



P R O P O S A L

CENTER **FOR** DISEASE DETECTION

**Request for Proposal
STD Testing Services**

Solicitation Number: 6212-Z1

**Nebraska
Department of Health
and Human Services
DHHS – 3rd Floor
301 Centennial Mall South
Lincoln, NE 68509**

March 2, 2020

From
Center for Disease Detection, LLC
11603 Crosswinds Way, Suite 100
San Antonio, Texas 78233
1-888-858-8663

ORIGINAL



March 2, 2020

Keith Roland / Jennifer Crouse
Nebraska Department of Health and Human Services
DHHS – 3rd Floor
301 Centennial Mall South
Lincoln, NE 68509

Dear Mr. Roland & Ms. Crouse:

Center for Disease Detection (CDD) is pleased to submit the enclosed response to Request for Proposal 6212-Z1, STD Testing Services. Our submission indicates acceptance of all terms and conditions contained in this solicitation with the exception of the frequency of the invoicing. As a laboratory that concentrates on providing testing services in the public health arena, we already perform many of the tasks detailed in this RFP for many state, city and county health department all across the country. You will find in the following pages all evidence and documentation requested under this RFP.

Should you have any questions or require further clarification do not hesitate to contact me.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "R. Nelson", is written over a light grey horizontal line.

Robert Nelson
Senior Vice President

II Terms and Conditions

II. TERMS AND CONDITIONS

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

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

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

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

A. GENERAL

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>RF</i>			

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

4. Request for Proposal and Addenda;
5. Amendments to the solicitation;
6. Questions and Answers;
7. Bidder’s proposal (Solicitation and properly submitted documents);
8. The executed Contract and Addendum One to Contract, if applicable; and,
9. Amendments/Addendums to the Contract.

These documents constitute the entirety of the contract.

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

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

B. NOTIFICATION

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>PA</i>			

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

Communications regarding the executed contract shall be in writing and shall be deemed to have been given if delivered personally or mailed, by U.S. Mail, postage prepaid, return receipt requested, to the parties at their respective addresses set forth below, or at such other addresses as may be specified in writing by either of the parties. All notices, requests, or communications shall be deemed effective upon personal delivery or five (5) calendar days following deposit in the mail.

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.

C. BUYER'S REPRESENTATIVE

The State reserves the right to appoint a Buyer's Representative to manage [or assist the Buyer in managing] the contract on behalf of the State. The Buyer's Representative will be appointed in writing, and the appointment document will specify the extent of the Buyer's Representative authority and responsibilities. If a Buyer's Representative is appointed, the Contractor will be provided a copy of the appointment document, and is required to cooperate accordingly with the Buyer's Representative. The Buyer's Representative has no authority to bind the State to a contract, amendment, addendum, or other change or addition to the contract.

D. GOVERNING LAW (Statutory)

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

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

E. BEGINNING OF WORK

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>PA</i>			

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

F. AMENDMENT

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>RL</i>			

This Contract may be amended in writing, within scope, upon the agreement of both parties.

G. CHANGE ORDERS OR SUBSTITUTIONS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>RL</i>			

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

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

No change shall be implemented by the Contractor until approved by the State, and the Contract is amended to reflect the change and associated costs, if any. If there is a dispute regarding the cost, but both parties agree that immediate implementation is necessary, the change may be implemented, and cost negotiations may continue with both Parties retaining all remedies under the contract and law.

In the event any product is discontinued or replaced upon mutual consent during the contract period or prior to delivery, the State reserves the right to amend the contract or purchase order to include the alternate product at the same price.

*****Contractor will not substitute any item that has been awarded without prior written approval of SPB*****

H. VENDOR PERFORMANCE REPORT(S)

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>RL</i>			

The State may document any instance(s) of products or services delivered or performed which exceed or fail to meet the terms of the purchase order, contract, and/or solicitation specifications. The State Purchasing Bureau may contact the Vendor regarding any such report. Vendor performance report(s) will become a part of the permanent record of the Vendor.

I. NOTICE OF POTENTIAL CONTRACTOR BREACH

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>DL</i>			

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

J. BREACH

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
		<i>DL</i>	<p>If CLIENT suspects or believes that a test result is incompatible with a patient's clinical condition, LABORATORY will repeat the test at no additional charge if a request to repeat the test is received from CLIENT within five (5) days following the date of the original test and specimen stability and volume permit. This policy applies only to specimens initially sent to and tested by LABORATORY.</p> <p>LABORATORY WARRANTS TO CLIENT THAT ALL SERVICES PROVIDED HEREUNDER SHALL BE IN ACCORDANCE WITH ESTABLISHED AND RECOGNIZED CLINICAL LABORATORY TESTING PROCEDURES AND WITH REASONABLE CARE IN ACCORDANCE WITH APPLICABLE FEDERAL, STATE AND LOCAL LAWS.</p> <p>D. NO OTHER WARRANTIES ARE MADE BY LABORATORY.</p> <p>E. IN NO EVENT SHALL LABORATORY BE RESPONSIBLE FOR ANY PUNITIVE DAMAGES OR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, OR SPECIAL DAMAGES OF CLIENT OR OF ANY THIRD PARTY.</p>

Either Party may terminate the contract, in whole or in part, if the other Party breaches its duty to perform its obligations under the contract in a timely and proper manner. Termination requires written notice of default and a thirty (30) calendar day (or longer at the non-breaching Party's discretion considering the gravity and nature of the default) cure period. Said notice shall be delivered by Certified Mail, Return Receipt Requested, or in person with proof of delivery. Allowing time to cure a failure or breach of contract does not waive the right to immediately terminate the contract for the same or different contract breach which may occur at a different time. In case of default of the Contractor, the State may contract the service from other sources. OR In case of breach by the Contractor, the State may, without unreasonable delay, make a good faith effort to make a reasonable purchase or contract to purchased goods in substitution of those due from the contractor. .

The State's failure to make payment shall not be a breach, and the Contractor shall retain all available statutory remedies and protections.

K. NON-WAIVER OF BREACH

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

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

L. SEVERABILITY

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>DL</i>			

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

M. INDEMNIFICATION

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
		<i>DL</i>	<p>Add the following language.</p> <p>Client and LabCorp each agree to be responsible for any and all claims, damages, or other expenses which arise, or are alleged to have arisen, in connection with this Agreement which such party controls. For clarity purposes, LabCorp shall not indemnify Client for claims, damages, or other expenses that arise in respect to Client's negligence or willful misconduct and Client shall not indemnify LabCorp for claims, damages or other expenses that arise in respect to LabCorp's negligence or willful misconduct.</p>

1. GENERAL

The Contractor agrees to defend, indemnify, and hold harmless the State and its employees, volunteers, agents, and its elected and appointed officials ("the indemnified parties") from and against any and all third party claims, liens, demands, damages, liability, actions, causes of action, losses, judgments, costs, and expenses of every nature, including investigation costs and expenses, settlement costs, and attorney fees and expenses ("the claims"), sustained or asserted against the State, arising out of, resulting from, or attributable to the willful misconduct, negligence, error, or omission of the Contractor resulting from this contract, except to the extent such Contractor liability is attenuated by any action of the State which directly and proximately contributed to the claims.

Client and LabCorp each agree to be responsible for any and all claims, damages, or other expenses which arise, or are alleged to have arisen, in connection with this Agreement which such party controls. For clarity purposes, LabCorp shall not indemnify Client for claims, damages, or other expenses that arise in respect to Client's negligence or willful misconduct and Client shall not indemnify LabCorp for claims, damages or other expenses that arise in respect to LabCorp's negligence or willful misconduct.

2. PERSONNEL

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

3. SELF-INSURANCE

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

4. ALL REMEDIES AT LAW

Nothing in this agreement shall be construed as an indemnification by one Party of the other for liabilities of a Party or third parties for property loss or damage or death or personal injury arising out of and during the performance of this contract. Any liabilities or claims for property loss or damages or for death or personal injury by a Party or its agents, employees, contractors or assigns or by third persons, shall be determined according to applicable law.

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

N. ATTORNEY'S FEES

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

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

O. PERFORMANCE BOND

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
			CDD has many contracts with Federal, State, County and City government entities and is a wholly owned subsidiary of Laboratory Corporation of America who currently has even more of these types of contracts. Both organizations understand that to default on any of these contracts for non-performance risks the ability to have these contracts awarded to us in the future. We have always and will continue to live up to the expectations set forth in these contracts.

The Contractor will be required to supply a bond executed by a corporation authorized to contract surety in the State of Nebraska, payable to the State of Nebraska, which shall be valid for the life of the contract to include any renewal and/or extension periods. The amount of the bond must be \$100,000 (one hundred thousand dollars). The bond will guarantee that the Contractor will faithfully perform all requirements, terms and conditions of the contract. Failure to comply shall be grounds for forfeiture of the bond as liquidated damages. Amount of forfeiture will be determined by the agency based on loss to the State. The bond will be returned when the contract has been satisfactorily completed as solely determined by the State, after termination or expiration of the contract.

P. ASSIGNMENT, SALE, OR MERGER

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

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

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

the transaction agrees in writing to be contractually bound by this contract and perform all obligations of the contract.

Q. CONTRACTING WITH OTHER NEBRASKA POLITICAL SUB-DIVISIONS OF THE STATE OR ANOTHER STATE

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

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

The Contractor may, but shall not be required to, allow other states, agencies or divisions of other states, or political subdivisions of other states to use this contract. The terms and conditions, including price, of this contract shall apply to any such contract, but may be amended upon mutual consent of the Parties. The State of Nebraska shall not be contractually or otherwise obligated or liable under any contract entered into pursuant to this clause. The State shall be notified if a contract is executed based upon this contract.

R. FORCE MAJEURE

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

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

S. CONFIDENTIALITY

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
			CDD is not long-term care ombudsman;

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

It is incumbent upon the Parties to inform their officers and employees of the penalties for improper disclosure imposed by the Privacy Act of 1974, 5 U.S.C. 552a. Specifically, 5 U.S.C. 552a (i)(1), which is made applicable by 5 U.S.C. 552a (m)(1), provides that any officer or employee, who by virtue of his/her employment or official position has possession of or access to agency records which contain individually identifiable information, the disclosure of which is prohibited by the Privacy Act or regulations established thereunder, and who knowing that disclosure of the specific material is prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000.

T. OFFICE OF PUBLIC COUNSEL (Statutory)

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

U. LONG-TERM CARE OMBUDSMAN (Statutory)

To the extent applicable to a reference clinical laboratory, Contractor must comply with the Long-Term Care Ombudsman Act, per Neb. Rev. Stat. §§ 81-2237 et seq. This section shall survive the termination of this contract.

V. EARLY TERMINATION

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>DA</i>			

The contract may be terminated as follows:

1. The State and the Contractor, by mutual written agreement, may terminate the contract at any time.
2. The State, in its sole discretion, may terminate the contract for any reason upon thirty (30) calendar day's written notice to the Contractor. Such termination shall not relieve the Contractor of warranty or other service obligations incurred under the terms of the contract. In the event of termination the Contractor shall be entitled to payment, determined on a pro rata basis, for products or services satisfactorily performed or provided.
3. The State may terminate the contract immediately for the following reasons:
 - a. if directed to do so by statute;
 - b. Contractor has made an assignment for the benefit of creditors, has admitted in writing its inability to pay debts as they mature, or has ceased operating in the normal course of business;
 - c. a trustee or receiver of the Contractor or of any substantial part of the Contractor's assets has been appointed by a court;
 - d. fraud, misappropriation, embezzlement, malfeasance, misfeasance, or illegal conduct pertaining to performance under the contract by its Contractor, its employees, officers, directors, or shareholders;
 - e. an involuntary proceeding has been commenced by any Party against the Contractor under any one of the chapters of Title 11 of the United States Code and (i) the proceeding has been pending for at least sixty (60) calendar days; or (ii) the Contractor has consented, either expressly or by operation of law, to the entry of an order for relief; or (iii) the Contractor has been decreed or adjudged a debtor;
 - f. a voluntary petition has been filed by the Contractor under any of the chapters of Title 11 of the United States Code;
 - g. Contractor intentionally discloses confidential information;
 - h. Contractor has or announces it will discontinue support of the deliverable; and,
 - i. In the event funding is no longer available.

W. CONTRACT CLOSEOUT

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>DA</i>			

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

1. Transfer all completed or partially completed deliverables to the State;

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

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

III Contractor Duties

II. CONTRACTOR DUTIES

A. INDEPENDENT CONTRACTOR / OBLIGATIONS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>PK</i>			

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

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

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

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

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

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

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

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

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

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

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

B. EMPLOYEE WORK ELIGIBILITY STATUS

Accept	Reject	Reject & Provide	NOTES/COMMENTS:
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(Initial)	(Initial)	Alternative within Solicitation Response (Initial)	
<i>ML</i>			

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

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

1. The Contractor must complete the United States Citizenship Attestation Form, available on the Department of Administrative Services website at <http://das.nebraska.gov/materiel/purchasing.html>
2. The completed United States Attestation Form should be submitted with the solicitation response.
3. 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.
4. The Contractor understands and agrees that lawful presence in the United States is required and the Contractor may be disqualified or the contract terminated if such lawful presence cannot be verified as required by Neb. Rev. Stat. §4-108.

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

The Contractor shall comply with all applicable local, state, and federal statutes and regulations regarding civil rights laws and equal opportunity employment. The Nebraska Fair Employment Practice Act prohibits Contractors of the State of Nebraska, and their Subcontractors, from discriminating against any employee or applicant for employment, with respect to hire, tenure, terms, conditions, compensation, or privileges of employment because of race, color, religion, sex, disability, marital status, or national origin (Neb. Rev. Stat. §48-1101 to 48-1125). The Contractor guarantees compliance with the Nebraska Fair Employment Practice Act, and breach of this provision shall be regarded as a material breach of contract. The Contractor shall insert a similar provision in all Subcontracts for goods and services to be covered by any contract resulting from this solicitation.

D. COOPERATION WITH OTHER CONTRACTORS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
		<i>ML</i>	LabCorp has agreements with thousands of customers, including various federal, state and local governmental agencies and departments, managed care plans, health systems, hospitals and physicians. Each of those arrangements provide for different terms of service, including fees that are based, in part, on the service requirements, test utilization projections, local market factors and other services that may be incorporated into the fee schedule. Therefore, LabCorp cannot agree to provide any specific customer with fees that are not higher than fees provided to any other customer. LabCorp can provide that the fee schedule proposed for the State of Nebraska will be, in the aggregate, comparable to the fees charged to similarly situated customers whose service requirements and test utilization are comparable to those required by the State of Nebraska.

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

E. DISCOUNTS

Prices quoted shall be inclusive of ALL trade discounts. Cash discount terms of less than thirty (30) days will not be considered as part of the proposal. Cash discount periods will be computed from the date of receipt of a properly executed claim voucher or the date of completion of delivery of all items in a satisfactory condition, whichever is later.

F. PRICES

Prices quoted shall be net, including transportation and delivery charges fully prepaid by the contractor, F.O.B. destination named in the solicitation. 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.

Prices submitted on the cost proposal form, once accepted by the State, shall remain fixed for the initial term of the contract. Any request for a price increase for each renewal period shall not exceed five percent (5%) of the price proposed for the period. Increases shall not be cumulative and will only apply to that period of the contract. The request for a price increase must be submitted in writing to the DHHS a minimum of 120 days prior to the end of the current contract period. Documentation may be required by the State to support the price increase.

The State reserves the right to deny any requested price increase. No price increases are to be billed to any State Agencies prior to written amendment of the contract by the parties.

LabCorp has agreements with thousands of customers, including various federal, state and local governmental agencies and departments, managed care plans, health systems, hospitals and physicians. Each of those arrangements provide for different terms of service, including fees that are based, in part, on the service requirements, test utilization projections, local market factors and other services that may be incorporated into the fee schedule. Therefore, LabCorp cannot agree to provide any specific customer with fees that are not higher than fees provided to any other customer. LabCorp can provide that the fee schedule proposed for the State of Nebraska will be, in the aggregate, comparable to the fees charged to similarly situated customers whose service requirements and test utilization are comparable to those required by the State of Nebraska.

G. COST CLARIFICATION

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

H. PERMITS, REGULATIONS, LAWS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>PA</i>			

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

I. OWNERSHIP OF INFORMATION AND DATA / DELIVERABLES

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

			
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The State shall have the unlimited right to publish, duplicate, use, and disclose all information and data developed or obtained by the Contractor on behalf of the State pursuant to this contract in accordance with all regulatory, federal and state law regarding patient confidentiality.

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

J. INSURANCE REQUIREMENTS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>DA</i>			

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

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

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

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

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

1. WORKERS' COMPENSATION INSURANCE

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

2. COMMERCIAL GENERAL LIABILITY INSURANCE AND COMMERCIAL AUTOMOBILE LIABILITY INSURANCE

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

The Commercial General Liability Insurance shall be written on an **occurrence basis**, and provide Premises/Operations, Products/Completed Operations, Independent Contractors, Personal Injury, and Contractual Liability coverage. **The policy shall include the State, and others as required by the contract documents, as Additional Insured(s).** This policy shall be primary, and any insurance or self-insurance carried by the State shall be considered secondary and non-contributory. The COI

shall contain the mandatory COI liability waiver language found hereinafter. The Commercial Automobile Liability Insurance shall be written to cover all Owned, Non-owned, and Hired vehicles.

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

3. EVIDENCE OF COVERAGE

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

Department of Health and Human Services
 Attn: STD Program Manager
 301 Centennial Mall S., 3rd floor
 Lincoln, NE 68509

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

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

4. DEVIATIONS

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

K. ANTITRUST

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>DL</i>			

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.

L. CONFLICT OF INTEREST

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>DL</i>			

By submitting a proposal, bidder certifies that no relationship exists between the bidder and any person or entity which either is, or gives the appearance of, a conflict of interest related to this Request for Proposal or project.

Bidder further certifies that bidder will not employ any individual known by bidder to have a conflict of interest nor shall bidder take any action or acquire any interest, either directly or indirectly, which will conflict in any manner or degree with the performance of its contractual obligations hereunder or which creates an actual or appearance of conflict of interest.

If there is an actual or perceived conflict of interest, bidder shall provide with its proposal a full disclosure of the facts describing such actual or perceived conflict of interest and a proposed mitigation plan for consideration. The State will then consider such disclosure and proposed mitigation plan and either approve or reject as part of the overall bid evaluation.

M. SITE RULES AND REGULATIONS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>DL</i>			

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 in writing between the State and the Contractor.

N. ADVERTISING

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

			
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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 goods or services are endorsed or preferred by the State. Any publicity releases pertaining to the project shall not be issued without prior written approval from the State.

O. NEBRASKA TECHNOLOGY ACCESS STANDARDS (Statutory)

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

P. DISASTER RECOVERY/BACK UP PLAN

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

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

Q. DRUG POLICY

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

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

R. WARRANTY

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

Despite any clause to the contrary, the Contractor represents and warrants that its services hereunder shall be performed by competent personnel and shall be of professional quality consistent with generally accepted industry standards for the performance of such services and shall comply in all respects with the requirements of this Agreement. For any breach of this warranty, the Contractor shall, for a period of ninety (90) days from performance of the service, perform the services again, at no cost to the State, or if Contractor is unable to perform the services as warranted, Contractor shall reimburse the State all fees paid to Contractor for the unsatisfactory services. The rights and remedies of the parties under this warranty are in addition to any other rights and remedies of the parties provided by law or equity, including, without limitation actual damages, and, as applicable and awarded under the law, to a prevailing party, reasonable attorneys' fees and costs.

IV Payment

IV. PAYMENT

A. PROHIBITION AGAINST ADVANCE PAYMENT (Statutory)

Neb. Rev. Stat. §§81-2403 states, “[n]o goods or services shall be deemed to be received by an agency until all such goods or services are completely delivered and finally accepted by the agency.”

B. TAXES (Statutory)

The State is not required to pay taxes and assumes no such liability as a result of this solicitation. The Contractor may request a copy of the Nebraska Department of Revenue, Nebraska Resale or Exempt Sale Certificate for Sales Tax Exemption, Form 13 for their records. Any property tax payable on the Contractor’s equipment which may be installed in a state-owned facility is the responsibility of the Contractor

C. INVOICES

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
			Invoices will be submitted monthly.

Invoices for payments must be submitted quarterly by the Contractor to the agency requesting the services with sufficient detail to support payment. Invoices should include, at a minimum, billing period, name of test, number of tests, unit cost of test, and extended cost. Invoices must be sent electronically to the STD Program Manager by the 15th of the month following the end of the quarter. An email address will be provided to the awarded bidder. The terms and conditions included in the Contractor’s invoice shall be deemed to be solely for the convenience of the parties. No terms or conditions of any such invoice shall be binding upon the State, and no action by the State, including without limitation the payment of any such invoice in whole or in part, shall be construed as binding or estopping the State with respect to any such term or condition, unless the invoice term or condition has been previously agreed to by the State as an amendment to the contract.

D. INSPECTION AND APPROVAL

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

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

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

E. PAYMENT (Statutory)

Payment will be made by the responsible agency in compliance with the State of Nebraska Prompt Payment Act (See Neb. Rev. Stat. §81-2403). The State may require the Contractor to accept payment by electronic means such as ACH deposit. In no event shall the State be responsible or liable to pay for any goods and services provided by the Contractor prior to the Effective Date of the contract, and the Contractor hereby waives any claim or cause of action for any such services.

F. LATE PAYMENT (Statutory)

The Contractor may charge the responsible agency interest for late payment in compliance with the State of Nebraska Prompt Payment Act (See Neb. Rev. Stat. §81-2401 through 81-2408).

G. SUBJECT TO FUNDING / FUNDING OUT CLAUSE FOR LOSS OF APPROPRIATIONS (Statutory)

The State's obligation to pay amounts due on the Contract for a fiscal years following the current fiscal year is contingent upon legislative appropriation of funds. Should said funds not be appropriated, the State may terminate the contract with respect to those payments for the fiscal year(s) for which such funds are not appropriated. The State will give the Contractor written notice thirty (30) calendar days prior to the effective date of termination. All obligations of the State to make payments after the termination date will cease. 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.

H. RIGHT TO AUDIT (First Paragraph is Statutory)

The State shall have the right to audit the Contractor's performance of this contract upon a thirty (30) days' written notice. Contractor shall utilize generally accepted accounting principles, and shall maintain the accounting records, and other records and information relevant to the contract (Information) to enable the State to audit the contract. (Neb. Rev. Stat. §84-304 et seq.) The State may audit and the Contractor shall maintain, the Information during the term of the contract and for a period of five (5) years after the completion of this contract or until all issues or litigation are resolved, whichever is later. The Contractor shall make the Information available to the State at Contractor's place of business or a location acceptable to both Parties during normal business hours. If this is not practical or the Contractor so elects, the Contractor may provide electronic or paper copies of the Information. The State reserves the right to examine, make copies of, and take notes on any Information relevant to this contract, regardless of the form or the Information, how it is stored, or who possesses the Information. Under no circumstance will the Contractor be required to create or maintain documents not kept in the ordinary course of contractor's business operations, nor will contractor be required to disclose any information, including but not limited to product cost data, which is confidential or proprietary to contractor.

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
<i>MM</i>			

The Parties shall pay their own costs of the audit unless the audit finds a previously undisclosed overpayment by the State. If a previously undisclosed overpayment exceeds one-half of one percent (0.5%) of the total contract billings, or if fraud, material misrepresentations, or non-performance is discovered on the part of the Contractor, the Contractor shall reimburse the State for the total costs of the audit. Overpayments and audit costs owed to the State shall be paid within ninety (90) days of written notice of the claim. The Contractor agrees to correct any material weaknesses or condition found as a result of the audit.

V Project Description and Scope of Work

V. PROJECT DESCRIPTION AND SCOPE OF WORK

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

A. PROJECT OVERVIEW

The Request for Proposal (RFP) is intended to provide a variety of Sexually Transmitted Disease (STD) testing for the Nebraska Department of Health and Human Services (DHHS) STD approved sites throughout the State of Nebraska. The Contractor will perform laboratory STD tests, including but not limited to: syphilis, chlamydia, and gonorrhea. DHHS may add STD tests throughout the term of the contract by written amendment per section II.F. The purpose of the RFP is to provide STD testing as required by DHHS STD Program in a timely manner. Samples are collected at DHHS STD Program approved testing sites. Samples will then be directly shipped to the Contractor by the collector to reduce the time the sample spends in route to the Contractor and to facilitate faster sample turnaround.

B. PROJECT ENVIRONMENT

Annually, the DHHS STD Program uses approximately 45,775 STD test. The estimated number of annual tests in no way commits the State to those figures as maximum or minimum contract amounts, but are for information purposes only. The tests are broken down in the following manner:

- 1. Syphilis IgG EIA Screen: 2,500
- 2. RPR Confirmation FTA: 50
- 3. GC Culture 0 (rare and requires approval from DHHS STD Program Manager)
- 4. RPR Titer: 90
- 5. RPR Quantitative: 120
- 6. GC/Chlamydia Amplified – Swab: 15
- 7. GC/Chlamydia Amplified - Urine: 43,000

There are approximately eighty-nine (89) STD testing sites across Nebraska which include local health departments, non-profits, correctional facilities, and universities. A listing of all testing sites can be found on Attachment 1. The number and location of testing sites may change throughout the term of this contract.

All testing sites collect samples to test for chlamydia and gonorrhea, while only about twenty-five (25) testing sites collect for syphilis testing. Testing sites across the state are responsible for screening and testing individuals who present themselves at a testing site and who have been exposed or fear exposure to an STD. Samples are collected by testing sites, electronically ordered, and shipped to the Contractor for laboratory testing. The DHHS STD Testing Program is funded by both state and federal dollars. The majority of the funding is through state funds.

State regulations regarding STD testing can be found at Title 173 of the Nebraska Administrative Code, chapter 1, and are available at the following link:

https://sos.nebraska.gov/rules-and-regs/regsearch/Rules/Health_and_Human_Services_System/Title-173/Chapter-01.pdf

C. MANDATORY REQUIREMENTS

- 1. The contractor must hold Clinical Laboratory Improvement Amendments (CLIA) waiver. See <https://www.cdc.gov/clia/waived-tests.html>

Acknowledge (Initial)	NOTES/COMMENTS:
	Center for Disease Detection (CDD) will maintain a valid CLIA accreditation throughout the term of this contract. I have included a copy of this certificate for your review.

- 2. Tests must be performed using the traditional syphilis algorithm, which is an initial workup for syphilis using the traditional algorithm includes rapid plasma regain (RPR) followed by confirmation using Treponema pallidum-specific antibody tests. Having the RPR titer first rapidly helps assess disease activity.

Acknowledge (Initial)	NOTES/COMMENTS:
	CDD will perform this test using the traditional algorithm of RPR w/reflex to TP-PA if reactive.

3. Maintain and/or utilize laboratories fully accredited by the College of American Pathologists that meet all appropriate standards for laboratories performing medical laboratory testing. The Contractor agrees that all laboratory services will meet standards of certification under the CLIA.

Acknowledge (Initial)	NOTES/COMMENTS:
	CDD will maintain a valid College of American Pathologists (CAP) accreditation throughout the term of this contract. I have included a copy of this certificate for your review.

4. Reporting of STD test results must be done via Electronic Lab Reporting (ELR). The Contractor must use ELR to report STD test results.

Acknowledge (Initial)	NOTES/COMMENTS:
	CDD will provide all test results (positive and negative) through a newly developed electronic lab interface with the Nebraska Department of Health ELR. All results for the submitting agencies will be reported through other means established between CDD and each agency.

D. SCOPE OF WORK

1. The Contractor must comply with all State statutes and regulations governing the performance of services required herein as listed in section V.B. Contractor must obtain all necessary permits, documents, and inspections at contractor's expense.
2. The Contractor must provide training regarding how to conduct sample collection, ordering tests, and shipping of samples.
3. The Contractor will do onsite or on the phone training with sites, when necessary, for technical assistance purposes.
4. All supplies, materials, services, and shipping costs required by this RFP, whether explicitly or not, must be provided at the Contractor's expense as part of the testing prices, and not additionally thereto.
5. If a sample must be re-collected due to error on the part of the Contractor, shipping expense from the testing site to the Contractor must be covered at the Contractor's expense.
6. The Contractor will also be the sole contact with all the subcontractors regarding any sample rejection, testing, reporting of results, billing, or any other concern.
7. The Contractor must supply sample collection kits, shipping containers and appropriate labels as requested by DHHS STD Program-approved testing sites.
8. If a specimen is inadequate or inappropriate for testing, lost, or damaged by the Contractor, the Contractor must notify the testing site by phone or email within two (2) State business days so the same specimen may be collected within two (2) State business days.
9. Contractor must notify DHHS within two (2) State business days of discovery of any analytic results that indicate a problem with:
 - a. A sample;
 - b. Sample collection;
 - c. Processing; or
 - d. Any event or concern that would delay or affect the reporting of results.
10. Contractor must maintain an internal Quality Control Program.
11. Contractor must use established methodologies and procedures to provide accurate results;
12. Contractor must seek approval in advance from the DHHS STD Program Manager, in writing, before any STD testing method changes can be made by the Contractor.
13. Results must be entered through Electronic Lab Reporting (ELR) within the turnaround time of seven (7) days after sample is received by Contractor.
14. Syphilis tests must be performed using the traditional syphilis algorithm.
15. Contractor must perform reflex testing (automatic confirmatory testing) on specimens submitted for syphilis screening.
16. Reflex testing will only be performed according to the mutually agreed-upon protocol and Centers for Disease Control (CDC) recommendations when indicated by a screening test or as requested by DHHS via email notification.
17. Contractor agrees to provide information on STD reportable diseases to CDC as required by state regulations and guidelines.
18. Contractor will provide DHHS with a monthly report accounting of tests performed under this contract.
19. As requested by DHHS, approximately two to four (2-4) times annually, the Contractor's Laboratory Director or equivalent position and requested staff will meet with or participate in a teleconference with DHHS STD Program Manager.
20. Any changes in status of the required CLIA waiver must be communicated to the DHHS STD Program Manager in writing within five (5) State business days of the change.

- 21. Contractor must notify DHHS of any major laboratory changes or events within five (5) State business days of discovery. Major laboratory changes or events include the loss or replacement of the laboratory director or any situation that affects the Contractor's ability to meet the provisions of this contract.
- 22. The Contractor must work with DHHS to manage the funds available under this contract, in the event that demand begins to exceed the available State budget.
- 23. Contractor will monitor the DHHS approved budget.

E. PROPOSAL REQUIREMENTS

	<p>Describe your plan for how to coordinate STD testing with the testing sites throughout Nebraska.</p> <p>Bidder's Response: CDD works primarily in the public health arena. We have contracts with many state, city and county health departments providing STD, HIV, PrEP and Cervical Cancer testing throughout the country. These programs are very similar to what you have described through this solicitation.</p> <p>The first obstacle we need to address is how to train staff from each authorized testing center on how to enter lab orders into our user friendly, electronic test request system (AFTIS), how to collect specimens for testing, how to package the specimens for next day shipping to our lab and how to access lab results. We would suggest a road show where we set up in-person training at several regional sites throughout the state and invite all staff from each center to attend a training that is most convenient for them. We would hold these sessions in hotel or local health department meeting rooms. We would set up laptops with the AFTIS software loaded, assign 1 – 2 people at each laptop, and walk them through the order entry process. Each person will have hands-on experience entering test patients so that when they get back to their health center, they will know exactly what to do.</p> <p>Most of this clinic staff will already know how to collect CT/GC and Syphilis specimens. We will have samples of all the supplies we use so they can see if there are any differences between what they are used to seeing vs. what we require. We will also answer any questions they would have using our supplies.</p> <p>1. We will have samples of all the shipping supplies we provide. This will include shipping boxes, specimen biohazard bags, ice packs and courier lab paks. We will review with each staff on how to properly prepare their specimens for shipping.</p> <p>We will then have some test results released and have each staff person access these results.</p> <p>For staff that cannot make any of the regional training sessions, we can conduct online training and give them the same hands-on training they would have received in person.</p> <p>Training sessions typically last about one hour. Once the training sessions are complete, all staff will have had hands-on experience from start to finish.</p> <p>The next obstacle will be the loading of our AFTIS software onto workstations at each of the clinic sites. AFTIS is the application we will use for order entry, collecting of the required patient demographic information and transmission of these orders and data to the lab. We will work with the designated IT professional at each agency / site to install AFTIS on a single workstation or multiple workstations throughout the clinic. All installation of this software will be done remotely through a web tool called Go-to-Assist. This will allow us to see what the clinic is seeing on their computer screen and either talk them through the process or ask them to let us take over and load it ourselves while they are watching what we are doing.</p> <p>While all of the above is taking place, all supplies are sent to each site. Once everyone is trained, software installed and supplies received, the sites are ready to start sending specimens to us. This whole process for 89 sites can be completed within 30 – 45 days.</p>
2.	<p>Describe how you will meet the requirements to report STD test results and turnaround time for results.</p> <p>Bidder's Response: CDD runs a highly automated laboratory that requires minimal human handling. As a result of this automation, well over 98% of the time we release STD results back to the ordering clinic the same day we receive specimens in the lab. What isn't released that day will be released the next business day. We understand the importance of getting quick and accurate results back to the clinicians. We coordinate with each clinic site to determine the days and times that is best to have our contracted couriers scheduled to pick up specimens for their site. We then coordinate this with</p>

	<p>either FedEx or UPS for them to schedule their couriers. We will provide each site with all the supplies to collect, package and ship these specimens safely to the lab. These couriers will pick up these specimen packages on the days and times already scheduled. All specimens will be shipped via next day service at no additional cost to the site or to DHHS. We will receive these packages the next morning by 6:30 AM Central time and after a short specimen sort, all specimens will move to their respective sections in the laboratory for test processing. Once the test is performed and the result validated, results will be released to the ordering site. The release of results will start at 10:45 AM Central time. Chlamydia/Gonorrhea specimens that experienced a rare issue during testing or Syphilis specimens that need to have confirmation testing performed will not have results released until later in the day or the next business day.</p>
3.	<p>Provide a comprehensive list of quality assurance best practices and quality assurance procedures.</p> <p>Bidder's Response:</p> <ol style="list-style-type: none"> 1. Facilities and equipment are sufficient, adequate and spacious enough to prevent cross-contamination of specimens. 2. Clean areas remain separate from testing areas, and include activities such as reagent and control preparation. 3. Quality assurance measures are collected throughout various phases of testing each day and are routinely evaluated to monitor trends, outliers, and deviation from desired outcomes. Some QA items evaluated include: <ol style="list-style-type: none"> a. Pre-Analytical Phase <ol style="list-style-type: none"> i. Specimen Acceptability – all specimens are evaluated in context of submission requirements to ensure adherence to manufacturer specifications for optimal testing conditions. ii. Specimen Receipt – all specimens are monitored for optimal condition upon receipt. iii. Specimen Processing – workflow patterns are routinely evaluated to ensure prompt processing and testing of specimens to ensure timely completion. b. Analytical Phase <ol style="list-style-type: none"> i. Test Results – Routine evaluation of positive, negative and unsatisfactory/invalid results is conducted to monitor long and short-term trends, standard deviations, and unexpected results. ii. Quality Control – Routine evaluation of positive, negative and internal controls is conducted to evaluate any patterns or drift, and to ensure controls are valid and performing as expected. iii. Decontamination Checks – Routine checks for contamination are performed and evaluated. c. Post-Analytical Phase <ol style="list-style-type: none"> i. Turn-Around Time – Time from specimen receipt to test completion is monitored to identify trends, outliers, and potential for process improvement. ii. Amended Reports – Reports requiring corrected results are closely monitored to evaluate sub-optimal practice. iii. Proficiency Testing – All staff routinely undergo proficiency testing using CAP-Accredited PT materials to ensure competency.
4.	<p>Describe procedures and methodology bidder will use to provide accurate test results.</p> <p>Bidder's Response:</p> <ol style="list-style-type: none"> 1. In order to achieve best practice standards, CDD employs the use of the most up to date testing instrumentation and methodologies. <ol style="list-style-type: none"> a. The Roche cobas® CT/NG test for <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> is based on two major processes: (1) automated sample preparation to obtain nucleic acids, including CT and NG DNA; (2) simultaneous PCR amplification of target DNA sequences using both CT and NG specific primer pairs and real-time detection of cleaved fluorescent-labeled CT and NG specific oligonucleotide detection probes. An internal control, containing CT and NG DNA, is added to all samples prior to automated sample preparation and is amplified and detected simultaneously with each sample to monitor the entire process. b. Cross-contamination is minimized through automated sample preparation with the

	<p>use of two linked instruments, one for sample preparation and one for amplification and detection.</p> <p>2. Optimal quality control is achieved by including a positive, negative, and internal control in each run. For any run, valid results must be obtained for each control in order to report test results from that run.</p> <p>Clinical performance characteristics have been fully established, including the evaluation of reproducibility, sensitivity, specificity, and predictive values. All study data can be furnished upon request.</p>
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- F. **DELIVERABLES**
See Cost Proposal.

Solicitation Number: 6212-Z1

Description: STD Testing Services

Opening Date: March 2, 2020

Buyers: Keith Roland and Jennifer Crouse

V. D. Scope of Work

1. Center for Disease Detection, LLC. (CDD) will comply with all State statutes and regulations governing the performance of services required herein as listed in section V. B. We will obtain all necessary permits, documents, and inspections at our expense.
2. CDD will provide training regarding how to conduct sample collection, ordering tests, and shipping of samples.
3. CDD will conduct onsite or on the phone training with sites, when necessary, for technical assistance purposes.
4. All supplies, materials, services, and shipping costs required by this RFP, whether explicitly or not, will be provided at the CDD's expense as part of the testing prices, and not additionally thereto.
5. If a sample must be re-collected due to error on the part of the CDD, shipping expense from the testing site to the lab will be covered at the our expense.
6. CDD will be the sole contact with any subcontractor regarding sample rejection, testing, reporting of results, billing, or any other concern.
7. CDD will supply sample collection kits, shipping containers and appropriate labels as requested by DHHS STD Program-approved testing sites.
8. If a specimen is inadequate or inappropriate for testing, lost, or damaged by the CDD, we will notify the testing site by phone or email within two (2) State business days so the same specimen may be collected within two (2) State business days.
9. CDD will notify DHHS within two (2) State business days of discovery of any analytic results that indicate a problem with:
 - a. A sample;
 - b. Sample collection;
 - c. Processing; or
 - d. Any event or concern that would delay or affect the reporting of results.
10. CDD will maintain an internal Quality Control Program.
11. CDD will use established methodologies and procedures to provide accurate results.
12. CDD will seek approval in advance from the DHHS STD Program Manager, in writing, before any STD testing method changes can be made.
13. Results will be entered through Electronic Lab Reporting (ELR) within the turnaround time of seven (7) days after sample is received at the lab.

14. Syphilis tests will be performed using the traditional syphilis algorithm.
15. CDD will perform reflex testing (automatic confirmatory testing) on specimens submitted for syphilis screening.
16. Reflex testing will only be performed according to the mutually agreed-upon protocol and Centers for Disease Control (CDC) recommendations when indicated by a screening test or as requested by DHHS via email notification.
17. CDD agrees to provide information on STD reportable diseases to CDC as required by state regulations and guidelines.
18. CDD will provide DHHS with a monthly report accounting of tests performed under this contract.
19. As requested by DHHS, approximately two to four (2-4) times annually, the CDD's Laboratory Director or equivalent position and requested staff will meet with or participate in a teleconference with DHHS STD Program Manager.
20. Any changes in status of the required CLIA waiver will be communicated to the DHHS STD Program Manager in writing within five (5) State business days of the change.
21. CDD will notify DHHS of any major laboratory changes or events within five (5) State business days of discovery. Major laboratory changes or events include the loss or replacement of the laboratory director or any situation that affects CDD's ability to meet the provisions of this contract.
22. CDD will work with DHHS to manage the funds available under this contract, in the event that demand begins to exceed the available State budget.
23. CDD will monitor the DHHS approved budget.

VI Corporate Overview

Solicitation Number: 6212-Z1

Description: STD Testing Services

Opening Date: March 2, 2020

Buyers: Keith Roland and Jennifer Crouse

VI. A. Proposal Submission

1. Corporate Overview

a. Bidder Identification and Information

- Center for Disease Detection, LLC.
- 11603 Crosswinds Way, Suite 100, San Antonio, TX 78233
- CDD is a wholly owned subsidiary of Laboratory Corp of America Holdings
- CDD is incorporated in the state of Delaware
- CDD was organized to do business on March 24, 1997
- CDD's name has remained the same since first organized

b. Financial Statements

- Included with this response is our most current (3rd Qtr. 2019) Form 10-Q filed with the United States Securities and Exchange Commission
- David P. King was the Chief Executive Officer and Glenn A. Eisenberg is the Chief Financial Officer who were responsible when this report was filed. Adam Schechter is the new Chief Executive Officer as of November 1, 2019. Both of the above individual's office at the principal executive offices located at 358 Main Street, Burlington, NC 27215. They can be reached at (336) 229-1127.
- No such condition is known to exist which might materially affect the viability or stability of the organization.

c. Change of Ownership

- There is no known change in ownership or control of the company anticipated during the twelve (12) months following the proposal due date.

d. Office Location

- CDD's office/laboratory located at 11603 Crosswinds Way, Suite 100, San Antonio, TX 78233 will be responsible for the performance pursuant to an award of a contract with the State of Nebraska.

e. Relationships with the State

- CDD nor LabCorp has contracted with the State of Nebraska over the previous five (5) years.

f. Bidder's Employee Relations to State

- No Party named in our response to this proposal is or was an employee of the State of Nebraska within the past twelve (12) months.

g. Contract Performance

- CDD has not had a contract terminated for default during the past five (5) years.
- CDD has not had a contract terminated for convenience, non-performance, non-allocation of funds, or any other reason during the past five (5) years.

h. Summary of Bidder's Corporate Experience

- **Pennsylvania Department of Health**

- a) CDD has continuously held this contract since 1997. There have been several contract during this time. We were just awarded a new three (3) year contract with two (2) one (1) year renewals beginning February 1, 2020.
- b) Our new contract runs through January 31, 2023.
- c) The Pennsylvania Department of Health contract is for providing STD/HIV (Chlamydia, Gonorrhea, Syphilis, HIV and PrEP) laboratory services to two hundred sixty-nine (269) clinic sites throughout the state. These clinic sites are composed of family planning and reproductive health, local health departments, STD clinics, correctional facilities and college and university student health centers. CDD is responsible for picking up specimens to be tested from each of these sites on a schedule determined by the clinic, transport these specimens via next day service, test and report results back to each site within five (5) days of receipt of specimen in the laboratory.

CDD is to provide all supplies to electronically order lab tests, all supplies to collect specimens, all supplies to package specimens for overnight shipping, and overnight shipping labels at no additional cost to the price per test.

CDD is to provide the electronic order entry system that collects and reports thirty-eight (38) required data elements (patient demographic information). We are to provide this data file along with all test results to the STD program manager on a daily basis.

This same electronic order entry system has a billing algorithm built in to determine if the patient qualifies for the testing paid for by the state. If the patient meets the qualifications based on the answers to the patient demographic questions asked, the invoicing for those tests go to the state. If the patient does not qualify, the billing goes to the ordering clinic or to the patient's insurance.

CDD enters all positive communicable disease results into their Electronic Lab Reporting (ELR) system on a daily basis.

In addition to the above-mentioned reporting requirements, we are to provide additional ad-hoc reporting upon request.

- d) Stephen J. Kowalewski, Senior PHA
Pennsylvania Department of Health, STD Program
Room 1023, Health & Welfare Building
625 Forster Street
Harrisburg, PA 17120
Phone: (717) 547-3443
Fax: (717) 772-4309
c-kowalew@pa.gov
- e) CDD is the prime Contractor for this contract. The scheduled completion date of this contract is January 31, 2023 with a total budget of \$8,017,524.00. The currently planned completion date is January 31, 2023 and the current planned budget is \$8,017,524.00.
- **Washington State Department of Health**
 - a) CDD has continuously held this contract since 2014. There have been annual contract renewals during this time. We were just awarded a new one (1) year contract with four (4) one (1) year renewals beginning October 1, 2019.
 - b) Our current contract runs through September 30, 2020.
 - c) The Washington Department of Health contract is for providing STD (Chlamydia, Gonorrhea, Hepatitis B and Hepatitis C) laboratory services to thirty (30) safety net clinic sites throughout the state. These clinic sites are composed of family planning and reproductive health, local health departments, STD clinics, correctional facilities and college and university student health centers. CDD is responsible for picking up specimens to be tested from each of these sites on a schedule determined by the clinic, transport these specimens via next day service, test and report results back to each site within three (3) days of receipt of specimen in the laboratory.

CDD is to provide all supplies to electronically order lab tests, all supplies to collect specimens, all supplies to package specimens for overnight shipping, and overnight shipping labels at no additional cost to the price per test.

CDD is to provide the electronic order entry system that collects and reports thirty (30) required data elements (patient demographic information). We are to provide this data file along with all test results to the STD program manager on a monthly basis.

This same electronic order entry system has a billing algorithm built in to determine if the patient qualifies for the testing paid for by the state. If the patient meets the qualifications based on the answers to the patient demographic questions asked, the invoicing for those tests go to the state. If the patient does not qualify, the billing goes to the ordering clinic or to the patient's insurance.

CDD enters all positive communicable disease results into their Electronic Lab Reporting (ELR) system on a daily basis.

In addition to the above-mentioned reporting requirements, we are to provide additional ad-hoc reporting upon request.

- d) Patrick Dinwiddie
HIV/STD Testing Coordinator
Office of Infectious Disease
Division of Disease Control and Health Statistics
Washington State Department of Health
310 Israel Road SE
Olympia, WA 98504
Phone: (360) 688-8084
Fax: (360) 236-3400
patrick.dinwiddie@doh.wa.gov
- e) CDD is the prime Contractor for this contract. The scheduled completion date of this contract is September 30, 2020 with a total budget of \$430,000.00. The currently planned completion date is September 30, 2020 and the current planned budget is \$405,000.00.

- **New Mexico Department of Health**

- a) CDD has continuously held this contract since 2014. There have been annual contract renewals during this time. We were awarded a new one (1) year contract with three (3) one (1) year renewals beginning July 2, 2018. We have just signed our third (3rd) one (1) year renewal that will take us through June 30, 2021.
- b) Our current contract extension runs through June 30, 2021.
- c) The New Mexico Department of Health contract is for providing laboratory services to seventy-five (75) clinic sites throughout the state. These clinic sites are composed of family planning and reproductive health, local health departments, STD clinics, teen health clinics, correctional facilities and college and university student health centers. This contract encompasses testing for several Public Health Division (PHD) Programs to include Breast and Cervical Cancer Early Detection, Family Planning, Maternal Health, PHD – Health and Safety, PHD – Supplemental Health Services, Refugee Health, Sexually Transmitted Disease (STD), and Tuberculosis (TB). CDD is responsible for picking up specimens to be tested from each of these sites on a schedule determined by the clinic, transport these specimens via next day service, test and report results back to each site within two (2) days of receipt of specimen in the laboratory.

CDD is to provide all supplies to electronically order lab tests, all supplies to collect specimens, all supplies to package specimens for overnight shipping, and overnight shipping labels at no additional cost to the price per test.

CDD has an electronic bi-directional lab interface between their statewide electronic health record system and our electronic lab order system.

CDD sends all positive communicable disease results into their Electronic Lab Reporting (ELR) system on a daily basis.

In addition to the above-mentioned reporting requirements, we are to provide additional ad-hoc reporting upon request.

- d) Andrew Gans
HIV, STD and Hepatitis Section Manager
Infectious Disease Bureau
Public Health Division
New Mexico Department of Health
310 Israel Road SE
Olympia, WA 98504
Phone: (505) 476-3624
andrew.gans@state.nm.us

- e) CDD is the prime Contractor for this contract. The scheduled completion date of this current contract extension is June 30, 2021 with a total budget of \$487,488.23. The currently planned completion date is June 30, 2021 and the current planned budget is \$487,488.23.

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

CDD will assign a Senior Account Manager along with their account management team to manage this project. This team will be responsible for the set-up of all clinic accounts, the initial shipping of all supplies needed to each clinic site, the installation of the software needed for lab orders and the training of all clinic staff on entering lab orders, collection of specimens, packaging and shipping of specimens to the laboratory and the results access process.

Once the clinics are sending specimens for testing, these same team members will be the liaison between the clinic staff and the laboratory. Any questions, concerns or issues that may arise, the account management team will be a single point of contact regarding anything with the laboratory. Should the team not be able to resolve the issue themselves, they will work with the appropriate subject matter expert in the laboratory to get the needed answers. For this contract, this could include Laboratory Section Managers for Clinical Laboratory or Molecular Biology, our Technical Director, Medical Director, Laboratory Director, IT Supervisor or Billing Manager.

Marian Tully, Senior Account Manager will head the account management team for this contract. Marian reports directly to our Technical Director, Dr. Mohammad Al-Ghoul. Barbara Castro, Account Manager and Veronica Sulin, Account Manager will support Marian in the management of this contract. I have included resumes for each.

The two managers who oversee the lab departments, which will be responsible for the Chlamydia/Gonorrhea and Syphilis tests, are Andrew Fenwick and Joe Lyons. Andrew is our Laboratory Manager for Molecular Biology, which performs the Chlamydia/Gonorrhea tests. Joe is the manager of Clinical Laboratory, which performs the Syphilis tests. Both managers are responsible for assuring that their respective sections of the laboratory are adhering to the specific Standard Operating Procedures (SOP) established by the test manufacturers, CLIA, CAP, as well as our Technical Director, Dr. Mohammad Al-Ghoul, Medical Director, Dr. Jane Dancer and Laboratory Director, Dr. Dean Skelley. Joe Lyons, Andrew Fenwick, Dr. Dancer and Dr. Skelley all report directly to Dr. Al-Ghoul. I have included resumes for each of these key staff members for your review.

The Nebraska Department of Health contract is very similar to many of the state contracts we currently manage. Below are the references requested who can attest to the competence and skill level of this team.

1. Jennifer Curtiss, M.Ed.
Texas IPP Coordinator
Cardea
8800 Business Park Drive, Suite 200
Austin, TX 78759
Phone: (512) 474-2166
jcurtiss@cardeaservices.org
2. Courtney Livingston, B.S.N., RN
Reproductive Health Program Nurse Coordinator
Arkansas Department of Health
Freeway Medical Building
5800 West 10th Street, Suite 810
Slot 16
Little Rock, AR 72204
Phone 501-280-4523
courtney.livingston@arkansas.gov
3. Deborah Polacek, RN
Vice President, Program Operations
New Jersey Family Planning League
238 Mulberry Street
Newark, NJ 07102
973-622-2425 ext. 2023
debbie@njfpl.org

j. Subcontractors

- No subcontractors will be used for the performance of this contract. All work will be performed by CDD.

2. Technical Approach

A. Narrative demonstrating an understanding of the project

CDD is a medical reference laboratory who concentrates on the public health market. Our clients are state departments of health, local city and county health departments, and

the family planning and reproductive health, STD clinics, HIV clinics, school-based programs, college and university student health centers and correctional facilities associated with these contracts. We work with STD and HIV programs and cervical cancer screening with each of these contracts. The requirements you spell out in this RFP are very similar to what we have been doing for years for many state department of health across the country. All had started as the Infertility Prevention Project (IPP) supported by The Centers for Disease Control and Prevention (CDC) back in the 1990's. Over the years, this program had ceased and each state department of health has developed their own version of this important program. Even though each state has continued this work on their own, most are still following the program the CDC set it up.

As was stated earlier, the Nebraska STD program is almost identical to other state department of health STD programs we have work with for years. This program is testing typically at-risk patients for Chlamydia/Gonorrhea from a number of different providers throughout the state. These patients are, for the most part, not insured and are seen at clinic sites such as family planning and reproductive health centers, STD clinics, HIV clinics, college and university student health centers, high school based outreach programs, correctional institutions, etc. The goal being to find those people with Chlamydia, Gonorrhea or Syphilis infections quickly and to treat them to reverse any lasting effects to their reproductive health and before they infect someone else.

CDD understands the importance of these programs and has built their company to support these efforts. We provide the latest testing technologies at the lowest cost, with the quickest turnaround time for results in the industry. Our tests for Chlamydia/Gonorrhea is a nucleic acid amplification test (NAAT) utilizing a polymerase chain reaction (PCR) methodology named cobas from Roche Diagnostics. This assay is FDA approved from clinician-collected or patient-collected vaginal sources, from patient provided urine sources or from a liquid-based Pap collection. The FDA has not authorized this test from pharyngeal or rectal sources. However, CDD has internally validated this test from these sources with the Analyte Specific Reagent (ASR) regulated by the FDA. The pricing for Chlamydia/Gonorrhea testing submitted in our proposal are from any of these sources.

The RFP states that the Syphilis assay should be performed using the traditional algorithm of Rapid Plasma Regain (RPR) with automatic reflex to *Treponema pallidum* particle agglutination (TP-PA) when the RPR is reactive. CDD will follow this requested algorithm. If the RPR is reactive, we will provide the RPR titer and the TP-PA result. If the RPR is non-reactive, a negative Syphilis result will be released.

CDD has built a proprietary software application that will be used at each clinic site. We call it AFTIS. AFTIS will serve the main purpose of ordering lab tests for patients. This application will take the place of a hand written lab order form. AFTIS is also designed to perform a couple of other tasks that would be of great benefit to the Nebraska STD Program. One of these is to collect needed patient demographic data on each patient. The answer to question number 18 in Addendum 1 – Questions and Answers states that the contractor must submit, along with the test results, certain pieces of patient demographic information. We will build a version of AFTIS to collect this information at the time of order entry. With AFTIS being a software application, we can make these fields mandatory so that a lab order cannot be completed until all mandatory fields are completed. This way we are able to guarantee that 100% of the data you need for each

patient is collected. We can send you an electronic file with all of this data along with the test results for every patient tested. We have states that want this data file daily, some want it weekly and some want it monthly. You decide how often you want this data file and in what format is best for you.

Another feature of AFTIS that you could benefit from is a billing algorithm that will decide if a patient meets the criteria for state paid STD testing. There always seems to be an age requirement for many state departments of health. If a patient is older than a specific age, the state should be invoiced for that test. In some states, there are gender requirements. Some will only accept female patients. Some will only accept males if they are considered high-risk. There are a number of requirements that Nebraska may have to determine if a patient qualifies for the STD testing program. CDD can build these requirements into AFTIS so that the system decides if a patient qualifies or not and not the clinician at the clinic site. This way, you are assured that you are only being invoiced for patient's tests who meet all qualification requirements.

AFTIS was also built to offer a custom test menu that gives the ordering sites the option to only order those tests that that CDD is contracted to do. This keeps staff from ordering tests that they should not be ordering.

CDD will provide all supplies necessary for the collection and packaging of specimens covered in this contract at no additional cost to the program. This will also include the overnight shipping charges to get the specimen package from the clinic site to the laboratory. AFTIS will keep track of the sites supply inventory. When we build the account for that site, we will get an estimate of their estimated monthly volume for each test. From this, we will set up minimum and maximum inventory levels for each supply item. Minimum will be about a three (3) week supply, maximum will be about a nine (9) week supply. As we receive specimens from the clinic, AFTIS will subtract one of each supply item it took to collect that specimen. On that very next specimen that drops a supply item to its minimum inventory level, AFTIS will automatically send a replenishment order for that item as well as all other supply items to bring everything back up to the maximum inventory level. This assures that a site will always have the supplies needed to collect and order tests and not rely on someone to place a supply order.

CDD will work with each of the eighty-nine (89) STD testing sites to collect the information needed to build an account for them. Once the account is built, a supply order will be sent to them and we will schedule times with each to install the AFTIS software. All software installation will be done remotely using a web tool called Go-to-Assist. With this, we can install the software while the site is monitoring what we are doing. If there are any questions during this process, we can talk over the telephone.

CDD is proposing conducting staff training at various central locations throughout Nebraska. We will coordinate all of this with the STD Program Manager to determine dates, times and regional locations. We will bring laptops loaded with AFTIS, specimen label printer for each laptop and all the supplies that will be used for Chlamydia/Gonorrhea and Syphilis testing. All staff that attend these regional training sessions will be shown how to order lab tests in AFTIS, how to collect the specimens, how to label the specimens, how to transmit the orders electronically to the lab, how to package the specimens for safe overnight shipping, and how to access the results. The

staff will also enter test patient orders, label specimens, packages sample specimens, transmit the test orders. Our staff back in the lab will accept these orders and release sample test results so we can finish the training on having them access the results. Once this training is completed, each person will have had hands-on experience in placing orders from start to finish. This training will last approximately one (1) hour.

For staff who are unable to attend one of these regional training sessions, we will offer remote training.

CDD will provide the overnight shipping labels at no additional cost. We will coordinate with each approved STD site the days of the week and the time of day that these specimens will be picked up by an overnight courier. We will use the services of either FedEx or UPS, which ever can best meet the needs of the site. We will provide this schedule to the appropriate courier so they know the pick-up schedule for each location. Staff will not have to worry about calling to schedule pick-ups.

CDD works on the premise that every day matters. We work diligently to provide the quickest turnaround time for results in the industry. Specimens will be delivered to the lab the morning after the specimen package was picked up at the site. We typically have all specimens in the lab before 6:30 AM central time. Once we receive the package, we will scan the barcode on the shipping label to confirm receipt of the specimen shipment. We then sort all specimens by which section of the laboratory it belongs. When the specimens reach their respective section in the laboratory we will scan the barcoded label on each specimen tube to confirm receipt of that specific specimen. The specimens are tested and after validation, results are released to the ordering clinic. We start releasing results at 10:45 AM central time that same day. Over 98% of our results are available the same day we receive the specimen in the laboratory. Tests that require additional work, such as indeterminate Chlamydia/Gonorrhea results or reactive RPR results will be released the next business day.

The Nebraska STD Program and each authorized STD site will have their own CDD account. All accounts participating in this program will be managed by a Client Care team headed by Marian Tully. Marian and her team members, Barbara Castro and Veronica Sulin will be responsible for every aspect of managing this contract. Together, this team has nearly thirty-seven (37) years of combined experience working with contracts similar to this. They will be responsible for building each account, sending supplies to each site, coordinating the build of the AFTIS version that will collect all of the patient demographic data and billing algorithms required, coordinating the installation of AFTIS at each authorized STD site, and coordinating the training of each staff member. Once the accounts start sending specimens, this team will be the main point of contact for each authorized STD user. They are well trained to provide world-class service in an accurate and timely fashion. If they are unable to answer a question or address a concern, they will find the correct subject matter expert in the lab to provide the needed help. There will be a strong relationship built between the clients at each site and Marian and her team.

B. Response to section V.C

1. The contractor must hold Clinical Laboratory Improvement Amendments (CLIA) waiver.

Center for Disease Detection (CDD) will maintain a valid CLIA accreditation throughout the term of this contract. I have included a copy of this certificate for your review.

2. Tests must be performed using the traditional syphilis algorithm, which is an initial workup for syphilis using the traditional algorithm includes rapid plasma regain (RPR) followed by confirmation using Treponema pallidum-specific antibody tests. Having the RPR titer first rapidly helps assess disease activity.

CDD will perform this test using the traditional algorithm of RPR w/reflex to TP-PA if reactive.

3. Maintain and/or utilize laboratories fully accredited by the College of American Pathologists that meet all appropriate standards for laboratories performing medical laboratory testing. The Contractor agrees that all laboratory services will meet standards of certification under the CLIA.

CDD will maintain a valid College of American Pathologists (CAP) accreditation throughout the term of this contract. I have included a copy of this certificate for your review.

4. Reporting of STD test results must be done via Electronic Lab Reporting (ELR). The Contractor must use ELR to report STD test results.

CDD will provide all test results (positive and negative) through a newly developed electronic lab interface with the Nebraska Department of Health ELR. All results for the submitting agencies will be reported through other means established between CDD and each agency.

C. Response to section V.E

1. Describe your plan for how to coordinate STD testing with the testing sites throughout Nebraska.

CDD works primarily in the public health arena. We have contracts with many state, city and county health departments providing STD, HIV, PrEP and Cervical Cancer testing throughout the country. These programs are very similar to what you have described through this solicitation.

The first obstacle we need to address is how to train staff from each authorized testing center on how to enter lab orders into our user friendly, electronic test request system (AFTIS), how to collect specimens for testing, how to package the specimens for next day shipping to our lab and how to access lab results. We would suggest a road show where we set up in-person training at several regional sites throughout the state and invite all staff from each center to attend a training that is most convenient for them. We would hold these sessions in hotel or local health department meeting rooms. We would set up laptops with the AFTIS software loaded, assign 1 – 2 people at each laptop, and walk them through the order entry process. Each person will have hands-on experience entering test patients so that when they get back to their health center, they will know exactly what to do.

Most of this clinic staff will already know how to collect CT/GC and Syphilis specimens. We will have samples of all the supplies we use so they can see if there are any differences between what they are used to seeing vs. what we require. We will also answer any questions they would have using our supplies.

We will have samples of all the shipping supplies we provide. This will include shipping boxes, specimen biohazard bags, ice packs and courier lab paks. We will review with each staff on how to properly prepare their specimens for shipping.

We will then have some test results released and have each staff person access these results.

For staff that cannot make any of the regional training sessions, we can conduct online training and give them the same hands-on training they would have received in person.

Training sessions typically last about one hour. Once the training sessions are complete, all staff will have had hands-on experience from start to finish.

The next obstacle will be the loading of our AFTIS software onto workstations at each of the clinic sites. AFTIS is the application we will use for order entry, collecting of the required patient demographic information and transmission of these orders and data to the lab. We will work with the designated IT professional at each agency / site to install AFTIS on a single workstation or multiple workstations throughout the clinic. All installation of this software will be done remotely through a web tool called Go-to-Assist. This will allow us to see what the clinic is seeing on their computer screen and either talk them through the process or ask them to let us take over and load it ourselves while they are watching what we are doing.

While all of the above is taking place, all supplies are sent to each site. Once everyone is trained, software installed and supplies received, the sites are ready to start sending specimens to us. This whole process for 89 sites can be completed within 30 – 45 days.

2. Describe how you will meet the requirements to report STD test results and turnaround time for results.

CDD runs a highly automated laboratory that requires minimal human handling. As a result of this automation, well over 98% of the time we release STD results back to the ordering clinic the same day we receive specimens in the lab. What isn't released that day will be released the next business day. We understand the importance of getting quick and accurate results back to the clinicians. We coordinate with each clinic site to determine the days and times that is best to have our contracted couriers scheduled to pick up specimens for their site. We then coordinate this with either FedEx or UPS for them to schedule their couriers. We will provide each site with all the supplies to collect, package and ship these specimens safely to the lab. These couriers will pick up these specimen packages on the days and times already scheduled. All specimens will be shipped via next day service at no additional cost to the site or to DHHS. We will receive these

packages the next morning by 6:30 AM Central time and after a short specimen sort, all specimens will move to their respective sections in the laboratory for test processing. Once the test is performed and the result validated, results will be released to the ordering site. The release of results will start at 10:45 AM Central time. Chlamydia/Gonorrhea specimens that experienced a rare issue during testing or Syphilis specimens that need to have confirmation testing performed will not have results released until later in the day or the next business day.

3. Provide a comprehensive list of quality assurance best practices and quality assurance procedures.
 1. Facilities and equipment are sufficient, adequate and spacious enough to prevent cross-contamination of specimens.
 2. Clean areas remain separate from testing areas, and include activities such as reagent and control preparation.
 3. Quality assurance measures are collected throughout various phases of testing each day and are routinely evaluated to monitor trends, outliers, and deviation from desired outcomes. Some QA items evaluated include:
 - a. Pre-Analytical Phase
 - i. Specimen Acceptability – all specimens are evaluated in context of submission requirements to ensure adherence to manufacturer specifications for optimal testing conditions.
 - ii. Specimen Receipt – all specimens are monitored for optimal condition upon receipt.
 - iii. Specimen Processing – workflow patterns are routinely evaluated to ensure prompt processing and testing of specimens to ensure timely completion.
 - b. Analytical Phase
 - i. Test Results – Routine evaluation of positive, negative and unsatisfactory/invalid results is conducted to monitor long and short-term trends, standard deviations, and unexpected results.
 - ii. Quality Control – Routine evaluation of positive, negative and internal controls is conducted to evaluate any patterns or drift, and to ensure controls are valid and performing as expected.
 - iii. Decontamination Checks – Routine checks for contamination are performed and evaluated.
 - c. Post-Analytical Phase
 - i. Turn-Around Time – Time from specimen receipt to test completion is monitored to identify trends, outliers, and potential for process improvement.
 - ii. Amended Reports – Reports requiring corrected results are closely monitored to evaluate sub-optimal practice.
 - Proficiency Testing – All staff routinely undergo proficiency testing using CAP-Accredited PT materials to ensure competency.
4. Describe procedures and methodology bidder will use to provide accurate test results.

1. In order to achieve best practice standards, CDD employs the use of the most up to date testing instrumentation and methodologies.
 - a. The Roche cobas® CT/NG test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* is based on two major processes: (1) automated sample preparation to obtain nucleic acids, including CT and NG DNA; (2) simultaneous PCR amplification of target DNA sequences using both CT and NG specific primer pairs and real-time detection of cleaved fluorescent-labeled CT and NG specific oligonucleotide detection probes. An internal control, containing CT and NG DNA, is added to all samples prior to automated sample preparation and is amplified and detected simultaneously with each sample to monitor the entire process.
 - b. Cross-contamination is minimized through automated sample preparation with the use of two linked instruments, one for sample preparation and one for amplification and detection.
2. Optimal quality control is achieved by including a positive, negative, and internal control in each run. For any run, valid results must be obtained for each control in order to report test results from that run.

Clinical performance characteristics have been fully established, including the evaluation of reproducibility, sensitivity, specificity, and predictive values. All study data can be furnished upon request.

FORMS

Form A

Bidder Proposal Point of Contact

Form A
Bidder Proposal Point of Contact
Request for Proposal Number 6212-Z1

Form A should be completed and submitted with each response to this solicitation. 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:	Center for Disease Detection, LLC.
Bidder Address:	11603 Crosswinds Way Suite 100 San Antonio, TX 78233
Contact Person & Title:	Michael Kossman
E-mail Address:	mike.kossman@cddmedical.com
Telephone Number (Office):	210-590-3033 x-11482
Telephone Number (Cellular):	210-378-9317
Fax Number:	210-590-3121

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

Communication with the State Contact Information	
Bidder Name:	Center for Disease Detection, LLC
Bidder Address:	11603 Crosswinds Way Suite 100 San Antonio, TX 78233
Contact Person & Title:	Michael Kossman
E-mail Address:	<u>mike.kossman@cddmedical.com</u>
Telephone Number (Office):	210-590-3033 x-11482
Telephone Number (Cellular):	210-378-9317
Fax Number:	210-590-3121

Request for Proposal for Contractual Services Form

REQUEST FOR PROPOSAL FOR CONTRACTUAL SERVICES FORM

BIDDER MUST COMPLETE THE FOLLOWING

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

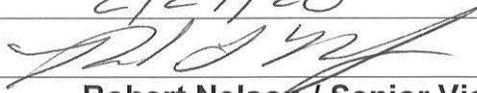
Per Nebraska's Transparency in Government Procurement Act, Neb. Rev Stat § 73-603 DAS is required to collect statistical information regarding the number of contracts awarded to Nebraska Contractors. This information is for statistical purposes only and will not be considered for contract award purposes.

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

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

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

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

FIRM:	Center for Disease Detection, LLC.
COMPLETE ADDRESS:	11603 Crosswinds Way Suite 100 San Antonio, TX 78233
TELEPHONE NUMBER:	210-590-3033 x-11482
FAX NUMBER:	210-590-3121
DATE:	<i>2/24/20</i>
SIGNATURE:	
TYPED NAME & TITLE OF SIGNER:	Robert Nelson / Senior Vice President

Certificates of Accreditation

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

LABORATORY NAME AND ADDRESS
CENTER FOR DISEASE DETECTION LLC
11603 CROSSWINDS WAY STE 100
SAN ANTONIO, TX 78233

CLIA ID NUMBER
45D0660475

EFFECTIVE DATE
05/20/2019

LABORATORY DIRECTOR
DEAN S SKELLEY Ph.D.

EXPIRATION DATE
05/19/2021

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

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



Karen W. Dyer

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

250 Certs2_042319

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

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
BACTERIOLOGY (110)	05/20/1999
MYCOLOGY (120)	04/12/2012
PARASITOLOGY (130)	04/12/2012
VIROLOGY (140)	09/21/2007
SYPHILIS SEROLOGY (210)	02/04/2003
GENERAL IMMUNOLOGY (220)	12/21/1999
ROUTINE CHEMISTRY (310)	03/31/2006
URINALYSIS (320)	05/01/2012
ENDOCRINOLOGY (330)	12/09/2011
TOXICOLOGY (340)	08/30/1999
HEMATOLOGY (400)	03/31/2006
ABO & RH GROUP (510)	04/10/2006
HISTOPATHOLOGY (610)	11/29/2005

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
CYTOLOGY (630)	08/16/2005



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



COLLEGE of AMERICAN
PATHOLOGISTS



The College of American Pathologists
certifies that the laboratory named below

**Laboratory Corporation of America
Center for Disease Detection
San Antonio, Texas
Dean S. Skelley, PhD**

CAP Number: 3175701
AU-ID: 1189744
CLIA Number: 45D0660475

has met all applicable standards for accreditation and is hereby accredited by the
College of American Pathologists' Laboratory Accreditation Program. Reinspection
should occur prior to May 14, 2020 to maintain accreditation.

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

Chair, Accreditation Committee

President, College of American Pathologists

Financial Statements

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2019
OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 1-11353

LABORATORY CORP OF AMERICA HOLDINGS

(Exact name of registrant as specified in its charter)

Delaware

13-3757370

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

358 South Main Street

Burlington, North Carolina

27215

(Address of principal executive offices)

(Zip Code)

(Registrant's telephone number, including area code) **336-229-1127**

Securities registered pursuant to Section 12(b) of the Exchange Act.

Title of Each Class	Trading Symbol	Name of exchange on which registered
Common Stock, \$0.10 par value	LH	New York Stock Exchange

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (paragraph 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No .

The number of shares outstanding of the issuer's common stock is 97.1 million shares as of October 29, 2019.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)

LABORATORY CORPORATION OF AMERICA HOLDINGS AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS(in millions)
(unaudited)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 361.1	\$ 426.8
Accounts receivable	1,617.2	1,467.9
Unbilled services	476.9	394.4
Supplies inventory	234.9	237.3
Prepaid expenses and other	297.7	309.0
Total current assets	2,987.8	2,835.4
Property, plant and equipment, net	2,462.8	1,740.3
Goodwill, net	7,815.3	7,360.3
Intangible assets, net	4,021.3	3,911.1
Joint venture partnerships and equity method investments	86.0	60.5
Deferred income tax assets	15.7	1.7
Other assets, net	458.9	276.0
Total assets	<u>\$ 17,847.8</u>	<u>\$ 16,185.3</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 607.8	\$ 634.6
Accrued expenses and other	830.3	870.0
Unearned revenue	403.8	356.4
Short-term operating lease liabilities	202.1	—
Short-term finance lease liabilities	8.3	7.9
Short-term borrowings and current portion of long-term debt	502.6	10.0
Total current liabilities	2,554.9	1,878.9
Long-term debt, less current portion	6,101.3	5,990.9
Operating lease liabilities	530.7	—
Financing lease liabilities	92.8	51.0
Deferred income taxes and other tax liabilities	969.0	940.0
Other liabilities	348.3	334.0
Total liabilities	10,597.0	9,194.8
Commitments and contingent liabilities		
Noncontrolling interest	19.7	19.1
Shareholders' equity:		
Common stock, 97.4 and 98.9 shares outstanding at September 30, 2019 and December 31, 2018, respectively	9.0	11.7
Additional paid-in capital	47.8	1,451.1
Retained earnings	7,676.5	7,079.8
Less common stock held in treasury	—	(1,108.1)
Accumulated other comprehensive loss	(502.2)	(463.1)
Total shareholders' equity	7,231.1	6,971.4
Total liabilities and shareholders' equity	<u>\$ 17,847.8</u>	<u>\$ 16,185.3</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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LABORATORY CORPORATION OF AMERICA HOLDINGS AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues	\$ 2,928.5	\$ 2,831.3	\$ 8,601.4	\$ 8,545.9
Cost of revenues	2,111.2	2,041.4	6,169.6	6,141.9
Gross profit	817.3	789.9	2,431.8	2,404.0
Selling, general and administrative expenses	401.5	381.8	1,210.6	1,174.0
Amortization of intangibles and other assets	61.7	54.7	179.0	175.5
Restructuring and other special charges	14.2	10.0	48.4	36.5
Operating income	339.9	343.4	993.8	1,018.0
Other income (expense):				
Interest expense	(60.5)	(59.4)	(176.3)	(186.0)
Equity method income, net	2.4	3.0	7.9	8.5
Investment income	2.9	2.8	4.8	4.2
Other, net	2.7	209.8	(18.2)	209.1
Earnings before income taxes	287.4	499.6	812.0	1,053.8
Provision for income taxes	66.4	180.6	214.4	328.1
Net earnings	221.0	319.0	597.6	725.7
Less: Net earnings (loss) attributable to the noncontrolling interest	(0.3)	(0.2)	(0.9)	0.1
Net earnings attributable to Laboratory Corporation of America Holdings	<u>\$ 220.7</u>	<u>\$ 318.8</u>	<u>\$ 596.7</u>	<u>\$ 725.8</u>
Basic earnings per common share	\$ 2.26	\$ 3.14	\$ 6.08	\$ 7.13
Diluted earnings per common share	\$ 2.25	\$ 3.10	\$ 6.04	\$ 7.04

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

LABORATORY CORPORATION OF AMERICA HOLDINGS AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE EARNINGS
(in millions, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net earnings	\$ 221.0	\$ 319.0	\$ 597.6	\$ 725.7
Foreign currency translation adjustments	(92.6)	0.3	(45.4)	(82.2)
Net benefit plan adjustments	3.2	2.9	8.7	9.1
Other comprehensive earnings (loss) before tax	(89.4)	3.2	(36.7)	(73.1)
Provision for income tax related to items of comprehensive earnings	(0.9)	(4.0)	(2.4)	(1.0)
Other comprehensive loss, net of tax	(90.3)	(0.8)	(39.1)	(74.1)
Comprehensive earnings	130.7	318.2	558.5	651.6
Less: Net earnings (loss) attributable to the noncontrolling interest	(0.3)	(0.2)	(0.9)	0.1
Comprehensive earnings attributable to Laboratory Corporation of America Holdings	<u>\$ 130.4</u>	<u>\$ 318.0</u>	<u>\$ 557.6</u>	<u>\$ 651.7</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

LABORATORY CORPORATION OF AMERICA HOLDINGS AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN
SHAREHOLDERS' EQUITY
(in millions)
(unaudited)

	Common Stock	Additional Paid-in Capital	Retained Earnings	Treasury Stock	Accumulated Other Comprehensive Earnings (Loss)	Total Shareholders' Equity
BALANCE AT DECEMBER 31, 2017	\$ 12.0	\$ 1,989.8	\$ 6,196.1	\$ (1,060.1)	\$ (333.7)	\$ 6,804.1
Net earnings attributable to Laboratory Corporation of America Holdings	—	—	173.2	—	—	173.2
Other comprehensive earnings, net of tax	—	—	—	—	52.5	52.5
Issuance of common stock under employee stock plans	—	28.4	—	—	—	28.4
Net share settlement tax payments from issuance of stock to employees	—	—	—	(25.0)	—	(25.0)
Stock compensation	—	25.8	—	—	—	25.8
Purchase of common stock	—	(75.0)	—	—	—	(75.0)
BALANCE AT MARCH 31, 2018	\$ 12.0	\$ 1,969.0	\$ 6,369.3	\$ (1,085.1)	\$ (281.2)	\$ 6,984.0
Net earnings attributable to Laboratory Corporation of America Holdings	—	—	233.8	—	—	233.8
Other comprehensive loss, net of tax	—	—	—	—	(125.8)	(125.8)
Issuance of common stock under employee stock plans	—	14.6	—	—	—	14.6
Net share settlement tax payments from issuance of stock to employees	—	—	—	(20.1)	—	(20.1)
Stock compensation	—	26.2	—	—	—	26.2
Purchase of common stock	—	(75.0)	—	—	—	(75.0)
BALANCE AT JUNE 30, 2018	\$ 12.0	\$ 1,934.8	\$ 6,603.1	\$ (1,105.2)	\$ (407.0)	\$ 7,037.7
Net earnings attributable to Laboratory Corporation of America Holdings	—	—	318.8	—	—	318.8
Other comprehensive loss, net of tax	—	—	—	—	(0.8)	(0.8)
Issuance of common stock under employee stock plans	—	24.4	—	—	—	24.4
Net share settlement tax payments from issuance of stock to employees	—	—	—	(1.1)	—	(1.1)
Conversion of zero-coupon convertible debt	—	0.3	—	—	—	0.3
Stock compensation	—	18.8	—	—	—	18.8
Purchase of common stock	(0.1)	(149.9)	—	—	—	(150.0)
BALANCE AT SEPTEMBER 30, 2018	\$ 11.9	\$ 1,828.4	\$ 6,921.9	\$ (1,106.3)	\$ (407.8)	\$ 7,248.1
BALANCE AT DECEMBER 31, 2018	\$ 11.7	\$ 1,451.1	\$ 7,079.8	\$ (1,108.1)	\$ (463.1)	\$ 6,971.4
Net earnings attributable to Laboratory Corporation of America Holdings	—	—	185.6	—	—	185.6
Other comprehensive earnings, net of tax	—	—	—	—	23.6	23.6
Issuance of common stock under employee stock plans	—	24.7	—	—	—	24.7
Net share settlement tax payments from issuance of stock to employees	—	—	—	(19.4)	—	(19.4)
Stock compensation	—	25.5	—	—	—	25.5
Purchase of common stock	(0.1)	(100.0)	—	—	—	(100.1)
BALANCE AT MARCH 31, 2019	\$ 11.6	\$ 1,401.3	\$ 7,265.4	\$ (1,127.5)	\$ (439.5)	\$ 7,111.3
Net earnings attributable to Laboratory Corporation of America Holdings	—	—	190.4	—	—	190.4
Other comprehensive earnings, net of tax	—	—	—	—	27.6	27.6
Issuance of common stock under employee stock plans	—	9.2	—	—	—	9.2
Net share settlement tax payments from issuance of stock to employees	—	—	—	(20.7)	—	(20.7)
Stock compensation	—	26.5	—	—	—	26.5
Retirement of treasury stock	(2.4)	(1,145.8)	—	1,148.2	—	—
Purchase of common stock	(0.1)	(199.8)	—	—	—	(199.9)
BALANCE AT JUNE 30, 2019	\$ 9.1	\$ 91.4	\$ 7,455.8	\$ —	\$ (411.9)	\$ 7,144.4
Net earnings attributable to Laboratory Corporation of America Holdings	\$ —	\$ —	\$ 220.7	\$ —	\$ —	\$ 220.7
Other comprehensive loss, net of tax	—	—	—	—	(90.3)	(90.3)
Issuance of common stock under employee stock plans	—	25.1	—	—	—	25.1
Net share settlement tax payments from issuance of stock to employees	—	(0.3)	—	—	—	(0.3)
Stock compensation	—	31.5	—	—	—	31.5
Purchase of common stock	(0.1)	(99.9)	—	—	—	(100.0)
BALANCE AT SEPTEMBER 30, 2019	\$ 9.0	\$ 47.8	\$ 7,676.5	\$ —	\$ (502.2)	\$ 7,231.1

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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LABORATORY CORPORATION OF AMERICA HOLDINGS AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions)
(unaudited)

	Nine Months Ended September 30,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net earnings	\$ 597.6	\$ 725.7
Adjustments to reconcile net earnings to net cash provided by operating activities:		
Depreciation and amortization	421.4	414.4
Stock compensation	83.5	70.8
Gain on sale of assets	(3.8)	(1.9)
Loss (gain) on sale of business	11.9	(209.4)
Contingent consideration adjustments	(13.9)	—
Accreted interest on zero-coupon subordinated notes	—	0.1
Operating lease right-of-use asset expense	144.1	—
Earnings less distributions deficit from equity method investments	18.3	0.3
Asset impairment	—	5.3
Deferred income taxes	23.3	12.1
Change in assets and liabilities (net of effects of acquisitions):		
Increase in accounts receivable	(144.3)	(8.5)
Increase in unbilled services	(59.5)	(5.5)
Increase in supplies inventory	(14.5)	(8.8)
Decrease (increase) in prepaid expenses and other	5.8	(40.1)
Decrease in accounts payable	(28.2)	(79.9)
Decrease in unearned revenue	(1.0)	(94.4)
Decrease (increase) in accrued expenses and other	(165.8)	38.8
Net cash provided by operating activities	<u>874.9</u>	<u>819.0</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital expenditures	(272.0)	(257.6)
Proceeds from sale of assets	5.8	50.1
Proceeds from sale of investments	9.4	—
Proceeds from sale of business	—	654.5
Investments in equity affiliates	(21.3)	(14.3)
Acquisition of businesses, net of cash acquired	(852.9)	(79.1)
Net cash (used for) provided by investing activities	<u>(1,131.0)</u>	<u>353.6</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from term loan	850.0	—
Payments on term loan	(250.0)	(295.0)
Proceeds from revolving credit facilities	473.0	449.2
Payments on revolving credit facilities	(473.0)	(449.2)
Payments on zero-coupon subordinated notes	(5.2)	(0.3)
Noncontrolling interest distributions	(0.8)	(6.1)
Deferred payments on acquisitions	(5.0)	—
Payments on other long-term obligations	(10.9)	(6.8)
Net share settlement tax payments from issuance of stock to employees	(40.4)	(46.2)
Net proceeds from issuance of stock to employees	59.0	67.4
Purchase of common stock	(400.0)	(300.0)
Net cash provided by (used for) financing activities	<u>196.7</u>	<u>(587.0)</u>
Effect of exchange rate changes on cash and cash equivalents	(6.3)	(9.6)
Net (decrease) increase in cash and cash equivalents	<u>(65.7)</u>	<u>576.0</u>
Cash and cash equivalents at beginning of period	426.8	316.6
Cash and cash equivalents at end of period	<u>\$ 361.1</u>	<u>\$ 892.6</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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1. BASIS OF FINANCIAL STATEMENT PRESENTATION

Laboratory Corporation of America[®] Holdings together with its subsidiaries (the Company) is a leading global life sciences company that is deeply integrated in guiding patient care, providing comprehensive clinical laboratory and end-to-end drug development services. The Company's mission is to improve health and improve lives by delivering world-class diagnostic solutions, bringing innovative medicines to patients faster and using technology to provide better care. The Company serves a broad range of customers, including managed care organizations (MCOs), biopharmaceutical companies, medical device companies, governmental agencies, physicians and other healthcare providers (e.g., physician assistants and nurse practitioners, generally referred to herein as physicians), hospitals and health systems, employers, patients and consumers, contract research organizations (CROs) and independent clinical laboratories.

The Company reports its business in two segments, LabCorp Diagnostics (LCD) and Covance Drug Development (CDD). For further financial information about these segments, see Note 16 (Business Segment Information). During the three months ended September 30, 2019, LCD and CDD contributed approximately 60% and 40%, respectively, of revenues to the Company. During the nine months ended September 30, 2019, LCD and CDD contributed approximately 61% and 39%, respectively, of revenues to the Company.

The condensed consolidated financial statements include the accounts of the Company and its majority-owned subsidiaries for which it exercises control. Long-term investments in affiliated companies in which the Company exercises significant influence, but which it does not control, are accounted for using the equity method. Investments in which the Company does not exercise significant influence (generally, when the Company has an investment of less than 20.0%) are accounted for at fair value or at cost minus impairment adjusted for observable price changes in orderly transactions for an identical or similar investment of the same issuer for those investments that do not have readily determinable fair values. All significant inter-company transactions and accounts have been eliminated. The Company does not have any significant variable interest entities or special purpose entities whose financial results are not included in the condensed consolidated financial statements.

The financial statements of the Company's operating foreign subsidiaries are measured using the local currency as the functional currency. Assets and liabilities are translated at exchange rates as of the balance sheet date. Revenues and expenses are translated at average monthly exchange rates prevailing during the period. Resulting translation adjustments are included in "Accumulated other comprehensive earnings (loss)."

The accompanying condensed consolidated financial statements of the Company are unaudited. In the opinion of management, all adjustments necessary for a fair statement of results of operations, cash flows and financial position have been made. Except as otherwise disclosed, all such adjustments are of a normal recurring nature. Interim results are not necessarily indicative of results for a full year. The year-end condensed consolidated balance sheet data was derived from audited financial statements but does not include all disclosures required by generally accepted accounting principles.

The condensed consolidated financial statements and notes are presented in accordance with the rules and regulations of the United States (U.S.) Securities and Exchange Commission (SEC) and do not contain certain information included in the Company's 2018 Annual Report on Form 10-K. Therefore, these interim statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report.

Recently Adopted Guidance

Leases

In February 2016, the Financial Accounting Standards Board (FASB) issued a new accounting standard that sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. The Company has elected to utilize the short-term lease exemption and not record leases with initial terms of 12 months or less on the balance sheet. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases and direct financing leases.

The Company adopted the standard on January 1, 2019, using the modified retrospective method. Comparative periods were not adjusted and are presented in accordance with lease guidance in effect for that period. The Company elected the package of practical expedients, which includes not reassessing whether existing contracts contain leases under the new definition of a lease,

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reassessing the classification of existing leases, and reassessing whether previously capitalized initial direct costs qualify for capitalization under the new standard. Leases with an initial term of 12 months or less are not recorded on the Condensed Consolidated Balance Sheets. Operating lease expense is recognized on a straight-line basis over the lease term.

Operating lease assets and liabilities are recognized at the commencement date, based on the present value of the future minimum lease payments over the lease term. A certain number of these leases contain rent escalation clauses either fixed or adjusted periodically for inflation or market rates that are factored into the Company's determination of lease payments. The Company also has variable lease payments that do not depend on a rate or index, for items such as volume purchase commitments, which are recorded as variable cost when incurred. As most of the Company's leases do not provide an implicit rate, the Company estimates an incremental borrowing rate based on the credit quality of the Company and by comparing interest rates available in the market for similar borrowings, and adjusting this amount based on the impact of collateral over the term of each lease. The Company uses this rate to discount payments to present value. Some operating leases contain renewal options, some of which also include options to early terminate the leases. The exercise of these options is at the Company's discretion. The Company determined that all renewal options within leases for main laboratories, STAT laboratories, branches or combination sites were reasonably possible to be exercised and therefore are included in the accounting lease term.

The standard had a material impact in the consolidated balance sheets, but no material impact in the consolidated income statements. The most significant impact was the recognition of right-of-use (ROU) assets and lease liabilities for operating leases.

New Accounting Pronouncements

In June 2016, the FASB issued a new accounting standard intended to provide financial statement users with more decision-useful information about expected credit losses and other commitments to extend credit held by the reporting entity. The standard replaces the incurred loss impairment methodology in current GAAP with one that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The update is effective on January 1, 2020, with early adoption permitted. The Company is currently evaluating the impact this new standard will have on the consolidated financial statements.

In August 2018, the FASB issued a new accounting standard to reduce, modify, and add to the disclosure requirements on fair value measurements. The standard is effective on January 1, 2020, with early adoption permitted. The Company is currently evaluating the impact this new standard will have on the consolidated financial statements.

In August 2018, the FASB issued a new accounting standard to reduce, modify, and add to the disclosure requirements on defined benefit pension and other postretirement plans. The standard is effective on January 1, 2021, with early adoption permitted. The Company is currently evaluating the impact this new standard will have on the consolidated financial statements.

In August 2018, the FASB issued a new accounting standard to align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The standard is effective on January 1, 2020, with early adoption permitted. The Company is currently evaluating the impact this new standard will have on the consolidated financial statements.

Reclassifications and Revisions

In conjunction with the adoption of the new lease standard, the Company reclassified the capital lease asset balance of \$44.4 at December 31, 2018, from Property, plant and equipment, net to Other assets.

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2. REVENUES

The Company's revenues by segment payers/customer groups for the three and nine months ended September 30, 2019, and 2018, are as follows:

For the Three Months Ended September 30, 2019							
	U.S.	Canada	U.K.	Switzerland	Other Europe	Other	Total
Payer/Customer							
<i>LCD</i>							
Clients	16%	1%	—%	—%	—%	—%	17%
Patients	8%	—%	—%	—%	—%	—%	8%
Medicare and Medicaid	8%	—%	—%	—%	—%	—%	8%
Third-party	25%	2%	—%	—%	—%	—%	27%
<i>Total LCD revenues by payer</i>	<u>57%</u>	<u>3%</u>	<u>—%</u>	<u>—%</u>	<u>—%</u>	<u>—%</u>	<u>60%</u>
<i>CDD</i>							
Biopharmaceutical and medical device companies	21%	—%	5%	4%	3%	7%	40%
Total revenues	<u><u>78%</u></u>	<u><u>3%</u></u>	<u><u>5%</u></u>	<u><u>4%</u></u>	<u><u>3%</u></u>	<u><u>7%</u></u>	<u><u>100%</u></u>

For the Three Months Ended September 30, 2018							
	U.S.	Canada	U.K.	Switzerland	Other Europe	Other	Total
Payer/Customer							
<i>LCD</i>							
Clients	17%	1%	—%	—%	—%	—%	18%
Patients	7%	—%	—%	—%	—%	—%	7%
Medicare and Medicaid	9%	—%	—%	—%	—%	—%	9%
Third-party	26%	2%	—%	—%	—%	—%	28%
<i>Total LCD revenues by payer</i>	<u>59%</u>	<u>3%</u>	<u>—%</u>	<u>—%</u>	<u>—%</u>	<u>—%</u>	<u>62%</u>
<i>CDD</i>							
Biopharmaceutical and medical device companies	20%	—%	4%	4%	3%	7%	38%
Total revenues	<u><u>79%</u></u>	<u><u>3%</u></u>	<u><u>4%</u></u>	<u><u>4%</u></u>	<u><u>3%</u></u>	<u><u>7%</u></u>	<u><u>100%</u></u>

For the Nine Months Ended September 30, 2019							
	U.S.	Canada	U.K.	Switzerland	Other Europe	Other	Total
Payer/Customer							
<i>LCD</i>							
Clients	16%	1%	—%	—%	—%	—%	17%
Patients	8%	—%	—%	—%	—%	—%	8%
Medicare and Medicaid	8%	—%	—%	—%	—%	—%	8%
Third-party	26%	2%	—%	—%	—%	—%	28%
<i>Total LCD revenues by payer</i>	<u>58%</u>	<u>3%</u>	<u>—%</u>	<u>—%</u>	<u>—%</u>	<u>—%</u>	<u>61%</u>
<i>CDD</i>							
Biopharmaceutical and medical device companies	20%	—%	4%	5%	3%	7%	39%
Total revenues	<u><u>78%</u></u>	<u><u>3%</u></u>	<u><u>4%</u></u>	<u><u>5%</u></u>	<u><u>3%</u></u>	<u><u>7%</u></u>	<u><u>100%</u></u>

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For the Nine Months Ended September 30, 2018

	U.S.	Canada	U.K.	Switzerland	Other Europe	Other	Total
Payer/Customer							
<i>LCD</i>							
Clients	17%	1%	—%	—%	—%	—%	18%
Patients	8%	—%	—%	—%	—%	—%	8%
Medicare and Medicaid	9%	—%	—%	—%	—%	—%	9%
Third-party	25%	2%	—%	—%	—%	—%	27%
<i>Total LCD revenues by payer</i>	<u>59%</u>	<u>3%</u>	<u>—%</u>	<u>—%</u>	<u>—%</u>	<u>—%</u>	<u>62%</u>
<i>CDD</i>							
Biopharmaceutical and medical device companies	20%	—%	3%	5%	3%	7%	38%
Total revenues	<u><u>79%</u></u>	<u><u>3%</u></u>	<u><u>3%</u></u>	<u><u>5%</u></u>	<u><u>3%</u></u>	<u><u>7%</u></u>	<u><u>100%</u></u>

Contract costs

CDD incurs sales commissions in the process of obtaining contracts with customers, which are recoverable through the service fees in the contract. Sales commissions that are payable upon contract award are recognized as assets and amortized over the expected contract term, along with related payroll tax expense. The amortization of commission expense is based on the weighted average contract duration for all commissionable awards in the respective business in which the commission expense is paid, which approximates the period over which goods and services are transferred to the customer. The amortization period of sales commissions ranges from approximately 12 months to 57 months, depending on the business. For businesses that enter into primarily short-term contracts, the Company applies the practical expedient which allows costs to obtain a contract to be expensed when incurred if the amortization period of the assets that would otherwise have been recognized is one year or less. Amortization of assets from sales commissions is included in selling, general, and administrative expense.

CDD incurs costs to fulfill contracts with customers, which are recoverable through the service fees in the contract. Contract fulfillment costs include software implementation costs and setup costs for certain endpoint and market access solutions. These costs are recognized as assets and amortized over the expected term of the contract to which the implementation relates, which is the period over which services are expected to be provided to the customer. This period typically ranges from 24-60 months. Amortization of deferred contract fulfillment costs is included in cost of goods sold.

	September 30, 2019	December 31, 2018
Sales commission assets	\$ 27.8	\$ 24.2
Deferred contract fulfillment costs	15.0	12.9
Total	<u>\$ 42.8</u>	<u>\$ 37.1</u>

Amortization related to sales commission assets and associated payroll taxes for the three months ended September 30, 2019, and 2018, was \$5.8 and \$4.2, respectively, and for the nine months ended September 30, 2019, and 2018, was \$15.3 and \$12.8, respectively. Amortization related to deferred contract fulfillment costs for the three-month periods ended September 30, 2019, and 2018, was \$2.3 and \$0.8, respectively, and for the nine months ended September 30, 2019, and 2018, was \$6.1 and \$3.3, respectively. Impairment expense related to contract costs was immaterial to the Company's consolidated statement of operations.

Receivables, Unbilled Services and Unearned Revenue

The following table provides information about receivables, unbilled services, and unearned revenue (contract liabilities) from contracts with customers for the CDD segment. Unbilled services are comprised primarily of unbilled receivables, but also include contract assets. A contract asset is recorded when a right to payment has been earned for work performed, but billing and payment for that work is determined by certain contractual milestones, whereas unbilled receivables are billable upon the passage of time. While CDD attempts to negotiate terms that provide for billing and payment of services prior or in close proximity to the provision of services, this is not always possible and there are fluctuations in the level of unbilled services and unearned revenue from period to period.

	September 30, 2019	December 31, 2018
Receivables, which are included in Accounts receivable	\$ 809.2	\$ 693.6
Unbilled services	479.3	396.9
Unearned revenue	<u>400.2</u>	<u>354.1</u>

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Revenues recognized during the period, which were included in the unearned revenue balance at the beginning of the period for the nine months ended September 30, 2019, and September 30, 2018, were \$232.8 and \$144.8, respectively. Bad debt expense on receivables for the nine months ended September 30, 2019, and 2018, was immaterial to the Company's consolidated statement of operations.

Performance Obligations Under Long-Term Contracts

Long-term contracts at the Company consist primarily of fully managed clinical studies within the CDD segment. The amount of existing performance obligations under such long-term contracts unsatisfied as of September 30, 2019, was \$4,310.7. The Company expects to recognize approximately 36% of the remaining performance obligations as revenues over the next 12 months, and the balance thereafter. The Company's long-term contracts generally range from 1 to 8 years.

Within CDD, revenues of \$67.7 and \$20.5 were recognized during the nine months ended September 30, 2019, and 2018, respectively, from performance obligations that were satisfied in previous periods. This revenue comes from adjustments related to changes in scope and estimates in full service clinical studies.

3. BUSINESS ACQUISITIONS AND DISPOSITIONS

On June 3, 2019, the Company's CDD segment acquired Envigo's nonclinical contract research services business, expanding CDD's global nonclinical drug development capabilities with additional locations and resources. Additionally, the Company divested the Covance Research Products (CRP) business, which was a part of the CDD segment, to Envigo. As part of this sale, CDD entered into a multi-year, renewable supply agreement. The Company paid cash consideration of \$601.0, received a floating rate secured note of \$110.0, and recorded a loss on the sale of CRP of \$11.9. The Company funded the transaction through a new term loan facility.

The preliminary valuation of acquired assets and assumed liabilities as of June 3, 2019, include the following:

Consideration Transferred				
Cash consideration	\$	601.0		
Fair value of CRP		110.0		
Total		<u>\$ 711.0</u>		
		Preliminary	Measurement	
		June 30,	Period	
		2019	Adjustments	
			Preliminary	
			September 30,	
			2019	
Net Assets Acquired				
Cash and cash equivalents	\$	15.1	\$ (3.9)	\$ 11.2
Accounts receivable		16.5	(1.2)	15.3
Unbilled services		26.5	—	26.5
Inventories		4.5	—	4.5
Prepaid expenses and other		3.5	—	3.5
Property, plant and equipment (including ROU operating lease assets)		99.1	(15.0)	84.1
Deferred income taxes		25.5	(9.3)	16.2
Goodwill		432.2	(18.0)	414.2
Customer relationships		125.8	18.7	144.5
Trade name and trademarks		0.6	—	0.6
Other assets		9.9	—	9.9
Total assets acquired		<u>759.2</u>	<u>(28.7)</u>	<u>730.5</u>
Accounts payable		15.4	(0.2)	15.2
Accrued expenses and other		11.6	(4.2)	7.4
Unearned revenue		49.9	—	49.9
Operating lease liabilities		15.0	(15.0)	—
Other liabilities		66.3	(9.3)	57.0
Total liabilities acquired		<u>158.2</u>	<u>(28.7)</u>	<u>129.5</u>
Net Envigo assets acquired		601.0	\$ —	\$ 601.0
Floating rate secured note receivable due 2022		110.0		
Total		<u>\$ 711.0</u>		

The preliminary purchase consideration for Envigo has been allocated to the estimated fair market value of the net assets acquired, including approximately \$144.5 in identifiable intangible assets and a residual amount of non-tax-deductible goodwill of approximately \$414.2. The amortization period for intangible assets acquired is 11 years for customer relationships.

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The Envigo transaction contributed \$52.0 and \$9.0 and \$68.5 and \$9.7 of revenues and operating income, respectively, during the three and nine months ended September 30, 2019, respectively.

The purchase price allocation for the Envigo transaction is still preliminary and subject to change. The areas of the purchase price allocation that are not yet finalized relate primarily to intangible assets, goodwill, fixed assets and the impact of finalizing deferred taxes. Accordingly, adjustments may be made as additional information is obtained about the facts and circumstances that existed as of the valuation date. The Company expects these purchase price allocations to be finalized by the second quarter of 2020. Any adjustments will be recorded in the period in which they are identified.

During the nine months ended September 30, 2019, the Company also acquired various businesses and related assets for approximately \$263.1 in cash (net of cash acquired). The purchase consideration for all acquisitions year to date has been allocated to the estimated fair market value of the net assets acquired, including approximately \$179.6 in identifiable intangible assets and a residual amount of non-tax-deductible goodwill of approximately \$98.1. The amortization periods for intangible assets acquired from these businesses range from 11 to 15 years for customer relationships. These acquisitions were made primarily to extend the Company's geographic reach in important market areas, enhance the Company's scientific differentiation and to expand the breadth and scope of the Company's CRO services. The excess of the fair value of the consideration conveyed over the fair value of the net assets acquired was recorded as goodwill. The goodwill reflects the Company's expectations to utilize the acquired businesses' workforce and established relationships and the benefits of being able to leverage operational efficiencies with favorable growth opportunities in these markets.

Additionally, the Company divested its food solutions and forensic testing services business in the United Kingdom (U.K.) and the U.S. in 2018. Total operating income for the three divested businesses was \$3.0 and \$8.4 for the three and nine months ended September 30, 2018, respectively. The Company recorded a net gain on sale of businesses of 209.4 for the nine months ended September 30, 2018, which is included in Other, net.

4. EARNINGS PER SHARE

Basic earnings per share is computed by dividing net earnings attributable to Laboratory Corporation of America Holdings by the weighted average number of common shares outstanding. Diluted earnings per share is computed by dividing net earnings including the impact of dilutive adjustments by the weighted average number of common shares outstanding plus potentially dilutive shares, as if they had been issued at the earlier of the date of issuance or the beginning of the period presented. Potentially dilutive common shares result primarily from the Company's outstanding stock options, restricted stock awards, restricted stock units, performance share awards, and shares issuable upon conversion of zero-coupon subordinated notes.

The following represents a reconciliation of basic earnings per share to diluted earnings per share:

	Three Months Ended September 30,						Nine Months Ended September 30,					
	2019			2018			2019			2018		
	Earnings	Shares	Per Share Amount	Earnings	Shares	Per Share Amount	Earnings	Shares	Per Share Amount	Earnings	Shares	Per Share Amount
Basic earnings per share:												
Net earnings	\$ 220.7	97.6	\$ 2.26	\$ 318.8	101.6	\$ 3.14	\$ 596.7	98.1	\$ 6.08	\$ 725.8	101.8	\$ 7.13
Dilutive effect of employee stock options and awards	—	0.7		—	1.0		—	0.7		—	1.2	
Net earnings including impact of dilutive adjustments	\$ 220.7	98.3	\$ 2.25	\$ 318.8	102.7	\$ 3.10	\$ 596.7	98.8	\$ 6.04	\$ 725.8	103.1	\$ 7.04

The following table summarizes the potential common shares not included in the computation of diluted earnings per share because their impact would have been antidilutive:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018		2019	2018	
Stock options		0.2	0.1	0.2		0.1

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5. RESTRUCTURING AND OTHER SPECIAL CHARGES

During the nine months ended September 30, 2019, the Company recorded net restructuring and other special charges of \$48.4: \$22.8 within LCD and \$25.6 within CDD. The charges were comprised of \$26.2 related to severance and other personnel costs and \$22.0 in costs associated with facility closures, impairment of operating lease right-of-use assets and general integration initiatives. The charges were increased by the adjustment of previously established reserves of \$0.4 in severance reserves and decreased by a reversal of \$0.2 in unused facility reserves.

During the nine months ended September 30, 2018, the Company recorded net restructuring and other special charges of \$36.5: \$13.2 within LCD and \$23.3 within CDD. The charges were comprised of \$30.0 related to severance and other personnel costs and \$8.8 in costs associated with facility closures and general integration initiatives. The Company reversed previously established reserves of \$1.2 and \$1.1 in unused facility reserves and unused severance reserves, respectively. The Company also recorded \$5.3 in impairment to land held for sale which is included in amortization expense.

The following represents the Company's restructuring reserve activities for the period indicated:

	LCD		CDD		Total
	Severance and Other Employee Costs	Facility Costs	Severance and Other Employee Costs	Facility Costs	
Balance as of December 31, 2018	\$ 2.1	\$ 7.4	\$ 6.5	\$ 27.6	\$ 43.6
Reclassification for ASC 842 adoption	—	(5.7)	—	(27.1)	(32.8)
Restructuring charges	15.3	6.6	10.9	1.8	34.6
Adjustments to prior restructuring accruals	(0.1)	(0.1)	0.5	(0.1)	0.2
Impairment of operating lease right-of-use asset	—	1.1	—	12.5	13.6
Cash payments and other adjustments	(17.0)	(6.4)	(11.0)	(10.0)	(44.4)
Balance as of September 30, 2019	\$ 0.3	\$ 2.9	\$ 6.9	\$ 4.7	\$ 14.8
Current					\$ 11.1
Non-current					3.7
					\$ 14.8

6. GOODWILL AND INTANGIBLE ASSETS

The changes in the carrying amount of goodwill for the nine months ended September 30, 2019, are as follows:

	LCD	CDD	Total
Balance as of January 1, 2019	\$ 3,638.8	\$ 3,721.5	\$ 7,360.3
Goodwill acquired during the period	72.8	467.2	540.0
Dispositions	—	(12.6)	(12.6)
Adjustments to goodwill	0.9	(73.3)	(72.4)
Balance as of September 30, 2019	\$ 3,712.5	\$ 4,102.8	\$ 7,815.3

The components of identifiable intangible assets are as follows:

	September 30, 2019			December 31, 2018		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Customer relationships	\$ 4,370.9	\$ (1,274.5)	\$ 3,096.4	\$ 4,119.4	\$ (1,146.7)	\$ 2,972.7
Patents, licenses and technology	450.2	(229.0)	221.2	447.3	(211.2)	236.1
Non-compete agreements	89.4	(58.4)	31.0	76.8	(53.7)	23.1
Trade name	405.4	(209.8)	195.6	404.0	(189.1)	214.9
Land use right	11.1	(5.2)	5.9	10.8	(4.1)	6.7
Canadian licenses	471.2	—	471.2	457.6	—	457.6
	\$ 5,798.2	\$ (1,776.9)	\$ 4,021.3	\$ 5,515.9	\$ (1,604.8)	\$ 3,911.1

Amortization of intangible assets for the three months ended September 30, 2019, and 2018, was \$61.7 and \$54.7, respectively and for the nine months ended September 30, 2019, and 2018, was \$179.0 and \$175.5, respectively. Amortization expense for the

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net carrying amount of intangible assets is estimated to be \$54.1 for the remainder of fiscal 2019, \$237.9 in fiscal 2020, \$231.1 in fiscal 2021, \$225.1 in fiscal 2022, \$221.4 in fiscal 2023 and \$2,580.3 thereafter.

7. LEASES

The Company has operating and finance leases for patient service centers, laboratories and testing facilities, clinical facilities, general office spaces, vehicles, and office and laboratory equipment. Leases have remaining lease terms of less than a year to 15 years, some of which include options to extend the leases for up to 15 years.

The components of lease expense were as follows:

	For the Three Months Ended September 30, 2019	For the Nine Months Ended September 30, 2019
Operating lease cost	\$ 58.9	\$ 169.7
Finance lease cost:		
Amortization of right-of-use assets	\$ 2.0	\$ 6.5
Interest on lease liabilities	1.6	4.8
Total finance lease cost	<u>\$ 3.6</u>	<u>\$ 11.3</u>

Supplemental cash flow information related to leases was as follows:

	For the Nine Months Ended September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ (174.3)
Operating cash flows from finance leases	(4.8)
Financing cash flows from finance leases	(6.7)
ROU assets obtained in exchange for lease obligations:	
Operating leases	\$ 50.8
Finance leases	0.2

Supplemental balance sheet information related to leases was as follows:

	September 30, 2019
Operating Leases	
Operating lease ROU assets (included in Property, plant and equipment, net)	\$ 681.1
Short-term operating lease liabilities	202.1
Operating lease liabilities	530.7
Total operating lease liabilities	<u>\$ 732.8</u>
Finance Leases	
Finance lease ROU assets (included in Other assets)	\$ 85.6
Short-term finance lease liabilities	\$ 8.3
Other long-term liabilities	92.8
Total finance lease liabilities	<u>\$ 101.1</u>
Weighted Average Remaining Lease Term	
Operating leases	7.4
Finance leases	16.5
Weighted Average Discount Rate	
Operating leases	4.3%
Finance leases	5.3%

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Maturities of lease liabilities are as follows:

Nine months ended September 30, 2019	Operating Leases	Finance Leases
2019	\$ 181.8	\$ 3.6
2020	146.3	13.8
2021	105.2	12.0
2022	77.7	10.8
2023	57.4	10.7
Thereafter	277.5	107.2
Total lease payments	845.9	158.1
Less imputed interest	(113.1)	(57.0)
Total	<u>\$ 732.8</u>	<u>\$ 101.1</u>

Rental expense for short term leases with a term less than one year for the three and nine months ended September 30, 2019, amounted to \$1.5 and \$7.4, respectively. The Company has variable lease payments that do not depend on a rate or index, primarily for purchase volume commitments, which are recorded as variable cost when incurred. Total variable payments for the three and nine months ended September 30, 2019, were \$5.1 and \$14.3, respectively. As of September 30, 2019, the Company has entered into approximately 20 additional operating leases, primarily for patient service centers, that have not yet commenced and are not significant to the overall lease portfolio. These operating leases will commence later in 2019 with lease terms ranging from less than a year to 5 years.

The Company leases various facilities and equipment under non-cancelable lease arrangements. Future minimum rental commitments for leases with non-cancelable terms of one year or more at December 31, 2018 under Accounting Standards Codification 840 are as follows:

Year Ended December 31, 2018	Operating Leases	Finance Leases
2019	\$ 191.1	\$ 8.6
2020	145.4	8.0
2021	107.0	6.7
2022	80.9	6.0
2023	61.5	6.5
Thereafter	155.6	23.1

Rental expense, which includes rent for real estate, equipment and automobiles under operating leases, amounted to \$100.0 and \$291.5, respectively, for the three and nine months ended September 30, 2019.

8. DEBT

Short-term borrowings and the current portion of long-term debt at September 30, 2019, and December 31, 2018, consisted of the following:

	September 30, 2019	December 31, 2018
Zero-coupon convertible subordinated notes	\$ 1.4	\$ 8.7
2.625% senior notes due 2020	500.0	—
Debt issuance costs	(0.2)	(0.5)
Current portion of note payable	1.4	1.8
Total short-term borrowings and current portion of long-term debt	<u>\$ 502.6</u>	<u>\$ 10.0</u>

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Long-term debt at September 30, 2019, and December 31, 2018, consisted of the following:

	September 30, 2019	December 31, 2018
2.625% senior notes due 2020	\$ —	\$ 500.0
4.625% senior notes due 2020	604.1	596.9
3.20% senior notes due 2022	500.0	500.0
3.75% senior notes due 2022	500.0	500.0
4.00% senior notes due 2023	300.0	300.0
3.25% senior notes due 2024	600.0	600.0
3.60% senior notes due 2025	1,000.0	1,000.0
3.60% senior notes due 2027	600.0	600.0
4.70% senior notes due 2045	900.0	900.0
Revolving credit facility	—	—
2019 Term Loan	850.0	—
2017 Term Loan	277.0	527.0
Debt issuance costs	(35.5)	(40.2)
Note payable	5.7	7.2
Total long-term debt	\$ 6,101.3	\$ 5,990.9

Senior Notes

During the third quarter of 2013, the Company entered into two fixed-to-variable interest rate swap agreements for its 4.625% senior notes due 2020 with an aggregate notional amount of \$600.0 and variable interest rates based on one-month LIBOR plus 2.298% to hedge against changes in the fair value of a portion of the Company's long-term debt. These derivative financial instruments are accounted for as fair value hedges of the senior notes due 2020. These interest rate swaps are included in other long-term assets or other long-term liabilities, as applicable, and added to or subtracted from the value of the senior notes, with an aggregate fair value asset of \$4.1 at September 30, 2019, and an aggregate fair value liability of \$3.1 at December 31, 2018.

Zero-Coupon Subordinated Notes

On September 11, 2019, the Company announced that for the period from September 11, 2019, to March 10, 2020, the zero-coupon subordinated notes will accrue contingent cash interest at a rate of no less than 0.125% of the average market price of a zero-coupon subordinated note for the five trading days ended September 6, 2019, in addition to the continued accrual of the original issue discount.

During the nine months ended September 30, 2019, the Company settled notices to convert \$7.7 aggregate principal amount of its zero-coupon subordinated notes with a conversion value of \$14.5. The total cash used for these settlements was \$7.3. As a result of these conversions, the Company also reversed deferred tax liabilities of \$1.7.

On October 15, 2019, the Company announced that its zero-coupon subordinated notes may be converted into cash and common stock at the conversion rate of 13.4108 per \$1,000.0 principal amount at maturity of the notes, subject to the terms of the zero-coupon subordinated notes and the Indenture, dated as of October 24, 2006, between the Company and The Bank of New York Mellon, as trustee and the conversion agent. In order to exercise the option to convert all or a portion of the zero-coupon subordinated notes, holders are required to validly surrender their zero-coupon subordinated notes at any time during the calendar quarter beginning October 1, 2019, through the close of business on the last business day of the calendar quarter, which is 5:00 p.m., New York City time, on Tuesday, December 31, 2019. If notices of conversion are received, the Company plans to settle the cash portion of the conversion obligation with cash on hand and/or borrowings under its revolving credit facility.

Credit Facilities

On June 3, 2019, the Company entered into a new \$850.0 2019 term loan facility in addition to its \$750.0 2017 term loan facility. The 2019 term loan facility will mature on June 3, 2021. Proceeds of the 2019 term loan facility were used for general corporate purposes, including to repay approximately \$250.0 of the 2017 term loan facility and in connection with the acquisition of Envigo's nonclinical research services business.

The 2019 term loan facility accrues interest at a per annum rate equal to, at the Company's election, either a LIBOR rate plus a margin ranging from 0.55% to 1.175%, or a base rate determined according to a prime rate or federal funds rate plus a margin ranging from 0.0% to 0.175%. The 2019 term loan balance at September 30, 2019, was \$850.0. As of September 30, 2019, the effective interest rate on the 2019 term loan was 2.84%.

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The 2017 term loan facility accrues interest at a per annum rate equal to, at the Company's election, either a LIBOR rate plus a margin ranging from 0.875% to 1.50%, or a base rate determined according to a prime rate or federal funds rate plus a margin ranging from 0.0% to 0.50%. The 2017 term loan balance at September 30, 2019, was \$277.0 and at December 31, 2018, was \$527.0. As of September 30, 2019, the effective interest rate on the 2017 term loan was 3.17%.

The Company maintains a revolving credit facility consisting of a five-year revolving facility in the principal amount of up to \$1,000.0, with the option of increasing the facility by up to an additional \$350.0, subject to the agreement of one or more new or existing lenders to provide such additional amounts and certain other customary conditions. The revolving credit facility also provides for a subfacility of up to \$100.0 for swing line borrowings and a subfacility of up to \$150.0 for issuances of letters of credit. The revolving credit facility is permitted to be used for general corporate purposes, including working capital, capital expenditures, funding of share repurchases and certain other payments, and acquisitions and other investments. The Company had no outstanding balance on its revolving credit facility at September 30, 2019, and December 31, 2018.

Advances under the revolving credit facility accrue interest at a per annum rate equal to, at the Company's election, either a LIBOR rate plus a margin ranging from 0.775% to 1.25%, or a base rate determined according to a prime rate or federal funds rate plus a margin ranging from 0.00% to 0.25%. Fees are payable on outstanding letters of credit under the revolving credit facility at a per annum rate equal to the applicable margin for LIBOR loans, and the Company is required to pay a facility fee on the aggregate commitments under the revolving credit facility, at a per annum rate ranging from 0.10% to 0.25%.

The interest margin applicable to the term loan and credit facilities, and the facility fee and letter of credit fees payable under the revolving credit facility, are based on the Company's senior credit ratings as determined by Standard & Poor's and Moody's.

Under the term loan facilities and the revolving credit facility, the Company is subject to negative covenants limiting subsidiary indebtedness and certain other covenants typical for investment grade-rated borrowers, and the Company is required to maintain certain leverage ratios. The Company was in compliance with all covenants in the term loan facilities and the revolving credit facility at September 30, 2019. As of September 30, 2019, the ratio of total debt to consolidated proforma trailing 12 month EBITDA was 3.3 to 1.0.

As of September 30, 2019, the Company had provided letters of credit aggregating approximately \$72.4, primarily in connection with certain insurance programs. The Company's availability of \$927.6 at September 30, 2019, under its revolving credit facility is reduced by the amount of these letters of credit.

9. PREFERRED STOCK AND COMMON SHAREHOLDERS' EQUITY

The Company is authorized to issue up to 265.0 shares of common stock, par value \$0.10 per share. The Company's treasury shares were recorded at aggregate cost and were retired during the second quarter of 2019. The Company is authorized to issue up to 30.0 shares of preferred stock, par value \$0.10 per share. There were no preferred shares outstanding as of September 30, 2019, and December 31, 2018.

The changes in common shares issued and held in treasury are summarized below:

	Issued	Held in Treasury	Outstanding
Common shares at December 31, 2018	122.4	(23.5)	98.9
Common stock issued under employee stock plans	1.2	—	1.2
Surrender of restricted stock and performance share awards	—	(0.1)	(0.1)
Retirement of common stock	(2.6)	—	(2.6)
Retirement of treasury stock	(23.6)	23.6	—
Common shares at September 30, 2019	<u>97.4</u>	<u>—</u>	<u>97.4</u>

Share Repurchase Program

At the end of 2018, the Company had outstanding authorization from the board of directors to purchase up to \$443.5 of Company common stock. During January 2019, the Company purchased 0.8 shares of its common stock at an average price of \$131.71 for a total cost of \$100.1 under this plan. On February 6, 2019, the board of directors replaced the Company's existing share repurchase plan with a new plan authorizing repurchases of up to \$1,250.0 of the Company's common stock. The repurchase authorization has no expiration. Since the new plan authorization, the Company has purchased 1.8 shares of its common stock at an average price of \$162.80 per share for a total cost of \$299.9. As of September 30, 2019, the Company had outstanding authorization from the board of directors to purchase up to \$950.0 of the Company's common stock.

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Accumulated Other Comprehensive Earnings (Loss)

The components of accumulated other comprehensive earnings (loss) are as follows:

	Foreign Currency Translation Adjustments	Net Benefit Plan Adjustments	Accumulated Other Comprehensive Earnings (Loss)
Balance as of December 31, 2018	\$ (389.8)	\$ (73.3)	\$ (463.1)
Other comprehensive earnings (loss)	(45.4)	8.7	(36.7)
Tax effect of adjustments	—	(2.4)	(2.4)
Balance as of September 30, 2019	<u>\$ (435.2)</u>	<u>\$ (67.0)</u>	<u>\$ (502.2)</u>

10. INCOME TAXES

The provision for income tax expense of \$66.4 and \$214.4 for the three months and nine months ended September 30, 2019, respectively, primarily resulted from the application of the Company's estimated effective blended U.S. federal and state income tax rate as well as a reduction in tax rates in a foreign jurisdiction. The provision for income tax expense of \$180.6 and \$328.1 for the three and nine months ended September 30, 2018, respectively, primarily resulted from the application of the Company's estimated effective blended U.S. federal and state income tax rate, the Company's foreign tax rates and the tax impact of acquisitions, divestitures and tax reform.

The Company does not recognize a tax benefit unless it concludes that it is more likely than not that the benefit will be sustained on audit by the taxing authority based solely on the technical merits of the associated tax position. If the recognition threshold is met, the Company recognizes a tax benefit measured at the largest amount of the tax benefit that it believes is greater than 50% likely to be realized.

The gross unrecognized income tax benefits were \$24.2 and \$18.0 at September 30, 2019, and December 31, 2018, respectively. It is anticipated that the amount of the unrecognized income tax benefits will change within the next 12 months; however, these changes are not expected to have a significant impact on the results of operations, cash flows or the financial position of the Company.

As of September 30, 2019, and December 31, 2018, \$24.2 and \$18.0, respectively, are the approximate amounts of gross unrecognized income tax benefits that, if recognized, would favorably affect the effective income tax rate in future periods.

The Company recognizes interest and penalties related to unrecognized income tax benefits in income tax expense. Accrued interest and penalties related to uncertain tax positions totaled \$5.2 and \$8.7 as of September 30, 2019, and December 31, 2018, respectively.

The Company has substantially concluded all U.S. federal income tax matters for years through 2015. Substantially all material state and local, and foreign income tax matters have been concluded through 2014.

The Company has various state and foreign income tax examinations ongoing throughout the year. The Company believes adequate provisions have been recorded related to all open tax years.

11. COMMITMENTS AND CONTINGENCIES

The Company is involved from time to time in various claims and legal actions, including arbitrations, class actions, and other litigation (including those described in more detail below), arising in the ordinary course of business. Some of these actions involve claims that are substantial in amount. These matters include, but are not limited to, intellectual property disputes; commercial and contract disputes; professional liability claims; employee-related matters; and inquiries, including subpoenas and other civil investigative demands, from governmental agencies, Medicare or Medicaid payers and MCOs reviewing billing practices or requesting comment on allegations of billing irregularities that are brought to their attention through billing audits or third parties. The Company receives civil investigative demands or other inquiries from various governmental bodies in the ordinary course of its business. Such inquiries can relate to the Company or other parties, including physicians and other health care providers. The Company works cooperatively to respond to appropriate requests for information.

The Company also is named from time to time in suits brought under the *qui tam* provisions of the False Claims Act and comparable state laws. These suits typically allege that the Company has made false statements and/or certifications in connection with claims for payment from U.S. federal or state healthcare programs. The suits may remain under seal (hence, unknown to the Company) for some time while the government decides whether to intervene on behalf of the *qui tam* plaintiff. Such claims are an inevitable part of doing business in the healthcare field today.

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The Company believes that it is in compliance in all material respects with all statutes, regulations and other requirements applicable to its commercial laboratory operations and drug development support services. The healthcare diagnostics and drug development industries are, however, subject to extensive regulation, and the courts have not interpreted many of the applicable statutes and regulations. Therefore, the applicable statutes and regulations could be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect the Company. Potential sanctions for violation of these statutes and regulations include significant civil and criminal penalties, fines, the loss of various licenses, certificates and authorizations, additional liabilities from third-party claims, and/or exclusion from participation in government programs.

Many of the current claims and legal actions against the Company are in preliminary stages, and many of these cases seek an indeterminate amount of damages. The Company records an aggregate legal reserve, which is determined using calculations based on historical loss rates and assessment of trends experienced in settlements and defense costs. In accordance with FASB Accounting Standards Codification Topic 450 "Contingencies," the Company establishes reserves for judicial, regulatory, and arbitration matters outside the aggregate legal reserve if and when those matters present loss contingencies that are both probable and estimable and would exceed the aggregate legal reserve. When loss contingencies are not both probable and estimable, the Company does not establish separate reserves.

The Company is unable to estimate a range of reasonably probable loss for the proceedings described in more detail below in which damages either have not been specified or, in the Company's judgment, are unsupported and/or exaggerated and (i) the proceedings are in early stages; (ii) there is uncertainty as to the outcome of pending appeals or motions; (iii) there are significant factual issues to be resolved; and/or (iv) there are novel legal issues to be presented. For these proceedings, however, the Company does not believe, based on currently available information, that the outcomes will have a material adverse effect on the Company's financial condition, though the outcomes could be material to the Company's operating results for any particular period, depending, in part, upon the operating results for such period.

As previously reported, the Company responded to an October 2007 subpoena from the U.S. Department of Health & Human Services Office of Inspector General's regional office in New York. On August 17, 2011, the U.S. District Court for the Southern District of New York unsealed a False Claims Act lawsuit, *United States of America ex rel. NPT Associates v. Laboratory Corporation of America Holdings*, which alleges that the Company offered UnitedHealthcare kickbacks in the form of discounts in return for Medicare business. The Plaintiff's Third Amended Complaint further alleges that the Company's billing practices violated the False Claims Acts of 14 states and the District of Columbia. The lawsuit seeks actual and treble damages and civil penalties for each alleged false claim, as well as recovery of costs, attorney's fees, and legal expenses. Neither the U.S. government nor any state government has intervened in the lawsuit. The Company's Motion to Dismiss was granted in October 2014 and Plaintiff was granted the right to replead. On January 11, 2016, Plaintiff filed a motion requesting leave to file an amended complaint under seal and to vacate the briefing schedule for the Company's Motion to Dismiss, while the government reviews the amended complaint. The Court granted the motion and vacated the briefing dates. Plaintiff then filed the Amended Complaint under seal. The Company will vigorously defend the lawsuit.

In addition, the Company has received various other subpoenas since 2007 related to Medicaid billing. In October 2009, the Company received a subpoena from the State of Michigan Department of Attorney General seeking documents related to its billing to Michigan Medicaid. The Company cooperated with this request. In October 2013, the Company received a Civil Investigative Demand from the State of Texas Office of the Attorney General requesting documents related to its billing to Texas Medicaid. The Company cooperated with this request. On October 5, 2018, the Company received a second Civil Investigative Demand from the State of Texas Office of the Attorney General requesting documents related to its billing to Texas Medicaid. The Company is cooperating with this request.

On August 31, 2015, the Company was served with a putative class action lawsuit, *Patty Davis v. Laboratory Corporation of America, et al.*, filed in the Circuit Court of the Thirteenth Judicial Circuit for Hillsborough County, Florida. The complaint alleges that the Company violated the Florida Consumer Collection Practices Act by billing patients who were collecting benefits under the Workers' Compensation Statutes. The lawsuit seeks injunctive relief and actual and statutory damages, as well as recovery of attorney's fees and legal expenses. In April 2017, the Circuit Court granted the Company's Motion for Judgment on the Pleadings. The Plaintiff appealed the Circuit Court's ruling to the Florida Second District Court of Appeal. On October 16, 2019, the Court of Appeal reversed the Circuit Court's dismissal, but certified a controlling issue of Florida law to the Florida Supreme Court. The Company will vigorously defend the lawsuit.

In December 2014, the Company received a Civil Investigative Demand issued pursuant to the U.S. False Claims Act from the U.S. Attorney's Office for South Carolina, which requested information regarding alleged remuneration and services provided by the Company to physicians who also received draw and processing/handling fees from competitor laboratories Health Diagnostic Laboratory, Inc. (HDL) and Singulex, Inc. (Singulex). The Company cooperated with the request. On April 4, 2018, the U.S. District Court for the District of South Carolina, Beaufort Division, unsealed a False Claims Act lawsuit, *United States of America*

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ex rel. Scarlett Lutz, et al. v. Laboratory Corporation of America Holdings, which alleges that the Company's financial relationships with referring physicians violate federal and state anti-kickback statutes. The Plaintiffs' Fourth Amended Complaint further alleges that the Company conspired with HDL and Singulex in violation of the Federal False Claims Act and the California and Illinois insurance fraud prevention acts by facilitating HDL's and Singulex's offers of illegal inducements to physicians and the referral of patients to HDL and Singulex for laboratory testing. The lawsuit seeks actual and treble damages and civil penalties for each alleged false claim, as well as recovery of costs, attorney's fees, and legal expenses. Neither the U.S. government nor any state government has intervened in the lawsuit. The Company filed a Motion to Dismiss seeking the dismissal of the claims asserted under the California and Illinois insurance fraud prevention statutes, the conspiracy claim, the reverse False Claims Act claim, and all claims based on the theory that the Company performed medically unnecessary testing. On January 16, 2019, the Court entered an order granting in part and denying in part the Motion to Dismiss. The Court dismissed the Plaintiffs' claims based on the theory that the Company performed medically unnecessary testing, the claims asserted under the California and Illinois insurance fraud prevention statutes, and the reverse False Claims Act claim. The Court denied the Motion to Dismiss as to the conspiracy claim. The Company will vigorously defend the lawsuit.

On August 3, 2016, the Company was served with a putative class action lawsuit, *Daniel L. Bloomquist v. Covance Inc., et al.*, filed in the Superior Court of California, County of San Diego. The Complaint alleges that Covance Inc. violated the California Labor Code and California Business & Professions Code by failing to provide overtime wages, failing to provide meal and rest periods, failing to pay for all hours worked, failing to pay for all wages owed upon termination, and failing to provide accurate itemized wage statements to Clinical Research Associates and Senior Clinical Research Associates employed by Covance in California. The lawsuit seeks monetary damages, civil penalties, injunctive relief, and recovery of attorney's fees and costs. On October 13, 2016, the case was removed to the U.S. District Court for the Southern District of California. On May 3, 2017, the U.S. District Court for the Southern District of California remanded the case to the Superior Court. This matter has been settled in principle and the settlement is subject to judicial review and approval.

Prior to the Company's acquisition of Sequenom, Inc. (Sequenom) between August 15, 2016, and August 24, 2016, six putative class-action lawsuits were filed on behalf of purported Sequenom stockholders (captioned *Malkoff v. Sequenom, Inc., et al.*, No. 16-cv-02054-JAH-BLM, *Gupta v. Sequenom, Inc., et al.*, No. 16-cv-02084-JAH-KSC, *Fruchter v. Sequenom, Inc., et al.*, No. 16-cv-02101-WQH-KSC, *Asiatrade Development Ltd. v. Sequenom, Inc., et al.*, No. 16-cv-02113-AJB-JMA, *Nunes v. Sequenom, Inc., et al.*, No. 16-cv-02128-AJB-MDD, and *Cusumano v. Sequenom, Inc., et al.*, No. 16-cv-02134-LAB-JMA) in the U.S. District Court for the Southern District of California challenging the acquisition transaction. The complaints asserted claims against Sequenom and members of its board of directors (the Individual Defendants). The *Nunes* action also named the Company and Savoy Acquisition Corp. (Savoy), a wholly owned subsidiary of the Company, as defendants. The complaints alleged that the defendants violated Sections 14(e), 14(d)(4) and 20 of the Securities Exchange Act of 1934 by failing to disclose certain allegedly material information. In addition, the complaints in the *Malkoff* action, *Asiatrade* action, and the *Cusumano* action alleged that the Individual Defendants breached their fiduciary duties to Sequenom shareholders. The actions sought, among other things, injunctive relief enjoining the merger. On August 30, 2016, the parties entered into a Memorandum of Understanding (MOU) in each of the above-referenced actions. On September 6, 2016, the Court entered an order consolidating for all pre-trial purposes the six individual actions described above under the caption *In re Sequenom, Inc. Shareholder Litig.*, Lead Case No. 16-cv-02054-JAH-BLM, and designating the complaint from the *Malkoff* action as the operative complaint for the consolidated action. On November 11, 2016, two competing motions were filed by two separate stockholders (James Reilly and Shikha Gupta) seeking appointment as lead plaintiff under the terms of the Private Securities Litigation Reform Act of 1995. On June 7, 2017, the Court entered an order declaring Mr. Reilly as the lead plaintiff and approving Mr. Reilly's selection of lead counsel. The parties agree that the MOU has been terminated. The Plaintiffs filed a Consolidated Amended Class Action Complaint on July 24, 2017, and the Defendants filed a Motion to Dismiss, which remains pending. On March 13, 2019, the Court stayed the action in its entirety pending the U.S. Supreme Court's anticipated decision in *Emulex Corp. v. Varjabedian*. On April 23, 2019, however, the U.S. Supreme Court dismissed the writ of certiorari in *Emulex* as improvidently granted. The Company will vigorously defend the lawsuit.

On March 10, 2017, the Company was served with a putative class action lawsuit, *Victoria Bouffard, et al. v. Laboratory Corporation of America Holdings*, filed in the U.S. District Court for the Middle District of North Carolina. The complaint alleges that the Company's patient list prices unlawfully exceed the rates negotiated for the same services with private and public health insurers in violation of various state consumer protection laws. The lawsuit also alleges breach of implied contract or quasi-contract, unjust enrichment, and fraud. The lawsuit seeks statutory, exemplary, and punitive damages, injunctive relief, and recovery of attorney's fees and costs. In May 2017, the Company filed a Motion to Dismiss Plaintiffs' Complaint and Strike Class Allegations; the Motion to Dismiss was granted in March 2018 without prejudice. On October 10, 2017, a second putative class action lawsuit, *Sheryl Anderson, et al. v. Laboratory Corporation of America Holdings*, was filed in the U.S. District Court for the Middle District of North Carolina. The complaint contained similar allegations and sought similar relief to the *Bouffard* complaint, and added

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additional counts regarding state consumer protection laws. On August 10, 2018, the Plaintiffs filed an Amended Complaint, which consolidated the *Bouffard* and *Anderson* actions. On September 10, 2018, the Company filed a Motion to Dismiss Plaintiffs' Amended Complaint and Strike Class Allegations. On August 16, 2019, the court entered an order granting in part and denying in part the Motion to Dismiss the Amended Complaint, and denying the Motion to Strike the Class Allegations. The Company will vigorously defend the lawsuit.

On September 7, 2017, the Company was served with a putative class action lawsuit, *John Seacock, et al. v. Covance Market Access Services, Inc.*, filed in the U.S. District Court for the Southern District of New York. The complaint alleged that Covance Market Access Services, Inc. violated the Fair Labor Standards Act and New York labor laws by failing to provide overtime wages, failing to pay for all hours worked, and failing to provide accurate wage statements. The lawsuit sought monetary damages, civil penalties, injunctive relief, and recovery of attorney's fees and costs. In November 2017, the Company filed a Motion to Strike Class Allegations, which was denied. In December 2017, the Plaintiff filed a Motion for Conditional Certification of a Collective Action, which was granted in May 2018. In December 2018, Plaintiff filed, and the Court granted, a second motion to conditionally certify an expanded class to a nationwide class action. This matter has been settled in principle and the settlement is subject to judicial review and approval.

On July 16, 2018, the Company reported that it had detected suspicious activity on its information technology network and was taking steps to respond to and contain the activity. The activity was subsequently determined to be a new variant of ransomware affecting certain LCD information technology systems. As part of its response, the Company took certain systems offline, which temporarily affected test processing and customer access to test results, and also affected certain other information technology systems involved in conducting Company-wide operations. Operations were returned to normal within a few days of the incident. As part of its in-depth investigation into this incident, the Company engaged outside security experts and worked with authorities, including law enforcement. The investigation determined that the ransomware did not and could not transfer patient or client data outside of Company systems and that there was no theft or misuse of patient or client data. The Company cooperated with law enforcement and regulatory authorities with respect to the incident.

The Company has insurance coverage for costs resulting from cyber-attacks and has filed a claim for recovery of its losses resulting from this incident. However, disputes over the extent of insurance coverage for claims are not uncommon and the Company has not recognized any estimated proceeds resulting from this claim. Furthermore, while the Company has not been the subject of any legal proceedings involving this incident, it is possible that the Company could be the subject of claims from persons alleging they suffered damages from the incident, or actions by governmental authorities.

On September 21, 2018, the Company was served with a putative class action lawsuit, *Alma Haro v. Laboratory Corporation of America, et al.*, which was filed in the Superior Court of California, County of Los Angeles. Plaintiff alleges that employees were not properly paid overtime compensation, minimum wages, meal and rest break premiums, did not receive compliant wage statements, and were not properly paid wages upon termination of employment. Plaintiff asserts these actions violate various California Labor Code provisions and constitute an unfair competition practice under California law. The lawsuit seeks monetary damages, civil penalties, and recovery of attorney's fees and costs. The Company will vigorously defend the lawsuit.

On December 20, 2018, the Company was served with a putative class action lawsuit, *Feckley v. Covance Inc., et al.*, filed in the Superior Court of California, County of Orange. The complaint alleges that Covance Inc. violated the California Labor Code and California Business & Professions Code by failing to properly pay commissions to employees under a sales incentive compensation plan upon their termination of employment. The lawsuit seeks monetary damages, civil penalties, punitive damages, and recovery of attorney's fees and costs. On January 22, 2018, the case was removed to the U.S. District Court for the Central District of California. The Company will vigorously defend the lawsuit.

On April 1, 2019, Covance Research Products was served with a Grand Jury Subpoena issued by the Department of Justice (DOJ) in Miami, Florida requiring the production of documents related to the importation into the United States of live non-human primate shipments originating from or transiting through China, Cambodia, and/or Vietnam from April 1, 2014 through March 28, 2019. The Company is cooperating with the DOJ.

On April 22, 2019, the Company was served with a putative class action lawsuit, *Kawa Orthodontics LLP, et al. v. Laboratory Corporation of America Holdings, et al.*, filed in the U.S. District Court for the Middle District of Florida. The lawsuit alleges that on or about February 6, 2019, the defendants violated the U.S. Telephone Consumer Protection Act (TCPA) by sending unsolicited facsimiles to Plaintiff and at least 40 other recipients without the recipients' prior express invitation or permission. The lawsuit seeks the greater of actual damages or the sum of \$0.0005 for each violation, subject to trebling under the TCPA, and injunctive relief. The Company filed a motion to dismiss the case on May 28, 2019. In response to the Motion to Dismiss, the Plaintiff filed an amended complaint, which contains additional allegations, including allegations related to another facsimile. The Company filed a Motion to Dismiss the amended complaint. The Company will vigorously defend the lawsuit.

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On May 14, 2019, Retrieval-Masters Creditors Bureau, Inc. d/b/a American Medical Collection Agency (AMCA), an external collection agency, notified the Company about a security incident AMCA experienced that may have involved certain personal information about some of the Company's patients (the AMCA Incident). The Company referred patient balances to AMCA only when direct collection efforts were unsuccessful. The Company's systems were not impacted by the AMCA Incident. Upon learning of the AMCA Incident, the Company promptly stopped sending new collection requests to AMCA and stopped AMCA from continuing to work on any pending collection requests from the Company. AMCA informed the Company that it appeared that an unauthorized user had access to AMCA's system between August 1, 2018 and March 30, 2019, and that AMCA could not rule out the possibility that personal information on AMCA's system was at risk during that time period. Information on AMCA's affected system from the Company may have included name, address, and balance information for the patient and person responsible for payment, along with the patient's phone number, date of birth, referring physician, and date of service. The Company was later informed by AMCA that health insurance information may have been included for some individuals, and because some insurance carriers utilize the Social Security Number as a subscriber identification number, the Social Security Number for some individuals may also have been affected. No ordered tests, laboratory test results, or diagnostic information from the Company were in the AMCA affected system. The Company notified individuals for whom it had a valid mailing address. For the individuals whose Social Security Number was affected, the notice included an offer to enroll in credit monitoring and identity protection services that will be provided free of charge for 24 months.

Twenty-two putative class action lawsuits were filed against the Company related to the AMCA Incident. Numerous similar lawsuits have been filed against other health care providers who used AMCA. The lawsuits against the Company were filed in various United States District Courts. The lawsuits generally allege that the Company did not adequately protect its patients' data, and assert various causes of action, including but not limited to negligence, breach of implied contract, unjust enrichment, and the violation of state data protection statutes. The lawsuits seek damages on behalf of a class of all affected Company consumers. The attorneys for certain of the Plaintiffs filed a motion with the Judicial Panel on Multi-District Litigation (JPML) seeking to have all cases related to the AMCA Incident consolidated for pre-trial proceedings in a multi-district litigation. The JPML ordered the transfer of the cases to the District of New Jersey. The Company will vigorously defend the multi-district litigation.

Certain governmental entities and individuals have requested information from the Company related to the AMCA Incident. The Company has received requests for information from United States Senators Robert Menendez and Cory A. Booker and from the Attorneys General of Colorado, Connecticut, Illinois, Florida, New York, and Indiana. The request from Indiana includes a Civil Investigative Demand, which requests certain documents from the Company. The Company also provided notice of the AMCA Incident to state and federal regulators where appropriate. The Company is cooperating with these requests.

On June 10, 2019, the Company was served with a class action lawsuit, *Ignacio v. Laboratory Corporation of America*, filed in Superior Court of the State of California for the County of Los Angeles. Plaintiff alleges that non-exempt employees based in California were not properly paid overtime compensation, minimum wages, and meal and rest break premiums, were not indemnified for business expenses, did not receive compliant wage statements, and were not properly paid wages upon termination of employment. Plaintiff asserts these actions violate various California Labor Code provisions and constitute an unfair competition practice under California law. The lawsuit seeks monetary damages, liquidated damages, injunctive relief, and recovery of attorney's fees and costs. The Company will vigorously defend the lawsuit.

On July 1, 2019, the Company was served with a class action lawsuit, *Jan v. Laboratory Corporation of America*, filed in the Superior Court for the State of California for the County of Sacramento. Plaintiff alleges that non-exempt employees based in California were not properly paid meal and rest break premiums, did not receive compliant wage statements, and were not properly paid wages upon termination of employment. Plaintiff asserts these actions violate various California Labor Code provisions and constitute an unfair competition practice under California law. The lawsuit seeks monetary damages, liquidated damages, injunctive relief, and recovery of attorney's fees and costs. The Company will vigorously defend the lawsuit.

On July 30, 2019, the Company was served with a class action lawsuit, *Mitchell v. Covance, Inc. et al.*, filed in the United States District Court for the Eastern District of Pennsylvania. Plaintiff alleges that certain individuals employed by Covance Inc. and Chiltern International Inc. were misclassified as exempt employees under the Fair Labor Standards Act and the Pennsylvania Minimum Wage Act and were thereby not properly paid overtime compensation. The lawsuit seeks monetary damages, liquidated damages, and recovery of attorneys' fees and costs. The Company will vigorously defend the lawsuit.

Under the Company's present insurance programs, coverage is obtained for catastrophic exposure as well as those risks required to be insured by law or contract. The Company is responsible for the uninsured portion of losses related primarily to general, professional and vehicle liability, certain medical costs and workers' compensation. The self-insured retentions are on a per-occurrence basis without any aggregate annual limit. Provisions for losses expected under these programs are recorded based upon the Company's estimates of the aggregated liability of claims incurred.

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12. PENSION AND POST-RETIREMENT PLANS

The Company has two defined contribution retirement plans (LabCorp 401K Plans) which cover substantially all U.S. employees. All employees eligible for the LabCorp 401K Plan receive a minimum 3% non-elective contribution concurrent with each payroll period. The 401K Plan also permits discretionary contributions by the Company of up to 3% of pay for eligible employees based on years of service with the Company. The cost of this plan was \$13.7 and \$17.3 for the three months ended September 30, 2019, and 2018, respectively, and was \$50.7 and \$49.1 for the nine months ended September 30, 2019, and 2018, respectively. All of the Covance U.S. employees, including legacy Chiltern employees, are eligible to participate in the Covance 401K plan, which features a maximum 4.5% Company match, based upon a percentage of the employee's contributions. Chiltern employees were previously eligible to participate in the Chiltern 401K plan, which featured a maximum 3.0% Company match, based upon a percentage of the employee's contributions. The Chiltern 401K plan merged into the Covance 401K plan effective January 7, 2019. The Company incurred expense of \$18.2 and \$16.3 for the Covance 401K plan during the three months ended September 30, 2019, and 2018, respectively, and \$56.0 and \$51.6 during the nine months ended September 30, 2019, and 2018, respectively. The Company also maintains several other small 401K plans associated with companies acquired over the last several years.

The Company also maintains a frozen defined benefit retirement plan (Company Plan), which as of December 31, 2009, covered substantially all employees. The benefits to be paid under the Company Plan are based on years of credited service through December 31, 2009, and ongoing interest credits. Effective January 1, 2010, the Company Plan was closed to new participants. The Company's policy is to fund the Company Plan with at least the minimum amount required by applicable regulations.

The Company maintains a second, unfunded, non-contributory, non-qualified defined benefit retirement plan (PEP), which as of December 31, 2009, covered substantially all of its senior management group. The PEP supplements the Company Plan and was closed to new participants effective January 1, 2010.

The effect on operations for the Company Plan and the PEP is summarized as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Service cost for administrative expenses	\$ 1.1	\$ 1.3	\$ 3.1	\$ 3.9
Interest cost on benefit obligation	3.4	3.3	10.4	9.8
Expected return on plan assets	(3.7)	(4.1)	(11.3)	(12.3)
Net amortization and deferral	3.0	2.9	8.2	8.8
Defined benefit plan costs	\$ 3.8	\$ 3.4	\$ 10.4	\$ 10.2

During the nine months ended September 30, 2019, the Company made no contributions to the Company Plan.

As a result of the Covance acquisition, the Company sponsors two defined benefit pension plans for the benefit of its employees at two U.K. subsidiaries (U.K. Plans) and one defined benefit pension plan for the benefit of its employees at a German subsidiary (German Plan), all of which are legacy plans of previously acquired companies. Benefit amounts for all three plans are based upon years of service and compensation. The German plan is unfunded while the U.K. pension plans are funded. The Company's funding policy has been to contribute annually amounts at least equal to the local statutory funding requirements. The related net pension obligation for these plans was \$37.5 and \$39.6 as of September 30, 2019 and December 31, 2018, respectively.

As a result of the Envigo acquisition, the Company assumed a defined benefit pension plan for the benefit of Envigo's U.K. employees (the Envigo plan), which is a legacy plan of a company previously acquired by Envigo. The Envigo plan is a funded plan that is closed to future accrual. The related net pension obligation of \$56.8, based on the preliminary valuation of acquired assets and assumed liabilities, is reported under Other liabilities in the Condensed Consolidated Balance Sheet as of September 30, 2019. The Company's funding policy has been to make annual contributions to the plan of amounts that are at least equal to the local statutory funding requirements, which is estimated to be \$7.0 based on preliminary valuation.

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13. FAIR VALUE MEASUREMENTS

The Company's population of financial assets and liabilities subject to fair value measurements as of September 30, 2019, and December 31, 2018, is as follows:

	Balance Sheet Classification	Fair Value as of September 30, 2019	Fair Value Measurements as of September 30, 2019 Using Fair Value Hierarchy		
			Level 1	Level 2	Level 3
Noncontrolling interest puts	Noncontrolling interest	\$ 15.5	\$ —	\$ 15.5	\$ —
Cross currency swap asset	Other assets, net	20.0	—	20.0	—
Interest rate swap	Other assets, net	4.1	—	4.1	—
Cash surrender value of life insurance policies	Other assets, net	75.9	—	75.9	—
Deferred compensation liability	Other liabilities	72.3	—	72.3	—
Contingent consideration	Other liabilities	6.2	—	—	6.2
Investment in equity securities	Other assets, net	22.0	22.0	—	—

	Balance Sheet Classification	Fair Value as of December 31, 2018	Fair Value Measurements as of December 31, 2018 Using Fair Value Hierarchy		
			Level 1	Level 2	Level 3
Noncontrolling interest put	Noncontrolling interest	\$ 15.0	\$ —	\$ 15.0	\$ —
Cross currency swap liability	Other liabilities	2.8	—	2.8	—
Interest rate swap	Other liabilities	3.1	—	3.1	—
Cash surrender value of life insurance policies	Other assets, net	63.5	—	63.5	—
Deferred compensation liability	Other liabilities	64.2	—	64.2	—
Contingent consideration	Other liabilities	18.6	—	—	18.6

Fair Value Measurement of Level 3 Liabilities	Contingent Consideration
Balance at December 31, 2018	18.6
Additions	1.5
Adjustments	(13.9)
Balance at September 30, 2019	\$ 6.2

During the three months ended September 30, 2019, the Company adjusted its estimate of an acquisition related contingent consideration liability and recorded a gain of \$13.9 million as a reduction to selling, general, and administrative expenses.

The Company has a noncontrolling interest put related to its Ontario subsidiary that has been classified as mezzanine equity in the Company's condensed consolidated balance sheets. The noncontrolling interest put is valued at its contractually determined value, which approximates fair value.

The Company offers certain employees the opportunity to participate in an employee-funded deferred compensation plan (DCP). A participant's deferrals are allocated by the participant to one or more of 22 measurement funds, which are indexed to externally managed funds. From time to time, to offset the cost of the growth in the participant's investment accounts, the Company purchases life insurance policies, with the Company named as beneficiary of the policies. Changes in the cash surrender value of these policies are based upon earnings and changes in the value of the underlying investments, which are typically invested in a manner similar to the participants' allocations. Changes in the fair value of the DCP obligation are derived using quoted prices in active markets based on the market price per unit multiplied by the number of units. The cash surrender value and the DCP obligations are classified within Level 2 because their inputs are derived principally from observable market data by correlation to the hypothetical investments.

The Company has contingent accrued earn-out business acquisition consideration liabilities which were recorded at fair value on the acquisition date and are remeasured quarterly based on the then assessed fair value and adjusted if necessary. The increases or decreases in the fair value of contingent consideration payable can result from changes in anticipated revenue levels and changes in assumed discount periods and rates. As the fair value measure is based on significant inputs that are not observable in the market, they are categorized as Level 3.

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The carrying amounts of cash and cash equivalents, accounts receivable, income taxes receivable, and accounts payable are considered to be representative of their respective fair values due to their short-term nature. The fair market value of the zero-coupon subordinated notes, based on market pricing, was approximately \$1.8 and \$16.9 as of September 30, 2019, and December 31, 2018, respectively. The fair market value of all of the senior notes, based on market pricing, was approximately \$5,763.9 and \$5,318.0 as of September 30, 2019, and December 31, 2018, respectively. The fair market value of the floating rate secured note due 2022 received for the sale of CRP was \$110.0 as of September 30, 2019. The effective interest rate on the floating rate secured note receivable was 7.63% as of September 30, 2019. The Company's note and debt instruments are classified as Level 2 instruments, as the fair market values of these instruments are determined using other observable inputs.

14. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

The Company addresses its exposure to market risks, principally the market risk associated with changes in interest rates and foreign currency exchange rates, through a controlled program of risk management that includes, from time to time, the use of derivative financial instruments such as interest rate and cross currency swap agreements (see Interest Rate Swap and Cross Currency Swap sections below). Although the Company's zero-coupon subordinated notes contain features that are considered to be embedded derivative instruments (see Embedded Derivatives Related to the Zero-Coupon Subordinated Notes section below), the Company does not hold or issue derivative financial instruments for trading purposes. The derivative financial instrument contracts are with major investment grade financial institutions and the Company does not anticipate any material non-performance by any of the counterparties. The Company does not believe that its exposure to market risk is material to the Company's financial position or results of operations.

Interest Rate Swap

The Company is party to two fixed-to-variable interest rate swap agreements for its 4.625% senior notes due 2020 with an aggregate notional amount of \$600.0 and variable interest rates based on one-month LIBOR plus 2.298% to hedge against changes in the fair value of a portion of the Company's long term debt. These derivative financial instruments are accounted for as fair value hedges of the senior notes due 2020. These interest rate swaps are included in other long-term assets or other long-term liabilities, as applicable, and added to or subtracted from the value of the senior notes, with an aggregate fair value of \$4.1 (asset) and \$3.1 (liability) at September 30, 2019, and December 31, 2018, respectively. As the specific terms and notional amounts of the derivative financial instruments match those of the fixed-rate debt being hedged, the derivative instruments are assumed to be perfectly effective hedges and accordingly, there is no impact to the Company's Condensed Consolidated Statements of Operations.

	Carrying amount of hedged liabilities as of		Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liabilities as of	
	September 30, 2019	December 31, 2018	September 30, 2019	December 31, 2018
<i>Balance Sheet Line Item in which Hedged Items are Included</i>				
Long-term debt, less current portion	\$ 604.1	\$ 597.0	\$ 4.1	\$ (3.1)

Cross Currency Swap

During the fourth quarter of 2018, the Company entered into six U.S. Dollar to Swiss Franc cross-currency swap agreements with an aggregate notional value of \$600.0 and which are accounted for as a hedge against its net investment in a Swiss subsidiary. Of the notional value, \$300.0 matures in 2022 and \$300.0 matures in 2025. These cross currency swaps maturing in 2022 and 2025 are included in other long-term assets with an aggregate fair value of \$8.5 and \$11.5, respectively, as of September 30, 2019 and are included in other long-term liabilities with an aggregate fair value of \$1.0 and \$1.8, respectively, as of December 31, 2018. Changes in the fair value of the cross-currency swaps are charged or credited through accumulated other comprehensive earnings in the Condensed Consolidated Balance Sheet until the hedged item is recognized in earnings. The cumulative amount of the fair value hedging adjustment included in the current value of the cross currency swaps is \$18.8 and \$22.8, respectively, for the three and nine months ended September 30, 2019, and was recognized as currency translation within the Condensed Consolidated Statement of Comprehensive Earnings. There were no amounts reclassified from the Condensed Consolidated Statement of Comprehensive Earnings to the Condensed Consolidated Statement of Operations during the three months ended September 30, 2019.

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The table below presents the fair value of derivatives on a gross basis and the balance sheet classification of those instruments:

	Balance Sheet Caption	September 30, 2019			December 31, 2018		
		Fair Value of Derivative			Fair Value of Derivative		
		Asset	Liability	U.S. Dollar Notional	Asset	Liability	U.S. Dollar Notional
<i>Derivatives Designated as Hedging Instruments</i>							
Interest rate swap	Other assets, net or Other liabilities	\$ 4.1	\$ —	\$ 600.0	\$ —	\$ (3.1)	\$ 600.0
Cross currency swaps	Other assets, net or Other liabilities	\$ 20.0	\$ —	\$ 600.0	\$ —	\$ (2.8)	\$ 600.0

The table below provides information regarding the location and amount of pretax (gains) losses of derivatives designated in fair value hedging relationships:

	Amount of pre-tax gain/(loss) included in other comprehensive income		Amounts reclassified to the Statement of Operations		Amount of pre-tax gain/(loss) included in other comprehensive income		Amounts reclassified to the Statement of Operations	
	Three Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018	2019	2018	2019	2018
Interest rate swap contracts	\$ 0.4	\$ 6.1	\$ —	\$ —	\$ 7.2	\$ (3.6)	\$ —	\$ —
Cross currency swaps	\$ 18.8	\$ (16.2)	\$ —	\$ —	\$ 22.8	\$ 8.1	\$ —	\$ —

No gains or losses from derivative instruments classified as hedging instruments have been recognized into income for the three and nine months ended September 30, 2019 and 2018.

Embedded Derivatives Related to the Zero-Coupon Subordinated Notes

The Company's zero-coupon subordinated notes contain the following two features that are considered to be embedded derivative instruments under authoritative guidance in connection with accounting for derivative instruments and hedging activities:

- 1) The Company will pay contingent cash interest on the zero-coupon subordinated notes after September 11, 2006, if the average market price of the notes equals 120% or more of the sum of the issue price, accrued original issue discount and contingent additional principal, if any, for a specified measurement period.
- 2) Holders may surrender zero-coupon subordinated notes for conversion during any period in which the rating assigned to the zero-coupon subordinated notes by Standard & Poor's Ratings Services is BB- or lower.

The Company believes these embedded derivatives had no fair value at September 30, 2019, and December 31, 2018. These embedded derivatives also had no impact on the Condensed Consolidated Statements of Operations for the nine months ended September 30, 2019, and 2018.

Other Derivative Instruments

The Company periodically enters into foreign currency forward contracts, which are recognized as assets or liabilities at their fair value. These contracts do not qualify for hedge accounting and the changes in fair value are recorded directly to earnings. The contracts are short-term in nature and the fair value of these contracts is based on market prices for comparable contracts. The fair value of these contracts is not significant as of September 30, 2019, and December 31, 2018.

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15. SUPPLEMENTAL CASH FLOW INFORMATION

	Nine Months Ended September 30,	
	2019	2018
Supplemental schedule of cash flow information:		
Cash paid during period for:		
Interest	\$ 216.5	\$ 276.3
Income taxes, net of refunds	181.6	235.0
Disclosure of non-cash financing and investing activities:		
Conversion of zero-coupon convertible debt	1.7	0.3
Change in accrued property, plant and equipment	(15.9)	6.9
Floating rate secured note receivable due 2022 from the sale of CRP	110.0	—

16. BUSINESS SEGMENT INFORMATION

The following table is a summary of segment information for the three and nine months ended September 30, 2019, and 2018. The management approach has been used to present the following segment information. This approach is based upon the way the management of the Company organizes its business unit operations for making operating decisions and assessing performance. Financial information is reported on the basis that it is used internally by the chief operating decision maker (CODM) for evaluating segment performance and deciding how to allocate resources to segments. The Company's chief executive officer has been identified as the CODM.

Segment asset information is not presented because it is not used by the CODM at the segment level. Operating earnings of each segment represents net revenues less directly identifiable expenses to arrive at operating income for the segment. General management and administrative corporate expenses are included in general corporate expenses below. The table below represents information about the Company's reporting segments for the three and nine months ended September 30, 2019, and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
LCD	\$ 1,759.2	\$ 1,752.0	\$ 5,242.1	\$ 5,336.3
CDD	1,175.4	1,081.5	3,376.4	3,214.1
Intercompany eliminations	(6.1)	(2.2)	(17.1)	(4.5)
Revenues	<u>2,928.5</u>	<u>2,831.3</u>	<u>8,601.4</u>	<u>8,545.9</u>
Operating earnings:				
LCD	262.2	289.4	843.0	929.2
CDD	123.8	87.9	277.6	195.3
Unallocated corporate expenses	(46.1)	(33.9)	(126.8)	(106.5)
Total operating income	339.9	343.4	993.8	1,018.0
Other income (expense), net	(52.5)	156.2	(181.8)	35.8
Earnings before income taxes	287.4	499.6	812.0	1,053.8
Provision for income taxes	66.4	180.6	214.4	328.1
Net earnings	221.0	319.0	597.6	725.7
Less (earnings) loss attributable to noncontrolling interests	(0.3)	(0.2)	(0.9)	0.1
Net income attributable to Laboratory Corporation of America Holdings	<u>\$ 220.7</u>	<u>\$ 318.8</u>	<u>\$ 596.7</u>	<u>\$ 725.8</u>

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

FORWARD-LOOKING STATEMENTS

Laboratory Corporation of America[®] Holdings together with its subsidiaries (the Company) has made in this report, and from time to time may otherwise make in its public filings, press releases and discussions by Company management, forward-looking statements concerning the Company's operations, performance and financial condition, as well as its strategic objectives. Some of these forward-looking statements can be identified by the use of forward-looking words such as "believes", "expects", "may", "will", "should", "seeks", "approximately", "intends", "plans", "estimates", or "anticipates" or the negative of those words or other comparable terminology. Such forward-looking statements are subject to various risks and uncertainties and the Company claims the protection afforded by the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Actual results could differ materially from those currently anticipated due to a number of factors in addition to those discussed elsewhere herein and in the Company's other public filings, press releases and discussion with Company management, including:

1. changes in government and third-party payer regulations, reimbursement, or coverage policies or other future reforms in the healthcare system (or in the interpretation of current regulations), new insurance or payment systems, including state, regional or private insurance cooperatives (e.g., health insurance exchanges) affecting governmental and third-party coverage or reimbursement for commercial laboratory testing, including the impact of the Protecting Access to Medicare Act of 2014 (PAMA);
2. significant monetary damages, fines, penalties, assessments, refunds, repayments, damage to the Company's reputation, unanticipated compliance expenditures, and/or exclusion or debarment from or ineligibility to participate in government programs, among other adverse consequences, arising from enforcement of anti-fraud and abuse laws and other laws applicable to the Company in jurisdictions in which the Company conducts business;
3. significant fines, penalties, costs, unanticipated compliance expenditures and/or damage to the Company's reputation arising from the failure to comply with applicable privacy and security laws and regulations, including the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, the European Union's General Data Protection Regulation and similar laws and regulations in jurisdictions in which the Company conducts business;
4. loss or suspension of a license or imposition of a fine or penalties under, or future changes in, or interpretations of applicable licensing laws or regulations regarding the operation of clinical laboratories and the delivery of clinical laboratory test results, including, but not limited to, the U.S. Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Improvement Amendments of 1988 and similar laws and regulations in jurisdictions in which the Company conducts business;
5. penalties or loss of license arising from the failure to comply with applicable occupational and workplace safety laws and regulations, including the U.S. Occupational Safety and Health Administration requirements and the U.S. Needlestick Safety and Prevention Act and similar laws and regulations in jurisdictions in which the Company conducts business;
6. fines, unanticipated compliance expenditures, suspension of manufacturing, enforcement actions, damage to the Company's reputation, injunctions, or criminal prosecution arising from failure to maintain compliance with current good manufacturing practice regulations and similar requirements of various regulatory agencies in jurisdictions in which the Company conducts business;
7. sanctions or other remedies, including fines, unanticipated compliance expenditures, enforcement actions, injunctions or criminal prosecution arising from failure to comply with the Animal Welfare Act or applicable national, state and local laws and regulations in jurisdictions in which the Company conducts business;
8. changes in testing guidelines or recommendations by government agencies, medical specialty societies and other authoritative bodies affecting the utilization of laboratory tests;
9. changes in applicable government regulations or policies affecting the approval, availability of, and the selling and marketing of diagnostic tests, drug development, or the conduct of drug development and medical device and diagnostic studies and trials, including regulations and policies of the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the Medicine and Healthcare products Regulatory Agency in the United Kingdom (U.K.), the State Drug Administration in China (formerly the China Food and Drug Administration), the Pharmaceutical and Medical Devices Agency in Japan, the European Medicines Agency and similar regulations and policies of agencies in jurisdictions in which the Company conducts business;

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10. changes in government regulations or reimbursement pertaining to the biopharmaceutical and medical device and diagnostic industries, changes in reimbursement of biopharmaceutical products or reduced spending on research and development by biopharmaceutical customers;
11. liabilities that result from the failure to comply with corporate governance requirements;
12. increased competition, including price competition, potential reduction in rates in response to price transparency and consumerism, competitive bidding and/or changes or reductions to fee schedules and competition from companies that do not comply with existing laws or regulations or otherwise disregard compliance standards in the industry;
13. changes in payer mix or payment structure, including insurance carrier participation in health insurance exchanges, an increase in capitated reimbursement mechanisms, the impact of a shift to consumer-driven health plans or plans carrying an increased level of member cost-sharing, and adverse changes in payer reimbursement or payer coverage policies (implemented directly or through a third-party utilization management organization) related to specific diagnostic tests, categories of testing or testing methodologies;
14. failure to retain or attract managed care organization (MCO) business as a result of changes in business models, including new risk-based or network approaches, out-sourced Laboratory Network Management or Utilization Management companies, or other changes in strategy or business models by MCOs;
15. failure to obtain and retain new customers, an unfavorable change in the mix of testing services ordered, or a reduction in tests ordered, specimens submitted or services requested by existing customers;
16. difficulty in maintaining relationships with customers or retaining key employees as a result of uncertainty surrounding the integration of acquisitions and the resulting negative effects on the business of the Company;
17. consolidation and convergence of MCOs, biopharmaceutical companies, health systems, large physician organizations and other customers, potentially causing material shifts in insourcing, utilization, pricing and reimbursement, including full and partial risk-based models;
18. failure to effectively develop and deploy new systems, system modifications or enhancements required in response to evolving market and business needs;
19. customers choosing to insource services that are or could be purchased from the Company;
20. failure to identify, successfully close and effectively integrate and/or manage acquisitions of new businesses;
21. inability to achieve the expected benefits and synergies of newly-acquired businesses, including due to items not discovered in the due-diligence process, and the impact on the Company's cash position, levels of indebtedness and stock price;
22. termination, loss, delay, reduction in scope or increased costs of contracts, including large contracts and multiple contracts;
23. liability arising from errors or omissions in the performance of testing services, contract research services or other contractual arrangements;
24. changes or disruption in the provision or transportation of services or supplies provided by third parties, or their termination for failure to follow the Company's performance standards and requirements;
25. damage or disruption to the Company's facilities;
26. damage to the Company's reputation, loss of business, or other harm from acts of animal rights activists or potential harm and/or liability arising from animal research activities;
27. adverse results in litigation matters;
28. inability to attract and retain experienced and qualified personnel;
29. failure to develop or acquire licenses for new or improved technologies, such as point-of-care testing, mobile health technologies, and digital pathology, or potential use of new technologies by customers and/or consumers to perform their own tests;
30. substantial costs arising from the inability to commercialize newly licensed tests or technologies or to obtain appropriate coverage or reimbursement for such tests;
31. failure to obtain, maintain and enforce intellectual property rights for protection of the Company's products and services and defend against challenges to those rights;
32. scope, validity and enforceability of patents and other proprietary rights held by third parties that may impact the Company's ability to develop, perform, or market the Company's products or services or operate its business;

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33. business interruption or other impact on the business due to adverse weather, fires and/or other natural disasters, acts of war, terrorism or other criminal acts, and/or widespread outbreak of influenza or other pandemic illness;
34. discontinuation or recalls of existing testing products;
35. a failure in the Company's information technology systems, including with respect to testing turnaround time and billing processes, or the failure of the Company or its third-party suppliers and vendors to maintain the security of business information or systems or to protect against cybersecurity attacks such as denial of service attacks, malware, ransomware and computer viruses, or delays or failures in the development and implementation of the Company's automation platforms, any of which could result in a negative effect on the Company's performance of services, a loss of business or increased costs, damages to the Company's reputation, significant litigation exposure, an inability to meet required financial reporting deadlines, or the failure to meet future regulatory or customer information technology, data security and connectivity requirements;
36. business interruption, increased costs, and other adverse effects on the Company's operations due to the unionization of employees, union strikes, work stoppages, general labor unrest or failure to comply with labor or employment laws;
37. failure to maintain the Company's days sales outstanding levels, cash collections (in light of increasing levels of patient responsibility), profitability and/or reimbursement arising from unfavorable changes in third-party payer policies, payment delays introduced by third party benefit management organizations and increasing levels of patient payment responsibility;
38. impact on the Company's revenues, cash collections and the availability of credit for general liquidity or other financing needs arising from a significant deterioration in the economy or financial markets or in the Company's credit ratings by Standard & Poor's and/or Moody's;
39. failure to maintain the expected capital structure for the Company, including failure to maintain the Company's investment grade rating;
40. changes in reimbursement by foreign governments and foreign currency fluctuations;
41. inability to obtain certain billing information from physicians, resulting in increased costs and complexity, a temporary disruption in receipts and ongoing reductions in reimbursements and net revenues;
42. expenses and risks associated with international operations, including, but not limited to, compliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act, other applicable anti-corruption laws and regulations, trade sanction laws and regulations, and economic, political, legal and other operational risks associated with foreign jurisdictions;
43. failure to achieve expected efficiencies and savings in connection with the Company's business process improvement initiatives;
44. changes in tax laws and regulations or changes in their interpretation, including the Tax Cuts and Jobs Act (TCJA); and
45. global economic conditions and government and regulatory changes, including, but not limited to the U.K.'s announced intention to exit from the European Union.

GENERAL (dollars in millions, except per share data)

During the nine months ended September 30, 2019, revenues were \$8,601.4, an increase of 0.6% from \$8,545.9 during the nine months ended September 30, 2018. The increase in revenues was primarily due to growth from acquisitions of 1.6% and organic growth of 1.4% (which includes the negative impact from PAMA of 0.9%), partially offset by the disposition of businesses of 1.7% and foreign currency translation of 0.7%.

Effective January 1, 2019, the Company adopted Accounting Standards Codification (ASC) 842 *Leases* using the effective date method. The Company elected the package of practical expedients, which includes not reassessing whether existing contracts contain leases under the new definition of a lease, reassessing the classification of existing leases, and reassessing whether previously capitalized initial direct costs qualify for capitalization under the new standard. The Company also elected not to separate lease and non-lease components.

On June 3, 2019, the Company's CDD segment completed the acquisition of Envigo's nonclinical contract research services business, expanding CDD's global nonclinical drug development capabilities with additional locations and resources. Additionally, the Company divested the Covance Research Products (CRP) business, which was a part of the CDD segment, to Envigo. As part of this sale, CDD entered into a multi-year, renewable supply agreement. The Company paid cash consideration of \$601.0, received a floating rate secured note of \$110.0, and recorded a loss on sale of CRP of \$11.9. The Company funded the transaction through a new term loan facility.

The Company remains on track to deliver \$150.0 of net savings from CDD's three-year LaunchPad initiative by the end of 2020. The Company expects phase II of LCD's LaunchPad initiative to deliver approximately \$200.0 in net savings over the next

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three years, while incurring approximately \$40.0 in one-time implementation costs. Approximately one-third of the total savings are expected to be realized each year.

On May 14, 2019, Retrieval-Masters Creditors Bureau, Inc. d/b/a American Medical Collection Agency (AMCA), an external collection agency, notified the Company about a security incident AMCA experienced that may have involved certain personal information about some of the Company's patients (the AMCA Incident). The Company referred patient balances to AMCA only when direct collection efforts were unsuccessful. The Company's systems were not impacted by the AMCA Incident. Upon learning of the AMCA Incident, the Company promptly stopped sending new collection requests to AMCA and stopped AMCA from continuing to work on any pending collection requests from the Company. AMCA informed the Company that it appeared that an unauthorized user had access to AMCA's system between August 1, 2018 and March 30, 2019, and that AMCA could not rule out the possibility that personal information on AMCA's system was at risk during that time period. Information on AMCA's affected system from the Company may have included name, address, and balance information for the patient and person responsible for payment, along with the patient's phone number, date of birth, referring physician, and date of service. The Company was later informed by AMCA that health insurance information may have been included for some individuals, and because some insurance carriers utilize the Social Security Number as a subscriber identification number, the Social Security Number for some individuals may also have been affected. No ordered tests, laboratory test results, or diagnostic information from the Company were in the AMCA affected system. The Company notified individuals for whom it had a valid mailing address. For the individuals whose Social Security Number was affected, the notice included an offer to enroll in credit monitoring and identity protection services that will be provided free of charge for 24 months.

PAMA, which went into effect on January 1, 2018, resulted in a net reduction of revenue of approximately \$70.0 in 2018 from all payers affected by the Clinical Lab Fee Schedule. A reduction of approximately \$80.8 has been incurred through the first nine months of 2019. Unless further implementation of PAMA is delayed or changed, an additional reduction of approximately \$30.0 is expected for 2019.

RESULTS OF OPERATIONS (dollars in millions)

Three months ended September 30, 2019, compared with three months ended September 30, 2018

Revenues

	Three Months Ended September 30,		Change
	2019	2018	
LCD	\$ 1,759.2	\$ 1,752.0	0.4%
CDD	1,175.4	1,081.5	8.7%
Intercompany eliminations	(6.1)	(2.2)	177.3%
Total	<u>\$ 2,928.5</u>	<u>\$ 2,831.3</u>	3.4%

The increase in revenues for the three months ended September 30, 2019, as compared with the corresponding period in 2018 was 3.4%. The increase in revenues was primarily due to acquisitions of 2.8% and organic growth of 2.2% (which includes the negative impact from PAMA of 0.9%), partially offset by the disposition of businesses of 1.3% and negative foreign currency translation of 0.3%.

LCD revenues for the quarter were \$1,759.2, an increase of 0.4% compared to revenues of \$1,752.0 in the third quarter of 2018. The increase in revenues was primarily due to organic growth of 0.9% and acquisitions of 0.8%, partially offset by the negative impact from disposition of businesses of 1.3%. The organic revenue growth of 0.9% includes the negative impact from PAMA of 1.5%.

Total LCD volume (measured by requisitions) excluding the disposition of businesses, increased by 0.7%, as acquisition volume contributed 0.5% and organic volume increased by 0.3%. Organic volume was negatively impacted by approximately 1.0% from managed care contract changes. Excluding the disposition of businesses, revenue per requisition increased by 1.0%, despite the negative impact from PAMA of 1.5%.

CDD revenues for the second quarter were \$1,175.4, an increase of 8.7% over revenues of \$1,081.5 in the third quarter of 2018. The increase was primarily due to acquisitions of 6.0% and organic growth of 4.7%, partially offset by the disposition of the Covance Research Products business of 1.2% and negative foreign currency translation of 0.8%.

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Cost of Revenues

	Three Months Ended September 30,		Change
	2019	2018	
Cost of revenues	\$ 2,111.2	\$ 2,041.4	3.4%
Cost of revenues as a % of revenues	72.1%	72.1%	

Cost of revenues increased 3.4% during the three months ended September 30, 2019, as compared with the corresponding period in 2018. Cost of revenues as a percentage of revenues during the three months ended September 30, 2019, remained consistent at 72.1% as compared to the corresponding period in 2018.

Selling, General and Administrative Expenses

	Three Months Ended September 30,		Change
	2019	2018	
Selling, general and administrative expenses	\$ 401.5	\$ 381.8	5.2%
Selling, general and administrative expenses as a % of revenues	13.7%	13.5%	

During the three months ended September 30, 2019, the Company incurred \$9.6 of acquisition and divestiture related costs, \$5.3 in management transition costs and \$11.3 in costs related to the AMCA data breach. In addition, the Company recorded \$2.4 of non-capitalized costs associated with the implementation of a major system as part of its LaunchPad business process improvement initiative and reversed \$13.9 related to the settlement of a contingent purchase price related to a 2016 acquisition. These items increased selling, general and administrative expenses by \$14.7.

During the three months ended September 30, 2018, the Company incurred \$5.5 in consulting expenses relating to fees incurred as part of its integration and management transition costs. As a direct result of the ransomware attack experienced during July 2018, the Company incurred \$5.8 in consulting fees and employee overtime during the recovery period following the attack. In addition, the Company recorded \$3.1 of non-capitalized costs associated with the implementation of a major system as part of its LaunchPad business process improvement initiative. The Company also reversed \$0.2 in accrued expenses incurred as part of integration and management transition costs. These items increased selling, general and administrative expenses by \$14.2.

Excluding these charges, selling, general and administrative expenses as a percentage of revenues were 13.2% and 13.0% during the three months ended September 30, 2019, and 2018, respectively, primarily due to the decrease in revenue from the implementation of PAMA.

Amortization of Intangibles and Other Assets

	Three Months Ended September 30,		Change
	2019	2018	
LCD	\$ 24.9	\$ 23.4	6.4%
CDD	36.8	31.3	17.6%
Total amortization of intangibles and other assets	\$ 61.7	\$ 54.7	12.8%

The increase in amortization of intangibles and other assets within the LCD segment primarily reflects the impact of acquisitions occurring after September 30, 2018, offset by the reduction of amortizable intangible assets pursuant to the divestiture of three LCD businesses in 2018. Amortization of intangible assets within the CDD segment increased primarily due to the impact of acquisitions occurring after September 30, 2018, offset by the reduction of amortizable intangible assets pursuant to the divestiture of one CDD business during the second quarter of 2019.

Restructuring and Other Special Charges

	Three Months Ended September 30,		Change
	2019	2018	
Restructuring and other special charges	\$ 14.2	\$ 10.0	42.0%

During the three months ended September 30, 2019, the Company recorded net restructuring and other special charges of \$14.2: \$6.7 within LCD and \$7.5 within CDD. The charges were comprised of \$5.9 related to severance and other personnel costs along with \$8.5 in costs associated with facility closures, impairment of operating lease right-of-use assets and general integration initiatives. The charges were offset by the reversal of previously established reserves of \$0.2 in unused facility reserves.

During the three months ended September 30, 2018, the Company recorded net restructuring and other special charges of \$10.0: \$4.1 within LCD and \$5.9 within CDD. The charges were comprised of \$6.6 related to severance and other personnel costs along with \$4.0 in costs associated with facility closures, impairment of land held for sale and general integration initiatives. The

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charges were offset by the reversal of previously established reserves of \$0.4 and \$0.2 in unused facility reserves and unused severance reserves, respectively.

Interest Expense

	Three Months Ended September 30,		Change
	2019	2018	
Interest expense	\$ (60.5)	(59.4)	1.9%

The increase in interest expense for the three months ended September 30, 2019, as compared with the corresponding period in 2018, is primarily due to the new 2019 term loan, partially offset by the repayment of the 2.50% senior notes in 2018, the repayment of the 2014 term loan and partial repayment of the 2017 term loan.

Equity Method Income

	Three Months Ended September 30,		Change
	2019	2018	
Equity method income, net	\$ 2.4	\$ 3.0	(20.0)%

Equity method income represents the Company's ownership share in joint venture partnerships along with equity investments in other companies in the health care industry. All of these partnerships and investments reside within LCD. The decrease in income for the three months ended September 30, 2019, as compared with the corresponding period in 2018, was primarily due to decreased profitability of the Company's joint ventures.

Other, net

	Three Months Ended September 30,		Change
	2019	2018	
Other, net	\$ 2.7	\$ 209.8	(98.7)%

The change in other, net for the three months ended September 30, 2019, as compared to the three months ended September 30, 2018, is primarily due to the gain of \$258.3 recognized on the sale of the Food Solutions business in the third quarter of 2018 offset by a \$48.9 loss on the divestiture of the Company's forensic testing services business in the U.K. During the three months ended September 30, 2019, the Company recognized other investment gains of \$8.6 which were partially offset by a \$3.1 loss on disposition of a business and a \$4.3 write-off of two of the Company's cost method investments. In addition, foreign currency transaction losses of \$2.9 were recognized for the three months ended September 30, 2019 and gains of \$1.3 were recognized in the corresponding period of 2018.

Income Tax Expense

	Three Months Ended September 30,		Change
	2019	2018	
Income tax expense	\$ 66.4	\$ 180.6	(63.2)%
Income tax expense as a % of earnings before income taxes	23.1%	36.1%	

The 2019 tax rate was favorable to 2018 primarily due to the unfavorable impact of acquisitions, divestitures and tax reform in 2018, the favorable impact of a reduction in tax rates in a foreign jurisdiction in 2019, and partially offset by a lower mix of earnings in lower tax rate foreign jurisdictions in 2019.

Operating Income by Segment

	Three Months Ended September 30,		Change
	2019	2018	
LCD operating income	\$ 262.2	\$ 289.4	(9.4)%
LCD operating margin	14.9%	16.5%	(1.6)%
CDD operating income	123.8	87.9	40.8 %
CDD operating margin	10.5%	8.1%	2.4 %
General corporate expenses	(46.1)	(33.9)	36.0 %
Total operating income	\$ 339.9	\$ 343.4	(1.0)%

LCD operating income was \$262.2 for the three months ended September 30, 2019, a decrease of 9.4% over operating income of \$289.4 in the corresponding period of 2018, and LCD operating margin decreased 190 basis points year-over-year. The decrease in operating income and margin were primarily due to the impact from PAMA of approximately \$26.8 and one additional payroll

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day. Organic revenue growth and LaunchPad savings were partially offset by higher personnel expense. The Company remains on track to deliver approximately \$200.0 of net savings from its three-year, phase II of LabCorp Diagnostics' LaunchPad initiative by the end of 2021.

CDD operating income was \$123.8 for the three months ended September 30, 2019, an increase of 40.8% over operating income of \$87.9 in the corresponding period of 2018, and CDD operating margin increased 240 basis points year-over-year. The increase in operating income and margin was primarily due to organic demand, acquisitions, and LaunchPad savings, partially offset by higher personnel costs and a business disposition. The Company is on track to deliver \$150.0 of net savings from its three-year CDD LaunchPad initiative by the end of 2020.

General corporate expenses are comprised primarily of administrative services such as executive management, human resources, legal, finance, corporate affairs, and information technology. Corporate expenses were \$46.1 for the three months ended September 30, 2019, an increase of 36.0% over corporate expenses of \$33.9 in the corresponding period of 2018. The increase in corporate expenses in 2019 is primarily due to higher personnel costs, including executive transition costs.

Nine months ended September 30, 2019, compared with nine months ended September 30, 2018

Revenues

	Nine Months Ended September 30,		Change
	2019	2018	
LCD	\$ 5,242.1	\$ 5,336.3	(1.8)%
CDD	3,376.4	3,214.1	5.0 %
Intercompany eliminations	(17.1)	(4.5)	280.0 %
Total	<u>\$ 8,601.4</u>	<u>\$ 8,545.9</u>	0.6 %

The increase in revenues for the nine months ended September 30, 2019, as compared with the corresponding period in 2018 was 0.6%. The increase in revenues was primarily due to growth from acquisitions of 1.6% and organic growth of 1.4% (which includes the negative impact from PAMA of 0.9%), partially offset by the disposition of businesses of 1.7% and negative foreign currency translation of 0.7%.

LCD revenues for the nine months ended September 30, 2019, were \$5.24 billion, a decrease of 1.8% over revenues of \$5.34 billion for the nine months ended September 30, 2018. The decline in revenues was primarily due to the negative impact from the disposition of businesses of 2.4% and negative currency translation of 0.2%, partially offset by acquisitions of 0.4%. Organic revenues grew 0.3% and includes the negative impact of 1.5% from PAMA.

Total volume (measured by requisitions) excluding the disposition of businesses increased 0.2% as acquisition volume contributed 0.2% and organic volume was flat. Organic volume was negatively impacted by approximately 1.8% from the combination of lower consumer genetics, managed care contract changes, and fewer revenue days. Excluding the disposition of businesses, revenue per requisition increased by 0.4%, including the negative impact from PAMA of 1.5%.

CDD revenues for the nine months ended September 30, 2019 were \$3,376.4, an increase of 5.0% over revenues of \$3,214.1 in the nine months ended September 30, 2018. The increase was primarily due to organic growth of 3.5% and acquisitions of 3.5%, partially offset by negative foreign currency translation of 1.5% and a business disposition of 0.5%.

Cost of Revenues

	Nine Months Ended September 30,		Change
	2019	2018	
Cost of revenues	\$ 6,169.6	\$ 6,141.9	0.5%
Cost of revenues as a % of revenues	71.7%	71.9%	

Cost of revenues increased 0.5% during the nine months ended September 30, 2019, as compared with the corresponding period in 2018. Cost of revenues as a percentage of revenues remained relatively consistent during the nine months ended September 30, 2019, decreasing slightly to 71.7% as compared to 71.9% in the corresponding period in 2018.

Selling, General and Administrative Expenses

	Nine Months Ended September 30,		Change
	2019	2018	
Selling, general and administrative expenses	\$ 1,210.6	\$ 1,174.0	3.1%
Selling, general and administrative expenses as a % of revenues	14.3%	13.9%	

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During the nine months ended September 30, 2019, the Company incurred \$53.9 of acquisition and divestiture related costs, \$8.2 in consulting expenses relating to fees incurred as part of its integration and management transition costs, \$0.7 in costs related to a ransomware attack and \$11.3 in costs related to the AMCA data breach. In addition, the Company recorded \$7.4 of non-capitalized costs associated with the implementation of a major system as part of its LaunchPad business process improvement initiative and reversed \$13.9 related to the settlement of a contingent purchase price related to a 2016 acquisition. These items increased selling, general and administrative expenses by \$67.6.

During the nine months ended September 30, 2018, the Company incurred integration and other related costs of \$43.1 primarily relating to the Chiltern acquisition and sale of the Food Solutions business. As a direct result of the ransomware attack experienced during July the Company incurred \$5.8 in consulting fees incurred during the recovery period following the attack. The Company also recorded \$4.3 in consulting expenses related to the Chiltern integration and management transition costs along with a special one-time bonus of \$31.1 (\$6.3 of which was recorded in selling, general and administrative expenses) to non-bonus eligible employees in recognition of the benefits the Company received from the passage of the TCJA. In addition, the Company incurred \$7.3 of non-capitalized costs associated with the implementation of a major system as part of its LaunchPad business process improvement initiative. These items increased selling, general and administrative expenses by \$66.8.

Excluding these charges, selling, general and administrative expenses as a percentage of revenues were 13.3% and 13.0% during the nine months ended September 30, 2019, and 2018, respectively, primarily due to the decreased revenue from the implementation of PAMA.

Amortization of Intangibles and Other Assets

	Nine Months Ended September 30,		Change
	2019	2018	
LCD	\$ 75.3	\$ 79.9	(5.8)%
CDD	103.7	95.6	8.5 %
Total amortization of intangibles and other assets	\$ 179.0	\$ 175.5	2.0 %

The decrease in amortization of intangibles and other assets within the LCD segment was primarily due to the reduction of amortizable intangible assets pursuant to the divestiture of three LCD businesses in 2018, partially offset by the impact of acquisitions occurring after September 30, 2018. Amortization of intangible assets within the CDD segment increased primarily due to the impact of acquisitions occurring after September 30, 2018, partially offset by the reduction of amortizable intangible assets pursuant to the divestiture of one CDD business during the second quarter of 2019.

Restructuring and Other Special Charges

	Nine Months Ended September 30,		Change
	2019	2018	
Restructuring and other special charges	\$ 48.4	\$ 36.5	32.6%

During the nine months ended September 30, 2019, the Company recorded net restructuring and other special charges of \$48.4: \$22.8 within LCD and \$25.6 within CDD. The charges were comprised of \$26.2 related to severance and other personnel costs along with \$22.0 in costs associated with facility closures, impairment of operating lease right-of-use assets and general integration initiatives. The charges were increased by the adjustment of previously established reserves of \$0.4 in severance reserves and decreased by a reversal \$0.2 in unused facility reserves.

During the nine months ended September 30, 2018, the Company recorded net restructuring and other special charges of \$36.5: \$13.2 within LCD and \$23.3 within CDD. The charges were comprised of \$30.0 related to severance and other personnel costs, \$8.8 in costs associated with facility closures and general integration initiatives, and \$5.3 in impairment to land held for sale. The Company reversed previously established reserves of \$1.2 and \$1.1 in unused facility reserves and unused severance reserves, respectively.

Interest Expense

	Nine Months Ended September 30,		Change
	2019	2018	
Interest expense	\$ (176.3)	(186.0)	(5.2)%

The decrease in interest expense for the nine months ended September 30, 2019, as compared with the corresponding period in 2018, is primarily due to the repayment of the 2.50% senior notes in 2018, the repayment of the 2014 term loan, partial repayment of the 2017 term loan and a reduced level of borrowing on the revolving credit facility, partially offset by the new 2019 term loan.

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Equity Method Income, Net

	Nine Months Ended September 30,		Change
	2019	2018	
Equity method income, net	\$ 7.9	\$ 8.5	(7.1)%

Equity method income represents the Company's ownership share in joint venture partnerships along with equity investments in other companies in the health care industry. All of these partnerships and investments reside within LCD. The decrease in income for the nine months ended September 30, 2019, as compared with the corresponding period in 2018, was primarily due to decreased profitability of the Company's joint ventures.

Other, net

	Nine Months Ended September 30,		Change
	2019	2018	
Other, net	\$ (18.2)	\$ 209.1	(108.7)%

The change in other, net for the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018, is primarily due the gain of \$258.3 recognized on the sale of the Food Solutions business in the third quarter of 2018 offset by a \$48.9 loss on the divestiture of the Company's forensic testing services business in the UK. During the nine months ended September 30, 2019, the Company recognized an \$11.9 loss on disposition of a business and a \$4.3 write-off of two of the Company's cost method investments. These losses were partially offset by other investment gains of \$11.7. In addition, foreign currency transaction losses of \$10.7 were recognized for the nine months ended September 30, 2019 and losses of \$2.3 in the corresponding period of 2018.

Income Tax Expense

	Nine Months Ended September 30,		Change
	2019	2018	
Income tax expense	\$ 214.4	\$ 328.1	(34.7)%
Income tax expense as a % of earnings before income taxes	26.4%	31.1%	

The 2019 tax rate was favorable to 2018 primarily due to the unfavorable impact of acquisitions, divestitures and tax reform in 2018, a favorable impact of higher stock compensation deductions in 2018, the favorable impact of a reduction in tax rates in a foreign jurisdiction in 2019, and partially offset by a lower mix of earning in lower tax rate foreign jurisdictions in 2019.

Operating Income by Segment

	Nine Months Ended September 30,		Change
	2019	2018	
LCD operating income	\$ 843.0	\$ 929.2	(9.3)%
LCD operating margin	16.7%	17.9%	(1.2)%
CDD operating income	277.6	195.3	42.1 %
CDD operating margin	7.0%	5.0%	2.0 %
General corporate expenses	(126.8)	(106.5)	19.1 %
Total operating income	\$ 993.8	\$ 1,018.0	(2.4)%

LCD operating income was \$843.0 for the nine months ended September 30, 2019, a decrease of 9.3% over operating income of \$929.2 in the corresponding period of 2018, and LCD operating margin decreased 120 basis points year-over-year. The decrease in operating income and margin was primarily due to lower Medicare and Medicaid pricing as a result of PAMA, higher personnel costs, disposition of businesses, and cybersecurity expenses, partially offset by the Company's LaunchPad initiatives, and acquisitions. The Company remains on track to deliver approximately \$200.0 of net savings from its three-year, phase II of LabCorp Diagnostics' LaunchPad initiative by the end of 2021.

CDD operating income was \$277.6 for the nine months ended September 30, 2019, an increase of 42.1% over operating income of \$195.3 in the corresponding period of 2018, and CDD operating margin increased 200 basis points year-over-year. The increase in operating income and margin were primarily due to organic demand, LaunchPad savings, acquisitions and currency translation, partially offset by personnel costs, cybersecurity investments, and rent expense to support the Company's global expansion. The Company is on track to deliver \$150.0 of net savings from its three-year CDD LaunchPad initiative by the end of 2020, and \$30.0 and \$10.0 of cost synergies from the integration of Chiltern and Envigo, respectively by the end of 2019.

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General corporate expenses are comprised primarily of administrative services such as executive management, human resources, legal, finance, corporate affairs, and information technology. Corporate expenses were \$126.8 for the nine months ended September 30, 2019, an increase of 19.1% over corporate expenses of \$106.5 in the corresponding period of 2018. The increase in corporate expenses in 2019 is primarily due to higher personnel costs, including executive transition costs and the benefit of a favorable legal settlement in 2018 offsetting normal corporate expenses.

LIQUIDITY AND CAPITAL RESOURCES (dollars and shares in millions)

The Company's ability to generate cash and its financial condition typically have provided ready access to capital markets. The Company's principal source of liquidity is operating cash flow, supplemented by proceeds from debt offerings and availability under its senior unsecured revolving credit facility. The Company's senior unsecured revolving credit facility is further discussed in Note 8 (Debt) to the Company's Unaudited Condensed Consolidated Financial Statements.

During the nine months ended September 30, 2019, and 2018, respectively, the Company's cash flows were as follows:

	Nine Months Ended September 30,	
	2019	2018
Net cash provided by operating activities	\$ 874.9	\$ 819.0
Net cash (used for) provided by investing activities	(1,131.0)	353.6
Net cash provided by (used for) financing activities	196.7	(587.0)
Effect of exchange rate changes on cash and cash equivalents	(6.3)	(9.6)
Net (decrease) increase in cash and cash equivalents	<u>\$ (65.7)</u>	<u>\$ 576.0</u>

Cash and Cash Equivalents

Cash and cash equivalents at September 30, 2019 and 2018, totaled \$361.1 and \$892.6, respectively. Cash and cash equivalents consist of highly liquid instruments, such as time deposits, commercial paper, and other money market investments, substantially all of which have original maturities of three months or less.

Operating Activities

During the nine months ended September 30, 2019, the Company's operations provided \$874.9 of cash as compared to \$819.0 during the same period in 2018. The \$55.9 increase in cash provided from operations in 2019 as compared with the corresponding 2018 period is primarily due to higher cash earnings and favorable working capital.

Investing Activities

Net cash used for investing activities for the nine months ended September 30, 2019, was \$1,131.0 as compared to net cash provided by investing activities of \$353.6 for the nine months ended September 30, 2018. The change in cash used for investing activities was primarily due to growth in business acquisitions during the nine months ended September 30, 2019 and the cash received from the sale of the Food Solutions business during the nine months ended September 30, 2018. Capital expenditures were \$272.0 and \$257.6 for the nine months ended September 30, 2019, and 2018, respectively. The Company expects capital expenditures in 2019 to be approximately 3.5% of revenues primarily in connection with projects to support growth in the Company's core businesses, including projects related to LaunchPad. The Company intends to continue to pursue acquisitions to fund growth and make important investments in its business, including in information technology, to improve efficiency and enable the execution of the Company's strategic vision. Such expenditures are expected to be funded by cash flow from operations, as well as borrowings under the Company's revolving credit facility or any successor facility, as needed.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2019, was \$196.7 compared to net cash used for financing activities of \$587.0 for the nine months ended September 30, 2018. The change in cash from financing activities for nine months ended September 30, 2019, as compared to 2018, was primarily the result of debt proceeds greater than payments during the period partially offset by increased share repurchases during the first nine months of 2019.

On June 3, 2019, the Company entered into a new \$850.0 term loan facility in addition to its \$750.0 2017 term loan facility. The 2019 term loan facility will mature on June 3, 2021. Proceeds of the 2019 term loan facility were used for general corporate purposes, including to repay approximately \$250.0 of the 2017 term loan facility and in connection with the acquisition of Envigo's nonclinical research services business. This net change of \$600.0 represents the only contractual obligation as of September 30, 2019, that materially changed from December 31, 2018.

The 2019 term facility accrues interest at a per annum rate equal to at the Company's election, either a LIBOR rate plus a margin ranging from 0.55% to 1.175%, or a base rate determined according to a prime rate or federal funds rate plus a margin

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ranging from 0.0% to 0.175%. The 2019 term loan balance at September 30, 2019, was \$850.0. As of September 30, 2019, the effective interest rate on the 2019 term loan was 2.84%.

The 2017 term loan facility accrues interest at a per annum rate equal to, at the Company's election, either a LIBOR rate plus a margin ranging from 0.875% to 1.50%, or a base rate determined according to a prime rate or federal funds rate plus a margin ranging from 0.0% to 0.50%. The 2017 term loan balance at September 30, 2019, was \$277.0 and at December 31, 2018, was \$527.0. As of September 30, 2019, the effective interest rate on the 2017 term loan was 3.17%.

The Company maintains a senior revolving credit facility consisting of a five-year revolving facility in the principal amount of up to \$1,000.0, with the option of increasing the facility by up to an additional \$350.0, subject to the agreement of one or more new or existing lenders to provide such additional amounts and certain other customary conditions. The revolving credit facility also provides for a subfacility of up to \$100.0 for swing line borrowings and a subfacility of up to \$150.0 for issuances of letters of credit. The revolving credit facility is permitted to be used for general corporate purposes, including working capital, capital expenditures, funding of share repurchases and certain other payments, and acquisitions and other investments. The Company had no outstanding balance on its revolving credit facility at September 30, 2019, and at December 31, 2018.

Under the Company's term loan credit facilities and the revolving credit facility, the Company is subject to negative covenants limiting subsidiary indebtedness and certain other covenants typical for investment grade-rated borrowers and the Company is required to maintain certain leverage ratios. The Company was in compliance with all covenants under the term loan credit facilities and the revolving credit facility at September 30, 2019. As of September 30, 2019, the ratio of total debt to consolidated proforma trailing 12 month EBITDA was 3.3 to 1.0.

As of September 30, 2019, the Company provided letters of credit aggregating \$72.4, primarily in connection with certain insurance programs. Letters of credit provided by the Company are issued under the Company's revolving credit facility and are renewed annually.

At the end of 2018, the Company had outstanding authorization from the board of directors to purchase up to \$443.5 of Company common stock. During January 2019, the Company purchased 0.8 shares of its common stock at an average price of \$131.71 for a total cost of \$100.1 under this plan. On February 6, 2019, the board of directors replaced the Company's existing share repurchase plan with a new plan authorizing repurchase of up to \$1,250.0 of the Company's common stock. The repurchase authorization has no expiration. Since the new plan authorization, the Company has purchased 1.8 shares of its common stock at an average price of \$162.80 per share for a total cost of \$299.9. As of September 30, 2019, the Company had outstanding authorization from the board of directors to purchase up to \$950.0 of the Company's common stock.

The Company had a \$29.4 and \$26.7 reserve for unrecognized income tax benefits, including interest and penalties, as of September 30, 2019, and December 31, 2018, respectively. Approximately \$5.2 and \$6.0 is classified in accrued expenses and other, and approximately \$24.2 and \$20.7 is classified in deferred income taxes and other tax liabilities in the Company's Condensed Consolidated Balance Sheets as of September 30, 2019, and December 31, 2018, respectively.

Zero-coupon Subordinated Notes

On September 11, 2019, the Company announced that for the period from September 11, 2019, to March 10, 2020, the zero-coupon subordinated notes will accrue contingent cash interest at a rate of no less than 0.125% of the average market price of a zero-coupon subordinated note for the five trading days ended September 6, 2019, in addition to the continued accrual of the original issue discount.

During the nine months ended September 30, 2019, the Company settled notices to convert \$7.7 aggregate principal amount of its zero-coupon subordinated notes with a conversion value of \$14.5. The total cash used for these settlements was \$7.3. As a result of these conversions, the Company also reversed deferred tax liabilities of \$1.7.

On October 15, 2019, the Company announced that its zero-coupon subordinated notes may be converted into cash and common stock at the conversion rate of 13.4108 per \$1,000.0 principal amount at maturity of the notes, subject to the terms of the zero-coupon subordinated notes and the Indenture, dated as of October 24, 2006, between the Company and The Bank of New York Mellon, as trustee and the conversion agent. In order to exercise the option to convert all or a portion of the zero-coupon subordinated notes, holders are required to validly surrender their zero-coupon subordinated notes at any time during the calendar quarter beginning October 1, 2019, through the close of business on the last business day of the calendar quarter, which is 5:00 p.m., New York City time, on Tuesday, December 31, 2019. If notices of conversion are received, the Company plans to settle the cash portion of the conversion obligation with cash on hand and/or borrowings under its revolving credit facility.

Credit Ratings

The Company's investment grade debt ratings from Moody's and Standard and Poor's contribute to its ability to access capital markets.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk is the potential loss arising from adverse changes in market rates and prices, such as foreign currency exchange rates, interest rates and other relevant market rate or price changes. In the ordinary course of business, the Company is exposed to various market risks, including changes in foreign currency exchange and interest rates, and the Company regularly evaluates its exposure to such changes. The Company addresses its exposure to market risks, principally the market risks associated with changes in foreign currency exchange rates and interest rates, through a controlled program of risk management that includes, from time to time, the use of derivative financial instruments such as foreign currency forward contracts and interest rate and cross currency swap agreements. Although, as set forth below, the Company's zero-coupon subordinated notes contain features that are considered to be embedded derivative instruments, the Company does not hold or issue derivative financial instruments for trading purposes.

Foreign Currency Exchange Rates

Approximately 12.6% of the Company's revenues for the nine months ended September 30, 2019, and approximately 14.0% of those for the nine months ended September 30, 2018, were denominated in currencies other than the U.S. dollar. The Company's financial statements are reported in U.S. dollars and, accordingly, fluctuations in exchange rates will affect the translation of revenues and expenses denominated in foreign currencies into U.S. dollars for purposes of reporting the Company's consolidated financial results. In the third quarter of 2019 and the year ended December 31, 2018, the most significant currency exchange rate exposures were to the Canadian dollar, Swiss Franc, Euro and British Pound. Excluding the impacts from any outstanding or future hedging transactions, a hypothetical change of 10% in average exchange rates used to translate all foreign currencies to U.S. dollars would have impacted income before income taxes for the nine months ended September 30, 2019, by approximately \$3.4. Gross accumulated currency translation adjustments recorded as a separate component of shareholders' equity were \$(45.4) and \$(82.2) at September 30, 2019, and 2018, respectively. The Company does not have significant operations in countries in which the economy is considered to be highly-inflationary.

The Company earns revenue from service contracts over a period of several months and, in some cases, over a period of several years. Accordingly, exchange rate fluctuations during this period may affect the Company's profitability with respect to such contracts. The Company is also subject to foreign currency transaction risk for fluctuations in exchange rates during the period of time between the consummation and cash settlement of transactions. The Company limits its foreign currency transaction risk through exchange rate fluctuation provisions stated in some of its contracts with customers, or it may hedge transaction risk with foreign currency forward contracts. At September 30, 2019, the Company had 28 open foreign exchange forward contracts relating to service contracts with various amounts maturing monthly through October 2019 with a notional value totaling approximately \$358.5. At December 31, 2018, the Company had 34 open foreign exchange forward contracts relating to service contracts with various amounts maturing monthly through January 2019 with a notional value totaling approximately \$487.9.

The Company is party to six U.S. Dollar to Swiss Franc cross currency swap agreements with an aggregate notional amount of \$600.0, maturing in 2022 and 2025, as a hedge against the impact of foreign exchange movements on its net investment in a Swiss Franc functional currency subsidiary.

Interest Rates

Some of the Company's debt is subject to interest at variable rates. As a result, fluctuations in interest rates affect the business. The Company attempts to manage interest rate risk and overall borrowing costs through an appropriate mix of fixed and variable rate debt including by the utilization of derivative financial instruments, primarily interest rate swaps.

Borrowings under the Company's term loan credit facilities and revolving credit facility are subject to variable interest rates, unless fixed through interest rate swaps or other agreements. As of September 30, 2019, the Company had \$277.0 of unhedged variable rate debt from the 2017 term loan credit facility, \$850.0 of unhedged variable debt from the 2019 term loan credit facility and \$0.0 outstanding on its revolving credit facility. As of December 31, 2018, the Company had \$527.0 of unhedged variable rate debt from the 2017 term loan credit facility and \$0.0 outstanding on its revolving credit facility.

To hedge against changes in the fair value of a portion of the Company's long-term debt, the Company is party to two fixed-to-variable interest rate swap agreements for the 4.625% senior notes due 2020 with an aggregate notional amount of \$600.0 and variable interest rates based on one-month LIBOR plus 2.298%.

The Company's zero-coupon subordinated notes contain the following two features that are considered to be embedded derivative instruments under authoritative guidance in connection with accounting for derivative instruments and hedging activities:

- 1) The Company will pay contingent cash interest on the zero-coupon subordinated notes after September 11, 2006, if the average market price of the notes equals 120% or more of the sum of the issue price, accrued original issue discount and contingent additional principal, if any, for a specified measurement period.

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- 2) Holders may surrender zero-coupon subordinated notes for conversion during any period in which the rating assigned to the zero-coupon subordinated notes by Standard & Poor's Ratings Services is BB- or lower.

Each quarter-point increase or decrease in the variable rate would result in the Company's interest expense changing by approximately \$2.8 per year for the Company's unhedged variable rate debt.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, the Company carried out, under the supervision and with the participation of the Company's management, including the Company's principal executive officer and principal financial officer, an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based upon this evaluation, the Company's principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures were effective as of September 30, 2019.

Changes in Internal Control Over Financial Reporting

On June 3, 2019, the Company completed the acquisition of Envigo's nonclinical contract research services business. The Company's management has extended its oversight and monitoring processes that support internal control over financial reporting to include the acquired Envigo operations. The Company's management is continuing to integrate the acquired operations of Envigo's nonclinical contract research services business into the Company's overall internal control over financial reporting process. However, management plans to exclude these operations from its annual assessment of internal controls over financial reporting for the year ending December 31, 2019.

There were no other changes in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) that occurred during the quarter ended September 30, 2019, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

LABORATORY CORPORATION OF AMERICA HOLDINGS AND SUBSIDIARIES

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

See Note 11 (Commitments and Contingencies) to the Company's unaudited condensed consolidated financial statements, above, which is incorporated herein by reference.

Item 1A. Risk Factors

There have been no material changes in the risk factors that appear in Part I - Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds (dollars in millions, except per share data)

The following table sets forth information with respect to purchases of shares of the Company's common stock based on settled trades made during the three months ended September 30, 2019, by or on behalf of the Company:

	Total Number of Shares Repurchased	Average Price Paid Per Share	Total Number of Shares Repurchased as Part of Publicly Announced Program	Maximum Dollar Value of Shares that May Yet Be Repurchased Under the Program
July 1 - July 31	0.3	\$ 175.13	0.3	\$ 1,000.0
August 1 - August 31	0.3	166.41	0.3	950.0
September 1 - September 30	—	—	—	950.0
	0.6	\$ 170.66	0.6	\$ 950.0

On February 6, 2019, the board of directors replaced the Company's existing share repurchase plan with a new plan authorizing repurchases of up to \$1,250.0 of the Company's common stock. The repurchase authorization has no expiration. During the three months ended September 30, 2019, the Company purchased 0.6 shares of its common stock at an average price of \$170.66 per share for a total cost of \$100.0. As of September 30, 2019, the Company had outstanding authorization from the board of directors to purchase up to \$950.0 of the Company's common stock.

Item 5. Other Information

On October 3, 2019, the Company announced that John Ratliff, currently CEO of Covance Drug Development (CDD), will become CEO of LabCorp Diagnostics, and Dr. Paul Kirchgraber, currently senior vice president and head of CDD's clinical trial testing solutions, will succeed Ratliff as CEO of CDD. Both business segment CEO roles are effective November 1, 2019, when Adam H. Schechter becomes president and CEO of LabCorp, and David P. King retires from those roles to become executive chairman of the board of directors as previously announced. The Company also selected Judi Seltz as its chief human resources officer effective October 15, 2019.

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Item 6. Exhibits

(a)	Exhibits
10.1	<u>Transition Agreement David P. King (incorporate herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-K filed on August 8, 2019)</u>
31.1*	<u>Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)</u>
31.2*	<u>Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)</u>
32**	<u>Written Statement of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)</u>
101.INS*	Inline XBRL Instance Document - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
*	filed herewith
**	furnished herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

LABORATORY CORPORATION OF AMERICA HOLDINGS

Registrant

By: /s/ DAVID P. KING
David P. King
Chairman of the Board, President
and Chief Executive Officer

By: /s/ GLENN A. EISENBERG
Glenn A. Eisenberg
Executive Vice President and
Chief Financial Officer

October 31, 2019

Exhibit 31.1

Certification

I, David P. King, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Laboratory Corporation of America Holdings;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 31, 2019

By: /s/ DAVID P. KING
David P. King
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32

Written Statement of
Chief Executive Officer and Chief Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)

The undersigned, the Chief Executive Officer and the Chief Financial Officer of Laboratory Corporation of America Holdings (the “Company”), each hereby certifies that, to his knowledge on the date hereof:

(a) the Form 10-Q of the Company for the Period Ended September 30, 2019, filed on the date hereof with the Securities and Exchange Commission (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(b) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ DAVID P. KING
David P. King
Chief Executive Officer
October 31, 2019

By: /s/ GLENN A. EISENBERG
Glenn A. Eisenberg
Chief Financial Officer
October 31, 2019

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Laboratory Corporation of America Holdings and will be retained by Laboratory Corporation of America Holdings and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 31.2

Certification

I, Glenn A. Eisenberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Laboratory Corporation of America Holdings;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 31, 2019

By: /s/ GLENN A. EISENBERG
Glenn A. Eisenberg
Chief Financial Officer
(Principal Financial Officer)

Resumes

CURRICULUM VITAE

MOHAMMAD AL-GHOUL Ph.D.

Personal Information

Work Address: Center for Disease Detection
11603 Crosswinds Way, Suite 100
San Antonio, TX 78233
Cell Phone / E-mail: (561) 213-0277 / Mohammad.al.ghoul@gmail.com

Positions

LabCorp / Center for Disease Detection (CDD), San Antonio TX
Technical Director / July 2010 - Present

School of Health Professions, University of Texas Health Science Center, San Antonio TX
Adjunct Professor Aug 2012 - Present

Dept. of Pathology and Laboratory Medicine, University of Louisville, Louisville KY
Clinical Chemistry and Toxicology - Fellow July 2007- July 2010

PG_{XL} Laboratories, Louisville KY
Pharmacogenomics – Fellow Oct 2008 - Jan 2010

Dept. of Chemistry and Biochemistry, Florida Atlantic University, Boca Raton FL
Research / Teaching Assistant Aug 2003 - July 2007

Health Science Department, Broward College, Florida
Instructor Jan 2004 - Jan 2007

Education

Florida Atlantic University (FAU), Boca Raton FL
Ph.D. Chemistry/Biochemistry Aug 2007
Advisor: Dr. Gregg B. Fields
Dissertation: *Proteomic Analysis of Melanoma Progression*

M.Sc. Chemistry/Biochemistry Sep 2003
Thesis: *Construction of mini-collagen ligands recognized by $\alpha 2\beta 1$ integrin and CD44/CSPG melanoma receptors: New method for the study of signaling pathways*

B.Sc. Chemistry with emphasis in Biochemistry Dec 1999

Dept. of Pathology and Lab Medicine, University of Louisville Medical Center
Advisor: Dr. Roland Valdes Jr.
Fellow - Clinical Chemistry and Toxicology July 2007 - July 2010
Recipient of an NIH NIEHS T-32 research grant

Fellow - Pharmacogenetics / Molecular Pathology Oct 2008 - Jan 2010



04/30/19

Professional Experience

Center for Disease Detection (CDD)/LabCorp, San Antonio TX July 2010 – Present

Technical Director

New York Certificate of Qualification – Laboratory Director

- Responsible for the laboratory technical and scientific operation
- Consult on laboratory test results and professional guidelines
- Established QA and QC programs in collaboration with QA manager
- Ensure laboratory compliance with regulatory agencies requirements
- Oversee method performance verifications and implementation of new technologies
- Manage laboratory supervisors/managers

IVD Trials / Studies

Principal Investigator

- Baseline - *Clinical Evaluation of the HPV Assay on the BD Viper LT System with Cervical Specimen*. Trial # BDS-USHP. BD Diagnostics
- Longitudinal - *Clinical Evaluation of the HPV Assay on the BD Viper LT System with Cervical Specimen*. Trial # BDS-USLHPV. BD Diagnostics
- *Architect Syphilis TP Assay Design Validation Protocol*. Trial # 9DY-02-15S01-01. Abbott Laboratories
- *Clinical Validation of the SurePath PostQuot Specimen*. Trial # BDS-USHPV-SS-001. BD Diagnostics
- *STAT High Sensitive Troponin-I*. Trial # 09DY-0315A01-01. Abbott Laboratories
- *Performance of the Cobas HPV Test Using Samples Collected in SurePath Preservative Fluid for Identification of High-Grade Cervical Disease When Used as an Adjunct to Cervical Cytology in Women >30 Years and as a Primary Screening Test in Women >25 Years*. Trial # (COB-HPV-301). Roche Diagnostics
- *CINtec PLUS Cytology Pilot Study*. Trial # D050103. Roche Diagnostics

University of Texas Health Science Center, San Antonio TX

Adjunct Assistant Professor

Aug 2012 – Present

- Mentor and evaluate graduate students during clinical rotations
- Committee member on graduate students research proposals and thesis preparation
- Present lectures and seminars

PGXL Laboratories, Louisville KY

Postdoctoral Fellow

Oct 2008 – Jan 2010

- Pharmacogenetics Diagnostic Testing Services
- Assay development and evaluation
- Manage laboratory staff
- Modify/ develop standard operating procedures as needed

University of Louisville Medical Center and Associated Hospitals, Louisville KY

Postdoctoral Fellow

July 2007- July 2010

- On-call two week per month (24 hours / 7 days)
- Help healthcare professionals interpret laboratory results
- Provide technical support in the chemistry and toxicology sections



04/30/19

- Provide educational seminars and case reports to medical and technical staff
- Present clinical cases at medicine morning report
- Manage assay evaluation / validation
- Modify laboratory procedures and policies
- Train pathology residents and medical students through clinical chemistry rotations: General Chemistry, Endocrinology, Toxicology, Therapeutic Drug Monitoring, and Basic Pharmacogenetics

Florida Atlantic University, Boca Raton FL
Teaching Assistant/Research Assistant

Aug 2001 - May 2007

- Supervised and evaluated students for general, organic, and biochemistry laboratories
- Trained students with research-directed independent study projects
- Helped manage the proteomics facility

Broward Community College, Fort Lauderdale, FL
Instructor

Jan 2004 - Jan 2007

- Chemistry for health science majors
- General chemistry
- Organic chemistry

Selected Awards

- American Association for Clinical Chemistry - Abstract award, Anaheim, CA, July 2010
- Mass Spectrometry Application for the Clinical Laboratory (MSACL) –Travel award, San Diego, CA, Feb 2010
- International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDMCT) – Best Oral Presentation award, Montréal, Québec, Canada October 2009
- American Association for Clinical Chemistry (Clinical Proteomics Section) – Abstract Award, July 2009
- Institute for Molecular Diversity and Drug Design (IMD3) – Poster award, Louisville, March 2009.
- Society for Young Clinical Laboratorians (SYCL) - Travel award to attend the AACC 2009 annual meeting in Chicago, February 2009.
- Van Slyke Foundation - Travel award to present at the American Association for Clinical Chemistry (AACC), Washington DC, July 2008.
- American Association for Clinical Chemistry – Poster award, July 2008

Invited Speaker (Selected Presentations)

- *New Developments in HPV Testing and Cancer*. Texas Association for Clinical Lab Scientists (TACLS), San Antonio, Texas, April 2016.
- *Drugs of Abuse Testing: Facts and Myths*. Department of Labor – Online Webinar, June 2015.
- *Sexual Transmitted Diseases; Testing Updates and New Guidelines*. Pennsylvania Department of Public Health Annual Meeting. Penn State, PA, April 2015.
- *Designer Drugs: What is New?* University of Texas Health Science Center, San Antonio, TX. Nov 2014.



04/30/19

- *All You Would Ever Want to Know about Urine Toxicology Screening*. Department of Labor - online webinar - May 2014
- *HIV New Testing Algorithm*, Department of Labor online webinar - November 2013
- *Toxicology Screening from Sample Collection to Patient Results*, Department of Labor - online webinar - November 2012
- *Is Viral Hepatitis The New Silent Epidemic?* The Society of Armed Forces Medical Laboratory Scientists, Memphis TN, April 2012
- *HIV Testing Past, Present, and Future*. The Society of Armed Forces Medical Laboratory Scientists Annual Meeting, New Orleans LA, March 2011
- *Mammalian Cardenolide Hormone (MCH-518): A Novel Biomarker in Breast Cancer Prevention*. AACC, Anaheim CA, July 2010
- *Endogenous MCH-518 Promotes Cell Death in Breast Cancer Cells*. Health Science Center, University of Texas, San Antonio, Texas, January 2010
- *DLIF is Cytotoxic to Breast Cancer Cells: A Novel Mechanism for Prevention of Breast Malignancies*. 11th International Congress of Therapeutic Drug Monitoring and Clinical Toxicology, Montreal Canada, October 2009

Selected Publications

- Al-Ghoul M. and Valdes R Jr. Fundamentals of pharmacology and applications in pharmacogenetics. *Clin Lab Med*. 28(4):485-97,2008.
- Al-Ghoul M. et al. Comparative proteomic analysis of matched primary and metastatic melanoma cell lines. *J Proteome Res*. 7(9):4107-18,2008.
- Al-Ghoul M. and Valdes R Jr. Mammalian cardenolides in cancer prevention and therapeutics. *Therap Drug Monit*. 30(2):234-8,2008.
- Baronas-Lowell D and Al-Ghoul M. Proteolytic profiling of the extracellular matrix degradome. *Methods Mol Biol*. 386:167-202,2007.
- Baronas-Lowell D and Al-Ghoul M. Differential modulation of human melanoma cell metalloproteinase expression by alpha2beta1 integrin and CD44 triple-helical ligands derived from type IV collagen. *J Biol Chem*. 279(42):43503-13,2004.

Selected Published Abstracts

- *Should viral hepatitis screening programs be implemented?* National STD Prevention Conference, Minneapolis MN, March 2012
- *Development of an application for the SimpleProbe CYP2C9/VKORC1 assay on the ABI 7500 Fast instrument*. AACC July 2010
- *Mammalian Cardenolide Hormone (MCH-518): A Novel Biomarker in Breast Cancer Prevention*. AACC July 2010
- *Negative Bias in Ionized Magnesium Results on Smokers*. Al-Ghoul M, Hiemer MF, Miller JJ, and Elin R. *Clin Chem* 54(6), A226-A226, Suppl. E103 JUN 2008

Professional Memberships

- **Communication Officer:** AACC CDID Division (Jan, 2017 – Dec, 2018)
- **Associate Editor:** SYCL360 Podcast (2011 – 2013)
- **Abstract Editor:** AACC annual meeting (2009 – 2012)
- **Treasurer:** AACC Ohio Valley – (2008-2010)
- **Member:** Golden Key International Society (Academic Honors Society)



04/30/19

Curriculum Vitae

Jane Y Dancer M.D. FCAP, FASCP

Contact Information

Work Address:

Pathologist/Medical Director
Laboratory Director for Cytopathology/Anatomic pathology
Center for Disease Detection (Laboratory Corporation of America)
11603 Crosswinds Way Suite 100, San Antonio, TX 78233
Work: 210.951.6246
Email: Jane.dancer@cddmedical.com

ABMS Board Certification

American Board of Pathology: Certified Anatomic and Clinical Pathology (2009)
American Board of Cytopathology: Certified (2010)

License History

1. Alabama Medical License: Active since 6/2014
2. Arkansas State Medical License: Active since 12/2011
3. Arizona Medical Board License: Active since 02/2011
4. Medical Board of California: Active since 12/2011
5. State of Colorado Medical License: Active since 06/2011
6. State of Florida Medical License: Active since 06/2011
7. Georgia Composite Medical Board: Active since 06/2014
8. Kansas Medical Board of Healing art: Active since 05/2014
9. Iowa Medical Board License: Active since 05/2011
10. Louisiana State Medical License: Active since 06/2011
11. Maryland Medical Board License: Active since 10/2011
12. Missouri Medical Physician & Surgeon License: Active since 06/2011
13. New Jersey Medical License: Active since 07/2011
14. New York Medical Board License: Active since 04/2011
15. State Medical Board of Ohio: Active since 02/2011
16. Pennsylvania Medical Board License: Active since 04/2011
17. State of South Carolina Medical License: Active since 08/2011
18. State of Texas Medical Board License: Active since 11/11/2007

Other Certification

Certification of Qualification for Laboratory Director, New York State Department of Health: General, Cytopathology, Anatomic pathology: Active since 01/2017

Specialty expertise

Gynecologic Pathology/General oncologic pathology
Cytopathology

Biographical History

Citizenship: United States

Post Graduate Training

- 07/ 2008 **Surgical Pathology Fellow**
06/ 2009 Department of Surgical Pathology
UT M.D. Anderson Cancer Center
Houston, Texas (Program Director, Aysegul Sahin, M.D.)
- 07/ 2007 **Cytopathology Fellow**
06/ 2008 Department of Cytopathology
The Methodist Hospital Houston, Texas, affiliate of Weil Medical
College of Cornell University, (Program Director, Dina Mody, M.D.)
- 10/ 2005 **Resident (PGY3-4, AP/CP)**
06/ 2007 Surgical Pathology and Lab Medicine
The Methodist Hospital, Houston, Texas, affiliate of Weil Medical
College of Cornell University, (Program Director, Suzanne Powell, M.D.)
- 09/ 2003 **Resident (PGY1-2, AP/CP)**
09/ 2005 Surgical Pathology and Lab Medicine
Louisiana State University Health Science Center
Shreveport, Louisiana (Program Director, Marjorie Fowler, M.D.)
- 03/ 1990 **Resident (PGY1- 4)**
02/ 1994 Department of Anatomic Pathology
Inje University, Pusan Paik Hospital, South Korea
- 03/ 1989 **Preliminary Medical Internship** including Internal Medicine
02/1990 Pediatrics, General Surgery and OBGYN
Inje University, Pusan Paik Hospital, South Korea

Medical Education

- 1989: **M.D.**
Pusan National University, College of Medicine, Pusan, South Korea
- 1985: Premedical school
Pusan National University, College of Medicine, Pusan, South Korea

Professional Work and Experience

- 11/2016 Pathologist/Medical director
Present Center for disease detection (Laboratory Corporation of America)
11603 Crosswinds Way suite 100, San Antonio, TX 78233
- 01/2011 Staff pathologist

- 11/2016 Center for disease detection
11603 Crosswinds Way suite 100, San Antonio, TX 78233
- 08/2009 Staff pathologist
01/2011 Southern AZ VA Health Care System
Pathology (6-113), 3601 S. 6th Ave. Tucson, AZ 85723-0002
- 03/2010 Clinical assistant professor
01/2011 Department of Pathology, University of Arizona
- 09/1997 Assistant professor
01/2002 Department of Diagnostic Pathology
Ulsan University Hospital, Ulsan University, School of Medicine,
South Korea
- 04/1997 Full-time lecturer
08/1997 Department of Diagnostic Pathology, Ulsan University Hospital, Ulsan
University School of Medicine, South Korea
- 03/1994 Medical director
03/1997 Department of Surgical Pathology
Haesung Hospital, Asan Welfare Foundation, South Korea

Professional Societies

United States and Canadian Academy of Pathology
College of American Pathologists
American Society for Clinical Pathology
American Society of Cytopathology

Committee activity

Educational Development Committee in the American Society of Cytopathology
(2007-2008)
Junior Ad Hoc Member in the Economic and Government Affairs Committee in the
American Society of Cytopathology (2008-2009)

Research Activity

Performance of the cobas® HPV Test Using Samples Collected in SurePath™
reservative Fluid™ for Identification of High-Grade Cervical Disease COBHPV-301.
Intended Use Study of the BD Sure Path™ Plus Pap.

Substudy of BD Sure Path™ Plus Pap: Longitudinal Study.
Clinical Evaluation of the HPV Assay on the BD Viper LT system with Cervical Specimens.

Publications

Q Si, **JY Dancer**, ML. Stanton, P. Tamboli, JY. Ro, BA. Czerniak, SS. Shen, CC. Guo.
Primary small cell carcinoma of the kidney: A clinicopathologic study of 14 cases Hum

Pathol. 2011 Nov; 42(11):1792-8.

CC Guo, **JY Dancer**, BA Czerniack. TMPRSS2-ERG Gene Fusion in Small Cell Carcinoma of the Prostate. Hum Pathol. 2011 Jan; 42(1):11-7.

Dancer JY, Henry SP, Bondaruk J, Lee S, Ayala AG, de Crombrughe B, Czerniack B. Expression of master regulatory genes controlling skeletal development in benign cartilage and bone forming tumors. Hum Pathol. 2010 Dec; 41(12):1788-93.

Dancer JY, Truong LD, Zhai Q, Shen SS. Expression of Galectin 3 in renal neoplasm: a diagnostic, possible prognostic marker. Arch Pathol Lab Med. 2010 Jan; 134 (1):90-4.

Cho HY, Lee M, Takei H, **Dancer J**, Ro JY, Zhai QJ. Immunohistochemical comparison of chordoma with chondrosarcoma, myxopapillary ependymoma, and chordoid meningioma. Appl Immunohistochem Mol Morphol. 2009 Mar; 17(2):131-8.

JY Dancer, HI Son, B Dhurandhar, DR Mody and H Takei Can ThinPrep (TP) Preparations Be Used in the Primary Mode in the Diagnosis of Pancreatic Ductal Adenocarcinomas in Material Obtained from Endoscopic Ultrasound Guided Fine Needle Aspirations (EUSFNA)? (In progress)

CH Kim, **J Y Dancer**, Q J. Zhai, M Reardon, AG. Ayala, Jae Y. Ro. Clinicopathologic study of 24 patients with Primary Cardiac Sarcomas: a 10- single institution experience. Human Pathol, 2008, Jun; 39 (6):933-8

Takei H, Bhattacharjee MB, Rivera A, **Dancer Y**, Powell SZ. New immunohistochemical markers in the evaluation of central nervous system tumors: a review of 7 selected adult and pediatric brain tumors. Arch Pathol Lab Med. 2007 Feb; 131(2):234-41. Review.

Takei H, Ruiz B, **Dancer J**, Hicks J. Fine needle aspiration of poorly defined indurated and well-defined breast lesions: a cytopathologic comparative study. Acta Cytol. 2007 Sept-Oct; 51(5):692-8

Jane Dancer, Hidehiro Takei, Jae Y. Ro, Mary Lowery-Nordberg, Coexpression of EGFR and HER-2 in Pancreatic Ductal Adenocarcinoma: a comparative study using Immunohistochemistry correlated with gene amplification by fluorescence in-situ hybridization. Oncol Rep. 2007 Jul; 18(1):151-5

Albores-Saavedra J, Simpson K, **Dancer YJ**, Hruban R. Intestinal type adenocarcinoma: a previously unrecognized histologic variant of ductal carcinoma of the pancreas. Ann Diagn Pathol. 2007Feb; 11(1):3-9.

Eric Xueying Wei, **Yeongju Dancer**, Diana M. Vellion, Andrea J Linscott, James D. Cotelingam. Pathology Case of the Month. J La State Med Soc 2005; 157:12-16

Sung Sook Kim, Hae Jung Shin, Dae Woon Eom, Joo Ryung Huh, **Yeongju Woo**: **Enhanced** Expression of neuronal Nitric Oxide Synthase and Phospholipase C-gamma1 in Regenerating Murine Neuronal Cells by Pulsed Electromagnetic Field, Experimental and Molecular Medicine 34(1); 2002

Sung Sook Kim, Dae Woon Eom, **Yeongju Woo**, Inpyo Choi; Altered Expression of

Tissue Inhibitor of Matrix metalloproteinase-2 in Complicated Mice Heart Secondary To Experimentally induced Viral Myocarditis. J of Korean Pathology 35(2):196-200, 2001

Dae Woon Eom, Sung Sook Kim, **Yeongju Woo**, Jooryung Huh, Pann-Ghill Suh; Expression of Phospholipase C gamma-1 and gamma-2 in Non-Hodgkin's and Hodgkin's Lymphoma, J of Korean Pathology 34; 113-118,2001

Jae Rak Chung, Ja Hyun Yoon, **Yeongju Woo**, Seung Won Choi; Case of Primary Sjogren's Syndrome with Myocarditis. Korean J of Rheumatology, 8; 208-213, 2001

References

Nathan Suh, M.D. Medical Director, Pathology & Laboratory Medicine
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3495 Piedmont Rd. N.E.
Atlanta, GA 30305
Tel: 470-217-0150
E-mail: nathan.suh@kp.org

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1501 Kings Highway
Shreveport, LA 71130
Tel: 318-675-5859
E-mail: rshack@lsuhsc.edu

Jae Y. Ro, M.D., Ph.D. Director of Surgical Pathology
Department of Pathology
The Methodist Hospital
6565 Fannin, M243
Houston, Texas 77030
Tel: 713-441-2263
Fax: 713- 793-1603
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Dina Mody, M.D. Director of Cytopathology,
The Methodist Hospital
6565 Fannin, M227
Houston, Texas 77030
Tel: 713-441-6483
Fax : 713-793-1603
E-mail : dmody@ houstonmethodist.org

Dean S. Skelley, PhD
Clinical Biochemist
Curriculum Vitae

Laboratory Director
Center for Disease Detection
(210) 590-3033 ex. 300

11603 Crosswinds Way, Suite 100
San Antonio, TX 78233
dean.skelley@cddmedical.com

Education

- Doctor of Philosophy in Biochemistry** 1968
Ohio State University, Columbus, OH
- Master of Science** 1966
Ohio State University, Columbus, OH
- Bachelor of Science** 1960
Bates College, Lewiston, ME

Academic and Professional Appointments

- Assistant Professor** 1970 – 1976
Department of Obstetrics and Gynecology
Baylor College of Medicine, Houston, TX

Professional Experience

- Laboratory Director** 2015 – Present
OnPoint Laboratory, Sugar Land, TX
- Laboratory Director** 2014 – 2015
PremierTox Laboratory, San Antonio, TX
- Laboratory Director** 2004 – Present
Center for Disease Detection, LLC, San Antonio, TX
- Laboratory Director** 2005 – 2012
CHRISTUS Santa Rosa Hospital (formerly McKenna Memorial Hospital)
New Braunfels, TX
- Director of Laboratory Services** 2000 – 2004
South Texas Blood and Tissue Center, San Antonio, TX
- Laboratory Director** 1989 – 1999
Laboratory Corporation of America, San Antonio, TX

Dean S Skelley 11/13/2019

President Technical & Professional Services, Incorporated, San Antonio, TX	1988 – Present
Director of Scientific Affairs MCLAS Technologies, Incorporated, San Antonio, TX	1986 – 1987
Director of Scientific Development Cone Biotech, Incorporated, Seguin, TX	1984 – 1986
Director of Operations Severance Reference Laboratory, San Antonio, TX	1983 – 1984
Clinical Biochemist Memorial Hospital System, Houston, TX	1976 – 1983
Assistant Laboratory Director & Assistant Professor Baylor college of Medicine, Houston, TX	1970 – 1976
Assistant Professor Ohio State University, Columbus, OH	1968 – 1970

Licensure and Certification

Laboratory Director Certificate of Qualification New York State Department of Health (SKELD2)	2005 – Present
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Professional Memberships

- Member, American Association for Clinical Chemistry
- Member, American Medical Writers Association
- Member, Council Science Editors
- Member, Texas Society of Histotechnology

Additional Accomplishments

- Chairperson, Bexar Area Harm Reduction Coalition (2005 – 2006)
- Editor and Publisher, *The Ligand Review* (1980 – 1982)
- Committee Member, Newborn Screening Task Force
Texas State Department of Health
- Member and Community Representative, Institutional Biosafety Committee
University of Texas Health Science Center, San Antonio, TX
- Inspector, College of American Pathologists Laboratory Accreditation Program


Signature

11/13/2019
Date

Andrew W. Fenwick

505 Hillocks Cove, Cibolo, TX 78108 | (210) 332-7333 | andrew.w.fenwick@gmail.com

Career Summary

Senior Laboratory Manager experienced in planning, organizing and directing multi-departmental operations within a high-visibility, client-forward, and highly regulated medical laboratory environment. Proven achievements include regulatory compliance, strategic planning and vision, change management, budgeting and fiscal stewardship for sustainable growth and maximum profitability.

Professional Appointments

- Center for Disease Detection/Laboratory Corporation of America, San Antonio, TX
Laboratory Manager – Surgical Pathology, Cytopathology & Molecular Microbiology, April 2019 – Present
- Center for Disease Detection/Laboratory Corporation of America, San Antonio, TX
Laboratory Manager – Cytopathology, March 2011 – April 2019
- Center for Disease Detection, San Antonio, TX
Laboratory Supervisor – Cytopathology, February 2010 – March 2011
- Center for Disease Detection, San Antonio, TX
Staff Cytotechnologist, February 2007 – February 2010

Relevant Experience

- Responsible for strategic planning and oversight of multi-department, high complexity laboratory
- Recruit, interview, hire and orient all department staff, to include training, development, performance management and assessment
- Design and implement strategic change for continual process improvement according to lean principles
- Develop and conduct audits to ensure compliance and effectiveness, to include operations, inventory control, and personnel compliance and contribution
- Partner with senior staff and directors, physicians, and supervisors to ensure consistent levels of service across all laboratory operations, providing timely and accurate delivery of test results
- Extensive knowledge of resource management, human resource and personnel management
- Thorough knowledge of federal, state and local regulatory bodies and the obligations necessary to exceed the compliance requirements of the CAP, CLIA, and CMS
- Experience with billing operations as they relate to CPT and ICD-10 coding
- Experienced Medical Technologist and Registered Cytotechnologist (ASCP)^{CM}

Education

- Liberty University
Master of Business Administration – 2007
- Johnson University
Bachelor of Science, Music – 1999
- The George Washington University
AAS, Health Science Laboratory Technology – 2003

Training, Certification & Honors

- United States Army Cytology Specialist Certification – 2004
- United States Army Medical Laboratory Specialist Certification – 2001
- American Society for Clinical Pathology – CT(ASCP)^{CM}
Registry # 13762 - 2004
- Military Honors
Army Superior Unit Award
Army Commendation Medal with Oak Leaf Cluster
Army Good Conduct Medal with Two Knot Device
National Defense Service Medal
Global War on Terrorism Service Medal
Army NCO Professional Development Ribbon
Army Service Ribbon

Joseph Lyons, BsC

Immunology Laboratory Manager
Center for Disease Detection, LLC
(210) 951-8166

11603 Crosswinds Way, Ste. 100
San Antonio, TX 78217
Email: joe.lyons@cddmedical.com

EDUCATION/CERTIFICATIONS

- Bachelor's Degree with emphasis in Biology and Information Technology
- State of Texas Teacher's Certification (Mathematics and Science)

Clinical Laboratory Manager/Technical Supervisor October 2014—Present
Center for Disease Detection, San Antonio, TX

- Manages and trains staff in the performance of laboratory functions - both administrative and technical operating procedures for 7 Technologists and 11 Lab Assistants.
- Evaluates staff proficiency and performance.
- Establishes and implements written operating procedures and protocols that are in compliance with OSHA.
- Establishes and maintains a routine documented schedule of quality control and quality assurance.
- Performs and monitors laboratory testing in the areas of immunology, chemistry, serology, toxicology, hematology and immunohematology.
- Evaluates and establishes costs/price for individual tests with Technical Director.
- Manages laboratory inventory to ensure adequate levels for testing requirements.

Assistant Quality Assurance Manager/Training Coordinator 2010-Present
Center for Disease Detection, San Antonio, TX

- Identifies laboratory training needs. Develops, implements and records training activities.
- Reviews testing, quality control, and other testing reports for accuracy, completeness and compliance to requirements to ensure that quality assurance standards and regulatory requirements are met.
- Leads audits of laboratory operations, documents audit findings and reports results to Laboratory Director.
- Hosts/coordinates OSHA, CLIA, CAP, and other inspections as necessary.
- Assists with and/or advises on laboratory procedure development and implementation.
- Reviews, tracks and communicates information regarding process variations and quality control samples as required by laboratory quality assurance procedures.
- Administrator for Master Control™ Document Management System.
- Administrator for Bio-Rad Unity Real Time® Data Management Software.

Specimen Management Process Supervisor/Laboratory Trainer 2001 - 2010
Cetero Research Clinical Trials, San Antonio, TX

- Directly supervises all staff and specimen processing in the laboratory
- Maintains employee evaluation and competency records
- Coordinates and manages laboratory activities to meet protocol objectives
- Developed and administered training of new laboratory personnel
- Evaluates competency of all laboratory personnel on complex procedures
- Reviews all laboratory Quality Control records for completion and adherence to good laboratory practice
- Maintained YSI 2300 STAT Plus analyzer
- Maintained Maintenance records for all laboratory equipment

Joseph Lyons, BsC

Immunology Laboratory Manager
Center for Disease Detection, LLC
(210) 951-8166

11603 Crosswinds Way, Ste. 100
San Antonio, TX 78217
Email: joe.lyons@cddmedical.com

Donor Center Instructor/ Lead Technician

1999 – 2001

Fort Sam Houston, San Antonio, TX

- Instructor for Phase II Medical Laboratory Technician Program
- Lectured and administered practical training
- Evaluated students and technicians on complex procedures
- Locally maintained and administered standards of the United States Army Blood Banking Program
- Maintained Abbott Cell-Dyn 3200 Hematology Analyzer and maintenance records

Medical Laboratory Technician

1997 – 1998

10th Combat Support Hospital, Colorado Springs, CO

- Performed varied laboratory testing in chemistry, hematology, microbiology and blood bank
- Supervisor for Troop Medical Clinic Laboratory
- Trained clinic personnel on laboratory procedures

Medical Laboratory Technician

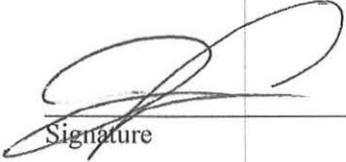
1994 – 1997

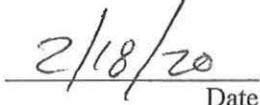
Landstuhl Regional Medical Center, Landstuhl, Germany

- Performed varied laboratory testing in chemistry, hematology, microbiology and blood bank
- Maintained laboratory instrumentation to include the Vitek analyzer, Microscan analyzer, Bactec analyzer, TechniconH1 analyzer, Coulter STKR/STKS analyzers, MLA 1000/750 analyzer, and Ciba Corning blood gas analyzer and associated maintenance records
- Verified results and quality control
- Performed CAP Proficiency Tests in Hematology
- Ensured readiness for JCAHO inspections

PROFESSIONAL TRAINING

- Medical Laboratory Technician Course, Basic
- Medical Laboratory Technician Course Advanced
- Medical Specialist Course
- Blood Donor Center Operations Course
- YSI 2300 STAT Plus Analyzer, YSI, Inc.
- Cell-Dyn 3200 Hematology Analyzer, Abbott Diagnostics
- 200 Series Blood Gas Analyzer Training, Ciba Corning Diagnostics
- CAP Inspector Training
- Master Control Document Management Administrator Training
- Architect i2000 Training, Abbott Diagnostics
- Instrument Manager Administrator Training, Abbott Diagnostics


Signature


Date

MARIAN F. TULLY

(210) 930-4433 - 2931 Moss Tree Street - San Antonio, TX 78232 - marian.tully@cddmedical.com

Qualifications for Customer Service/Account Management

Customer Service management professional with over 28 years in the healthcare industry and almost 17 years with Center for Disease Detection (CDD). Currently co-managing a department of twelve. Detail-oriented, self-motivated achiever with diversified leadership and project management experience. Dedicated, highly-effective implementer of efficiency innovations with outstanding verbal and written communication skills. Additional areas of expertise include:

- Project Management • Quality Monitoring • Policy/Procedure Development • Process Improvement •
 - Reporting • Staff Coaching and Development • Budget and Forecasting • Customer Service • Training • Sales
-

CAREER TRACK

CENTER FOR DISEASE DETECTION -----2003 to Present

Customer Service Manager (current position)

Senior Account Manager

Account Manager

Co-manage the Customer Service Department. Primary contact for many government and public health contracts. Responsible for hiring, staffing, payroll, personnel records, and routine management duties as well as client management, client retention, training and staff development. Well versed in all aspects of the company to include billing, laboratory services, sales and more. Point of contact between clientele and CDD Lab personnel.

Work to ensure that the clients (external and internal) receive world class customer service. Maintain an account management and relationship building philosophy to maintain and ensure long term client relationships. Resolve escalated client questions and concerns in a timely manner to assure timely patient care. Ensure customer service team is successful meeting deadlines and goals with new client rollouts, client requests, client questions, client satisfaction and new projects. Provide technical support for CDD AFTIS client software. Prepare sales agreement forms for existing clients. Travel (as needed) to visit clients to provide training and in-services.

BEXAR COUNTY MEDICAL SOCIETY -----2002

Office Manager/Receptionist

Managed single physician practice for Dr. Thilo Burzlaff. Responsibilities included; set up of electronic health records, patient scheduling, billing, referral paperwork, maintain office supplies along with file and records management.

MATRIA HEALTHCARE, INC. -----1992 to 2001

Sales/Account Executive

Administrative Coordinator

Administrative Assistant/Receptionist

Sales/Account Executive - Defined and developed over 250 physician and hospital accounts in San Antonio, Austin, Corpus Christi and South Texas. Identified accounts for high risk OB screening and education. Increased referral base by 5% in first year. Presentations to individual and large groups in OB/Gyn sector to include physicians, medical directors, staff and hospital nurses, medical staff, and insurance case managers. Designed and implemented marketing materials.

Administrative Coordinator – Provided guidance to administrative staff regarding training and implementation of policies and procedures. Coached administrative staff on account management and customer service. Provided weekly, monthly and quarterly reports. Frequent travel to other locations to conduct training and recruitment of Account Executives, Account Coordinators and Perinatal Clinicians. Responsible for insurance authorization and weekly reporting to Case Managers

CREDENTIALS

Education: Douglas MacArthur High School, San Antonio College, Texas A&M University

Software Skills: Windows OS, MS Word, MS Excel, MS PowerPoint, MS Access, MS Project, SharePoint, Call & Contact Management Systems, CDD Proprietary LIS and CDD AFTIS client software systems

Production Leader/Trainer

Trained and supervised new employees in all aspects of the restaurant from cash register operation to food preparation. Assisted management in opening restaurant, daily deposits of funds, coordinating employee breaks and schedules.

1986-1989

Denny's Restaurants

Las Vegas, NV

Certified Trainer/Waitress

Trained new employees and performed all wait staff duties. Assisted management as needed.

Education:

1978-1981

O.W. Holmes HS

San Antonio, TX

State finalist for DECA (Distributive Education Clubs of America)

Mu Alpha Theta member (State UIL winner)

Computer experience:

Proficient in the use of all Windows systems and Microsoft Office applications

Familiar with CISCO, KANA, CARES, ETT, ACMS and LIS

Veronica C. Sulin

3110 Satellite Dr.
San Antonio, Texas 78217

Ph. (210) 387-7274
veronicasulin@gmail.com

A resourceful and seasoned manager highly skilled in growing and maintaining efficiency and profitability.

EDUCATION

University of Phoenix **Master of Business Administration, 2016**
University of Phoenix **Bachelor of Science, Business Management, 2009**

SKILLS

- Fluent in Spanish, both verbally and in writing.
- Proficient in Microsoft office suite and web-based applications.

EXPERIENCE

Account Manager- Center for Disease Detection **2011 to Present**
San Antonio, Texas

- Directly assists with providing department services to other areas of the office, employees and general public.
- Assists with special projects using independent decision-making and judgment.
- Maintains statistics and develops complex reports.
- Prepares requisitions and purchase orders, verifies invoices, price and software set up procedures.
- Maintains and updates personnel records such as schedules for training, software installations and troubleshooting.
- Respond to general and complex questions and address client concerns.
- Supervises, leads, trains internal support personnel.
- Main customer focal for product training, troubleshooting and respond to both general and complex questions. Provide client education and training on several diverse service platforms.
- Develops office administration procedures to improve workflow. Orders and maintains supplies for clients. Performs general administrative tasks such as copying, answering telephones, updating and maintaining files.
- Active team member in both domestic and international marketing campaigns. Responsible for sustainment of current customer base and expansion of market share efforts.
- Increase base profitability seeking new sources of revenue from existing clients with new product offerings.
- Monitor, evaluate, and report client satisfaction. Create and implement action plans to address customer concerns and recommend appropriate process improvements.
- Act as liaison between laboratory managers and clientele.

Mobility Consultant - The Scooter Store

2003 to 2010

New Braunfels, Texas

- Exceeded stated sales goals, generating approximately one million in sales annually.
- Mastered product knowledge and delivered effective sales presentations.
- Acted as quality assurance representative on account compliance.
- Delegated customer accounts to appropriate departments based on government regulations.
- Mentored junior consultants.

Quality Assurance Representative - Billing Concepts

2000 to 2003

San Antonio, Texas

- Monitored customer service representatives for accuracy and provided feedback to improve skills.
- Reported grades of calls that were monitored to upper level management.
- Resolved disputes on escalated calls; granted or denied adjustments to invoices.

Addendum 1
Questions and Answers

ADDENDUM 1 QUESTIONS and ANSWERS

Date: February 9, 2020
 To: All Bidders
 From: Keith Roland & Jennifer Crouse, Buyers
 Department of Health and Human Services
 RE: Addendum for STD Testing Request for Proposals

Questions and Answers

Following are the questions submitted and answers provided for the above mentioned Request for Qualifications. The questions and answers are to be considered as part of the Request for Qualifications. It is the Bidder's responsibility to check the project information page for all addenda or amendments.

<u>Question Number</u>	<u>Question</u>	<u>State Response</u>
1.	[Redacted] is a sister agency to DHHS and as such does not require and RFP.	Bidders who are interested in providing STD Testing services to DHHS should submit a response to the RFP.
2.	We got this RFP for DHHS STD testing. Is your program going out for bid?	Yes, DHHS is soliciting bids for STD Testing services.
3.	Is RFP 6212-Z1 focused on vendors(bidders) who can perform the STD testing at the bidder's laboratory, ie. Quest, Lab Corp, ARUP, etc., or is the Nebraska PHL interested in performing the laboratory testing at one of their facilities?	DHHS is focused on bidders who can perform STD testing at the bidder's laboratory.
4.	Is it possible to get a copy of the current contract and utilization report per site?	See Addenda 2 and 3 for copies of the current contract and Amendment 1. Utilization data per site is not available.

5.	p. 3 item H: Submission of Proposals, is the signatory representing the vendor expected to sign/initial all boxes in the RFP?	The bidder should initial all the boxes within the RFP, and if necessary, provide notes or comments. The individual who signs the proposal on the Request for Proposal for Contractual Services Form can, but does not need to be, the same individual who initials the boxes within the RFP.
6.	For those items without a comment box, for example p. 19 item F Prices, can the vendor also provide notes and comments?	Items without a comment box cannot be negotiated.
7.	p. 6 item S: References and Credit Checks. Do the reference checks apply to those references submitted by the vendor to the RFP or is it the expectation that the State can contact all the vendors clients? If the later, how will the state identify all the vendors client base?	DHHS may contact the references provided by the bidder, clients discovered through its own research, or both.
8.	p. 28 item #4: ELR – Electronic Lab Reporting. Is the Nebraska DHHS's willing to work with the Vendor's ELR? Does Nebraska DHHS have its own ELR system? If so, what is the system?	DHHS will work with the Contractor to format the Contractor's messages so they can flow into NEDSS/NBS without error. DHHS receives ELR via Rhapsody to process the ELR and then DHHS uses NEDSS/NBS.
9.	Please clarify how turnaround time is determined and what are the expectations?	Turnaround time is determined by 173 NAC 1. https://www.nebraska.gov/rules-and-regs/regsearch/Rules/Health_and_Human_Services_System/Title-173/Chapter-01.pdf
10.	How are specimens currently delivered to the testing site today from the 89 STD testing sites across Nebraska?	Specimens are delivered via mail to the Contractor.
11.	The RFP states "all proposals or responses received regarding this solicitation will be posted to the State Purchasing bureau public website." Will the State be posting all submitted proposals or only the awarded proposal?	All proposals will be posted on State Purchasing Bureau's public website.

12.	At what time in the RFP process will vendor proposals be posted on the public website?	Proposals will be posted to State Purchasing Bureau's public website after an Intent to Award has been issued.
13.	Please clarify Attachment 2, DHHS HIPAA Business Associate Agreement Provisions Services Contracts, and how it is applicable to Reference Laboratories. Reference Laboratories are covered entities under HIPAA and does not become a business associate (as that term is defined in the HIPAA Privacy Rule) of another covered health care provider, such as a hospital or physician, by providing laboratory services to that covered health care provider.	Attachment 2 – HIPAA Business Associate Agreement Provisions is hereby removed from the RFP.
14.	Solicitation Section V. B. Page Number 27 Question – Are any STD testing sites operated by the Nebraska Department of Health and Human Services or are all independent agencies?	All STD testing sites are independent entities and are not operated by DHHS.
15.	Solicitation Section V. B. Page Number 27 Question – Are there any requirements where the costs associated with lab interfaces with a sites Electronic Health Record System should be figured into our responses to this RFP?	Prices provided on the Cost Proposal must be inclusive of all fees and expenses.
16.	Solicitation Section V. C. 2. Page Number 27 Question – It states that the Syphilis test performed must use the traditional algorithm starting with the Rapid Plasma Regain (RPR) followed by confirmation using Treponema pallidum-specific antibody tests. However, you are requesting pricing on a Syphilis IgG EIA screen. Does this mean that you would also approve contractors use of the CDC approved reverse-sequence algorithm, Syphilis IgG EIA screen followed by the RPR and if necessary a TP-PA?	DHHS would not approve using the reverse algorithm. Syphilis testing must be performed using the CDC approved traditional algorithm which provides a quicker understanding of the disease activity. Syphilis IgG EIA will only be used as requested.

17.	Solicitation Section V. C. 4. Page Number 28 Question – States that STD results must be done via Electronic Lab Reporting (ELR). Are you referring to just positive results going to Nebraska DHHS?	No. All results must be submitted via ELR.
18.	Solicitation Section V. C. 4. Page Number 28 Question – Many times, state STD programs require additional patient demographic information to be sent along with the test results. Information such as Patient Sex at Birth, Current Sex of Client, Number of Sexual Partners in the Last 90 Days, Reason for Exam, Presumptive Treatment, etc. Are any of these types of demographic information required of this RFP?	Section V.D of the RFP is amended to add: 24. Along with each test result, the Contractor must submit to DHHS additional patient demographic information, including but not limited to Current Sex of Client, Number of Sexual Partners in the Last Ninety (90) Days, Reason for Exam, Race and Ethnicity, Pregnancy Status, and Presumptive Treatment.
19.	Solicitation Section V. C. 4. Page Number 28 Question – Are results that go to the ordering clinic okay to be sent via normal channels approved by the ordering site?	There is not enough information provided in the question for DHHS to provide a response.
20.	Solicitation Section V. D. 2. Page Number 28 Question – Little is written regarding the initial training of each site on how to conduct sample collection, ordering tests, and shipping of samples. Do you require that this training be conducted in person?	DHHS does not require such training to be conducted in person.
21.	Solicitation Section V. D. 2. Page Number 28 Question – If training is to be conducted in person, would regional trainings where clinics located within a region of the state would come to a location central to that region meet your requirements?	Yes, this meets requirements of DHHS. See response to question #20.

22.	Solicitation Section V. D. 18. Page Number 28 Question – Do you have a report format you prefer for the monthly report accounting of tests performed under this contract?	The format is flexible, but would need to include, but may not be limited to: name of test, test order code, price per test, total tests used, total tests used per site, and site name.
23.	Will invoicing for all tests go to the Nebraska DHHS or should the Nebraska DHHS be the payer of last resort and billing go to the patients insurance provider if applicable?	All invoicing will be sent to DHHS.
24.	What percentage of testing will be billed to a patients insurance vs. Nebraska DHHS?	STD testing sites with a DHHS agreement, are not permitted to charge patients for chlamydia, gonorrhea, and syphilis testing when using a DHHS contracted lab. See response to question #23.
25.	Who is currently providing these testing services for the Nebraska STD program?	The Nebraska Public Health Laboratory is the current Contractor for STD Testing services.
26.	What is the current pricing for GC/Chlamydia Amplified Swab, GC/Chlamydia Amplified Urine, Syphilis IgG EIA Screen, RPR Confirmation, RPR Titer, RPR Quantitative, and GC Culture?	GC/Chlamydia Amplified Swab: \$14.50 GC/Chlamydia Amplified Urine: \$14.50 Syphilis IgG EIA Screen: \$7.20 RPR Confirmation: \$26.16 RPR Titer: \$7.20 RPR Quantitative: \$15.20 GC Culture: \$10.50 See also Addendum 2.
27.	Do you require GC/Chlamydia specimen testing from non-FDA approved rectal and pharyngeal sources?	DHHS does not currently approve self-collecting rectal and pharyngeal GC/CT specimen testing.

This addendum will become part of the RFP and should be acknowledged with the Request for Proposal response.

Addendum 2
Services Contract

ADDENDUM 2

88198 O4

SERVICES CONTRACT

BETWEEN

THE NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

UNIVERSITY OF NEBRASKA BOARD OF REGENTS - NEBRASKA PUBLIC HEALTH
LABORATORY

This services contract, including any addenda and attachments (collectively, "Contract") is entered into by and between the Nebraska Department of Health and Human Services, Division of Public Health Health Promotion, Infectious Disease, STD Prevention (hereinafter "DHHS"), and University of Nebraska Board of Regents - Nebraska Public Health Laboratory (hereinafter "Contractor").

DHHS CONTRACT MANAGER:

Tami Washam
PO Box 95026
301 Centennial Mall South
Lincoln, NE 68509-5026
402-471-6459
Tami.washam@nebraska.gov

PURPOSE: The purpose of this Contract is to provide and report laboratory testing related to the DHHS Sexually Transmitted Disease (STD) Prevention and Partner Services Program.

FUNDING: This Contract involves state and federal funds

HIPAA: This Contract involves the sharing of or access to Protected Health Information and includes a Business Associate Agreement for compliance with the Health Insurance Portability and Accountability Act (HIPAA).

1. DURATION

- 1.1. TERM. This Contract is in effect from September 20, 2019 through June 30, 2021.
- 1.2. TERMINATION. This Contract may be terminated at any time upon mutual written consent, or by either party for any reason upon submission of written notice to the other party at least thirty (30) days prior to the effective date of termination. In the event of termination under this section, the Contractor shall be entitled to payment, determined on a pro rata basis, for products or services satisfactorily performed or provided. DHHS may also terminate the contract to the extent otherwise provided herein.

2. PAYMENT TERMS AND STRUCTURE

- 2.1. TOTAL PAYMENT. DHHS shall pay the Contractor a total amount not to exceed \$348,505 (three hundred, forty-eight thousand, five hundred and five dollars) for the services specified herein during the period September 20, 2019 to June 30, 2020.
 - 2.1.1. Of the amount specified in section 2.1, \$300,000 (three hundred thousand dollars) will be spent in accordance with Laws 2019, LB 294, Section 108.
 - 2.1.2. Of the amount specified in section 2.1, \$48,505 (forty-eight thousand, five hundred and five dollars) are from the FY 2018 block grant and must be spent by September 30, 2019.
 - 2.1.3. Funds for services conducted during the period July 1, 2020 to June 30, 2021 are to be mutually agreed upon at a later date in accordance with and subject to Laws 2019, LB 294, Section 108 or any applicable legislative appropriation.
- 2.2. PAYMENT STRUCTURE. Payment shall be structured as follows.

- 2.2.1. The Contractor shall bill DHHS on a monthly basis an interagency billing transaction (IBT) for reimbursement of costs incurred for STD tests done at a cost per test as set out in Attachment 1.

3. SCOPE OF WORK

- 3.1. THE CONTRACTOR shall do the following:

- 3.1.1. Provide medically related laboratory services at a per test cost as outlined in Attachment 1 and incorporated into this contract by reference.

- 3.1.1.1. Utilize only testing permitted and limited to:

- 3.1.1.1.1. Syphilis IgG EIA Screen;
- 3.1.1.1.2. RPR Confirmation FTA;
- 3.1.1.1.3. GC Culture;
- 3.1.1.1.4. RPR Screen;
- 3.1.1.1.5. RPR Quantitative; and
- 3.1.1.1.6. GC/Chlamydia Amplified (Swab and Urine).

No other testing is permitted without the written permission of the DHHS. All necessary test supplies and U.S. Mail shipping of specimens and test supplies shall be included in the total cost outlined in Attachment 1.

- 3.1.2. Perform reflex testing (automatic confirmatory testing) on specimens submitted for syphilis screening.

- 3.1.2.1. Reflex testing will only be performed according to the mutually agreed upon protocol and Centers for Disease Control (CDC) recommendations when indicated by a screening test or as requested by DHHS via email notification.

- 3.1.2.2. The number of approved reflex tests must be performed within the dollar limit set in this scope of services.

- 3.1.3. Perform laboratory analyses on all samples submitted for tests listed on Attachment 1 and to make available the necessary sample kits to medical providers.

- 3.1.4. Provide laboratory results of the testing performed to the medical services provider and DHHS.

- 3.1.5. Provide information on STD reportable diseases to DHHS as required by Title 173, Chapter 1 of the Nebraska Administrative Code. The Contractor agrees to provide information on STD reportable diseases to CDC as required by state regulations and guidelines.

- 3.1.6. Provide DHHS with a monthly accounting of tests performed under this contract.

- 3.1.7. Maintain and/or utilize laboratories fully accredited by the College of American Pathologists that meet all appropriate standards for laboratories performing medical laboratory testing. The Contractor agrees that all laboratory services will meet standards of certification under the federal Clinical Laboratory Improvement Act, all amendments thereto, and the regulations adopted hereunder.

- 3.1.8. Notify DHHS of any major laboratory changes or events within five (5) working days of discovery. Major laboratory changes or events include the loss or replacement of the laboratory director or any situation that affects the Contractor's ability to meet the provisions of this contract.

- 3.1.9. Notify DHHS within two (2) working days of discovery of any analytic results that indicate a problem with a sample; or sample collection; or processing; or any event or concern that would delay or affect the reporting of results.

- 3.1.10. Periodically, the Laboratory Director and requested staff will meet with DHHS.

- 3.1.11. At the request of DHHS, meet with various groups to discuss laboratory operations services or other related topics as appropriate. The meetings shall include the Contractor's Director of Clinical Laboratories or other appropriate personnel.

- 3.2. DHHS shall do the following:

- 3.2.1. Determine the release and disposition of information to the public as a result of testing under this contract.

4. ADDENDA

- A. DHHS General Terms – University of Nebraska Contracts
- B. University of Nebraska Statement of Self-Insurance – University of Nebraska Contracts
- C. DHHS HIPAA Business Associate Agreement Provisions – Services Contracts

5. ATTACHMENTS

- 1. Per test cost

6. NOTICES

Notices shall be in writing and shall be effective upon mailing. All deliverables and required reports under this Contract shall be sent to the DHHS Contract Manager. Written notices, such as notices of termination or notice of breach, shall be sent to the DHHS Contract Manager identified above, and to the following addresses:

FOR DHHS:

Contract Administrator
Nebraska Department of Health and Human Services
301 Centennial Mall South
Lincoln, NE 68509-5026

FOR CONTRACTOR:

William M. Lawlor
Assistant Vice Chancellor for Business &
Financial Services
University of Nebraska Medical Center
985070 Nebraska Medical Center
Omaha, NE 68198-5070

WLawlor@unmc.edu

DHHS may change the DHHS Contract Manager to be notified under this section via letter to the Contractor sent by U.S. Mail, postage prepaid, or via email.

IN WITNESS THEREOF, the parties have duly executed this Contract hereto, and that the individual signing below has authority to legally bind the party to this contract.

FOR DHHS:

DocuSigned by:

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Gary Anthone

GaryMD

Department of Health and Human Services
Division of Public Health

DATE: 9/27/2019 | 06:40:46 CDT

FOR CONTRACTOR:

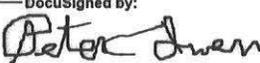
DocuSigned by:

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Steve D. Kuss, MBA
Administrator, Pathology and Microbiology
University of Nebraska Medical Center

DATE: 9/23/2019 | 11:48:16 CDT

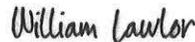
FOR CONTRACTOR:

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Peter C. Iwen, PhD (ABMM)
Director, Nebraska Public Health Lab
University of Nebraska Medical Center

DATE: 9/23/2019 | 10:16:05 CDT

FOR CONTRACTOR:

DocuSigned by:

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William Lawlor
Assistant Vice Chancellor for Business &
Financial Services
University of Nebraska Medical Center

DATE: 9/23/2019 | 14:40:13 CDT

**ATTACHMENT 1
NPHL/DHHS FEE SCHEDULE**

Nebraska Medicine	STD	FTA	\$ 26.16	FTA-ABS	Fluorescent Treponemal Antibody
Nebraska Medicine	STD	GCSCR	\$ 10.50	GC Screen	Gonorrhea Culture, Jembec Plate
Nebraska Medicine	STD	RPR	\$ 7.20	RPR	RPR Screen
Nebraska Medicine	STD	RPRQ	\$ 15.20	RPR Quantitative	RPR Quantitative
Nebraska Medicine	STD	STDSW	\$ 14.50	CL/GC DNA Detection	GenProbe CT/GC Amplified DNA Detection
Nebraska Medicine	STD	SYPIGG	\$ 7.20	Syphilis IGG	Syphilis IgG EIA Screen

ADDENDUM A**DHHS GENERAL TERMS – UNIVERSITY OF NEBRASKA CONTRACTS**

Throughout this addendum, all references to "University" shall refer to the same party termed as "Contractor" in the services contract.

1. **ACCESS TO RECORDS AND AUDIT RESPONSIBILITIES.** All University 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 DHHS. These records shall be maintained for a period of three (3) years; provided however, records that fall under the provisions of HIPAA and all associated rules and regulations shall be maintained for six (6) 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 this Contract, the University shall agree that it will be held liable for audit exceptions, and shall return to DHHS all payments made under this Contract for which an exception has been taken or which has been disallowed because of such an exception. The University agrees to correct immediately any material weakness or condition reported to DHHS in the course of an audit.
2. **AMENDMENT.** This Contract may be modified only by written amendment, executed by both parties. No alteration or variation of the terms and conditions of this Contract shall be valid unless made in writing and signed by the parties.
3. **ASSIGNMENT.** The University shall not assign or transfer any interest, rights, or duties under this Contract without prior written consent of DHHS. In the absence of such written consent, any assignment or attempt to assign shall constitute a breach of this Contract. DHHS shall provide reasonable notice to University should it assign this Agreement to another party.
4. **AVAILABILITY OF FUNDING.** Due to possible future reductions in State and/or Federal appropriations, DHHS cannot guarantee the continued availability of funding for this Contract. In the event funds to finance this Contract become unavailable either in full or in part due to such reductions in appropriations, DHHS may terminate the Contract or reduce the consideration upon thirty (30) days prior notice in writing to the University. DHHS shall be the final authority as to the availability of funds. The effective date of such Contract termination or reduction in consideration shall be specified in the notice as the date of service of said notice or the actual effective date of the funding reduction, whichever is later. Reductions shall not apply to payments made for services satisfactorily completed and all non-cancelable commitments incurred prior to the said effective date. In the event of a reduction in consideration, the University may terminate this Contract as of the effective date of the proposed reduction upon the provision of advance written notice to DHHS.
5. **CLEAN AIR ACT.** If this Contract involves federal funds and the total value exceeds \$150,000, the University shall ensure that it in compliance with all applicable standards, orders or regulations issued pursuant to the Clean Air Act, 42 U.S.C. §§ 7401 et seq., and the Federal Water Pollution Control Act as amended, 33 U.S.C. §§ 1251 et seq.
6. **CONFIDENTIALITY.** Any and all information gathered in the performance of this Contract, either independently or through DHHS, shall be held in the strictest confidence and shall be released to no one other than DHHS without the prior written authorization of DHHS, provided, however, that contrary contract provisions set forth in the contract shall be deemed to be authorized exceptions to this general confidentiality provision.
7. **CONFLICTS OF INTEREST.** In the performance of this Contract, the University agrees to avoid all conflicts of interest and all appearances of conflicts of interest; the University will notify DHHS of any such instances encountered in the course of its work that other arrangements can be made to complete

the work. The University further agrees to abide by University of Nebraska Board of Regents Bylaws 3.4.5 and 3.8 and Board of Regents Policy 3.2.8 on Conflict of Interest.

8. CORRECTIVE ACTION PLAN AND BREACH OF CONTRACT.

8.1. *Corrective Action Plan.* If the University fails to meet the Scope of Work as set forth in the Contract, DHHS may require the University to complete a Corrective Action Plan (hereinafter "CAP").

8.1.1. DHHS shall set a deadline for the CAP to be provided to DHHS, but shall provide University reasonable notice of said deadline. In its notice, DHHS shall identify each issue to be resolved.

8.1.2. The CAP will include, but is not limited to, a written response noting the steps being taken by the University to resolve each issue(s), including a date that the issue(s) will be resolved.

8.1.3. If the University fails to provide a CAP by the deadline set by DHHS, fails to provide DHHS with a CAP demonstrating the issues regarding performance will be remedied, or fails to meet the deadline(s) set in the CAP for resolution of the issue(s), DHHS may choose to consider such failure to be a breach of the Contract, or choose to exercise any other remedy available set forth in this Contract or under law.

8.2. *Breach of Contract.* Should either party breach this Contract, the non-breaching party may, at its discretion, exercised in good faith, suspend performance under this Contract immediately upon written notice to the breaching party. Should the non-breaching party exercise its right to suspend performance as set forth herein, the breaching party shall be afforded a reasonable opportunity, not to exceed 30 days, to cure or otherwise resolve the breach. If the breaching party does not cure the breach within the timeframe specified by the non-breaching party, the non-breaching party may terminate the Contract immediately. In the event DHHS suspends performance or terminates this Contract, DHHS shall pay the University only for such performance as has been properly completed prior to notice of suspension or termination.

8.2.1. In the event DHHS terminates this Contract, the University shall provide to DHHS all work in progress, work completed, and materials provided to it by DHHS in connection with this Contract immediately. This provision shall not preclude the pursuit of other remedies for breach of Contract allowed by law.

8.2.2. The waiver by either party of a breach of this Contract by the other party shall not operate or be construed as a waiver of any subsequent breach. No waiver shall be valid unless in writing and signed by the party.

9. DATA OWNERSHIP AND COPYRIGHT.

9.1. *Data.* All data collected as a result of this project shall be the property of DHHS.

9.1.1. If this Contract involves federal funds, the federal funding agency reserves the right to obtain, reproduce, publish, or otherwise use the data produced under this Contract, and to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes.

9.1.2. The University will have the right to submit a written request for release of data of relevance to academic publications or other research conducted by the University, and DHHS will make a written response to such request. The term "research" shall mean the investigation, analysis, or review of information, other than aggregate statistical information, which is used for purposes unconnected with this agreement.

9.1.3. When the services performed under this Contract are complete, or DHHS has made the information available to the public, the University will no longer be obligated to obtain DHHS authorization, pursuant to subsection 1 of this provision, for use of the data developed in conjunction with this Contract. Notwithstanding the foregoing, the University may not release any data or information that has been identified by DHHS as being, or that the University is otherwise aware is, subject to provisions governing disclosure under federal or state law, including, but not limited to HIPAA and Neb. Rev. Stat. § 84-712.05, unless the University has prior written authorization from DHHS. This provision shall survive termination of this Contract.

- 9.2. *Copyright.* The University may copyright any of the copyrightable material produced in conjunction with the performance required under this agreement. DHHS and the appropriate federal funding agency hereby reserve a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use the copyrightable material for State or Federal Government purposes.
- 9.3. *Patent Rights.* As consistent with 37 C.F.R. § 401.14 and the clause contained therein, DHHS agrees that all inventions or discoveries of any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, produced by the University based upon said data shall be the property of the University.
10. DEBARMENT, SUSPENSION OR DECLARED INELIGIBLE. The University certifies that neither it nor its principals are debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any state or federal department or agency.
11. DOCUMENTS INCORPORATED BY REFERENCE. All references in this Contract to laws, rules, regulations, guidelines, directives, addenda and attachments that set forth standards and procedures to be followed by the University in discharging its obligations under this Contract shall be deemed incorporated by reference and made a part of this Contract with the same force and effect as if set forth in full text herein.
12. DRUG-FREE WORKPLACE. University certifies that it maintains a drug-free workplace environment to ensure worker safety and workplace integrity. University shall provide a copy of its drug-free workplace policy at any time upon request by DHHS.
13. EARLY TERMINATION.
- 13.1. DHHS may terminate the Contract immediately for the following reasons:
- 13.1.1. If directed to do so by statute;
- 13.1.2. Fraud, misappropriation, embezzlement, malfeasance, misfeasance, or illegal conduct pertaining to performance under the Contract by the University, its employees or officers;
- 13.1.3. University intentionally discloses Confidential Information; or
- 13.1.4. University has or announces it will discontinue support of the deliverable.
- 13.2. DHHS and the University may also terminate this Contract in accord with any other provision of this Contract, as expressly stated in that provision.
- 13.3. In the event either party terminates this Contract for any reason, the University shall provide to DHHS all work in progress, work completed, and materials provided to it by DHHS in connection with this Contract immediately.
14. FEDERAL FINANCIAL ASSISTANCE. If this Contract involves federal funds, the University will comply with all applicable provisions of 45 C.F.R. §§ 87.1-87.2. The University shall not use direct federal financial assistance to engage in inherently religious activities, such as worship, religious instruction, and/or proselytization.
15. FEDERAL FUNDING AGENCY APPROVAL. If this Contract involves federal funds, and requires pre-approval by the federal funding agency, said approval is a condition precedent to this Contract and absent said approval, the Contract shall be considered void and unenforceable.
16. FORCE MAJEURE. Neither party shall be liable for any costs or damages resulting from its inability to perform any of its obligations under this Contract due to a natural disaster, or other unforeseeable 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 this Contract. The party so affected shall immediately give notice to the other party of the Force Majeure Event. Upon such notice, all obligations of the affected party under this Contract that are reasonably related to the Force Majeure Event shall be suspended, and the affected party shall do everything reasonably necessary to resume performance as soon as possible. Labor disputes with the impacted party's own employees will not be considered a "Force Majeure Event" and will not suspend performance requirements under this Contract.

17. FUNDING AVAILABILITY. DHHS may terminate the Contract, in whole or in part, in the event funding is no longer available. Should funds not be appropriated, DHHS may terminate the Contract with respect to those payments for the fiscal years for which such funds are not appropriated. DHHS shall give the University written notice thirty (30) days prior to the effective date of any termination. The University shall be entitled to receive just and equitable compensation for any authorized work that has been satisfactorily performed or provided as of the termination date and for all non-cancelable commitments incurred prior to said termination date. In no event shall the University be paid for a loss of anticipated profit.
18. GOVERNING LAW.
- 18.1. The Contract shall be governed in all respects by the laws and statutes of the State of Nebraska. Any legal proceedings against DHHS or the State of Nebraska regarding this Contract shall be brought in Nebraska administrative or judicial forums as defined by Nebraska State law.
- 18.2. The parties shall comply with all applicable federal, state, and local law in the performance of this Contract. Legal obligations required hereunder include, but are not limited to: all applicable confidentiality and privacy statutes and regulations, current and as amended, including but not limited to HIPAA.
19. HOLD HARMLESS. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
20. INDEPENDENT AGENCIES. The University and DHHS are separate State agencies within the State of Nebraska. As an independent agency, the University shall employ and direct such personnel as it requires to perform its obligations under this Contract, exercise full authority over its personnel, and comply with all workers' compensation, employer's liability and other federal, state, county, and municipal laws, ordinances, rules and regulations required of an employer providing services as contemplated by this Contract.
21. INTEGRATION. This written Contract, along with Addenda and attachments, represents the entire Contract between the parties, and any prior or contemporaneous representations, promises, or statements by the parties, which are not incorporated herein, shall not serve to vary or contradict the terms set forth in this Contract.
22. INVOICES AND PAYMENT.
- 22.1. *Invoices*. Invoices for payments submitted by the University shall contain sufficient detail to support payment. Any terms and conditions included in the University's invoice shall be deemed to be solely for the convenience of the parties. No payment shall be made for any deliverable or cost unless specifically authorized in the terms of the Contract.
- 22.2. *Prompt Payment*. As applicable, payment shall be made in compliance with the Nebraska Prompt Payment Act, Neb. Rev. Stat. §§ 81-2401 et seq. Unless otherwise provided herein, payment shall be made by electronic means.
- 22.3. *Interagency Billing Transaction*. Payment may be made by Interagency Billing Transaction.
23. LOBBYING.
- 23.1. As set forth in 45 CFR § 93 et seq.:
- 23.1.1. No federal appropriated funds shall be paid, by or on behalf of the University, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Contract or (a) the awarding of any federal agreement; (b) the making of any Federal grant; (c) the entering into of any cooperative agreement; and (d) the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement.
- 23.1.2. If any funds other than federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Contract, the University shall complete and submit

- Federal Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
- 23.2. If this Contract involves federal funds, and if the below is consistent with applicable law and the terms and conditions of the applicable federal funding source of the contract:
- 23.2.1. No funds under this Contract shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation of the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government itself.
- 23.2.2. No funds under this Contract shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than normal and recognized executive legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.
- 23.2.3. The prohibitions in the two sections immediately above shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale of marketing, including but not limited to the advocacy or promotion of gun control.
24. NEBRASKA TECHNOLOGY ACCESS STANDARDS. The University agrees to ensure compliance with current Nebraska Access Technology Standards. The intent is to ensure that all newly procured information technology equipment; software and services can accommodate individuals with disabilities. Information technology products, systems, and services including data, voice, and video technologies, as well as information dissemination methods will comply with the Nebraska Technology Access Standards. A complete listing of these standards can be found at website <http://www.nitc.nebraska.gov/standards/>.
25. NEW EMPLOYEE WORK ELIGIBILITY STATUS. The University shall 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.
- 25.1. If the University subcontracts to an individual or sole proprietorship, the following applies:
- 25.1.1. The University or the subcontractor must complete the United States Citizenship Attestation Form, available on the Department of Administrative Services website at www.das.state.ne.us.
- 25.1.2. If an individual indicates on such attestation form that he or she is a qualified alien, the University and subcontractor agree to provide the U.S. Citizenship and Immigration Services documentation required to verify the subcontractor's lawful presence in the United States using the Systematic Alien Verification for Entitlements (SAVE) Program.
- 25.1.3. The University and subcontractor understands and agrees that lawful presence in the United States is required and the University and the subcontractor may be disqualified or the contract terminated if such lawful presence cannot be verified as required by Neb. Rev. Stat. § 4-108.
26. NON-DISCRIMINATION. The parties agree to comply fully with Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq.; the Rehabilitation Act of 1973, 29 U.S.C. §§ 794 et seq.; the Americans

With Disabilities Act of 1990, 42 U.S.C. §§ 12101 et seq.; the Age Discrimination in Employment Act, 29 U.S.C. §§ 621 et seq.; the Age Discrimination Act of 1975, 42 U.S.C. §§ 6101 et seq.; and the Nebraska Fair Employment Practice Act, Neb. Rev. Stat. §§ 48-1101 to 48-1125. The parties shall not discriminate against any employee who is employed in the performance of this Contract, or against any applicant for such employment, because of age, color, national origin, ancestry, race, religion, creed, disability, sex or marital status. This provision shall include, but not be limited to the following: employment, promotion, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training including apprenticeship. The parties agree that no qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity of the party. The University further agrees to insert similar provisions in all sub-contracts for services allowed under this Contract under any program or activity.

27. ORDER OF PREFERENCE.

27.1. 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:

1. Amendments to the Contract with the most recently dated amendment having the highest priority;
2. The Contract, excluding attachments, with the following Addenda in order of preference: DHHS General Terms – University of Nebraska Contracts; DHHS HIPAA Business Associate Agreement (if included); University of Nebraska Statement of Self-Insurance; any other attachments.

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

28. PUBLIC COUNSEL. In the event University provides health and human services to individuals on behalf of DHHS under the terms of this Contract, University 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, Neb. Rev. Stat. §§ 73-401 et seq.

29. SEVERABILITY. If any term or condition of this 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 this Contract did not contain the particular provision held to be invalid.

30. SUBCONTRACTORS. The University shall not subcontract any portion of this Contract without notice to DHHS. DHHS reserves the right to reject a subcontractor; such rejection shall not be arbitrary or capricious. . If the University subcontracts a portion of the work involved in this Contract and has obtained approval for such subcontracting, it shall ensure that the subcontractor complies with all workers' compensation, employer's liability and other federal, state, county, and municipal laws, ordinances, rules and regulations required of an employer providing services as contemplated by this Contract.

31. SURVIVAL. All provisions hereof that by their nature are to be performed or complied with following the expiration or termination of this Contract, including but not limited to the obligations in the Confidentiality section, above, shall survive the expiration or termination of this Contract.

32. TAXPAYER TRANSPARENCY ACT. Pursuant to Neb. Rev. Stat. § 84-602.04, all state contracts including, at least in part, state funds, and that are in effect as of January 1, 2014, shall be posted on a public website. All non-proprietary and non-confidential information as defined by law will be posted for public viewing.

ADDENDUM B

UNIVERSITY OF NEBRASKA STATEMENT OF SELF-INSURANCE

Throughout this addendum, all references to "University" shall refer to the same party termed as "Contractor" in the attached contract.

As of the date of the execution of this contract, the University is self-insured pursuant to the University of Nebraska Self-Insurance Trust Program ("Program"). Subject to the terms, conditions, exclusions, and limits of the Statement of Self-Insurance Coverage contained in the Program, the Program shall pay on behalf of the University during any of its fiscal years all sums for which the University shall become legally obligated to pay as damages for liability occurrences, up to the limits of \$1,000,000 per liability occurrence and \$3,000,000 in the aggregate of liability occurrences in any fiscal year. The University shall provide DHHS with a copy of the University of Nebraska Self-Insurance Trust Fund Program Statement evidencing such coverage, upon request.

Personal property insurance shall be the responsibility of the owner of the property regardless of the location of the loss.

ADDENDUM C**DHHS HIPAA BUSINESS ASSOCIATE AGREEMENT PROVISIONS
SERVICES CONTRACTS**

1. **BUSINESS ASSOCIATE.** "Business Associate" shall generally have the same meaning as the term "business associate" at 45 CFR § 160.103, and in reference to the party in this contract, shall mean Contractor.
2. **COVERED ENTITY.** "Covered Entity" shall generally have the same meaning as the term "covered entity" at 45 CFR § 160.103, and in reference to the party to this contract, shall mean DHHS.
3. **HIPAA RULES.** "HIPAA Rules" shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.
4. **OTHER TERMS.** The following terms shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required by Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.
5. **THE CONTRACTOR** shall do the following:
 - 5.1. Not use or disclose Protected Health Information other than as permitted or required by this contract or as required by law. Contractor may use Protected Health Information for the purposes of managing its internal business processes relating to its functions and performance under this contract. Use or disclosure must be consistent with DHHS' minimum necessary policies and procedures.
 - 5.2. Implement and maintain appropriate administrative, physical, and technical safeguards to prevent access to and the unauthorized use and disclosure of Protected Health Information. Comply with Subpart C of 45 CFR Part 164 with respect to electronic Protected Health Information, to prevent use or disclosure of Protected Health Information other than as provided for in this contract and assess potential risks and vulnerabilities to the individual health data in its care and custody and develop, implement, and maintain reasonable security measures.
 - 5.3. To the extent Contractor is to carry out one or more of the DHHS' obligations under Subpart E of 45 CFR Part 164, comply with the requirements of Subpart E that apply to DHHS in the performance of such obligations. Contractor may not use or disclosure Protected Health Information in a manner that would violate Subpart E of 45 CFR Part 164 if done by DHHS.
 - 5.4. In accordance with 45 CFR §§ 164.502(E)(1)(ii) and 164.308(b)(2), if applicable, ensure that any agents and subcontractors that create, receive, maintain, or transmit Protected Health Information received from DHHS, or created by or received from the Contractor on behalf of DHHS, agree in writing to the same restrictions, conditions, and requirements relating to the confidentiality, care, custody, and minimum use of Protected Health Information that apply to the Contractor with respect to such information.
 - 5.5. Obtain reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and the person notifies the Contractor of any instances of which it is aware that the confidentiality of the information has been breached.
 - 5.6. Within fifteen (15) days:
 - 5.6.1. Make available Protected Health Information to DHHS as necessary to satisfy DHHS' obligations under 45 CFR § 164.524;
 - 5.6.2. Make any amendment(s) to Protected Health Information as directed or agreed to by DHHS pursuant to 45 CFR § 164.526, or take other measures as necessary to satisfy DHHS' obligations under 45 CFR § 164.526;
 - 5.6.3. Maintain and make available the information required to provide an accounting of disclosures to DHHS as necessary to satisfy DHHS' obligations under 45 CFR § 164.528.
 - 5.7. Make its internal practices, books, and records relating to the use and disclosure of Protected

Health Information received from, or created or received by the Contractor on behalf of the DHHS available to the Secretary for purposes of determining compliance with the HIPAA rules. Contractor shall provide DHHS with copies of the information it has made available to the Secretary.

- 5.8. Report to DHHS within fifteen (15) days, any unauthorized use or disclosure of Protected Health Information made in violation of this contract, or the HIPAA rules, including any security incident that may put electronic Protected Health Information at risk. Contractor shall, as instructed by DHHS, take immediate steps to mitigate any harmful effect of such unauthorized disclosure of Protected Health Information pursuant to the conditions of this contract through the preparation and completion of a written Corrective Action Plan subject to the review and approval by DHHS. The Contractor shall report any breach to the individuals affected and to the Secretary as required by the HIPAA rules.
6. TERMINATION.
 - 6.1. DHHS may immediately terminate this contract and any and all associated contracts if DHHS determines that the Contractor has violated a material term of this contract.
 - 6.2. Within thirty (30) days of expiration or termination of this contract, or as agreed, unless Contractor requests and DHHS authorizes a longer period of time, Contractor shall return or at the written direction of DHHS destroy all Protected Health Information received from DHHS (or created or received by Contractor on behalf of DHHS) that Contractor still maintains in any form and retain no copies of such Protected Health Information. Contractor shall provide a written certification to DHHS that all such Protected Health Information has been returned or destroyed (if so instructed), whichever is deemed appropriate. If such return or destruction is determined by the DHHS be infeasible, Contractor shall use such Protected Health Information only for purposes that makes such return or destruction infeasible and the provisions of this contract shall survive with respect to such Protected Health Information.
 - 6.3. The obligations of the Contractor under the Termination Section shall survive the termination of this contract.

Addendum 3
Services Contract

ADDENDUM 3

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SERVICES CONTRACT

BETWEEN THE

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

UNIVERSITY OF NEBRASKA BOARD OF REGENTS - NEBRASKA PUBLIC HEALTH LABORATORY

AMENDMENT ONE

This contract is entered into by and between the Nebraska Department of Health and Human Services, Division of Public Health Health Promotion, Infectious Disease, STD Prevention (hereinafter "DHHS"), and UNIVERSITY OF NEBRASKA BOARD OF REGENTS - NEBRASKA PUBLIC HEALTH LABORATORY (hereinafter "Contractor").

The contract between the parties dated September 27, 2019 is hereby amended as follows:

Section 2.1. is amended to read:

TOTAL PAYMENT. DHHS shall pay the Contractor a total amount not to exceed \$428,505 (four hundred twenty-eight thousand, five hundred and five dollars) for the services specified herein during the period September 20, 2019 to June 30, 2020.

Section 2.1.1. is amended to read:

Of the amount specified in section 2.1., \$380,000 (three hundred eighty thousand dollars) will be spent in accordance with Laws 2019, LB 294, Section 108.

All other terms and conditions remain in full force and effect.

IN WITNESS THEREOF, the parties have duly executed this contract hereto, and each party acknowledges the receipt of a duly executed copy of this contract with original signatures.

FOR DHHS:

DocuSigned by:

Gary Anthone, M.D.

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Signature

Gary Anthone, M.D.

CMO

Department of Health and Human Services
Division of Public Health

FOR CONTRACTOR:

DocuSigned by:

William Lawlor

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Signature

William Lawlor

For the Board of Regents, University of Nebraska, si

UNIVERSITY OF NEBRASKA BOARD OF
REGENTS - NEBRASKA PUBLIC HEALTH
LABORATORY

DATE: 12/23/2019 | 18:03:22 CST

DocuSigned by:
Steven Kuss

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Signature

Steven Kuss

Administrative Director, Pathology & Microbiology

DATE: 12/23/2019 | 16:12:10 CST

DocuSigned by:
Peter C. Iwen 

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Signature

Peter C. Iwen, Ph.D.

Director of NPHL

DATE: 12/6/2019 | 10:54:19 CST

DATE: 12/6/2019 | 10:37:32 CST