disorder of biotin vitamin metabolism in which an enzyme defect results in impaired biotin function leading to abnormal metabolism of amino acids, carbohydrates and lipids. If not identified and left untreated, infants develop metabolic acidosis, seizures, dermatitis, hearing loss, coma, mental retardation and possibly death.

NBSAC-approved protocols mean follow-up practices recommended by the Newborn Screening Advisory Committee and adopted by the Nebraska Newborn Screening Follow-up Program, to rule out or help diagnose conditions in response to screening results that are out of

range. For most out-of-range results, only a repeat dried blood spot specimen is needed. For substantially out-of-range results, or results from serial screens that continue to be out of range, other confirmatory specimens and tests often with higher specificity and sensitivity to measure an analyte or analytes are usually recommended.

Newborn means an infant who is 28 days old or less.

Newborn Screening means a laboratory test applied to newborn specimens in a search for newborns with metabolic diseases. Screening will detect a high proportion of newborns with the disease (true positive). Some newborns who do not have the disease will be identified by the screening test as possibly affected (false positive).

NNSP means the Nebraska Newborn Screening Program.

Newborn Screening Advisory Committee means a committee whose membership is determined by the Department Director which is comprised of a minimum of 15 and maximum of 25 stakeholders and representatives from but not limited to the following areas: Newborn and pediatric primary health care providers; medical and allied professionals from the sub-specialties associated with treatment for the disorders screened; clinical laboratorians; and consumers with technical, professional, and/or personal experience with newborn screening for congenital and inherited disorders.

Phenylketonuria (PKU) means a disorder of amino acid metabolism in which an enzyme defect results in increased levels of phenylalanine. If not identified and left untreated, it may lead to mental retardation and seizures.

Propionic Acidemia (PROP or PA) means a disorder of amino acid metabolism in which an enzyme defect results in increased propionic acid. If not identified and left untreated, it can result in failure to thrive, metabolic acidosis, vomiting, dehydration, hyperammonemia, mental retardation and death.

Physician means a person licensed to practice medicine and surgery or osteopathic medicine and surgery pursuant to the Medicine and Surgery Practice Act.

Presumptive Positive means a screening test result that is above or below the cutoff value and/or outside the normal range or value determined by an algorithm for assigning an interpretation of presumptive positive, depending on the test method.

Public Health means the art and science dealing with the protection and improvement of community health by organized community effort and including preventive medicine and sanitary and social science.

Public Health Emergency (the condition that requires the Governor to declare a state of public health emergency) means an occurrence or imminent threat of an illness or health condition, caused by bioterrorism, epidemic or pandemic disease, or a novel and highly fatal infectious agent or biological toxin that poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability (WHO/CDC, 2001). The declaration of a state of public health emergency permits the Governor to suspend state regulations and/or change the functions of state agencies.

Public Health Research is research intended to generate or contribute to generalizable knowledge to improve public health practice. Generalizable knowledge is new information that has relevance beyond the population or program from which it was collected. Intended benefits of the research project may or may not include study participants, but always extend beyond study participants, and usually to society. Data collected exceed requirements for care of the study participants or extend beyond the scope of the activity.

For purposes of defining public health research, “generalizable” does not refer to the statistical concept of population estimation, or to the traditional public health method of collecting information from a sample to understand health in the sampled population. Holding public health activities to a standard of studying every case in order to classify an activity as non-research is not practical or reasonable.

Residual Dried Blood Spots means the portion of the initial or repeat dried blood spot specimen remaining, after all punches have been removed for testing of the specimen for newborn screening purposes.

Submitter means the person who sends the Collection and Reporting (CARE) Form to the testing laboratory for initial, repeat, or confirmatory screening tests, including, but not limited to, the hospital, the laboratory, or the physician.

Test Method means a laboratory examination which measures blood constituents associated with metabolic diseases.

Tyrosinemia (TYR) means a disorder of amino acid metabolism in which various related enzyme defects result in elevation of tyrosine. Effects of untreated disease may include failure to thrive, liver failure, skin and eye lesions, developmental delay or mental retardation. (Tyrosinemia type 1 might not be detected during the immediate newborn period).

Trifunctional Protein Deficiency (TFP) means a disorder of fatty acid metabolism in which a genetic defect results in deficiency of 3 enzymes that act sequentially in fatty acid degradation. During periods of fasting, if not identified and left untreated, children can develop hypoglycemia, failure to thrive, cardiomyopathy, liver disease and death.

Very Long-chain Acyl-CoA Dehydrogenase Deficiency (VLCAD) means a disorder of fatty acid metabolism in which an enzyme defect results in an inability to degrade long-chain fatty acids. If not identified and left untreated, it may lead to fasting hypoglycemia, liver disease, seizures, skeletal myopathy, cardiomyopathy and sudden death.

3-Hydroxy 3-Methyl Glutaric Aciduria (also known as 3-Hydroxy-3-Methylglutaryl-CoA Lyase Deficiency or HMG) means a disorder of organic acid metabolism in which an enzyme defect results in elevation of leucine in the blood and impaired production of ketones. If not identified and left untreated, it can result in mental retardation, metabolic acidosis, hypoglycemia, hyperammonemia, seizures, coma and death.

3-Methylcrotonyl-CoA Carboxylase Deficiency (3MCC) means a disorder of amino acid metabolism in which an enzyme defect results in an inability to metabolize leucine. If not identified and left untreated, it can lead to vomiting, metabolic acidosis, apnea, hyptonia, seizures and possibly death.

2-003 SPECIFICATION OF DISEASES: All infants born in the state of Nebraska must be tested for the 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 the following diseases:

1. Argininosuccinic Acidemia (beginning July 1, 2008);
2. Beta-ketothiolase Deficiency (beginning July 1, 2008);
3. Biotinidase Deficiency;
4. Carnitine Uptake Defect (beginning July 1, 2008);
5. Citrullinemia (beginning July 1, 2008);
6. Congenital Adrenal Hyperplasia;
7. Congenital Primary Hypothyroidism;
8. Cystic Fibrosis;
9. Galactosemia;
10. Glutaric Acidemia type 1 (beginning July 1, 2008);
11. Hemoglobinopathies;
12. Homocystinuria (beginning July 1, 2008);
13. Isovaleric Acidemia (beginning July 1, 2008);
14. Long-chain Hydroxyacyl-CoA Dehydrogenase Deficiency (beginning July 1, 2008);
15. Maple Syrup Urine Disease (beginning July 1, 2008);
16. Medium Chain Acyl-CoA Dehydrogenase Deficiency;
17. Methylmalonic Acidemia (Mutase Deficiency) (beginning July 1, 2008);
18. Methylmalonic Acidemia (Cbl A and B) (beginning July 1, 2008);
19. Multiple Carboxylase Deficiency (beginning July 1, 2008);
20. Phenylketonuria;
21. Propionic Acidemia (beginning July 1, 2008);
22. Tyrosinemia (beginning July 1, 2008);
23. Trifunctional Protein Deficiency (beginning July 1, 2008);
24. Very Long-chain Acyl-CoA Dehydrogenase Deficiency (beginning July 1, 2008);
25. 3-Hydroxy 3-Methyl Glutaric Aciduria (beginning July 1, 2008); and
26. 3-Methylcrotonyl-CoA Carboxylase Deficiency (beginning July 1, 2008).

2-004 SPECIMEN COLLECTION

2-004.01 Specimen Requirements

2-004.01A The specimen requirements of the testing laboratory for each specific analyte must be followed. The testing laboratory must accept only specimens that are dried blood spots that have been collected on the CARE Form.

2-004.01B Collection of dried blood spot specimens must comply with the Clinical and Laboratory Standards Institute (CLSI) "Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard", most current edition.

Heel stick with direct application is the preferred method. That method is illustrated and described on Attachment 1, which is incorporated into these regulations with this reference. The submitter must forward the dried blood spots to the testing laboratory

within 24 hours of specimen collection. On weekends and holidays if no transport service is available, the next earliest available transport service must be used.

2-004.01C Umbilical cord blood must not be used.

2-004.01D Urine must not be substituted for blood specimens.

2-004.02 Collection and Reporting Form (CARE Form): The Collection and Reporting Form (CARE Form), which is attached to these regulations as Attachment 2 and incorporated herein by reference, must be the sole method of dried blood spot specimen collection for all newborn screening. Forms are available from the Department at cost.

2-005 PHYSICIAN DUTIES

2-005.01 Specimen Collection: For all live births, the newborn's physician must cause the collection for testing of a newborn screening specimen for metabolic diseases between 24 to 48 hours of age or immediately prior to the newborn's discharge, whichever occurs first.

2-005.01A Prior to 24 Hours of Age: If the initial specimen for any infant is collected prior to 24 hours of age, the newborn's physician or designee must collect or cause to be collected a repeat amino acid profile and hypothyroidism screening specimen by 7 days of age, regardless of prior test results.

2-005.01B Sick, Low Birth Weight, or Premature Infants: Newborns transferred to neonatal intensive care units (NICU) must have a specimen collected prior to transfer, and information communicated as required at 181 NAC 2-005.01E3. The attending physician at the hospital NICU must verify and otherwise ensure a specimen is collected prior to the provision of any treatment, excluding respiratory treatment. The specimen may be collected prior to 24 hours of age. If the first specimen is collected at less than 24 hours of age, or if the newborn was less than 2000 grams at birth, a repeat specimen must be collected at 48-72 hours of age. A third specimen must be collected at 28 days of life or upon discharge, whichever occurs first, on all infants less than 2000 grams at birth, or who had any prior abnormal screen result.

2-005.01C Blood Transfusion: If a newborn requires a blood transfusion, even if prior to 24 hours of age, the specimen must be collected before the blood transfusion. The specimen should be collected at the time blood is collected for the typing and cross match prior to transfusion unless a dried blood spot specimen was verified to have been collected prior to the typing and cross match. The newborn's physician or designee must collect or cause to be collected a repeat specimen for the amino acid profile and hypothyroidism screening by 48-72 hours of age if the pre-transfusion specimen was collected at less than 24 hours of age, regardless of prior test results.

2-005.01D No Specimen Collected: Upon notification by the hospital that a newborn was discharged before a screening sample was collected, the newborn's physician or designee must collect or cause to be collected a screening specimen within 48 hours of parental notification.

2-005.01E Newborn Transfer To Another Hospital

2-005.01E1 Before 24 Hours of Age: The physician at the hospital of birth must collect or cause to be collected a blood specimen immediately prior to discharge for testing for metabolic diseases if the newborn is transferred to another hospital, either in- or out-of-state, even if this occurs before the infant is 24 hours of age. If the specimen is collected at less than 24 hours of age, the physician or designee at the hospital of birth must document and inform the receiving physician that a specimen for testing for metabolic diseases was collected prior to 24 hours of age and notify the receiving physician that another specimen must be collected between 48 and 72 hours of age.

2-005.01E2 After 24 Hours of Age: The physician at the hospital of birth must collect or cause to be collected a blood specimen for testing for metabolic diseases from any newborn being transferred to another hospital after the newborn is 24 hours of age and notify the physician upon transfer that a blood specimen for metabolic diseases has been collected. The transferring physician must immediately notify the receiving physician if the specimen needs to be repeated, or if confirmatory testing is required.

2-005.01E3 Transfer Forms: All physicians transferring newborns to another hospital or the physician's designee at the hospital must notify the receiving physician in writing of the following information and fax a copy of the written information to the NNSP within 24 hours:

1. Date of transfer;
2. Person completing form or other written notification;
3. Hospital of birth;
4. Infant's name;
5. Date and time of birth;
6. Date and time of specimen collection;
7. Transferring physician;
8. Whether the newborn screening specimen was or was not collected at the hospital of birth;
9. Whether the newborn screening specimen was or was not collected prior to 24 hours of age;
10. Whether the newborn was transfused, and if so, whether the specimen was collected prior to transfusion;
11. The type and time of transfusion if the specimen was collected post-transfusion;
12. If the tests have not been performed and an initial specimen needs to be collected;
13. If the specimen was collected prior to 24 hours, or following transfusion, and a repeat specimen needs to be collected;
14. Receiving hospital; and
15. Receiving physician, if known.

The Transfer Form, Attachment 3 of these regulations, may be used to notify the receiving physician and is included as a convenience for the transferring physician.

2-005.02 Unsatisfactory Specimen: Upon receiving notice from the testing laboratory that a specimen is unsatisfactory, the newborn's physician or designee must collect or cause to be collected a repeat specimen within 48 hours of parental notification.

2-005.02A The physician or designee must make a reasonable attempt to cause the collection of a repeat specimen. A reasonable attempt includes that the physician or designee must:

1. Immediately notify the parent, guardian, or custodian by telephone, if possible, and in writing;
2. If there has been no response within 5 days, notify the parent, guardian, or custodian in writing by certified mail, return receipt requested, or equivalent; and
3. If there has been no response within 10 days of first notification, notify the Nebraska Newborn Screening Program (NNSP) in writing that obtaining a repeat specimen was not accomplished.

2-005.03 Screening Test Results Received: Once the physician receives the results of the newborn screening tests, the physician or designee must place or cause to be placed the results in the newborn's patient record.

2-005.04 Presumptive Positive Screening Test Result: The newborn's physician or designee must obtain a specimen for repeat or confirmatory testing from the newborn within 48 hours after notification by the testing laboratory of any presumptive positive screening result. Repeat dried blood spot specimens must be submitted to the newborn screening laboratory that tested the initial specimen in accordance with NBSAC-approved protocols for follow-up. Confirmatory tests must be ordered and confirmatory specimens sent in accordance with NBSAC-approved protocols only to laboratories meeting standards established by the Department on the advice of the Newborn Screening Advisory Committee as set forth in 181 NAC 2-007.01E.

2-005.04A The physician or designee must make a reasonable attempt to cause the collection of a repeat specimen. A reasonable attempt includes that the physician or designee must:

1. Immediately notify the parent, guardian, or custodian by telephone, if possible, and in writing;
2. If there has been no response within 5 days, notify the parent, guardian, or custodian in writing by certified mail, return receipt requested, or equivalent; and
3. If there has been no response within 10 days of first notification, notify the NNSP in writing that obtaining a repeat specimen was not accomplished.

2-005.04B Specific Responses to Presumptive Positive Screening Test Results

2-005.04B1 Congenital Adrenal Hyperplasia (CAH): If screening test results are positive for CAH, the physician must monitor the newborn for vomiting, poor weight gain, and elevated potassium, and collect or cause to be collected a specimen for a confirmatory test.

2-005.04B2 Congenital Primary Hypothyroidism (CPH): If screening test results are positive for congenital primary hypothyroidism, thyroxine therapy must not be given prior to obtaining confirmatory testing.

2-005.04B3 Cystic Fibrosis: If screening test results are positive for Cystic Fibrosis, the physician must order a repeat or confirmatory test as indicated.

2-005.04B4 Galactosemia: If screening test results are positive for galactosemia, the physician must take the child off milk, place the child on a powder-based soy formula, and then collect or cause to be collected a specimen for a confirmatory test.

2-005.04B5 Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCAD): If screening test results are positive for MCAD, parent(s) should be advised to avoid fasting of the newborn for greater than 4 hours, and the physician should consider carnitine supplementation until confirmatory results are known.

2-005.04B6 Phenylketonuria: If screening test results are positive for phenylketonuria, formula with reduced or absent phenylalanine must not be given prior to obtaining positive confirmatory phenylalanine and tyrosine levels and other necessary confirmatory tests.

1. Phenylalanine levels of 20 mg/dL (or 1210 $\mu\text{mol/L}$) or greater on 2 occasions 24 hours or more apart while the infant is on full feeding and a phenylalanine to tyrosine ratio of 10 to 1 or higher is indicative of classical phenylketonuria.
2. Phenylalanine levels of greater than 3.0 mg/dL (or 182 $\mu\text{mol/L}$) but less than 20 mg/dL (or 1210 $\mu\text{mol/L}$) on 2 occasions 24 hours or more apart while the infant is on full feeding, and a phenylalanine to tyrosine ratio of 5 to 1 or higher is indicative of nonclassical or variant phenylketonuria.

2-005.05 Enforcement: In the event that a parent fails to respond to notification, the physician must assure that such steps are taken as indicated in 181 NAC 2-009 and Neb. Rev. Stat. § 71-524.

2-005.06 Patient Education: The physician or an individual to whom the physician has delegated authority, must:

2-005.06A Provide information to the newborn's parent/legal guardian about the diseases for which newborn screening tests are required. Patient education materials provided by the Department about the required tests must be used to aid in informing the parent/legal guardian. There is no provision for dissent from or refusal of the required newborn screening tests specified at 181 NAC 2-003.

2-006 HOSPITAL OR OTHER SUBMITTER DUTIES

2-006.01 Collection and Reporting Form (CARE Form): The hospital or other submitter designated by the newborn's attending physician must complete all information and collect the specimen on the CARE Form. The hospital or other submitter must retain the designated copy for inclusion into the newborn's medical record and send the remaining copies to the testing laboratory designated by the Department within 24 hours after specimen collection.

2-006.02 No Specimen Collected: The hospital or other submitter designated by the newborn's attending physician must immediately notify the newborn's physician or designee by telephone and in writing if the newborn was discharged before a screening sample was collected, and document this notification in the newborn's medical record.

2-006.03 No Test Results: The birthing hospital or facility must maintain a monitoring mechanism to track results for all births occurring at or en route and admitted to their facility. If test results are not received by the hospital or other submitter within 10 days after the specimen was submitted to the testing laboratory, the hospital or other submitter must immediately contact the testing laboratory to determine if the testing laboratory received the specimen and performed the appropriate analyses, and document this contact in the newborn's medical record:

2-006.03A If the testing laboratory did not receive a specimen, the hospital or other submitter must immediately notify the physician by telephone and in writing, and document this notification in the newborn's medical record.

2-006.03B If the testing laboratory did receive the specimen and completed the appropriate analyses, a duplicate report must be obtained and placed in the newborn's medical record.

2-006.03C If the testing laboratory did receive the specimen but has not yet performed the appropriate analyses, the hospital or other submitter must immediately notify the NNSP.

2-006.04 Screening Test Results Received: When the hospital or other submitter receives the completed copy of the CARE Form or other record of screening test results from the testing laboratory, the hospital or other submitter must place the screening test results in the newborn's medical record and appropriately retain those results for 25 years from the newborn's date of birth.

2-006.05 Contact Person: The hospital must keep the NNSP informed of the contact person responsible for newborn screening.

2-007 TESTING LABORATORY DUTIES

2-007.01 General Rules

2-007.01A Electronic Transmission: The testing laboratory must report all of the information on the CARE Form electronically, at its own expense, to the NNSP central database utilizing software developed and provided by the Department or in electronic format that provides complete demographic and test results records for each infant and that provides the reporting functions as specified by the Department in 181 NAC 2-

007.02A and in contract. The testing laboratory must provide, at its own expense, the necessary hardware.

2-007.01B Test Performance: The testing laboratory must perform all tests required in the contract between the Department and the laboratory at least six days a week.

2-007.01C Contact Person: The testing laboratory must keep the NNSP informed of the contact person responsible for newborn screening.

2-007.01D Screening Tests: Except as provided in the disaster preparedness plan as required in the contract, the screening tests must be completed only by the laboratory designated by contract with the Department beginning with the effective date of the contract.

2-007.01E Confirmatory Tests: Confirmatory tests may be done by any laboratory including the laboratory designated by the Department as long as it is certified under the Clinical Laboratory Improvement Amendments (CLIA) and meets standards as set forth at 181 NAC 2-007.01E, items 1 and 2. The contracted newborn screening laboratory will append to the laboratory report for all presumptive positive screening results, disorder specific recommendations for immediate testing and clinical follow-up, as approved by the Department and the Newborn Screening Advisory Committee.

1. Confirmatory testing laboratories must be CLIA certified, and maintain data to support validation of the assays and normal reference ranges for neonates and infants for whom confirmatory testing is provided.
2. Confirmatory testing laboratories must provide at a minimum written or electronic laboratory reports back to the specimen submitter that include:
 - a. Name of test.
 - b. Validated age-appropriate normal reference ranges for the analytes tested when confirming for endocrinopathies (CAH and CPH) and hemoglobinopathies.
 - c. Test method and relative amounts of hemoglobins when confirming for hemoglobinopathies.
 - d. Identification of ratios when hemoglobins A and S are present.
 - e. Test results in quantitative values (except hemoglobins above) and units of measure consistent with units of measure in the normal reference ranges or values.
 - f. Interpretation of results appropriate to the age of the newborn or infant.
 - g. Name and address where testing was completed.
 - h. Name and phone number of reviewer/person providing the interpretation.
 - i. Written acknowledgement of conditions that may interfere with the appropriate interpretation of results.

2-007.02 Record Keeping and Reporting: Testing laboratories must maintain records and make reports in the following manner:

2-007.02A Electronic Report: The laboratory must make an electronic report to the Department which includes the following information:

1. All information contained on the CARE Form;
2. The serial number located on the CARE Form;
3. If applicable, identification of any unsatisfactory specimen and the reason for its unsatisfactory nature;
4. Screening, repeat, and confirmatory test results, including numerical data where applicable; and
5. Any notifications to the physician, NNSP, or the submitter.

2-007.02B When Receiving a Specimen: The testing laboratory must enter the data identified in 181 NAC 2-007.02A, items 1 and 2, into the electronic database specified at 181 NAC 2-007.01A at the time of receiving the specimen.

2-007.02C After Individual Test Completion: Tests results must be entered into the database within 24 hours of individual completion.

2-007.02D Transfer of Electronic Report: The testing laboratory must transmit to the Department's electronic database or allow electronic access by the NNSP to all data identified in 181 NAC 2-007.02A at least once every 24 hours.

2-007.02E Transfer of Screening Test Results: Within 24 hours of completing all screening tests on each newborn, the laboratory must return a copy of the completed CARE Form or other record of test results to the hospital or other submitter.

2-007.02F Blood Spot Storage, Use and Disposal Records: The testing laboratory must maintain for 25 years an index or catalog of the residual dried blood spots processed in the laboratory that includes the following information:

1. The serial number or unique identifier of each specimen processed;
2. The test results of each specimen processed;
3. Verification of disposal of specimens not released for research, public health, quality assurance, or diagnostic purposes. This information may be batched by test completion date so long as each serial number or unique identifier can be linked with its test completion date;
4. Date of disposal;
5. Location of disposal if other than the laboratory;
6. For specimens released for public health research, documentation as required at 181 NAC 2-007.08; and
7. Signature of the person who released, disposed of, or witnessed the disposal of the specimen; or for specimens disposed of by a contractor, written evidence that the contract for disposal of residual dried blood spots requires disposal be done in accordance with 181 NAC 2-007.02F, items 3, 4, and 5.

2-007.02G Quality Assurance Reports: The testing laboratory must provide to the NNSP, copies of written reports of participation in and results of appropriate quality assurance proficiency testing programs offered by the Centers for Disease Control and

Prevention of the United States Department of Health and Human Services and any other professional laboratory organization.

2-007.03 Unsatisfactory Specimen: If a specimen is unsatisfactory for any reason for any test(s), including but not limited to, being of insufficient volume or quality, the testing laboratory must reject it. Within 24 hours of receiving any unsatisfactory specimen, the testing laboratory must:

1. Notify the submitter and physician or designee by telephone and in writing that the specimen was unsatisfactory and that a repeat specimen must be collected within 48 hours of notification to the parent, guardian, or custodian;
2. Schedule any tests possible on the specimen received in accordance with the testing laboratory's standard operating procedure and testing times; and
3. Enter the applicable information identified in 181 NAC 2-007.02A into the Department's electronic database.

2-007.04 Negative Screening, Negative Repeat Screening, and Negative Confirmatory Test Results: Within 24 hours of obtaining a negative screening, negative repeat screening, or negative confirmatory test result, the testing laboratory must:

1. Send a copy of the CARE Form or other record of test results to the submitter; and
2. Enter the applicable information identified in 181 NAC 2-007.02A into the Department's electronic database.

2-007.05 Presumptive Positive Screening, Positive Repeat Screening, or Positive Confirmatory Test Results: Immediately after obtaining any presumptive positive screening, positive repeat screening, or positive confirmatory test result, the testing laboratory must:

1. Provide test result information to the submitter and physician or designee by telephone and in writing;
2. Utilize the NNSP telephone number provided by the Department and relay the information on the CARE Form and the presumptive positive or positive results; and
3. Enter the applicable information identified in 181 NAC 2-007.02A into the Department's electronic database.

2-007.06 Standardized Laboratory Test Methods: The testing laboratory must use only the standardized test methods provided for in the contract with the Department and the methods used must produce results for which the specified cutoff value and/or algorithms for assigning presumptive positive results is/are appropriate. The screening test approved analytical method, cutoff value and/or algorithms for assigning presumptive positive results (identification protocol) will be specified in the contract between the Department and the laboratory conducting newborn screening testing for

the diseases specified in these regulations. Identification protocols used by the performing laboratory must be agreed upon in contract by the Department with the advice of the Newborn Screening Advisory Committee.

The Newborn Screening Advisory Committee is responsible for reviewing technical aspects of the identification protocol for the initial screening test relevant to repeat and confirmatory testing. The Committee must make recommendations for approval, disapproval or revision to identification protocols. The Department has final decision authority for contractually agreed upon tests, analytic methods and identification protocols for normal and abnormal results and reporting specifications.

2-007.07 Storage of Residual Dried Blood Spots: The testing laboratory must store the residual dried blood spots for 90 days. Specimens must be refrigerated in sealed bags of low gas permeability.

2-007.08 Use of Residual Dried Blood Spots: Residual dried blood spots may be used for public health research, further patient diagnostic testing, and public health purposes, for example, but not limited to, quality assurance and improvement of newborn screening practices.

2-007.08A Residual dried blood spots may be used for public health research only when:

1. The Chief Medical Officer and the Newborn Screening Advisory Committee or its proxy sub-committee have reviewed and approved the application for research containing but not limited to the following information:
 - a. The full report of the review and approval of the research by a Human Subjects Review or Institutional Review Board;
 - b. The qualifications of the applicant and of the principal investigator, if other than the applicant, including education, experience, prior publications, and recommendations of professional colleagues who have knowledge and experience of scientific or medical research;
 - c. The purpose of the research project, a summary of the project, and the anticipated time of completion of the project;
 - d. The location where the research project will be conducted and the equipment, personnel, and other resources available to the applicant to carry out the project;
 - e. The identity of the individual or entity funding the research project, a description of the availability of funds for the research project, and any conditions on the receipt or continuation of the funding;
 - f. The specific data or biological sample information requested and a description of the use to be made of it and, if subject-identifying data is requested, a substantiation of the need for access to the subject-identifying data;
 - g. A description of the measures to be taken to secure the data and biological sample information and to maintain the confidentiality of such during the research project, for disposal of the data and biological sample upon completion of the study, and to assure that the results of the study

- will not divulge or make public, information that will disclose the identity of any individual subject;
- h. A description of the process that will be used for obtaining written consent from the legally responsible parent or guardian of the individuals whose specimens will be requested;
 - i. If contact with a subject or subject's parent or legal guardian is planned or expected beyond obtaining consent as required under 181 NAC 2-007.08A1h, substantiation of the need for the contact and a description of the method to be used to obtain permission from the subject or subject's parent or legal guardian for the contact; and;
 - j. Such additional information as the Department determines to be necessary to assure that release of data to the applicant is appropriate and consistent with these regulations, Title 181 NAC 2.
2. For every specimen released for research, with or without patient identifying information, the laboratory must document:
 - a. Who had access to the specimen;
 - b. To whom the specimen was released;
 - c. The amount of specimen released; and
 - d. Evidence from the research entity that written consents were obtained from the legally responsible parent or guardian of the individuals whose specimens were released.
 3. The blood spot is not released for public health research until after the 90-day storage time. During the 90-day storage time, it must be available for clinical purposes for the patient.
 4. Records required at 181 NAC 2-007.08A, items 1 and 2, must be retained for 25 years.

2-007.08B Residual dried blood spots may be used for patient diagnostic testing when the ordering physician files with the laboratory a written request for specimen retrieval and a written authorization for release of the specimen signed by the parent or legal guardian.

2-007.08C Residual dried blood spots may be used for public health purposes as follows.

1. They may be used for quality assurance and improvement of newborn screening practices subject to the following:
 - a. Only dried blood spots deemed unsatisfactory for testing may be released to the submitting hospital to use as examples of poor specimen quality;
 - b. The filter paper portion of the CARE form containing the dried blood spots must be detached from the written patient identification part of the form prior to release;

- c. The bar code and filter paper serial number linking the dried blood spot to the patient identification information must be removed from the residual dried blood spot prior to release; and
 - d. Requests for return of unsatisfactory specimens must be made by the submitting facility through the NNSP.
2. They may be used for other public health purposes when:
- a. The Chief Medical Officer has determined there is a valid public health purpose;
 - b. The Chief Medical Officer has informed the Newborn Screening Advisory Committee about the public health use of the residual dried blood spots;
 - c. Patient information linking the specimen to the patient will be protected;
 - d. There are assurances that all applicable provisions of federal law will be complied with; and
 - e. The blood spot is not released or used for the public health purpose until after the 90-day storage time. During the 90-day storage time it must be available for clinical or identification purposes for the patient, unless a public health emergency is declared.

2-007.09 Data Reports: Reported data may be made available by the Department for purposes of research in aggregate statistical form or de-identified anonymous form. Written requests for release of this data for the purposes of research must be made to the NNSP. Review and approval of such requests will be at the discretion of the Chief Medical Officer.

2-007.10 Disposal of Residual Dried Blood Spots: Residual dried blood spots not released under 181 NAC 2-007.08 must be disposed of within 30 days of the end of the 90-day storage time. Destruction of the specimens, by incineration, by autoclaving and shredding, or by some other reasonable and prudent means, must ensure that identifying information cannot be linked to the residual dried blood spots.

2-007.11 Laboratory Provision of Access: Records required at 181 NAC 2-007.02F, 2-007.08, and 2-007.09 must be made available to the Department for inspection upon request.

2-008 BIRTHS NOT ATTENDED BY A PHYSICIAN: In the event a birth is not attended by a physician, the person registering the birth (who may be the parent) must ensure that:

- 1. The newborn has a newborn screening blood spot specimen collected as set out in 181 NAC 2-005.01 (between 24 and 48 hours of birth);
- 2. The specimen is submitted to the testing laboratory designated by the Department as set out in 181 NAC 2-006.01 (within 24 hours of collection); and
- 3. In response to a positive screening result, a confirmatory specimen is submitted to a testing laboratory in accordance with 181 NAC 2-007.01E within 48 hours of receipt of the newborn screening result.

2-009 ENFORCEMENT: Neb. Rev. Stat. § 71-524 provides as follows: In addition to any other remedies which may be available by law, a civil proceeding to enforce section 71-519 may be brought in the district court of the county where the infant is domiciled or found. The attending physician, the hospital or other birthing facility, the Attorney General, or the county attorney of the county where the infant is domiciled or found may institute such proceedings as are necessary to enforce such section. It shall be the duty of the Attorney General or the county attorney to whom the Department of Health and Human Services reports a violation to cause appropriate proceedings to be initiated without delay. A hearing on any action brought pursuant to this section shall be held within 72 hours of the filing of such action, and a decision shall be rendered by the court within 24 hours of the close of the hearing.

2-010 LABORATORY COLLECTION AND REMITTANCE OF FEES: There is hereby assessed a fee of \$10 for each infant screened for the diseases specified in 181 NAC 2-003. The laboratory conducting the tests for such diseases must collect a fee of \$10 per infant screened, and submit the amounts collected to the Department for credit to the Department of Health and Human Services Cash Fund on a monthly basis.

Specimen Collection for Newborn Screening

Excerpt from *Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fifth Edition (LA4-A5)*

I PREPARATION

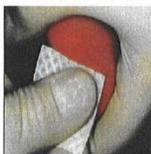
- 1.1 Wash hands vigorously.
- 1.2 Wear powder-free gloves and change gloves between infants.
- 1.3 Confirm identity of infant and ensure that all data elements on the form are complete, accurate, and consistent.

2 SAMPLING TECHNIQUE

- 2.1 **Warm heel for puncture (incision/stick) site.** Heel warming devices containing an exothermic thermochemical composition are commercially available, or warm site with soft cloth, moistened with warm water (**less than 42 °C**) for three to five minutes. In some situations, warming site may not be necessary to increase blood flow and volume.

- 2.2 Position the infant's leg lower than the heart to increase venous pressure.

- 2.3 Wearing gloves, wipe infant's heel with 70% isopropyl alcohol. *



- 2.4 Allow heel to air dry.

- 2.5 The puncture should be made within the shaded area as illustrated in the figure to the right. *



* Photos reprinted with permission from New York State Department of Health.

† Photo reprinted with permission from GE Healthcare.

- 2.6 Using a sterile lancet of recommended length, perform puncture (depth <2.0 mm) as illustrated or use an incision device. An incision device may provide superior blood flow by making a standardized incision 1.0 mm deep by 2.5 mm long.



- 2.7 Gently wipe off first drop of blood with sterile gauze or cotton ball. (Initial drop contains tissue fluids, which might dilute sample.)

- 2.8 Wait for formation of large blood droplet.

- 2.9 Apply gentle pressure with thumb around the heel but not near the puncture site, and ease intermittently as drops of blood form.

- 2.10 Gently touch the filter paper card to the blood drop and fill each printed circle with a SINGLE application of blood. Apply blood to one side only. Observe the saturation of each printed circle as the blood flows through the filter paper. *



- 2.11 All used items should be disposed of in an appropriate biohazard container.

- 2.12 After the specimen is collected, elevate the infant's foot and, using sterile gauze or cotton ball, briefly apply gentle pressure to the puncture site until the bleeding stops. Do not apply adhesive bandages.

- 2.13 Allow blood specimen to AIR DRY THOROUGHLY, on a horizontally level, nonabsorbent, open surface, such as a drying rack or plastic-coated test tube rack, for a minimum of three hours at ambient temperature. Keep

specimen away from direct sunlight. (Do not stack or heat.) †



- 2.14 After the specimen has dried, place in an approved container for transport. (See local regulations.)

3 PITFALLS

- 3.1 Failure to allow residual alcohol to dry might dilute the specimen and adversely affect test results.

- 3.2 Puncturing the heel on posterior curvature will permit blood to flow away from puncture, making proper spotting difficult. DO NOT USE PREVIOUS PUNCTURE SITES.

- 3.3 Milking or squeezing the puncture might cause hemolysis and admixture of tissue fluids with specimen.

- 3.4 Do not layer successive drops of blood on the target spot. If blood flow diminishes to incompletely fill circles, REPEAT sampling technique 2.1 through 2.10.

- 3.5 Avoid touching the area within the circle before and after blood collection. Do not allow water, feeding formulas, antiseptic solutions, or powder from gloves or other materials to come into contact with the specimen card before or after use.

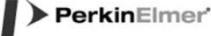
- 3.6 Do not place the specimens in the transport container until thoroughly dry. Insufficient drying adversely affects test results. Use of sealed plastic bags requires desiccation. Ideally, transport specimens within 24 hours of collection.

Text describing how to collect an acceptable blood spot specimen reprinted with permission from Clinical and Laboratory Standards Institute.

Attachment 2

Collection and Reporting (CARE) Form – Nebraska Newborn Screening Program

Request for Proposal Number 4229Z1

<p style="text-align: center;">Whatman 903® Lot W071 XXXXXXXXXX</p>	 SN XXXXXXXX	<p style="text-align: center;">COLLECTION AND REPORTING (CARE) FORM - NEBRASKA NEWBORN SCREENING PROGRAM</p> <p> Birth Date ___/___/___ Time ___:___ (Military) Collection Date ___/___/___ Time ___:___ (Military) Collector's initials _____ Initial <input type="checkbox"/> Repeat <input type="checkbox"/> <input type="checkbox"/> Specimen collected prior to 24 hours <input type="checkbox"/> Transfused prior to specimen collected If ✓'d specify type _____ date ___/___/___ time ___:___ <input type="checkbox"/> TPN <input type="checkbox"/> Meconium Ileus <input type="checkbox"/> Baby on antibiotics Gestational age _____ (wks) Birth Weight _____ </p> <p>NEWBORN'S INFORMATION:</p> <p>Name _____ Last _____ First _____ Middle _____ Patient Record Number _____ Place of Birth _____ Home Birth Yes <input type="checkbox"/> No <input type="checkbox"/> Sex M <input type="checkbox"/> F <input type="checkbox"/></p> <p>MOTHER'S INFORMATION:</p> <p>Name _____ Last _____ First _____ Middle _____ Address _____ Telephone (____)____-____ Birthdate ___/___/___</p>	RECEIVED SN XXXXXXXX REPORTED	REF 10534670 Rev.2 Lot W071 XXXXXXXX Use By YYYY-MM
		 PerkinElmer PerkinElmer Genetics 90 Emerson Lane, Suite 1403 P.O. Box 219 Bridgeville, PA 15017 Phone: 412-220-2300		

Note: Filter paper form not to scale.

Attachment 3

Newborn Transfer Form Nebraska Newborn Screening Program

Request for Proposal Number 4229Z1

Date of Transfer: _____ Person Completing Form: _____

Hospital of Birth: _____

Infant's Name: _____

Date of Birth: _____ Time of Birth: _____

Date of Specimen Collection: _____ Time of Specimen Collection: _____

Transferring Physician: _____

Newborn Screening Specimen Collected at Hospital of Birth: Yes No

Newborn Screening Specimen Collected Prior to 24 Hours of Age: Yes No

Infant transfused? Yes No

If yes, was specimen collected prior to transfusion? Yes No

If collected post-transfusion, indicate type: _____ and time of transfusion ____:____

Receiving Hospital: _____

Receiving Physician: _____

Person Receiving Form: _____

ATTENTION RECEIVING PHYSICIAN: If the newborn screening tests have not been performed or tests need to be repeated when you take charge of the infant, you are responsible for ordering a specimen and returning the results recorded on this form to the hospital of birth.

Forward one copy of this form to the receiving hospital and fax one copy to:

Nebraska Newborn Screening Program
Department of Health & Human Services
P.O. Box 95026
Lincoln, NE 68509
Fax 402-471-1863

Appendix C

Table of Test Results

Request for Proposal Number 4229Z1

Denominator: Total number initial specimens tested 2011:

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 Negative	Inconclusive Rate
Arginininosuccinic academia (Arg)					
CUD(low C0)					
CIT					
GAI (C5DC or C10- OH, or C8 + C10)					
HCY (Met & Homocy)					
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)					
MCD (C3 or C5OH)					
PKU (Phe, Phe/Tyr)					
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)					
HMG (C5:OH, C6:DC w/ C5:OH)					
3-MCC (C5:OH or C5:1 w/ C5:OH)					
Other MS/MS findings					
Biotinidase					

CAH					
CPH					
CF					
Gal					
Hgb's S, SC, Thal					

*Positive results include all abnormal results. Most oftenthes results indicate the need for a repeat newborn screen and less frequently confirmatory/diagnostic testing.

Denominator: Total number initial specimens tested 2011: _____

Condition/ Analyte	# Screened	# Positive on screen	# Confirmed/ Diagnosed Positive	# Confirmed Negative	Presumptive Positive Rate
Argininosuccinic acidemia (ASA)					
CUD(low C0)					
CIT					
GAI (C5DC or C10-OH, or C8 + C10)					
HCY (Met & Homocy)					
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)					
MCD (C3 or C5OH)					
PKU (Phe, Phe/Tyr)					
PA (C3,C3:C2, C3:C16)					
Tyr (Tyr)					
TFP C16-OH, C18:1-OH with C16-OH)					
VLCAD (C14, C14:1, C14:2, & C14:1/C12:1)					
HMG (C5:OH, C6:DC w/ C5:OH)					
3-MCC (C5:OH or C5:1 w/ C5:OH)					
Other MS/MS findings					
SCID					
Biotinidase					
CAH					
CPH					
CF					

Gal					
Hgb's S, SC, Thal					

Unsatisfactory / Rejected Specimens

(Numerator: Total # unsatisfactory specimens 2011: _____)

(Denominator: Total # initial specimens tested in 2011: _____)

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 D

Emergency/Disaster Preparedness & Proprietary Information

Request for Proposal Number 4229Z1

In accordance with the federal CON-PLAN for newborn screening, the laboratory will:

4. Establish back up testing methods or plans
5. Obtain documentation that manufacturer or supplier has:
 - a. Adequate forward stocking established
 - b. Alternate transportation plans established
6. 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 E

Follow-up/Monitoring and Quality Assurance Reports

Request for Proposal Number 4229Z1

The following reports used for follow-up and monitoring can be run entering any date range. Examples 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.

ABNORMAL HEMOGLOBINOPATHIES REPORT (variable date range)

(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))

Filter Paper	Last Name	First Name	Birth Date/time	Birth Place	City of Birth	Test	Hem Result	Age Type	in days
123456789	Doe	Jane	1/1/07 13:02	Hospital name	Anytown	HEM	FAS	8	

CYSTIC FIBROSIS INCONCLUSIVE TESTS (variable date range)

(Report lists every pending inconclusive CF screen, until closed by the State program)

Last Name	First Name	Birth Date	Filter Paper	Birth Place	City of Birth	Test/Result	Age(days)
Doe	Jane	1/1/07 13:02	123456789	Hospital name	Anytown	IRT Inconclusive	12

MECONIUM ILEUS (variable date range)

(Report lists every pending newborn with Meconium Ileus or other bowel obstructed identified, until closed by the State Program).

Last name	First Name	Birth Date	Filter Paper	IRT Outcome	DNA Results
Doe	Jane	01/01/07 13:02	123456789	POS	Homo
Doe	John	01/10/07 15:15	12357890	POS	CPDHET(compound hetzygt)
Roe	Jane	03/03/07 22:15	12358989	COMM	WT (wild type)

TESTS DRAWN TOO EARLY (variable date range)

(Report lists every specimen collected at less than 24 hours of age, until closed by the State Program. Sorted by hospital).

PLACE OF BIRTH:	Hospital A	CITY:	Anytown	
Last Name	First Name	Birth Date	Filter Paper	Results
Doe	Jane	1/1/07 13:02	123456789	Inconclusive AA's

UNSATISFACTORY SPECIMENS (variable date range)

(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.)

PLACE OF BIRTH: Hospital A			CITY: Anytown		
Last Name	First Name	Birth Date	Filter Paper	Disorder(s) Not Screened For	Reason
Doe	Jane	1/1/07 13:02	123456789	Hgb. / TSH	Unsatisfactory Quantity not sufficient

PRESUMPTIVE POSITIVE TESTS (variable date range)

(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.)

Last Name	First Name	Birth Date	Filter Paper	Birth Place	City	Test Result	Age in days
Doe	Jane	1/1/07 13:02	123456789	Hospital A	Anytown	Abnormal Bio Pos	10

ABNORMAL MS/MS REPORT (variable date range)

(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.)

Last Name	First Name	Birth Date	Filter Paper	Birth Place	City	Test Result	profile	Age in days
Doe	Jane	1/1/07 13:02	123456789	Hospital A	Anytown	Abnormal C3	AC	10
Doe	Jean	1/1/07 13:03	123555555	Hospital A	Anytown	Tyr	AA	10

TSH Values >=20

Last Name	First Name	Birth Date	Filter Paper	Birth Place	City	TSH Value	Age in days
Doe	Jane	1/1/07 13:02	123456789	Hospital A	Anytown	65.2	10

CAH EXTRACTED INCONCLUSIVE TESTS (variable date range)

(Report lists every specimen determined to be inconclusive - in need of repeat testing. Names come off list when the State Program closes the record.)

Last Name	First Name	Birth Date	Filter Paper	Birth Place	City of Birth	Test/Result	Age in days
Doe	Jane	1/1/07 13:02	123456789	Hospital A	Anytown	17-OHP	Incon 10

POSSIBLE TRANSFUSIONS (variable date range)

(Report lists all specimens marked as "transfused", and those which have more Adult than Fetal hemoglobin. Report is sorted according to hospital. Names come off report when the State program closes the record.)

Place of Birth: Hospital A		Birth Date	Filter Paper	City
Last Name	First Name			
Doe	Jane	1/1/07 13:02	123456789	Anytown

INFANTS SCREENING RESULTS (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 listed below without sample data:

Birth date	Birth Facility	Submitter	City	Last Name	First Name	Date	Collected
17OHP	17OHPext	AA	AC	Bio	Gal	GalBEU	Hgb.
IRT	IRT Text	T4		TSH			

The following reports used for monitoring and follow-up are run routinely daily or at least once a week:

OUT OF HOSPITAL REPORT (variable date range, but pulls specimens for report based on date of collection not date of birth as in other reports.), report of all babies screened not born in hospitals (home, auto, etc.)

Last name	First Name	Birth Date	Filter Paper	Collected Date	Submitter	Age at Collection
Doe	Jane	01/01/07 13:02	123456789	01/03/07 13:01	Hospital B	2 day

LOST TO FOLLOW-UP REPORT

(List of all babies, the State program has designated/closed as “lost to follow-up”)

City	Birth Place	Birth Date/time	Last Name	First Name	Lost to Follow-up Date
Anytown	Home Birth	01/01/07 13:02	Doe	Jane	10/10/2007

MISSING TESTS

(List of all babies for whom the specimen was unsatisfactory or for some reason some or all of the screening panel tests were not conducted. Identifies which tests still need to be done. Names come off report when the State program closes the record. Sorted by hospital.)

Place of Birth: Hospital A	City: Anytown					
Last Name	First Name	Birth Date	Filter Paper	Result(s)	Tests(s) Missing	Age (Days)
Doe	Jane	01/01/07 13:02	123456789	AC, Hgb, Bio, IRT,	6	

MONTHLY MATCH REPORT

(List of all babies for whom a screening specimen has been received and tested. Data is exported by the NNSP into Excel® and merged with exported data from the birth certificate registry to identify any newborns who did not get a screen).

City	Birth Place	Birth Date Time	Last Name	First Name	Mother’s First Name
Anytown	Hospital A	01/01/07 13:02	Doe	Jane	Jill

METABOLIC SCREENING STATISTICS REPORT (Variable date range available)

Nebr. Births Screened.....	21,594
Out of Hospital Births (home, auto, clinic, prison, parking lot)...	64
Drawn Early.....	228
Unsatisfactory Specimens.....	74

CONFIRMED POSITIVE TEST RESULTS (Variable date range available)

(List of all babies with confirmed positive/diagnosed conditions identified by newborn screening for the calendar year. Sorted by Hospital.)

Last Name	First name	Birth Date	Birth City	Birth Place	Disorder Confirmed
Doe	Jane	01/01/07 13:02	Anytown	Hospital A	CPH
Doe	John	01/10/07 15:15	Anytown	Hospital A	FS
Doe	Jill	02/10/07 23:10	Anytown	Hospital A	CAH

Last Name	First name	Birth Date	Birth City	Birth Place	Disorder Confirmed
Roe	Jane	01/20/07 10:10	Anytown	Hospital B	Bio

Last Name	First name	Birth Date	Birth City	Birth Place	Disorder Confirmed
Roe	John	3/07/07 09:09	Othertown	Hospital C	Gal

QUALITY ASSURANCE REPORTS (variable date range) The following reports are run at least once every quarter and provided to the Nebraska Newborn Screening Advisory Committee. The last report is provided to each hospital with their own hospital's data compared to the State numbers and averages.

INITIAL T4 AVERAGE VALUE REPORT (variable date range)

T4 - µg/dL

# Initial Screens	984
Total of Values	16,531.900
Mean Avg. Value	16.801
Variance:	19.235
Standard Deviation	4.386
Minimum	2.000
25% ile	14
Median	16.500
75% ile	19.5
Maximum	30.800
Mode:	15.400

This report also lists the values for all T4's that were in the bottom 10%ile with a corresponding TSH > 20, and lists the TSH values.

INITIAL TSH AVERAGE VALUE REPORT (variable date range)

# Initial Screens	781
Total of Values	4,813.000
Mean Avg. Value	6.163
Variance:	78.547
Standard Deviation	8.863
Minimum	.100
25% ile	2.8
Median	5.100
75% ile	7.8
Maximum	220.000
Mode:	1.000

INITIAL GALACTOSEMIA AVERAGE VALUE REPORT

Total Galactose Values - mg/dL

# Initial Screens	979
Total of Values	2,623.300
Mean Avg. Value	2.680
Variance:	.855
Standard Deviation	.925
Minimum	.600
25% ile	2.1
Median	2.500
75% ile	3
Maximum	10.200
Mode:	2.200

This report also lists every presumptive positive galactosemia result with both the total galactose and UT values

GALT VALUES (galactose-1-phosphate uridylyltransferase) - μM

# Initial Screens	979
Total of Values	300,621.000
Mean Avg. Value	307.069
Variance:	7,050.789
Standard Deviation	83.969
Minimum	108.000
25% ile	244
Median	302.000
75% ile	361
Maximum	628.000
Mode:	226.000

INITIAL CAH AVERAGE VALUE REPORT

CAH - ng/ml

# Initial Screens	979
Total of Values	15,459.500
Mean Avg. Value	15.791
Variance:	171.600
Standard Deviation	13.100
Minimum	3.400
25% ile	9.7
Median	13.300
75% ile	17.7
Maximum	189.000
Mode:	10.900

CAH – Extracted

# Initial Screens	7
Total of Values	75.600
Mean Avg. Value	10.800
Variance:	48.520
Standard Deviation	6.966
Minimum	2.900
25% ile	3.8
Median	9.400
75% ile	13.5
Maximum	20.800
Mode:	8.5

This report also lists the presumptive positive screen results for CAH with both the 17-OHP and extracted 17-OHP results.

INITIAL BIOTINIDASE DEFICIENCY AVERAGE VALUE REPORT

Biotinidase – ERU

# Initial Screens	979
Total of Values	40,834.600
Mean Avg. Value	41.711
Variance:	122.322
Standard Deviation	11.060
Minimum	13.300
25% ile	34
Median	41.000
75% ile	49
Maximum	92.000
Mode:	39.000

This report also lists the presumptive positive screen results for biotinidase deficiency with the ERU values.

Cystic Fibrosis – IRT

# Initial Screens	
Total of Values	
Mean Avg. Value	
Variance:	
Standard Deviation	
Minimum	
25% ile	
Median	
75% ile	
Maximum	
Mode:	

This report also lists the presumptive positive screen results for CF.

INFANT'S AGE AT TIME OF FIRST (INITIAL) NEWBORN SPECIMEN COLLECTION

Total Births	984		
# collected between 0-12 hours of age:	5	% of total	0.51
# collected between 12-24 hours of age:	5	% of total	0.51
# collected day 1:	10	% of total	1.02
# collected day 2:	920	% of total	93.50
# collected day 3:	51	% of total	5.18
# collected day 4:	1	% of total	0.10
# collected day 5:	1	% of total	0.10
# collected day 6:	0	% of total	0
# collected day 7:	1	% of total	0.10
Over 7 days:	0	% of total	0.00
Time of collection unknown:	0	% of total	0.00

Average, Minimum & Maximum turnaround times report

(Can run this report in its entirety for every birth during a designated time frame, or for select hospitals. Also can export data for additional analysis) (Also can run this report for specific submitters/hospitals).and the specific dates for each filter paper are listed

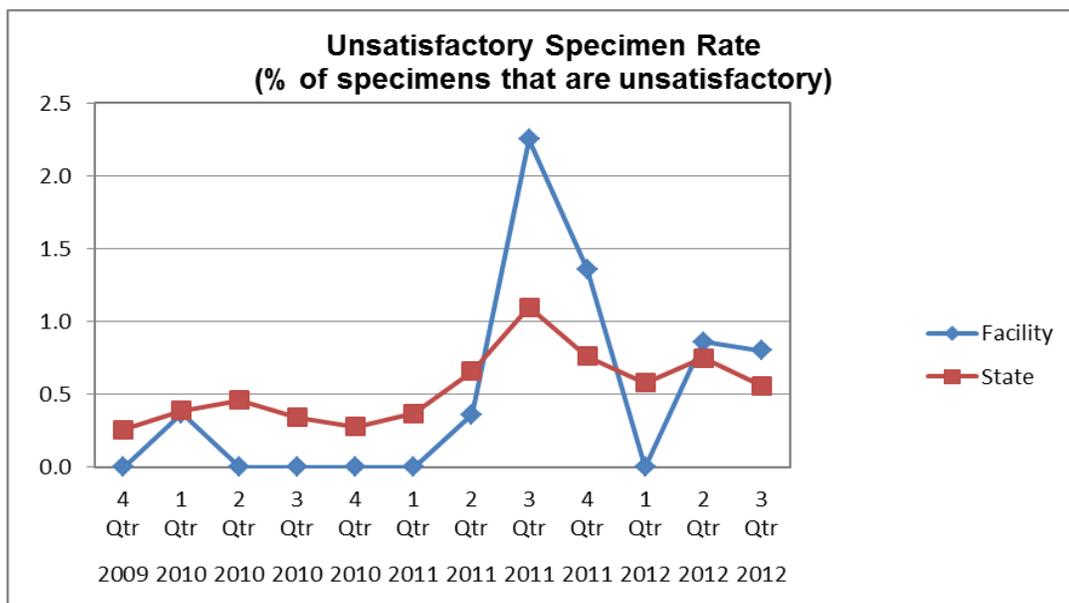
Filter paper #	Birthdate	Collection date	Receipt date	Release date
01234567	08/01/2012	08/02/2012	08/03/2012	08/04/2012

	Birth-Collection	Collect-Receipt	Receipt-Release	Birth-Release
AVG	1.43	2.26	1.38	5.06
MIN	.00	1.00	1.00	2.00
MAX	6.00	6.00	3.00	10.00

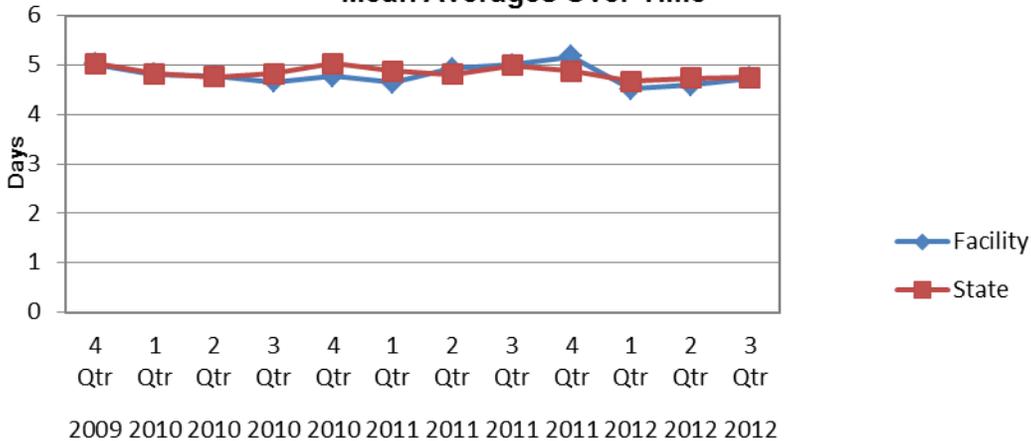
HOSPITAL QUARTERLY QUALITY ASSURANCE REPORT

Data Presented for 3Q 2012	Nebraska Statewide		(HOSPITAL NAME)	
	Number	Percent	Number	Percent
Newborns born in your facility	6,852		312	
Initial newborn specimens submitted	6,893		319	
Total Specimens (Includes initial repeat specimens & home births)	7,921		376	
Unsatisfactory specimens	44	0.56%	3	0.80%
Specimens drawn early (<24 hours)	710	8.96%	47	12.50%
Initial specimens collected post-transfusion	0	0.00%	0	0.00%
Average turn-around time from birth to report (days)	4.75		4.73	
Average time from birth to collection	1.22		1.37	
Fastest 25th percentile	< 1.15			
Fastest 50th percentile	< 1.22			
Fastest 75th percentile	< 1.37			
Average time collection to receipt at the screening lab	2.11		1.89	
Fastest 25th percentile	< 1.89			
Fastest 50th percentile	< 2.07			
Fastest 75th percentile	< 2.29			
Average time from receipt to report	1.42		1.46	
Fastest 25th percentile	< 1.3			
Fastest 50th percentile	< 1.4			
Fastest 75th percentile	< 1.48			

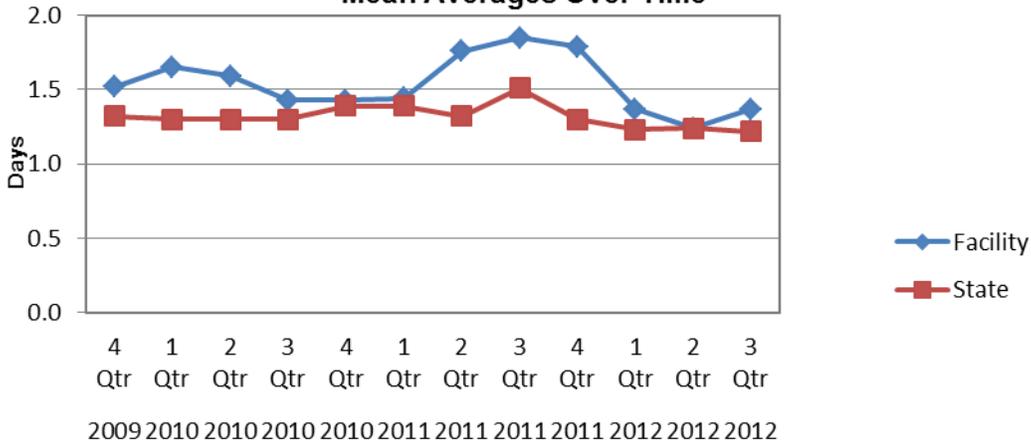
The revised (July 2008) report provides the breakdown of the fastest turnaround times by percentile so you can see where your facility's numbers are relative to the best performers in the top 25% vs. the slower turnaround times in the bottom 25%. This routine report replaces prior special QA reports on turnaround times.



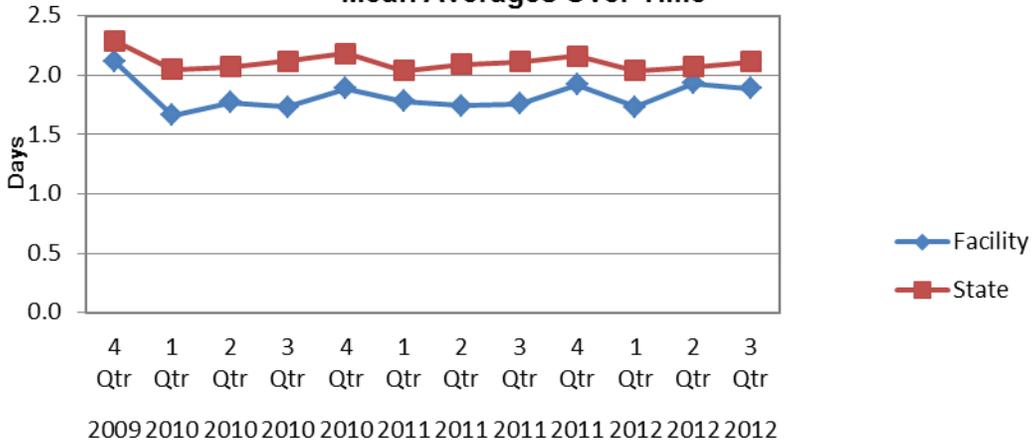
**Total Turn Around Time (Birth to Result)
Mean Averages Over Time**



**Birth to Collection
Mean Averages Over Time**



**Collection to Receipt at PerkinElmer Lab
Mean Averages Over Time**



HOSPITAL MISSING DEMOGRAPHICS REPORT

Newborn Screening Filter Paper Dried Blood Spot Collection Device CARE Form (Collection and Reporting Form) Missing Demographic Information

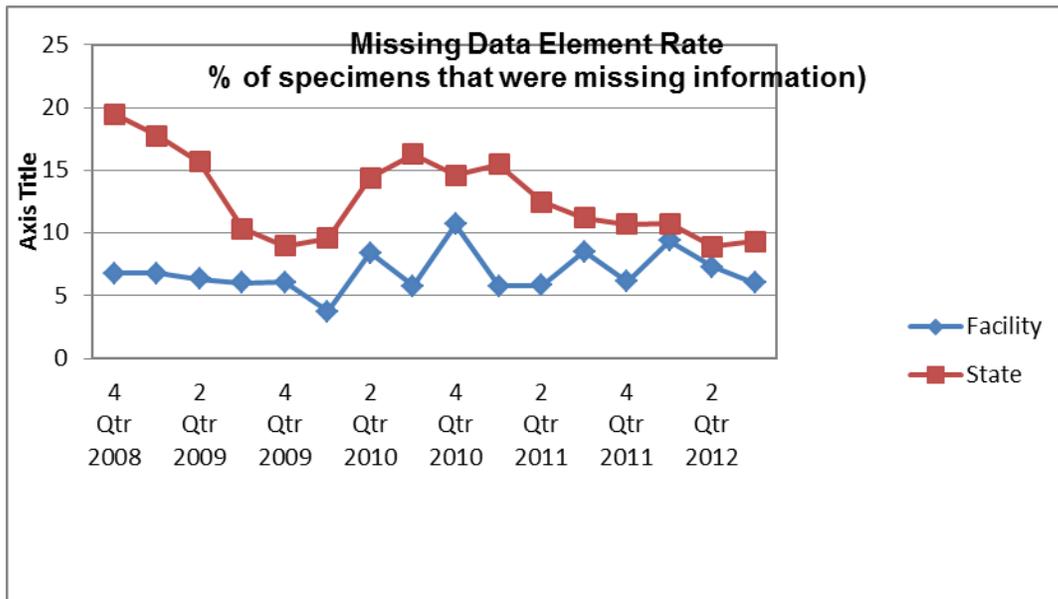
The demographic information recorded by hospital personnel on the newborn screening dried blood spot collection device is entered into the database at the newborn screening laboratory. Some of the information is critical to proper laboratory result interpretation (e.g. birth weight is used for weight-adjusted 17-OHP reference ranges used to screen for congenital adrenal hyperplasia). All of the information is used to properly identify the right patient, and assist with follow-up in contacting newborns physicians and families in the event of positive or inconclusive (abnormal) screening results, unsatisfactory specimens, or specimens drawn too early. Rapid retrieval, confirmatory testing, diagnosis and treatment are essential to prevention of mental retardation, physical disability and infant mortality from the screened for conditions. Missing information can impact the ability to properly screen and follow-up in time to prevent damage to the newborn.

In addition Nebraska Regulations Title 181, NAC 2 Screening of Infants for Metabolic Diseases 2-006.01 requires "The hospital or other submitter designated by the newborn's attending physician must complete all information and collect the specimen on the CARE form." The hospital or other submitter must retain the designated copy for inclusion into the newborn's medical record and send the remaining copies to the testing laboratory designated by the Department with 24 hours after specimen collection.

The following demographic information was missing on CARE forms submitted by your facility. Raw data identifying which CARE forms had missing information is listed on the next page.

QUARTER 3, 2012 (HOSPITAL NAME)

Data element:	Number of times element was missing:
Birth Date	0
Birth Time	1
Collection Date	0
Collection Time	0
Gender	1
Mom Address	0
Mom Birth Date	2
Mom City	0
Mom First Name	1
Mom Last Name	0
Mom Phone Number	5
Mom Zip	5
Patient First Name	2
Patient Last Name	0
Physician Name	0
Physician Phone	1
Weeks Gestation	6
Birth Weight	5



The_Year	The_Quarter	Sub_Code	Submitter_Name	Info Missing	Filter Paper
2012	3	Submitter	Name	Birth Time	Filter
2012	3	code #	deleted	Birth Weight	paper #'s
2012	3	deleted to	to provide	Birth Weight	deleted to
2012	3	provide	example	Birth Weight	provide
2012	3	example		Birth Weight	example
2012	3			Birth Weight	
2012	3			Gender	
2012	3			Mom Birth Date	
2012	3			Mom Birth Date	
2012	3			Mom First Name	
2012	3			Mom Phone Number	
2012	3			Mom Phone Number	
2012	3			Mom Phone Number	

NEW REPORTS for tracking and quality assurance monitoring **WILL BE REQUIRED** WHEN **REGULATION REVISIONS** are adopted adding SCID and changing the filter paper blood collection form to collect NICU data. The bidder agrees to work with the Nebraska Newborn Screening Program to develop these data reports based on criteria determined necessary by the NNSP. SCID follow-up/tracking report development will take priority in order to support the follow-up function.

Appendix F

Screening Algorithms and Reporting Procedures

Request for Proposal Number 4229Z1

All Initial specimens collected at less than 24 hours of age are tested for all conditions except CAH, CPH and CF. All Initial specimens collected at greater than 24 hours of age are tested for all conditions. All repeat specimens collected due to the earlier specimen being collected at less than 24 hours of age are tested for all conditions. Repeat specimens collected due to earlier abnormalities may only be tested for that condition, (e.g.. inconclusive initial biotinidase result, repeat specimen only requires biotinidase testing). All babies admitted to the NICU weighing less than 2000 grams at birth require a third specimen at 28 days or upon discharge if earlier. These third specimens will be tested for all conditions on the panel.

ASA: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

BKT: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

BIO: The method is described at C.1. Scope of Work & Project Requirements. Enzyme reaction units (ERU) from 0-8.0 reflex to DNA. These results are reported as positive and confirmatory serum quantification testing and referral to metabolic specialist are recommended. ERU's 8.1-16.0 on initial screens are reported as inconclusive and a repeat DBS is requested. ERU's 8.1-16 on a repeat screen when the initial ERU was low reflex to DNA and referral to metabolic specialist is recommended. All inconclusive and positive results are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required only for Positives, or on repeat screens when the initial was inconclusive and the repeat continues to be inconclusive

CIT: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second

abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

CUD: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

CAH: The primary assay 17-OHP has 5 birthweight adjusted cut-offs above which trigger immediate notification of critical positive results recommending confirmatory testing and referral to pediatric endocrinology. There are also 5 birthweight adjusted reference ranges. Results above the reference range but below the critical cut-off reflex to an extracted 17-OHP assay. If the birthweight is greater than or equal to 1.5 kg the extracted 17-OHP cut off is 44. If the birthweight is less than 1.5 kg the extracted cut off is 19. Those above the 17-OHP reference range and pending the extracted result who are greater than 1.5 kg are reported out as preliminary positive or inconclusive, and a final report is made after the extracted is complete, either amending to within normal limits no further follow-up necessary, inconclusive recommend repeat DBS, or positive with recommended confirmatory testing and referral to pediatric endocrinology. Those above the 17-OHP reference range and pending the extracted result who are less than or equal to 1.5 kg are not reported out until the extracted is complete which often eliminates false positives/inconclusives in premature newborns. The CAH assay is not run on initial specimens collected at less than 24 hours. All inconclusives, preliminary positives and positives are reported by phone and fax to the NNSP, submitter and physician during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for all positives and inconclusives, including preliminary positives.

CPH: The primary assay is a T4 run on all initial specimens except those collected at less than 24 hours. The bottom 10% of T4's in the run, reflex to TSH. TSH's greater than or equal to 20 are reported as positive and recommended for confirmatory testing and consultation with pediatric endocrinology. All positives are reported by phone and fax to the NNSP, physician and submitter during normal working hours and by phone only after hours to the NNSP, physician and submitter.

CF: The primary assay is IRT. The normal reference range for IRTs is the bottom 98.8% of the run. IRTs in the highest 1.2% of the run reflex to DNA to look for the $\Delta F508$ mutation. If no mutation is found it is reported out as inconclusive and a repeat DBS is recommended. If one $\Delta F508$ mutation is found, the assay reflexes to the Luminex x-TAG 39+4 mutation panel. If no additional mutations are found it is reported out as inconclusive and referral to an accredited CF center and sweat testing is recommended. If two $\Delta F508$ copies are found or one $\Delta F508$ and another mutation are found, it is reported out as positive and referral to an accredited CF center is recommended.

Repeat screens collected due to an initial elevated IRT with no $\Delta F508$ mutation are recommended at 2 weeks of age. If baby is already greater than 2 weeks of age a repeat is requested when results are received. IRTs on repeats collected at < 12 days of age in the highest 1.2% of the run are considered elevated and reflex to the Luminex x-TAG 39+4 mutation panel. IRTs on specimens collected at ≥ 12 days of age > 80 ng/mL are considered elevated and reflex to the Luminex x-Tag 39+4 mutation

panel. If one mutation is found it is reported as inconclusive and sweat testing and referral to an accredited CF center is recommended. If two mutations are found it is reported as positive and referral to an accredited CF center is recommended.

If at any time a baby is reported to have meconium ileus or other bowel obstruction, the specimen is checked with the Luminex x-TAG 39+4 mutation panel bypassing the IRT. Results with 2 mutations are positive and referred to an accredited CF center. Results with one or no mutations are inconclusive and referral to an accredited CF center is recommended.

All positive and inconclusive results are reported by phone and fax during normal working hours to the NNSP, submitter and physician. No after-hours reporting is required for any CF screening results.

GAL: The method is described at C.1. Scope of Work & Project Requirements. On initial specimens, galactose >15 mg/dL and <30 are reported as inconclusive and reported with the level of uridyl transferase and total galactose. Initial specimens galactose >30 mg/dL reflex to DNA, are reported as positive and reported with the level of uridyl transferase, total galactose and DNA. Repeat specimens collected due to inconclusive results for galactosemia on the initial specimen with repeat results of ; galactose >15<20 mg/dL with normal UT (>40) are considered normal; galactose >20< 30 with normal UT are reported to continue to be inconclusive but confirmatory testing referral to metabolic specialist is recommended, and; galactose > 30 are reported as positive with the UT and total galactose and DNA. All positives and inconclusives are reported by phone and fax during normal working hours to the NNSP, submitter and physician. After hours phone reporting to the NNSP, physician and submitter is required for all positives, and repeat specimens with continued inconclusive results.

GAI: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

HGB's: Isoelectric focusing, to detect hemoglobins F, A, S, C, D, E, O_{ARAB}, Bart's and other unidentified variants, is currently used to screen for hemoglobinopathies. Hemoglobins are reported in order of quantity from the highest to lowest. When clinically significant findings: FS, FC, FSC, FE (or any of these plus Bart's hemoglobin) or F only appear, the screen reflexes to DNA for confirmation. When clinically significant findings such as FSA, FCA, FEA, (or any of these plus Bart's hemoglobin) or F only that are suggestive of Beta Thalassemia are found, additional DNA testing for some Beta Thalassemia mutations is done.

Clinically significant hemoglobinopathy results may be repeated at the screening laboratory at no charge. All other hemoglobinopathies are recommended for confirmatory testing. Babies with hemoglobin with an unidentified variant result are recommended to have confirmatory testing by IEF and HPLC.

All hemoglobin results other than FA and AF (when collected post transfusion) are reported by phone and fax to the NNSP, the physicians and submitter during normal working hours. No after-hours reporting is required for any of the abnormal hemoglobin types.

HCY: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

HMG: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

IVA: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

LCHAD: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

MSUD: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

MCAD: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported

by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

MMA (Mutase and Cb. A, B): proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

MCD: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

PKU: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

PA: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

SCID: Screening for SCID will begin 5 days following promulgation of revised regulations Title 181, NAC 2. The screening method is PCR amplification to detect copy numbers of T-Cell Receptor Excision Circles (TRECS). When TRECs are < 40 copy numbers, the assay reflexes to determine adequacy of amplification, by testing for beta-Actin. TRECs copy number >6 and ≤ 25 with beta-Actin copy number > 10,000, or TRECS copy number 0-5 with beta-Actin copy number > 5000 are reported by phone and fax to the NNSP, submitter and physician as positive and recommended for confirmatory testing and immediate consultation with the SCID treatment team. TRECs copy number >6 and ≤ 25 with beta-Actin $\leq 10,000$ or 0-5 with beta-Actin copy number ≤ 5000 are reported by phone and fax to the NNSP, submitter and physician as inconclusive and recommended for repeat screening. Because premature, low birth weight and sick infants admitted to the NICU are likely to

represent a disproportionate number of abnormal SCID screens, a special protocol for requested repeat screens to be done at no additional charge, will be developed and agreed upon between the laboratory and screening program.

TFP: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

TYR: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

VLCAD: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

3-MCC: A proprietary MS/MS method of screening is currently used. Current procedure involves reporting slight abnormalities and recommending repeat screening, abnormal (moderate risk) abnormalities and requesting an urgent repeat within 48 hours, and substantial abnormalities recommending confirmatory testing and referral to pediatric metabolic specialist. A second abnormality results in recommendations to refer to metabolic specialist. All abnormalities are reported by phone and fax to the NNSP, physician and submitter during normal working hours. After hours phone reporting to the NNSP, physician and submitter is required for the substantial abnormalities and second or repeat abnormalities.

If alternative methods are proposed, bidder must provide: The descriptions for the alternatives specified by condition, which algorithm/reporting procedure(s) are proposed to be replaced and specify in detail the method, reference range, cut-off, decision points, any specific modifications such as birth weight ranges, gestational age, age at collection, and recommended follow-up actions to include in the report. The rationale describing why the alternative is better than the existing protocols must also be included.

Proprietary Information

Every screening algorithm/interpretation guideline that is not described in detail as part of this proposal under protection of registration, copyright or patent must be made available in writing to the Nebraska Newborn Screening Program within 30 days of the effective date of the contract award. Updates to screening algorithms/interpretation guidelines must be provided to and agreed upon with the Nebraska Newborn Screening Program in writing prior to implementing them.