



DDC

DNA Diagnostics Center

Genetic Testing Services
CRFQ 0511 CSE1500000002

ORIGINAL

01/20/15 11:27:45
West Virginia Purchasing Division

Submitted to:

State of West Virginia
Department of Administration
Purchasing Division

Due: January 21, 2015





Purchasing Division
 2019 Washington Street East
 Post Office Box 50130
 Charleston, WV 25305-0130

State of West Virginia
 Request for Quotation
 33 - Service - Misc

Proc Folder: 25653

Doc Description: Addendum 2: Genetic testing open end contract

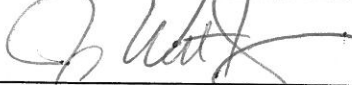
Proc Type: Central Master Agreement

| Date Issued | Solicitation Closes | Solicitation No | Version |
|-------------|------------------------|-------------------------|---------|
| 2015-01-08 | 2015-01-21 13:30:00 | CRFQ 0511 CSE1500000002 | 3 |

BID RECEIVING LOCATION
 BID CLERK
 DEPARTMENT OF ADMINISTRATION
 PURCHASING DIVISION
 2019 WASHINGTON ST E
 CHARLESTON WV 25305
 US

VENDOR
 Vendor Name, Address and Telephone Number:
 DNA Diagnostics Center, Inc.
 One DDC Way
 Fairfield, OH 45014
 Phone: (800) 310-9868

FOR INFORMATION CONTACT THE BUYER
 Robert Kilpatrick
 (304) 558-0067
 robert.p.kilpatrick@wv.gov

Signature X  FEIN # 26-4435457 DATE 1/16/2015

All offers subject to all terms and conditions contained in this solicitation

| INVOICE TO | | SHIP TO | |
|--|--|---|--|
| FISCAL UNIT MANAGER 304-356-4715 HEALTH AND HUMAN RESOURCES CHILD SUPPORT ENFORCEMENT 350 CAPITOL ST, RM 147 CHARLESTON WV25301-3703 US | | FISCAL UNIT MANAGER 304-356-4715 HEALTH AND HUMAN RESOURCES CHILD SUPPORT ENFORCEMENT 350 CAPITOL ST, RM 147 CHARLESTON WV 25301-3703 US | |

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Total Price |
|------|---|------------|------------|------------|--------------|
| 1 | Buccal Swab Collection and Analysis by Vendor | 3310.00000 | EA | \$33.00 | \$109,230.00 |

| Comm Code | Manufacturer | Specification | Model # |
|-----------|--------------|---------------|---------|
| 85131709 | | | |

Extended Description :

Buccal Swab Collection and Analysis by Vendor

| INVOICE TO | | SHIP TO | |
|--|--|---|--|
| FISCAL UNIT MANAGER 304-356-4715 HEALTH AND HUMAN RESOURCES CHILD SUPPORT ENFORCEMENT 350 CAPITOL ST, RM 147 CHARLESTON WV25301-3703 US | | FISCAL UNIT MANAGER 304-356-4715 HEALTH AND HUMAN RESOURCES CHILD SUPPORT ENFORCEMENT 350 CAPITOL ST, RM 147 CHARLESTON WV 25301-3703 US | |

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Total Price |
|------|---|------------|------------|------------|-------------|
| 2 | Buccal Swab collection by BCSE/Analysis by Vendor | 2654.00000 | EA | \$23.00 | \$61,042.00 |

| Comm Code | Manufacturer | Specification | Model # |
|-----------|--------------|---------------|---------|
| 85131709 | | | |

Extended Description :

Buccal Swab Collection by BCSE/Analysis by Vendor

| INVOICE TO | | SHIP TO | |
|--|--|---|--|
| FISCAL UNIT MANAGER 304-356-4715 HEALTH AND HUMAN RESOURCES CHILD SUPPORT ENFORCEMENT 350 CAPITOL ST, RM 147 CHARLESTON WV25301-3703 US | | FISCAL UNIT MANAGER 304-356-4715 HEALTH AND HUMAN RESOURCES CHILD SUPPORT ENFORCEMENT 350 CAPITOL ST, RM 147 CHARLESTON WV 25301-3703 US | |

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Total Price |
|------|---|----------|------------|------------|-------------|
| 3 | Collection/Analysis for Special Circumstances | 10.00000 | EA | \$33.00 | \$330.00 |

| Comm Code | Manufacturer | Specification | Model # |
|-----------|--------------|---------------|---------|
| 85131709 | | | |

Extended Description :

Special Circumstances

e.g. Deceased Individuals, Collection/Analysis of Blood or Other Tissue Samples

THE WV PURCHASING DIVISION IS SOLICITING BIDS ON BEHALF OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, BUREAU FOR CHILD SUPPORT ENFORCEMENT TO ESTABLISH A CONTRACT FOR STATEWIDE GENETIC TESTING TO DETERMINE AND ESTABLISH PATERNITY THROUGH THE COLLECTION OF TISSUE SAMPLES, TESTING AND ANALYSIS OF SUCH SAMPLES BY ACCEPTED SCIENTIFIC TECHNIQUES, AND THE REPORTING OF SAID RESULTS TO THE AGENCY, AS WELL AS PROVIDING EXPERT TESTIMONY WHEN NECESSARY IN JUDICIAL PROCEEDINGS.

| | | | |
|----------------------|--------------------------------|---|------------------------------|
| CSE1500000002 | Document Phase Final | Document Description Addendum 2: Genetic testing op en end contract | Page 4 of 4 |
|----------------------|--------------------------------|---|------------------------------|

ADDITIONAL TERMS AND CONDITIONS

See attached document(s) for additional Terms and Conditions

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: CSE1500000002

Instructions: Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

Acknowledgment: I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

Addendum Numbers Received:

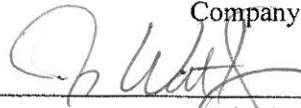
(Check the box next to each addendum received)

- | | |
|--|--|
| <input checked="" type="checkbox"/> Addendum No. 1 | <input type="checkbox"/> Addendum No. 6 |
| <input checked="" type="checkbox"/> Addendum No. 2 | <input type="checkbox"/> Addendum No. 7 |
| <input type="checkbox"/> Addendum No. 3 | <input type="checkbox"/> Addendum No. 8 |
| <input type="checkbox"/> Addendum No. 4 | <input type="checkbox"/> Addendum No. 9 |
| <input type="checkbox"/> Addendum No. 5 | <input type="checkbox"/> Addendum No. 10 |

I understand that failure to confirm the receipt of addenda may be cause for rejection of this bid. I further understand that any verbal representation made or assumed to be made during any oral discussion held between Vendor's representatives and any state personnel is not binding. Only the information issued in writing and added to the specifications by an official addendum is binding.

DNA Diagnostics Center, Inc.

Company



Authorized Signature

January 16, 2015

Date

NOTE: This addendum acknowledgment should be submitted with the bid to expedite document processing.

Revised 6/8/2012

STATE OF WEST VIRGINIA
Purchasing Division

PURCHASING AFFIDAVIT

MANDATE: Under W. Va. Code §5A-3-10a, no contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and: (1) the debt owed is an amount greater than one thousand dollars in the aggregate; or (2) the debtor is in employer default.

EXCEPTION: The prohibition listed above does not apply where a vendor has contested any tax administered pursuant to chapter eleven of the W. Va. Code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

DEFINITIONS:

"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Employer default" means having an outstanding balance or liability to the old fund or to the uninsured employers' fund or being in policy default, as defined in W. Va. Code § 23-2c-2, failure to maintain mandatory workers' compensation coverage, or failure to fully meet its obligations as a workers' compensation self-insured employer. An employer is not in employer default if it has entered into a repayment agreement with the Insurance Commissioner and remains in compliance with the obligations under the repayment agreement.

"Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceeds five percent of the total contract amount.

AFFIRMATION: By signing this form, the vendor's authorized signer affirms and acknowledges under penalty of law for false swearing (W. Va. Code §61-5-3) that neither vendor nor any related party owe a debt as defined above and that neither vendor nor any related party are in employer default as defined above, unless the debt or employer default is permitted under the exception above.

WITNESS THE FOLLOWING SIGNATURE:

Vendor's Name: DNA Diagnostics Center, Inc.

Authorized Signature: [Signature] Date: January 16, 2015

State of Ohio

County of Butler, to-wit:

Taken, subscribed, and sworn to before me this 16th day of January, 2015.

My Commission expires December 21, 2016.

AFFIX SEAL HERE

NOTARY PUBLIC [Signature]

Purchasing Affidavit (Revised 07/01/2012)



TERESA NORTHROP, Notary Public
In and for the State of Ohio
My Commission Expires Dec. 21, 2016

VENDOR PREFERENCE CERTIFICATE

Certification and application* is hereby made for Preference in accordance with West Virginia Code, §5A-3-37. (Does not apply to construction contracts). West Virginia Code, §5A-3-37, provides an opportunity for qualifying vendors to request (at the time of bid) preference for their residency status. Such preference is an evaluation method only and will be applied only to the cost bid in accordance with the West Virginia Code. This certificate for application is to be used to request such preference. The Purchasing Division will make the determination of the Vendor Preference, if applicable.

1. Application is made for 2.5% vendor preference for the reason checked:

- Bidder is an individual resident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this certification; or, Bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or 80% of the ownership interest of Bidder is held by another individual, partnership, association or corporation resident vendor who has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or, Bidder is a nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; or,

2. Application is made for 2.5% vendor preference for the reason checked:

- Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; or,

3. Application is made for 2.5% vendor preference for the reason checked:

- Bidder is a nonresident vendor employing a minimum of one hundred state residents or is a nonresident vendor with an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia employing a minimum of one hundred state residents who certifies that, during the life of the contract, on average at least 75% of the employees or Bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; or,

4. Application is made for 5% vendor preference for the reason checked:

- Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; or,

5. Application is made for 3.5% vendor preference who is a veteran for the reason checked:

- Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; or,

6. Application is made for 3.5% vendor preference who is a veteran for the reason checked:

- Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.

7. Application is made for preference as a non-resident small, women- and minority-owned business, in accordance with West Virginia Code §5A-3-59 and West Virginia Code of State Rules.

- Bidder has been or expects to be approved prior to contract award by the Purchasing Division as a certified small, women- and minority-owned business.

Bidder understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the requirements for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty against such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency or deducted from any unpaid balance on the contract or purchase order.

By submission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and authorizes the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid the required business taxes, provided that such information does not contain the amounts of taxes paid nor any other information deemed by the Tax Commissioner to be confidential.

Under penalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true and accurate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate changes during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.

Bidder: DNA Diagnostics Center, Inc. Signed: [Signature]

Date: January 16, 2015 Title: Executive Vice President, COO

11. MISCELLANEOUS:

- a. **Contract Manager:** During its performance of this Contract, Vendor must designate and maintain a primary contract manager responsible for overseeing Vendor's responsibilities under this Contract. The Contract manager must be available during normal business hours to address any customer service or other issues related to this Contract. Vendor should list its Contract manager and his or her contact information below.

Contract Manager: Kathy Leis, Vice President, Operations

Vendor's Address: One DDC Way

Fairfield, OH 45014

Telephone Number: (513) 881-4005

Fax Number: (513) 881-4004

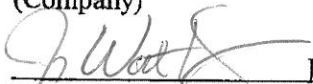
Email Address: kleis@dnacenter.com

CERTIFICATION AND SIGNATURE PAGE

By signing below, or submitting documentation through wvOASIS, I certify that I have reviewed this Solicitation in its entirety; understand the requirements, terms and conditions, and other information contained herein; that I am submitting this bid, offer or proposal for review and consideration; that I am authorized by the vendor to execute and submit this bid, offer, or proposal, or any documents related thereto on vendor's behalf; that I am authorized to bind the vendor in a contractual relationship; and that to the best of my knowledge, the vendor has properly registered with any State agency that may require registration.

DNA Diagnostics Center, Inc.

(Company)



Jerry Watkins, Executive VP, COO

(Authorized Signature) (Representative Name, Title)

(800) 310-9868; (513) 881-4004; January 16, 2015

(Phone Number) (Fax Number) (Date)

WV STATE GOVERNMENT

HIPAA BUSINESS ASSOCIATE ADDENDUM

This Health Insurance Portability and Accountability Act of 1996 (hereafter, HIPAA) Business Associate Addendum ("Addendum") is made a part of the Agreement ("Agreement") by and between the State of West Virginia ("Agency"), and Business Associate ("Associate"), and is effective as of the date of execution of the Addendum.

The Associate performs certain services on behalf of or for the Agency pursuant to the underlying Agreement that requires the exchange of information including protected health information protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the American Recovery and Reinvestment Act of 2009 (Pub. L. No. 111-5) (the "HITECH Act"), any associated regulations and the federal regulations published at 45 CFR parts 160 and 164 (sometimes collectively referred to as "HIPAA"). The Agency is a "Covered Entity" as that term is defined in HIPAA, and the parties to the underlying Agreement are entering into this Addendum to establish the responsibilities of both parties regarding HIPAA-covered information and to bring the underlying Agreement into compliance with HIPAA.

Whereas it is desirable, in order to further the continued efficient operations of Agency to disclose to its Associate certain information which may contain confidential individually identifiable health information (hereafter, Protected Health Information or PHI); and

Whereas, it is the desire of both parties that the confidentiality of the PHI disclosed hereunder be maintained and treated in accordance with all applicable laws relating to confidentiality, including the Privacy and Security Rules, the HITECH Act and its associated regulations, and the parties do agree to at all times treat the PHI and interpret this Addendum consistent with that desire.

NOW THEREFORE: the parties agree that in consideration of the mutual promises herein, in the Agreement, and of the exchange of PHI hereunder that:

- f. **Definitions.** Terms used, but not otherwise defined, in this Addendum shall have the same meaning as those terms in the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.
 - a. **Agency Procurement Officer** shall mean the appropriate Agency individual listed at: <http://www.state.wv.us/admin/purchase/vrc/agencyli.html>.
 - b. **Agent** shall mean those person(s) who are agent(s) of the Business Associate, in accordance with the Federal common law of agency, as referenced in 45 CFR § 160.402(c).
 - c. **Breach** shall mean the acquisition, access, use or disclosure of protected health information which compromises the security or privacy of such information, except as excluded in the definition of Breach in 45 CFR § 164.402.
 - d. **Business Associate** shall have the meaning given to such term in 45 CFR § 160.103.
 - e. **HITECH Act** shall mean the Health Information Technology for Economic and Clinical Health Act. Public Law No. 111-05. 111th Congress (2009).

- f. **Privacy Rule** means the Standards for Privacy of Individually Identifiable Health Information found at 45 CFR Parts 160 and 164.
- g. **Protected Health Information or PHI** shall have the meaning given to such term in 45 CFR § 160.103, limited to the information created or received by Associate from or on behalf of Agency.
- h. **Security Incident** means any known successful or unsuccessful attempt by an authorized or unauthorized individual to inappropriately use, disclose, modify, access, or destroy any information or interference with system operations in an information system.
- i. **Security Rule** means the Security Standards for the Protection of Electronic Protected Health Information found at 45 CFR Parts 160 and 164.
- j. **Subcontractor** means a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.

2. Permitted Uses and Disclosures.

- a. **PHI Described.** This means PHI created, received, maintained or transmitted on behalf of the Agency by the Associate. This PHI is governed by this Addendum and is limited to the minimum necessary, to complete the tasks or to provide the services associated with the terms of the original Agreement, and is described in Appendix A.
- b. **Purposes.** Except as otherwise limited in this Addendum, Associate may use or disclose the PHI on behalf of, or to provide services to, Agency for the purposes necessary to complete the tasks, or provide the services, associated with, and required by the terms of the original Agreement, or as required by law, if such use or disclosure of the PHI would not violate the Privacy or Security Rules or applicable state law if done by Agency or Associate, or violate the minimum necessary and related Privacy and Security policies and procedures of the Agency. The Associate is directly liable under HIPAA for impermissible uses and disclosures of the PHI it handles on behalf of Agency.
- c. **Further Uses and Disclosures.** Except as otherwise limited in this Addendum, the Associate may disclose PHI to third parties for the purpose of its own proper management and administration, or as required by law, provided that (i) the disclosure is required by law, or (ii) the Associate has obtained from the third party reasonable assurances that the PHI will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the third party by the Associate; and, (iii) an agreement to notify the Associate and Agency of any instances of which it (the third party) is aware in which the confidentiality of the information has been breached. To the extent practical, the information should be in a limited data set or the minimum necessary information pursuant to 45 CFR § 164.502, or take other measures as necessary to satisfy the Agency's obligations under 45 CFR § 164.502.

3. Obligations of Associate.

- a. **Stated Purposes Only.** The PHI may not be used by the Associate for any purpose other than as stated in this Addendum or as required or permitted by law.
- b. **Limited Disclosure.** The PHI is confidential and will not be disclosed by the Associate other than as stated in this Addendum or as required or permitted by law. Associate is prohibited from directly or indirectly receiving any remuneration in exchange for an individual's PHI unless Agency gives written approval and the individual provides a valid authorization. Associate will refrain from marketing activities that would violate HIPAA, including specifically Section 13406 of the HITECH Act. Associate will report to Agency any use or disclosure of the PHI, including any Security Incident not provided for by this Agreement of which it becomes aware.
- c. **Safeguards.** The Associate will use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent use or disclosure of the PHI, except as provided for in this Addendum. This shall include, but not be limited to:
 - i. Limitation of the groups of its workforce and agents, to whom the PHI is disclosed to those reasonably required to accomplish the purposes stated in this Addendum, and the use and disclosure of the minimum PHI necessary or a Limited Data Set;
 - ii. Appropriate notification and training of its workforce and agents in order to protect the PHI from unauthorized use and disclosure;
 - iii. Maintenance of a comprehensive, reasonable and appropriate written PHI privacy and security program that includes administrative, technical and physical safeguards appropriate to the size, nature, scope and complexity of the Associate's operations, in compliance with the Security Rule;
 - iv. In accordance with 45 CFR §§ 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions, conditions, and requirements that apply to the business associate with respect to such information.
- d. **Compliance With Law.** The Associate will not use or disclose the PHI in a manner in violation of existing law and specifically not in violation of laws relating to confidentiality of PHI, including but not limited to, the Privacy and Security Rules.
- e. **Mitigation.** Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Associate of a use or disclosure of the PHI by Associate in violation of the requirements of this Addendum, and report its mitigation activity back to the Agency.

f. **Support of Individual Rights.**

- i. **Access to PHI.** Associate shall make the PHI maintained by Associate or its agents or subcontractors in Designated Record Sets available to Agency for inspection and copying, and in electronic format, if requested, within ten (10) days of a request by Agency to enable Agency to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 CFR § 164.524 and consistent with Section 13405 of the HITECH Act.
- ii. **Amendment of PHI.** Within ten (10) days of receipt of a request from Agency for an amendment of the PHI or a record about an individual contained in a Designated Record Set, Associate or its agents or subcontractors shall make such PHI available to Agency for amendment and incorporate any such amendment to enable Agency to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 CFR § 164.526.
- iii. **Accounting Rights.** Within ten (10) days of notice of a request for an accounting of disclosures of the PHI, Associate and its agents or subcontractors shall make available to Agency the documentation required to provide an accounting of disclosures to enable Agency to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 CFR § 164.528 and consistent with Section 13405 of the HITECH Act. Associate agrees to document disclosures of the PHI and information related to such disclosures as would be required for Agency to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528. This should include a process that allows for an accounting to be collected and maintained by Associate and its agents or subcontractors for at least six (6) years from the date of disclosure, or longer if required by state law. At a minimum, such documentation shall include:
 - the date of disclosure;
 - the name of the entity or person who received the PHI, and if known, the address of the entity or person;
 - a brief description of the PHI disclosed; and
 - a brief statement of purposes of the disclosure that reasonably informs the individual of the basis for the disclosure, or a copy of the individual's authorization, or a copy of the written request for disclosure.
- iv. **Request for Restriction.** Under the direction of the Agency, abide by any individual's request to restrict the disclosure of PHI, consistent with the requirements of Section 13405 of the HITECH Act and 45 CFR § 164.522, when the Agency determines to do so (except as required by law) and if the disclosure is to a health plan for payment or health care operations and it pertains to a health care item or service for which the health care provider was paid in full "out-of-pocket."
- v. **Immediate Discontinuance of Use or Disclosure.** The Associate will immediately discontinue use or disclosure of Agency PHI pertaining to any individual when so requested by Agency. This includes, but is not limited to, cases in which an individual has withdrawn or modified an authorization to use or disclose PHI.

- g. **Retention of PHI.** Notwithstanding section 4.a. of this Addendum, Associate and its subcontractors or agents shall retain all PHI pursuant to state and federal law and shall continue to maintain the PHI required under Section 3.f. of this Addendum for a period of six (6) years after termination of the Agreement, or longer if required under state law.
- h. **Agent's, Subcontractor's Compliance.** The Associate shall notify the Agency of all subcontracts and agreements relating to the Agreement, where the subcontractor or agent receives PHI as described in section 2.a. of this Addendum. Such notification shall occur within 30 (thirty) calendar days of the execution of the subcontract and shall be delivered to the Agency Procurement Officer. The Associate will ensure that any of its subcontractors, to whom it provides any of the PHI it receives hereunder, or to whom it provides any PHI which the Associate creates or receives on behalf of the Agency, agree to the restrictions and conditions which apply to the Associate hereunder. The Agency may request copies of downstream subcontracts and agreements to determine whether all restrictions, terms and conditions have been flowed down. Failure to ensure that downstream contracts, subcontracts and agreements contain the required restrictions, terms and conditions may result in termination of the Agreement.
- j. **Federal and Agency Access.** The Associate shall make its internal practices, books, and records relating to the use and disclosure of PHI, as well as the PHI, received from, or created or received by the Associate on behalf of the Agency available to the U.S. Secretary of Health and Human Services consistent with 45 CFR § 164.504. The Associate shall also make these records available to Agency, or Agency's contractor, for periodic audit of Associate's compliance with the Privacy and Security Rules. Upon Agency's request, the Associate shall provide proof of compliance with HIPAA and HITECH data privacy/protection guidelines, certification of a secure network and other assurance relative to compliance with the Privacy and Security Rules. This section shall also apply to Associate's subcontractors, if any.
- k. **Security.** The Associate shall take all steps necessary to ensure the continuous security of all PHI and data systems containing PHI. In addition, compliance with 74 FR 19006 Guidance Specifying the Technologies and Methodologies That Render PHI Unusable, Unreadable, or Indecipherable to Unauthorized Individuals for Purposes of the Breach Notification Requirements under Section 13402 of Title XIII is required, to the extent practicable. If Associate chooses not to adopt such methodologies as defined in 74 FR 19006 to secure the PHI governed by this Addendum, it must submit such written rationale, including its Security Risk Analysis, to the Agency Procurement Officer for review prior to the execution of the Addendum. This review may take up to ten (10) days.
- l. **Notification of Breach.** During the term of this Addendum, the Associate shall notify the Agency and, unless otherwise directed by the Agency in writing, the WV Office of Technology immediately by e-mail or web form upon the discovery of any Breach of unsecured PHI; or within 24 hours by e-mail or web form of any suspected Security Incident, intrusion or unauthorized use or disclosure of PHI in violation of this Agreement and this Addendum, or potential loss of confidential data affecting this Agreement. Notification shall be provided to the Agency Procurement Officer at www.state.wv.us/admin/purchase/vrc/agencyli.htm and,

unless otherwise directed by the Agency in writing, the Office of Technology at incident@wv.gov or <https://apps.wv.gov/ot/ir/Default.aspx>.

The Associate shall immediately investigate such Security Incident, Breach, or unauthorized use or disclosure of PHI or confidential data. Within 72 hours of the discovery, the Associate shall notify the Agency Procurement Officer, and, unless otherwise directed by the Agency in writing, the Office of Technology of: (a) Date of discovery; (b) What data elements were involved and the extent of the data involved in the Breach; (c) A description of the unauthorized persons known or reasonably believed to have improperly used or disclosed PHI or confidential data; (d) A description of where the PHI or confidential data is believed to have been improperly transmitted, sent, or utilized; (e) A description of the probable causes of the improper use or disclosure; and (f) Whether any federal or state laws requiring individual notifications of Breaches are triggered.

Agency will coordinate with Associate to determine additional specific actions that will be required of the Associate for mitigation of the Breach, which may include notification to the individual or other authorities.

All associated costs shall be borne by the Associate. This may include, but not be limited to costs associated with notifying affected individuals.

If the Associate enters into a subcontract relating to the Agreement where the subcontractor or agent receives PHI as described in section 2.a. of this Addendum, all such subcontracts or downstream agreements shall contain the same incident notification requirements as contained herein, with reporting directly to the Agency Procurement Officer. Failure to include such requirement in any subcontract or agreement may result in the Agency's termination of the Agreement.

- m. **Assistance in Litigation or Administrative Proceedings.** The Associate shall make itself and any subcontractors, workforce or agents assisting Associate in the performance of its obligations under this Agreement, available to the Agency at no cost to the Agency to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against the Agency, its officers or employees based upon claimed violations of HIPAA, the HIPAA regulations or other laws relating to security and privacy, which involves inaction or actions by the Associate, except where Associate or its subcontractor, workforce or agent is a named as an adverse party.

4. Addendum Administration.

- a. **Term.** This Addendum shall terminate on termination of the underlying Agreement or on the date the Agency terminates for cause as authorized in paragraph (c) of this Section, whichever is sooner.
- b. **Duties at Termination.** Upon any termination of the underlying Agreement, the Associate shall return or destroy, at the Agency's option, all PHI received from, or created or received by the Associate on behalf of the Agency that the Associate still maintains in any form and retain no copies of such PHI or, if such return or destruction is not feasible, the Associate shall extend the protections of this Addendum to the PHI and limit further uses and disclosures to the purposes that make the return or destruction of the PHI infeasible. This shall also apply to all agents and subcontractors of Associate. The duty of the Associate and its agents

and subcontractors to assist the Agency with any HIPAA required accounting of disclosures survives the termination of the underlying Agreement.

- c. **Termination for Cause.** Associate authorizes termination of this Agreement by Agency, if Agency determines Associate has violated a material term of the Agreement. Agency may, at its sole discretion, allow Associate a reasonable period of time to cure the material breach before termination.
- d. **Judicial or Administrative Proceedings.** The Agency may terminate this Agreement if the Associate is found guilty of a criminal violation of HIPAA. The Agency may terminate this Agreement if a finding or stipulation that the Associate has violated any standard or requirement of HIPAA/HITECH, or other security or privacy laws is made in any administrative or civil proceeding in which the Associate is a party or has been joined. Associate shall be subject to prosecution by the Department of Justice for violations of HIPAA/HITECH and shall be responsible for any and all costs associated with prosecution.
- e. **Survival.** The respective rights and obligations of Associate under this Addendum shall survive the termination of the underlying Agreement.

5. **General Provisions/Ownership of PHI.**

- a. **Retention of Ownership.** Ownership of the PHI resides with the Agency and is to be returned on demand or destroyed at the Agency's option, at any time, and subject to the restrictions found within section 4.b. above.
- b. **Secondary PHI.** Any data or PHI generated from the PHI disclosed hereunder which would permit identification of an individual must be held confidential and is also the property of Agency.
- c. **Electronic Transmission.** Except as permitted by law or this Addendum, the PHI or any data generated from the PHI which would permit identification of an individual must not be transmitted to another party by electronic or other means for additional uses or disclosures not authorized by this Addendum or to another contractor, or allied agency, or affiliate without prior written approval of Agency.
- d. **No Sales.** Reports or data containing the PHI may not be sold without Agency's or the affected individual's written consent.
- e. **No Third-Party Beneficiaries.** Nothing express or implied in this Addendum is intended to confer, nor shall anything herein confer, upon any person other than Agency, Associate and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.
- f. **Interpretation.** The provisions of this Addendum shall prevail over any provisions in the Agreement that may conflict or appear inconsistent with any provisions in this Addendum. The interpretation of this Addendum shall be made under the laws of the state of West Virginia.
- g. **Amendment.** The parties agree that to the extent necessary to comply with applicable law they will agree to further amend this Addendum.
- h. **Additional Terms and Conditions.** Additional discretionary terms may be included in the release order or change order process.

AGREED:

Name of Agency: DHHR/BCSE

Signature: _____

Title: _____

Date: _____


Name of Associate: DNA Diagnostics Center, Inc.

Signature: 

Title: Executive Vice President, COO

Date: January 16, 2015

Form - WVBAA-012004
Amended 06.26.2013

APPROVED AS TO FORM THIS 26th
DAY OF Jan 20 13

Patrick Morrissey
Attorney General
BY _____

Appendix A

(To be completed by the Agency's Procurement Officer prior to the execution of the Addendum, and shall be made a part of the Addendum. PHI not identified prior to execution of the Addendum may only be added by amending Appendix A and the Addendum, via Change Order.)

Name of Associate: DNA Diagnostics Center, Inc.

Name of Agency: DHHR / BCSS

Describe the PHI (do not include any actual PHI). If not applicable, please indicate the same.

All [types of PHI listed on App. A] in paper, electronic, verbal or any other form. Including, but not limited to:

1. The names of a child and its alleged father.
2. DATE OF OBTAINING samples for genetic testing.
3. IDENTIFICATION OF individual's various alleles.
4. Statement regarding the combined paternity index and the probability of paternity.

aa **BB** Accreditation

DDC/DNA Diagnostics Center

*having been assessed by AABB, has been found to meet
the requirements of applicable Standards of this organization and therefore is granted this*

CERTIFICATE OF ACCREDITATION

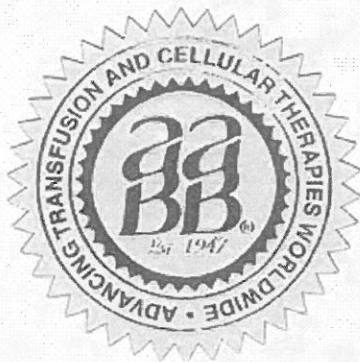
for the following activities:

Relationship Testing Activities

*In Witness whereof the undersigned, being duly authorized, have caused this Certificate
to be issued and the AABB Corporate Seal to be affixed.*

Effective Dates

October 01, 2014 - September 30, 2016



A handwritten signature in black ink, appearing to read "C. ...".

President, AABB

A handwritten signature in black ink, appearing to read "W. ...".

Chair, Accreditation Program Committee



CERTIFICATE OF LIABILITY INSURANCE

5/15/2015

DATE (MM/DD/YYYY)
11/4/2014

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

| | | |
|---|--|----------------|
| PRODUCER Lockton Insurance Brokers, LLC 725 S. Figueroa Street, 35th Fl. CA License #0F15767 Los Angeles CA 90017 (213) 689-0065 | CONTACT NAME: | |
| | PHONE (A/C, No, Ext): | FAX (A/C, No): |
| INSURED 13 12605 DDC-MTS Holdings, Inc. DNA Diagnostics Center, Inc. 1001 DDC Way Fairfield, OH 45014 | E-MAIL ADDRESS: | |
| | INSURER(S) AFFORDING COVERAGE | |
| | INSURER A : Allied World Surplus Lines Insurance Company | |
| | INSURER B : Atlantic Specialty Insurance Company | |
| | INSURER C : | |
| | INSURER D : | |
| INSURER E : | | |
| INSURER F : | | |
| NAIC # | | |
| 24319 | | |
| 27154 | | |

COVERAGES RFLHO01

CERTIFICATE NUMBER: 10640912

REVISION NUMBER: XXXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS |
|----------|---|-----------|----------|-------------------|-------------------------|-------------------------|--|
| A | <input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR | N | N | 0307-0967 | 11/14/2014 | 11/14/2015 | EACH OCCURRENCE \$ 1,000,000 DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 100,000 MED EXP (Any one person) \$ 5,000 PERSONAL & ADV INJURY \$ 1,000,000 GENERAL AGGREGATE \$ 3,000,000 PRODUCTS - COMP/OP AGG \$ 3,000,000 \$ |
| | GEN'L AGGREGATE LIMIT APPLIES PER: <input type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC <input type="checkbox"/> OTHER | | | | | | |
| B | <input checked="" type="checkbox"/> AUTOMOBILE LIABILITY <input checked="" type="checkbox"/> ANY AUTO <input checked="" type="checkbox"/> ALL OWNED AUTOS <input type="checkbox"/> SCHEDULED AUTOS <input checked="" type="checkbox"/> HIRED AUTOS <input checked="" type="checkbox"/> NON-OWNED AUTOS | N | N | 711-01-44-32-0000 | 5/15/2014 | 5/15/2015 | COMBINED SINGLE LIMIT (Ea accident) \$ 1,000,000 BODILY INJURY (Per person) \$ XXXXXXXX BODILY INJURY (Per accident) \$ XXXXXXXX PROPERTY DAMAGE (Per accident) \$ XXXXXXXX \$ XXXXXXXX |
| A | <input checked="" type="checkbox"/> UMBRELLA LIAB <input checked="" type="checkbox"/> OCCUR <input type="checkbox"/> EXCESS LIAB <input checked="" type="checkbox"/> CLAIMS-MADE DED RETENTION \$ | N | N | 0307-0968 | 11/14/2014 | 11/14/2015 | EACH OCCURRENCE \$ 4,000,000 AGGREGATE \$ 4,000,000 \$ XXXXXXXX |
| | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below | Y/N | N/A | NOT APPLICABLE | | | PER STATUTE OTH-ER E.L. EACH ACCIDENT \$ XXXXXXXX E.L. DISEASE - EA EMPLOYEE \$ XXXXXXXX E.L. DISEASE - POLICY LIMIT \$ XXXXXXXX |
| A | Professional Liability Claims Made | N | N | 0307-0967 | 11/14/2014 | 11/14/2015 | Each Occurrence: \$1,000,000 General Aggregate: \$3,000,000 |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (Attach ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

CANCELLATION

10640912

Evidence of Coverage

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE