DNA Diagnostics Center

Genetic Testing Services

RFP 6205 Z1

Technical Proposal

Submitted to: State of Nebraska

Due: June 4, 2020

2:00 PM Central Time

Table of Contents

Form A
Contractor Proposal Point of Contact
Request for Proposal Number 6205 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 contractor's name and address, and the specific person(s) who are responsible for preparation of the contractor's response.

Preparation of Response Contact Information	
Contractor Name:	DNA Diagnostics Center
Contractor Address:	1 DDC Way Fairfield, OH 45014
Contact Person & Title:	Lori Neff, Director Customer Service/Government Contracts
E-mail Address:	lneff@dnacenter.com
Telephone Number (Office):	(513) 881-4031
Telephone Number (Cellular):	(937) 271-7041
Fax Number:	(513) 881-4004

Each contractor should also designate a specific contact person who will be responsible for responding to the State if any clarifications of the contractor'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	
Contractor Name:	DNA Diagnostics Center
Contractor Address:	1 DDC Way Fairfield, OH 45014
Contact Person & Title:	Lori Neff, Director Customer Service/Government Contracts
E-mail Address:	lneff@dnacenter.com
Telephone Number (Office):	(513) 881-4031
Telephone Number (Cellular):	(937) 271-7041
Fax Number:	(513) 881-4004

REQUEST FOR PROPOSAL FOR CONTRACTUAL SERVICES FORM

CONTRACTOR MUST COMPLETE THE FOLLOWING

By signing this Request for Proposal for Contractual Services form, the contractor 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:	DNA Diagnostics Center
COMPLETE ADDRESS:	1 DDC Way, Fairfield, OH 45014
TELEPHONE NUMBER:	(513) 881-4005
FAX NUMBER:	(513) 881-4004
DATE:	June 2, 2020
SIGNATURE:	Kathy Leis
TYPED NAME & TITLE OF SIGNER:	Kathy Leis, VP Operations

DNA Diagnostics Center

June 2, 2020

Julie Schlitz and Annette Walton
State Purchase Bureau
1526 K Street, Suite 130
Lincoln, NE 68508

Re RFP 6205 Z1 – Genetic Testing Services

Dear Ms. Schlitz and Ms. Walton:

DNA Diagnostics Center (DDC) respectfully submits the following proposal to the State of Nebraska, State Purchase Bureau to continue providing genetic parentage testing services to the State of Nebraska, Department of Health and Human Services, and Child Support Enforcement. DDC has been the sole provider of parentage testing services to the State for the past 10 years, (including our corporate predecessor Orchid Cellmark). We firmly believe the partnership formed a decade ago between our two organizations has benefitted the State and its citizens and will continue to do so in the future.

DDC's laboratory has an extensive history in the field of parentage testing and other DNA identification services, including those provided for child support, child welfare agencies and private individuals. DDC is a market leader for government-funded paternity testing in the U.S., with an exemplary reputation for quality and service. The contracts we are currently servicing cover all sizes of child support offices and programs, with varying levels of staffing, computerization, and technologies for testing. Throughout 25 years of experience working with many jurisdictions throughout the country, DDC has developed sophisticated automated processes and has fine-tuned its skills at tailoring our services to meet customer needs specifically in the areas of specimen collection, testing parameters, turnaround time requirements, invoicing structures and statistical report generation. Given the history and experience of our company, and knowledgeable personnel resources at our disposal, DDC will continue to provide top quality services to the State of Nebraska.

DDC's approach to delivering paternity testing services is one of having a trusted and effective partnership with the State. This philosophy is reflected in every aspect of our operations, from having reliable specimen collectors consistently appear at draw sites to skilled scientists who generate the most accurate and reliable DNA testing results. Throughout DDC's transition to becoming a leading genetic testing services provider, we believe we have retained the customer-oriented focus characteristic of a smaller organization. DDC provides service to accounts ranging from a limited number of samples to over 65,000 samples per year, and each customer is treated as a valued partner.

All work will continue to be performed at DDC's Fairfield, Ohio facility (in metropolitan Cincinnati), which has been servicing Nebraska since 2012. This laboratory has been involved in the paternity testing industry for many years, and its qualified staff possesses a comprehensive understanding of the federal legislation under Title IV-D of the Social

DNA Diagnostics Center

Security Act as it relates to the delivery of child support programs in each state and commonwealth. DDC sees itself in a partnership role with every client to provide genetic testing services to establish paternity. We understand the need for efficient, accurate and conclusive results.

Many of DDC's quality assurance procedures exceed those required by the AABB. We are also pleased to state that our average probability of paternity for inclusions exceeds the AABB standard by 1,000,000-fold. DDC is financially stable, with sufficient financial flexibility, working capital, trained personnel, equipment and other management resources to continue to provide the services specified in this proposal to the State of Nebraska for the duration of this contract.

This submission has not been arrived at collusively nor is it in violation of federal or Nebraska laws. Furthermore, DDC accepts the Terms and Conditions and the Offeror's Representations and Authorizations listed in the RFP and its attachments. Should any officials with Nebraska have any questions or need additional information regarding this proposal, please contact:

Kathy Leis, Vice President, Operations
Phone: (513) 881-4005
Email: kleis@dnacenter.com

We acknowledge the following addendums associated with RFP 6205 Z1 – Genetic Testing Services:

2/27/20	Addendum One-REVISED Schedule of Events
2/28/20	Addendum Two - Questions and Answers
3/9/20	Addendum Three - Questions and Answers
3/16/20	Addendum Four - REVISED Schedule of Events
3/24/20	Addendum Five - Electronic Submission
5/4/20	Addendum Six - Revised Schedule of Events

In summary, we have proven that we are well qualified to continue performing the services specified in this RFP, and we are confident that we will continue to exceed your expectations of quality and customer service. The entire staff of DDC looks forward to continue serving the paternity testing needs of the State of Nebraska, the Department of Health and Human Services, and Child Support Enforcement. If we can answer any questions or clarify this proposal in any way, please do not hesitate to contact me.

Sincerely,

Kathy Leis

Kathy Leis
Vice President, Operations
DNA Diagnostics Center, Inc.

II. TERMS AND CONDITIONS

Bidders should complete Sections II through VI as part of their proposal. Bidder is expected to read the Terms and Conditions and should initial either accept, reject, or reject and provide alternative language for each clause. The bidder should also provide an explanation of why the bidder rejected the clause or rejected the clause and provided alternate language. By signing the 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:
KL			

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

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

These documents constitute the entirety of the contract.

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

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

B. NOTIFICATION

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

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. GOVERNING LAW (Statutory)

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

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

D. BEGINNING OF WORK

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

E. AMENDMENT

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

F. CHANGE ORDERS OR SUBSTITUTIONS

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
KL	Type text here		

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.

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

G. NOTICE OF POTENTIAL CONTRACTOR BREACH

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

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.

H. BREACH

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

Either Party may terminate the contract, in whole or in part, if the other Party breaches its duty to perform its obligations under the contract in a timely and proper manner. Termination requires written notice of default and a thirty (30) calendar day (or longer at the non-breaching Party's discretion considering the gravity and nature of the default) cure period. Said notice shall be delivered by Certified Mail, Return Receipt Requested, or in person with proof of delivery. Allowing time to cure a failure or breach of contract does not waive the right to immediately terminate the contract for the same or different contract breach which may occur at a different time. In case of default of the Contractor, the State may contract the service from other sources and hold the Contractor responsible for any excess cost occasioned thereby. 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 may recover from the Contractor as damages the difference between the costs of covering the breach. Notwithstanding any clause to the contrary, the State may also recover the contract price together with any incidental or consequential damages defined in UCC Section 2-715, but less expenses saved in consequence of Contractor's breach.

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

PERFORMANCE MEASURES

1. Contractor must meet the timeframes set forth on least ninety percent (90%) of all genetic tests requested by DHHS.
2. DHHS will measure the timeframes at least two (2) times per year.

3. If the contractor does not meet the performance measure in section II.H.1, DHHS may require the contractor to submit a Corrective Action Plan. A Corrective Action Plan must be submitted for review and approval to DHHS within thirty (30) business days of the request. If DHHS requires revisions to the Corrective Action Plan, it will so notify the contractor within ten (10) business days.

I. NON-WAIVER OF BREACH

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

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.

J. SEVERABILITY

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

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.

K. INDEMNIFICATION

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

1. GENERAL

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

2. 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 (Section 81-8,294), Tort (Section 81-8,209), and Contract Claim Acts (Section 81-8,302), as outlined in Neb. Rev. Stat. § 81-8,209 et seq. and under any other provisions of law and accepts liability under this agreement to the extent provided by law.

4. 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.

L. ATTORNEY'S FEES

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

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 attorney's fees and costs, if the other Party prevails.

M. PERFORMANCE BOND

Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within Solicitation Response (Initial)	NOTES/COMMENTS:
		KL	Will provide Bond for $100,000 as provided in the RFP Q & A

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 cashier's check or bond must $500,000 five 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.

N. ASSIGNMENT, SALE, OR MERGER

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

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.

O. 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:
KL			

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.

P. FORCE MAJEURE

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

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.

Q. CONFIDENTIALITY

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

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.

R. 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.

S. LONG-TERM CARE OMBUDSMAN (Statutory)

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.

T. SUSPENSION OF SERVICES

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

SPB, upon notice from DHHS may, at any time and without advance notice, require Contractor to suspend any or all activities provided under this Contract. A suspension may be the result of a reduction in federal or state funds, budget freeze, emergency, contract compliance issues, investigation, or other reasons not stated here.

1. In the event of such suspension, SPB, upon notice from the DHHS Chief Operating Officer/Contract Administrator or designee will issue a written Stop Work Order to the Contractor. The Stop Work Order will specify which activities are to be immediately suspended, the reason(s) for the suspension, and, if possible, the known duration period of the suspension.

2. Upon receipt of the Stop Work Order, the Contractor shall immediately comply with its terms and take all necessary steps to minimize the incurrence of costs allocable to the work affected by the order during the period of suspension.

3. SPB, upon notice from the DHHS Chief Operating Officer/Contract Administrator or designee may extend the duration of the suspension by issuing a modified Stop Work Order which states the new end date of the suspension and the reason for the extension.

4. The suspended activity may resume when (i) the suspension period identified in the Stop Work Order has ended or (ii) when SPB, upon notice from the DHHS Chief Operating Officer/Contract Administrator or designee has issued a formal written notice cancelling the Stop Work Order or directing Contractor to resume partial services.

U. EARLY TERMINATION

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

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.

V. CONTRACT CLOSEOUT

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

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

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

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

III. CONTRACTOR DUTIES

A. INDEPENDENT CONTRACTOR / OBLIGATIONS

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

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 contractor's proposal. The Contractor shall agree that it will not utilize any subcontractors not specifically included in its proposal in the performance of the contract without the prior written authorization of the State.

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

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

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

B. EMPLOYEE WORK ELIGIBILITY STATUS

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

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:
KL			

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 first five (5) years of the contract. Any request for a price increase subsequent to the first five (5) years of the contract shall not exceed three percent (3%) 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 State Purchasing Bureau a minimum of 120 days prior to the end of the current contract period. Documentation may be required by the State to support the price increase.

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.

The State will be given full proportionate benefit of any decreases for the term of the contract.

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:
KL			

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:
KL			

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

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

J. INSURANCE REQUIREMENTS

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

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

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

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

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

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

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

1. WORKERS' COMPENSATION INSURANCE

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

2. COMMERCIAL GENERAL LIABILITY INSURANCE AND COMMERCIAL AUTOMOBILE LIABILITY INSURANCE

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

The Commercial General Liability Insurance shall be written on an **occurrence basis**, and provide Premises/Operations, Products/Completed Operations, Independent Contractors, Personal Injury, and

Contractual Liability coverage. **The policy shall include the State, and others as required by the contract documents, as Additional Insured(s). This policy shall be primary, and any insurance or self-insurance carried by the State shall be considered secondary and non-contributory**. **The COI shall contain the mandatory COI liability waiver language found hereinafter.** The Commercial Automobile Liability Insurance shall be written to cover all Owned, Non-owned, and Hired vehicles.

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

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
Child Support Enforcement
Attn: Title IV-D Program Director
1033 O Street, Suite 200
Lincoln, NE 68508

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:
KL			

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:
KL			

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

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

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

The Parties shall not knowingly, for a period of two (2) years after execution of the contract, recruit or employ any employee or agent of the other Party who has worked on the solicitation or project, or who had any influence on decisions affecting the Solicitation or project.

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:
KL			

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:
KL			

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:
KL			

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:
KL			

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:
KL			

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 the 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

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:
KL			

Invoices for payments must be submitted by the Contractor to the agency requesting the services with sufficient detail to support payment. 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.

The Contractor shall submit all invoices monthly to DHHS with all necessary supporting documentation prior to any reimbursement of allowable costs. The Contractor shall meet with a DHHS representative to design the invoice. Such invoices will, at a minimum, include:

1. The name and phone number of child support worker requesting test;
   - **a.** County name;
   - **b.** County attorney, if known;
   - **c.** Mother's name (Last, First, Middle Initial) and social security number;
   - **d.** Child's name (Last, First, Middle Initial) and social security number;
   - **e.** Alleged father(s) name(s) (Last, First, Middle Initial) and social security number(s);
   - **f.** A unique and anonymized identifying number of test subjects;
   - **g.** Specimen collection site; and
   - **h.** Date of specimen collection.

D. INSPECTION AND APPROVAL

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

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:
KL			

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.

IV. PAYMENT

A. PROHIBITION AGAINST ADVANCE PAYMENT (Statutory)

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Invoices for payments must be submitted by the Contractor to the agency requesting the services with sufficient detail to support payment. 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.

The Contractor shall submit all invoices monthly to DHHS with all necessary supporting documentation prior to any reimbursement of allowable costs. The Contractor shall meet with a DHHS representative to design the invoice. Such invoices will, at a minimum, include:

1. The name and phone number of child support worker requesting test;
   - **a.** County name;
   - **b.** County attorney, if known;
   - **c.** Mother's name (Last, First, Middle Initial) and social security number;
   - **d.** Child's name (Last, First, Middle Initial) and social security number;
   - **e.** Alleged father(s) name(s) (Last, First, Middle Initial) and social security number(s);
   - **f.** A unique and anonymized identifying number of test subjects;
   - **g.** Specimen collection site; and
   - **h.** Date of specimen collection.

D. INSPECTION AND APPROVAL

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

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:
KL			

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

A. SCOPE OF WORK

The Contractor shall provide genetic testing and associated services and meet or exceed all conditions and standards as contained in the RFP. The Contractor shall provide and perform the following services:

1.Specimen Collection

The Contractor shall provide or subcontract for specimen collection at times specified by DHHS and locations statewide as solely determined by DHHS. DHHS must approve all locations and sites. There may be situations that would require site changes due to changing business needs. DHHS reserves the right at its sole discretion to direct that the specimen be collected by Contractor within twenty-four (24) hours of such request when in the opinion of DHHS an exigent or emergency circumstance exists.

Response: DDC will continue to provide the sample collection site, trained and qualified personnel to perform the collections, all required supplies, and transportation to the testing laboratory. DDC's Specimen Collection Network will continue to coordinate with each specific DHHS/CSE office to locate and approve a mutually agreeable collection site. Our staff, both as DDC and our predecessor Orchid Cellmark, have been working with Nebraska for more than ten (10) years with collection sites and logistics. Our associates have extensive experience with setting up and establishing statewide specimen collection facility networks, including those for both large and small states such as Texas (65,000 samples annually), Florida (32,000 samples annually), Mississippi (15,000 samples annually), Illinois (14,500 samples annually), Michigan (22,000 samples annually), Missouri (17,000 samples annually), Kentucky (15,000 samples annually), Pennsylvania (19,500 samples annually), and West Virginia (5,000 samples annually). DDC is currently utilizing forty-two collection facilities within the State, including clinical laboratories, hospitals, clinics, physicians, and health departments.

DDC understands that DHHS must approve all locations and sites, and there may be situations that would require site changes due to changing business needs. DDC will also work with DHHS to direct that the specimen be collected by DDC

within twenty-four (24) hours of such request when in the opinion of DHHS an exigent or emergency circumstance exists.

The Contractor shall secure and schedule qualified collection site personnel. It shall be the responsibility of the Contractor to provide the necessary instruction and procedure to establish and provide a reliable and legal chain of custody. The Contractor's cost must be inclusive of all cost associated with collection and transportation of specimen samples to the testing facility.

Response: DDC will continue to provide specimen collection staff/ phlebotomists as required by the State. Under the existing contract, Lauren Elkins and DDC staff worked closely with each of the DHHS offices to determine a schedule that would meet the needs of the county. With DDC's experience in Nebraska, we have a network of specimen collection options and would work with the local offices to determine their needs. DDC will continue to conduct the specimen collection training, provide site specifics, and ensure the collector met DDC standards as well as contract requirements. All fees associated with the collection and transportation of the specimens are included in our per person cost.

Training of Individuals to Perform Collections

DDC provides the same process-relevant training to all collectors who perform services on its behalf, whether they are employees, subcontractors, or child support staff. For purposes of this proposal, DDC will specifically discuss the training of the specimen collectors who collect samples for DHHS. DDC will continue to provide all training and the necessary supplies for collectors to collect buccal swab specimens in accordance with all applicable standards and regulations. All collection training will be managed by Lori Neff, Director, Government Contracts, and will be provided by Ms. Neff, Lauren Elkins, Tonya Williams-Powell.

DDC's Specimen Collection Manual and PowerPoint presentation (**Attachment #1**) is used for training and reference purposes. It will be provided to all DDC specimen collectors. DDC will train these individuals on collection procedures, proper completion of paperwork, and the importance of maintaining chain of custody documentation to ensure the legal validity of all samples. In light of the recent Covid-19 pandmic, DDC has also developed an amended protocol for "No Contact" sample collection (**Attachment #1**) that is relevant for those collectors going into a DHHS agency locations for specimen collections. The comprehensive training will cover the following aspects of specimen collection:

- Buccal swab collection procedures;
- Identification procedures for parties collected;
- Quality control procedures to ensure that samples are not contaminated or inadvertently switched;

- Proper paperwork completion, including chain of custody, specimen packaging, shipping documentation, internal forms, etc.;
- Safety protocols and use of personal protective equipment;
- Collection supplies and maintaining proper inventory;
- Procedures for obtaining additional supplies;
- Shipping procedures.

In addition, there is a specimen collection training video available on DDC's interactive website at: https://contracts.dnacenter.com/resources-collection.html. This video demonstrates the entire process for performing buccal swab specimen collections and accurate completion of chain of custody documentation. DDC will also provide each collector with the initial inventory of supplies and will instruct them on procedures to request future stocks of collection supplies at no charge.

DDC's specimen collectors are required to maintain all DDC specimen collection standards and to follow all chain of custody protocols. They ensure the site has adequate coverage to perform in-county collections as well as jail collections on an ongoing basis. Phlebotomists and specimen collectors must have the ability to analyze and interpret instructions, correspondence and contractual requirements. They are also required to recognize problems and respond to emergencies as well as have the ability to solve problems and deal with the different variables that arise while providing DNA collections. It is imperative that collectors pay close attention to detail and understand the impact the specimen collection process has on the outcome of testing. Collectors must have the ability to effectively present information to and respond to requests and questions from donors, customers, supervisors, and other DHHS/Child Support employees. DDC recognizes that the specimen collector represents the company, has direct interaction with every client, and is one of the most important links between the client and laboratory. Specimen collectors must project a professional image, have confidence to perform their job competently, and demonstrate skill and compassion, all of which instill confidence in our clients.

Ensuring Collection Site Coverage

DDC's Specimen Collection Network is available 24 hours per day, 7 days per week for specimen collectors to call if they are unable to make a scheduled appointment (e.g., due to last minute illness or other unavoidable issues). Once alerted to a problem, DDC staff will promptly contact the account to apprise them of the situation and arrange to have back-up staff in place to cover in an emergency situation. Since this hotline is answered 24 hours per day, 7 days per week, in most cases alternate arrangements are made prior to the scheduled collection to ensure uninterrupted service. The availability of DDC's Specimen Collection Network significantly reduces the chance that a collection site will ever

be unstaffed.

The Contractor must have the capability to collect genetic testing samples and to perform genetic testing on deceased persons, the parents of deceased or otherwise unavailable persons, and to perform genetic testing in "motherless" cases. In cases where blood samples or any other sample materials are used rather than buccal swab samples, there shall be no cost differential between the collection or the testing of these sample types.

Response: DDC's processing protocols embrace the scientific reality that certain types of cases will require alternative collection methods and/or extended testing. This includes motherless testing, kinship analysis, and working with non-traditional specimens. DDC's doctoral staff, led by Dr. Michael Baird, works closely with customers when it is determined that alternative samples are required. DDC is experienced at arranging and coordinating with local agencies such as physicians, coroners, and medical facilities to ensure an adequate buccal, blood, or tissue sample is obtained. DDC will assume any related cost for alternative collection or sample arrangements.

Potential scenarios involve cases where the alleged father or another party who is required to participate as a test subject is deceased. There are several options for successfully obtaining samples that are suitable for DNA analysis and completing the case. DDC can work with samples from a hospital, morgue, coroner's office, or funeral home. If a deceased-party blood draw is no longer an option, DDC's customer service and technical staff will discuss other collection options based on the unique circumstances of the case. DDC can extract DNA from many biological materials including standard cheek swabs and blood samples, as well as more complicated tissue, fingernail, bone, teeth, pathology, and hair samples. In addition to PCR-STR testing, DDC can also provide testing using Y-STRs (paternal lineage), and mitochondrial DNA testing (maternal lineage) as needed to resolve certain difficult cases.

DDC exceeds the requirements of this specification through its extensive experience with and capability of offering additional testing methodologies used in forensic applications that are not generally available to paternity testing laboratories; i.e. Y-STR and mitochondrial DNA testing. DDC actively pursues additional systems as an ongoing process to improve the ability to provide more extensive testing when it is required. Furthermore, DDC's staff of experienced scientists, let by Dr. Michael Baird and Dr. Debra Davis, will ensure the DHHS that our laboratory has the ability to resolve virtually any paternity or family relationship case. DDC understands that there shall be no cost differential between the collection or the testing of these special sample types (as compared to the basic swab analysis in a standard case).

2. Supplies

The Contractor shall provide all supplies necessary for the collection, identification, preservation, preparation and transportation of specimens to the laboratory

Response:

Specimen Collection Supplies

DDC will continue to ensure that all specimen collectors and sites are adequately supplied with all necessary materials for collecting, preserving, and transporting buccal swab specimens including:

- Sterile cotton buccal swabs
- Color-coded sample envelopes
- Packaging with tamper-proof seals to securely contain the samples and chain of custody documentation
- Sterile, disposable gloves
- Instant or digital camera and film
- Fingerprint pads
- Color-coded Client Identification/Chain of Custody Forms
- Overnight courier shipping pouches
- Prepaid air bills

DDC Specimen Collection Kit

All equipment and supplies necessary for sample collection, identification, preservation, safeguarding, and transportation will be provided at no additional cost to the DHHS. In the event that a blood specimen is required, DDC will provide the phlebotomist with all necessary supplies for collection, including protective cover needles, blood collection tubes, personal protective equipment,

alcohol pads, adhesive bandages, biohazard and sharps containers, syringes, and containers approved for shipments of blood. Blood samples will be obtained, shipped, tested, and evaluated at no additional cost to the DHHS. DDC has provided sample specimen collection kits in a separate envelope for evaluation by the proposal evaluation team.

Specimen Transportation to the Laboratory

Specimen collectors are responsible for the shipment of samples to DDC's testing laboratory in Fairfield, Nebraska. DDC has agreements with several national overnight courier services for the shipment of specimens to its laboratories. The collectors will be responsible for shipping the specimens to DDC's laboratory using one of the contracted courier services. By utilizing professional overnight courier services, DDC can track any shipment and ensure its prompt and secure arrival at the laboratory. Specimen collectors are responsible for shipment of specimens to our laboratory using hand delivery or one of these contracted courier services. The specimen collector may also elect to transport specimens to a secured receptacle provided by the courier service for such purposes. All associated courier and transportation services are provided at no additional charge to the DHHS.

3. Individual and Specimen Identification

The Contractor shall:

a. Identify the mother, putative father, and child(ren) present at the tissue collection by:

i. The use of photographs;

ii. Forms of positive identification including at least one (1) picture identification; and

iii. If appropriate, unique identifier such as a thumbprint or fingerprint.

b. Verify information about each individual by the signature of that person or his/her guardian;

c. Identify the tissue specimens obtained by labeling each sample with a unique identification label.

Response: DDC's specimen collectors will continue to ensure proper identification of individuals that the DHHS directs to be tested. DDC has a comprehensive procedural process to ensure an uncompromised and legally admissible chain of custody. DDC's protocols require positive identification for all parties to be tested, regardless of location.

- Adult parties must provide government-issued photo identification, which may include a driver's license, passport, military ID, or other acceptable form

of identification. After the specimen collector verifies the identification, the identification number is recorded on the chain of custody form along with the last four (4) digits of social security numbers, and dates of birth.

- Instant photographs are taken of the Alleged Father, the Mother and the Child(ren). These photographs are signed and dated by the tested party or the person providing legal consent for specimen collection (as in the case of a minor child). The specimen collector is responsible for taking the photographs and maintaining adequate photographic supplies.

- The specimen collector will obtain a thumbprint for each individual from whom a specimen is collected and place it directly on the chain of custody form.

Specimen Collection

According to the Process Control Section 5.0 of the *Standards for Relationship Testing Laboratories* published by the AABB, the following guidelines apply to sample collection and are strictly adhered to by DDC's specimen collectors:

- The laboratory obtains informed consent for all participating individuals to indicate they had knowledge of and granted consent for the test. This consent will be in the written authorization taken at the time of sample collection.

- The collection is performed and witnessed by a competent person that has no interest in the testing outcome. DDC's specimen collectors act as witnesses to the sample collection process, and their name and contact information become part of the laboratory's permanent record.

- The person performing the collection will confirm the identity of the person tested and record the stated family relationship. The specimen collector is required to obtain government-issued photo identification of the parties collected to ensure that the sample is collected from the appropriate individual, or in the case of a minor child, written parental or guardian consent. If a minor child is being collected, a parent or legal guardian must sign indicating their relationship to the minor child and provide documentation of that relationship.

- In addition, the collected party must initial the swab packet to verify that the label on the specimen is accurate, and all specimens are sealed in tamper-proof packaging prior to shipment to DDC's laboratory.

- The following information is obtained and recorded for each sample collected: name, alleged relationship, race/ethnic background (of mother and alleged father), date of birth, location and date of sample collection, signature, record of identification number from the government-issued photo identification,

thumbprint, and an instant photograph taken of the positively identified individual prior to specimen collection. Photos must be sufficiently clear to identify the individual(s) in the photograph. Individuals will be asked to remove hats, sunglasses, scarves and anything else that would obscure their facial features.

- DDC requires that all of this information be obtained and recorded on the Client Identification/Chain of Custody form.

The chain of custody form is completed with all required information and adult parties are asked to verify the accuracy of all information prior to sample collection. DDC's chain of custody documentation has been introduced and readily accepted without challenge as an item of evidence in many paternity hearings across the country. The instant photographs and thumbprints are attached directly to the form and are sealed with the samples in a tamper-proof envelope before forwarding to DDC's testing laboratory for analysis. DDC requires witnessed client signatures on all chain of custody forms as well as client initials on swab envelopes, thus verifying correct labeling information.

For buccal swab collections, swabs are inserted into corresponding color-coded envelopes to protect against the possibility of switching samples: four (4) swabs are inserted into the blue envelope for the alleged father; four (4) swabs are inserted into the pink envelope for the mother; and four (4) swabs are inserted into the yellow envelope for the child(ren). Specimen envelopes are never pre-labeled.

4. Chain of Custody

The Contractor shall provide a reliable, detailed, and notarized legal chain of custody, beginning with the draw of the sample by:

a. Ensuring that samples be identified accurately at the time of drawing with firmly attached label bearing a unique identification for each individual and the date of collection;

b. Ensuring that a record is kept at the testing facility of all identifying information I ncluding but not limited to:

i. Name;
ii. Relationship;
iii. Race;
iv. Place of collection of sample; and
v. Date of collection of sample.

c. Ensuring that specimens are handled and stored in a manner which precludes contamination, tampering or substitution.

Response: DDC's comprehensive processes ensure an intact, legally admissible chain of custody that will meet the requirements of the State of Nebraska and are in compliance with the directives of the DHHS. DDC's chain of custody

procedures meet or exceed the requirements established by the AABB. DDC is responsible for maintaining chain of custody throughout all phases of the testing process from specimen collection through storage and archiving of case files and samples. DDC handles all samples in such a manner to ensure that they will not be contaminated, tampered with, or substituted. DDC's current chain of custody documentation is provided in **Attachment #2**. Chain of custody procedures are also described in detail in DDC's Sample Collection Manual provided in **Attachment #1.**

Specimen Collection

According to the Process Control Section 5.0 of the *Standards for Relationship Testing Laboratories* published by the AABB, the following guidelines apply to sample collection and are strictly adhered to by DDC's specimen collectors:

- The laboratory obtains informed consent for all participating individuals to indicate they had knowledge of and granted consent for the test. This consent will be in the written authorization taken at the time of sample collection.

- The collection is performed and witnessed by a competent person that has no interest in the testing outcome. DDC's specimen collectors act as witnesses to the sample collection process, and their name and contact information become part of the laboratory's permanent record.

- The person performing the collection will confirm the identity of the person tested and record the stated family relationship. The specimen collector is required to obtain government-issued photo identification of the parties collected to ensure that the sample is collected from the appropriate individual, or in the case of a minor child, written parental or guardian consent. If a minor child is being collected, a parent or legal guardian must sign indicating their relationship to the minor child and provide documentation of that relationship.

- In addition, the collected party must initial the swab packet to verify that the label on the specimen is accurate, and all specimens are sealed in tamper-proof packaging prior to shipment to DDC's laboratory.

- The following information is obtained and recorded for each sample collected: name, alleged relationship, race/ethnic background (of mother and alleged father), date of birth, location and date of sample collection, signature, record of identification number from the government-issued photo identification, thumbprint, and an instant photograph taken of the positively identified individual prior to specimen collection. Photos must be sufficiently clear to identify the individual(s) in the photograph. Individuals will be asked to remove hats, sunglasses, scarves and anything else that would obscure their facial features.

- DDC requires that all of this information be obtained and recorded on the Client Identification/Chain of Custody form.

The chain of custody form is completed with all required information and adult parties are asked to verify the accuracy of all information prior to sample collection. DDC's chain of custody documentation has been introduced and readily accepted without challenge as an item of evidence in many paternity hearings across the country. The instant photographs and thumbprints are attached directly to the form and are sealed with the samples in a tamper-proof envelope before forwarding to DDC's testing laboratory for analysis. DDC requires witnessed client signatures on all chain of custody forms as well as client initials on swab envelopes, thus verifying correct labeling information.

For buccal swab collections, swabs are inserted into corresponding color-coded envelopes to protect against the possibility of switching samples: four (4) swabs are inserted into the blue envelope for the alleged father; four (4) swabs are inserted into the pink envelope for the mother; and four (4) swabs are inserted into the yellow envelope for the child(ren). Specimen envelopes are never pre-labeled.

As stated above, four (4) swabs are collected for each individual to be tested. A minimum of two (2) swabs are routinely used for the initial testing, and the remaining swabs are stored intact in the event additional testing is required in the future.

Transportation of Specimens

DDC has agreements with several national overnight courier services for the shipment of specimens to its laboratories. The collectors will be responsible for shipping the specimens to DDC's laboratory using one of the contracted courier services. By utilizing professional overnight courier services, DDC can track any shipment and ensure its prompt and secure arrival at the laboratory.

DDC will require a record of the samples collected that must be provided on the day the samples are collected. DDC will provide all collectors a Collection Completion Report. The Collection Completion Report will identify the county/site name, date, collector name, names of parties collected, and a space for the tracking number. The form will be faxed to DDC after the samples for each site are collected for each day. DDC will then review daily shipments to confirm delivery of samples. DDC will immediately track and escalate any packages that do not have movement in the courier system. The CSE/DHHS contact will be notified and updated. Upon receipt of the samples, DDC will also immediately investigate any discrepancies between names listed on the Collection Completion Report. See **Attachment #1** Specimen Collector Manual and Associated Documents.

Laboratory

Samples and chain of custody documents are received at the laboratory and examined for accuracy and completeness by DDC's Case Management Team, led by Donna Dougherty. The integrity of sample shipping containers is verified to ensure that no tampering has occurred between the time of sample collection and the time the package arrives at the laboratory. The accessioning technician signs and dates the chain of custody form as an affirmation that the chain of custody is complete and that all samples were correctly labeled and received intact. If the integrity of the packaging has been compromised, the DHHS will be notified and a second sample requested.

When samples are deemed acceptable for testing, the samples and chain of custody forms are bar coded with a unique numerical identifier, logged into DDC's Laboratory Information Management System (LIMS), and the corresponding client data is entered. The courier tracking number is scanned and recorded in LIMS for each sample that is received. All entry of client data must pass a quality audit prior to samples being processed in the laboratory. This process involves a system-driven required concordance check for duplicate entry by a second individual to ensure samples meet all acceptance criteria and to confirm accurate data entry for spelling of names, dates of birth, etc. Samples are then submitted to the laboratory for processing. DDC utilizes automated processes and equipment whenever possible. By using sophisticated robotic sample handling equipment, the potential for human error in manipulating the layout and placement of samples during the testing process is greatly reduced.

Final case review by the Laboratory Director or Assistant Laboratory Directors, led by Dr. Michael Baird and Dr. Debra Davis, ensures technical and scientific accuracy of paternity test reports. Client names, collection dates, race, case numbers, and unique specimen bar code identifiers are all verified against the information on the chain of custody form as part of this final review. After the results have been issued, all samples and records are stored according to AABB prescribed procedures.

There is complete documentation for each case processed which includes the individuals involved in collecting the samples, courier tracking number, accessioning the samples, testing the samples, data analysis, final review, and storage/archiving. Thus, an intact chain of custody from initial specimen collection is created and these records will be maintained for a minimum of five (5) years to meet AABB and DHHS contractual requirements.

We believe DDC exceeds the requirements of this specification. DDC currently utilizes a rigid procedure to inspect each incoming package for deviations or non-conformances to identify and address situations that could result in preventing an intact chain of custody. The types of instances that are classified as such include packaging that is not properly sealed or appears to be tampered with, or missing

chain of custody information such as names or required signatures. As mandated by our accrediting agencies, all such instances are documented, and the customer is promptly notified. If necessary, the affected sample(s) will be recollected at no charge. We view the ability to detect such problems and correct them promptly as a testament to the stringency of our chain of custody procedures and as an opportunity to implement new procedures to avoid recurring issues.

5. Testing and Report Standards

The Contractor shall perform genetic tests or sets of tests in a manner that meets or exceeds the requirements of the latest edition of Standards for Parentage Testing Laboratories published by the American Association of Blood Banks (AABB). The Contractor shall use controls appropriate to the test system being used. Tests used by the Contractor shall be subject to verification, including but not limited to confirmatory testing by independent laboratories which meet AABB standards.

Response: The ability to perform scientifically valid genetic testing that conforms to industry guidelines and the ability to defend its results in court if necessary are essential in the execution of this contract. DDC is committed to providing every client with accurate, thorough, and expedient paternity test results. DDC provides its clients with DNA testing performed using PCR (Polymerase Chain Reaction) technology and STR (Short Tandem Repeat) markers for routine analysis. DDC has been using STR technology since 1997, having conducted testing on over ten million samples (10,000,000) to date. This technology is approved by the AABB and is by far the most prevalent DNA testing methodology currently in use by AABB accredited laboratories.

All STR markers employed by DDC for its routine parentage testing are commercially available, and their performance characteristics are well understood, reproducible, validated, and accepted by the scientific and legal communities. DDC will utilize either the Promega Fusion Kit or Life Technologies Global Filer Kit as the initial routine testing battery. Both of these kits are fully validated and offer twenty-four (24) loci that are common and informative allowing for greater discriminatory power than many other testing batteries. Additionally, they have rapid thermal cycling protocols, which results in reduced
turnaround times and enables the focus of the laboratory to be on more value added activities. When necessary, DDC has additional systems that will be used for extended testing. In total, DDC has thirty-six (36) validated and commercially available STR systems (including Amelogenin) which will be deployed as necessary to ensure that tests completed for the State of Nebraska will achieve a guaranteed minimum probability of paternity of 99.999% for standard cases though the majority of standard cases will have an average probability of paternity of 99.999999%. The available STR markers for use in the paternity testing panel are identified in the table below:

D3S1358	D8S1179	D18S51	CSF1P0	D13S317
D5S818	D21S11	TP0X	FGA	F13B
D7S820	D16S539	LPL	TH01	vWA
Penta E	Penta D	D2S1338	D19S433	Amelogenin
F13A01	FESFPS	Penta C	D8S1115	D6S474
D22S1045	D2S441	SE33	D10S1248	D9S1122
D17S1301	D9S2157	D3S4529	D14S1434	D1S1656
D12S391				

6. Inclusion/Exclusion of Putative Father

Testing by the Contractor shall include multiple independent genetic systems which result in a finding of non-paternity, or when the alleged father is not excluded, to reach a probability of paternity of at least ninety-nine percent (99%). If testing produces no exclusion, and if the likelihood of paternity is less than ninety-nine percent (99%), the Contractor shall administer additional tests sufficient to result in either an exclusionary result, or a likelihood of paternity of at least ninety-nine percent (99%). Findings of non-paternity shall be based on at least two (2) independent exclusions.

Response:

DDC will report findings of either a solid exclusion or will exceed the minimum stated probability of paternity requirement of 99.0%. When analytical data indicates exclusionary results, a minimum of three (3) exclusions will be required, although the majority of cases will have four (4) or more exclusions. DDC's average power of exclusion in routine operations is in excess of 99.999999%. For inclusions, the testing battery and DDC's standard operating procedures offer powerful discriminating ability that translates into an average probability of paternity typically exceeding 99.999999% with a prior probability of 0.5 (50%).

DDC will guarantee that all inclusion reports for the State of Nebraska will meet or exceed a minimum probability of paternity of 99.999% for standards cases, which exceeds the requirements specified in this RFP. Additional testing will be performed on all cases that fail to meet these threshold requirements until these minimum standards are achieved.

Additional Testing Capabilities

DDC also has the capability to perform mitochondrial DNA (mtDNA) testing and Y- Chromosome STR testing for complex and challenging cases. In addition, DDC can extract DNA from many different types of biological samples including standard buccal cheek swabs and blood samples as well as other tissue samples such as fingernail, bone, tissue, teeth, and hair samples. DNA testing will be performed initially unless other testing methodologies are deemed necessary.

7. Delivery of Test Results

The personnel or agent of DHHS requesting the test shall receive a certified and notarized report plus two (2) photocopies of the same for each case. The report shall be sent to the person and office making the referral in a form acceptable to DHHS and shall contain at a minimum:

- **a. Date of sample collection;**
- **b. Name of each individual tested and the relationship to the child; racial origin(s) assigned by the laboratory to the mother and alleged father(s) for the purpose of the calculation;**
- **c. Description of test(s) performed;**
- **d. A statement as to whether or not the alleged father can be excluded; and**
- **e. If there is a failure to exclude, the report shall include:**
  - **i. The individual Paternity Index for each genetic system reported;**
  - **ii. The cumulative Paternity Index;**
  - **iii. The probability of parentage expressed as a percentage and calculations used to determine the probability of paternity.**
  - **iv. Other mathematical or verbal expressions are optional. If they are included in a report, such expressions should be defined and explained.**
- **d. The signature of the Laboratory Director, or his/her qualified designee; and**
- **e. All photographs taken at the time the samples were drawn, photocopies of all identifications, and all thumbprints taken at that time.**
- **f. The Contractor must store and transmit scanned secured documents electronically.**

Prior to the delivery of the test results by way of certified and notarized letter, Contractor agrees to notify the appropriate child support enforcement caseworker by way of email of the test results at such time as that result

becomes known and available to the Contractor, so that the caseworker has an additional time period to process that particular case.

Response: DDC will continue to submit standard written reports including an interpretation of test results for each individual case in accordance with Nebraska state law and all applicable statutes. Paternity evaluation reports include clear, concise language to provide an understandable interpretation of testing results. Each paternity evaluation report will include, at a minimum, the following information:

- The tester's name, title and qualifications (including title of lab);
- Date of test;
- Donors' names (tested parties) and their relationship to the child(ren);
- Racial origin(s) of the mother, alleged father, and any other necessary individuals (if applicable, such as in a family study):
- Child Support/DHHS case number and court or administrative order numbers;
- Type/description of test performed;
- Percentage probability of paternity;
- Power of exclusion;
- Combined paternity index (inclusions);
- Conclusions; and
- Donors' photographs and thumbprint
- Table of Results;
- Interpretation of the results;
- Effect of prior probability and likelihood of paternity; and
- Statement of exclusion, if applicable.
- Date(s) of specimen collection
- Signed Chain of Custody form
- Copy of judicial or administrative order for genetic testing, if provided
- Signature of Ph.D. Laboratory Director conducting case review
- Notary signature and seal

DDC is also able to provide, upon request, reports in Spanish and many other languages. Copies of sample inclusionary and exclusionary paternity reports are provided in **Attachment #3**. All paternity test reports will be issued to the CSE/DHHS office that requested the test. The personnel or agent of DHHS requesting the test will receive a certified and notarized report plus two (2) photocopies of the same for each case. DDC will continue to store and transmit scanned secured documents electronically. Prior to the delivery of the test results by way of certified and notarized letter, you will have the option for the child support

enforcement caseworker to receive notification by way of email that test results are available.

In addition, testing outcomes will be available to authorized CSE representatives via DDC's secure website. This website provides caseworkers with the ability to track and collect performance data on all cases received in our laboratory 24 hours a day. Our proprietary interface, https://contracts.dnacenter.com, offers a direct link to child support offices allowing immediate access to information stored in our database for paternity cases. This service feature provides our customers with the option of an almost paperless and convenient interface with our laboratory. An added feature allows for DDC to provide email notification that test results are completed, uploaded to the web interface, and ready to be viewed. Authorized CSE staff may print a fully completed report ensuring legibility and accuracy.

Like the traditional hard copy report, this electronic report includes the Ph.D. signature, report of findings, conclusions, chain of custody documentation, thumbprints, and photographic images of the tested parties. This notification feature is especially useful for lower volume offices, as they can opt to receive the alert, whereas higher volume offices often choose to log in and retrieve their results on a daily basis without the notification.

8. **Contractor Record Retention**
   The Contractor shall maintain records of the test results for a period of not less than five (5) years after the final payment under the contract and, upon request, furnish an electronic copy to DHHS at no cost.

   Response: All records are stored and maintained at DDC's laboratory as required by AABB protocols and other accrediting body and industry standards. DDC will continue to maintain all archived samples and/or results, case files and results associated with this contract for a minimum of five (5) years after the final payment in accordance with AABB standards and contractual requirements unless instructed otherwise.

   DDC's laboratory has on-site document storage allowing for rapid retrieval of case files as well as secure archived storage. The records will be maintained for a minimum of five (5) years per AABB and DHHS contractual requirements. All testing records are also electronically imaged and will be available through our secure website for DHHS to access at any time. DDC, upon authorization from DHHS, will use the existing genetic samples and/or profiles for testing comparison and conclusion in cases where samples have been previously collected and a new

referral is made. DDC will ensure that all required authorizations are obtained and that proper consent and court orders are on record prior to proceeding.

All persons duly authorized by the State will continue to have full access to and the right of examination of any and all records and supporting documentation related to services provided pursuant to this Contract. DDC will provide any requested test results or documentation to DHHS upon request.

9. Consultations

The Contractor shall provide a toll-free telephone number answered by a person for use by DHHS personnel or its agents for consultation and to check on status of testing procedures. The service shall be available at a minimum Monday through Friday (except Federal and State holidays) from 8:00 a.m. to 6:00 p.m. Central time.

Response: DDC offers a highly trained and professional customer service organization who will answer questions regarding any Nebraska case. DDC's Customer Service and Scheduling Associates, managed by Tonya Williams-Powell, are available at the following toll-free number Monday through Friday during standard business hours 7:00 am to 6:00 pm Central Time: (800) 310-9868. In the event that technical consultation is required with one of DDC's Ph.D. staff, all eleven (11) can be accessed at the same toll-free number listed above.

DDC has assigned a dedicated Customer Service Associate to this account (versus requiring that CSE personnel contact a call center which may result in speaking with different people each time they require assistance). Ms. Paula Cooper has over twenty years of experience and has worked with Nebraska's CSE/DHHS offices during her tenure at Orchid Cellmark and DDC. Ms. Cooper will continue to serve as the point person for all day-to-day needs, and she is familiar with the CSE staff and their unique contractual requirements. During absences or if Paula is assisting other customers, CSE calls will be routed to a designated back-up staff member - Sarah Ballard - who is also familiar with CSE account specifics and will provide the same level of prompt service. As a previous and current provider of genetic paternity testing services to the State of Nebraska, DDC currently has several individuals who are familiar with many Nebraska counties and can easily serve in a back-up role or in addition to Ms. Cooper during peak times. These Customer Service Associates and management personnel include Lori Neff, Diana Holland, Beth Potter, and Luann Wilcox, all of which previously worked at Orchid Cellmark (and now at DDC) and provided exemplary customer service to the State of Nebraska.

DDC also provides each county CSE with a contact list of key staff along with daytime and mobile phone numbers for urgent matters or after-hours needs. DDC's Specimen Collection Network is also available twenty-four (24) hours per day, seven (7) days per week for specimen collection personnel to contact to ensure uninterrupted collection services in the event of emergency.

10. Expert Witness Service

The Contractor must respond to reasonable written interrogatories, provide depositions, and/or appear in court to give expert testimony, at the request of DHHS, the Court, or the attorney representing the State at no additional cost to DHHS. The individual providing the expert testimony shall be personally familiar with the processes and procedures used in the laboratory and shall be a licensed medical doctor and/or Ph.D. Other professionals may be acceptable if the office that requested expert testimony consents to the appearance in particular cases.

Response: DDC's highly qualified doctoral staff provides litigation support to our customers, including pre-trial preparation and in-court explanation of genetic paternity testing procedures and subsequent results. DDC's expert witnesses have testified in hundreds of cases, and consistently provide clear, accurate testimony. DDC's Chief Science Officer, Dr. Michael Baird, Ph.D. was the **first** DNA expert to testify in a U.S. court using DNA evidence. Since then, he has testified over 500 times in courtrooms throughout the United States. DDC staff members have provided expert witness services for both paternity-related and criminal trials. Their technology-specific knowledge, qualifications and experience are highly respected in the industry. DDC's expert witnesses will provide the following services to the State of Nebraska at no additional charge:

- General consultation on paternity analysis;
- Statistical analysis for non-standard paternity cases including avuncular analysis and family reconstruction and all necessary consultation to understand the results;
- Expert testimony for trial and hearings;
- Assist in the cross examination of defense experts;
- Provide written and/or telephone technical consultations;
- Telephonic/video depositions;
- Provide pattern trial questions for expert testimony;
- Assist counsel in preparation for the presentation of scientific evidence at trial and in depositions;
- Fulfill requests for document production;

- Provide affidavits regarding specific case events;
- Explain difficult to understand case results in layman's terms.

Curricula Vitae for DDC's doctoral staff who will provide expert witness services to DHHS are provided in **Attachment #4** of this response. All DDC Laboratory Directors and Assistant Laboratory Directors are required to have completed a doctoral degree in a biological science in addition to advanced training in genetic testing. All Laboratory Directors at DDC meet these minimum qualifications and requirements and are competent to testify to the theory and practice of current DNA technology as used in the parentage determinations, laboratory procedures, specimen chain of custody, statistical analysis, and interpretation of test results. In total, the expert witness staff at DDC includes eight (8) prominent Ph.D.s., led by Dr. Michael Baird and Dr. Debra Davis, who will supply technical consultation and litigation support services.

DDC has extensive experience providing testimony services for paternity establishment. Due to the increased admissibility and acceptance of genetic testing results, the necessity for expert witness testimony has decreased dramatically in the past several years. With our eight (8) Ph.D.s,, DDC offers tremendous ability to provide on-site testimony and legal support services when such situations arise.

11. Accreditation

The Contractor shall have accreditation as a parentage-testing laboratory by the AABB. The Contractor must complete all work under the contract in a manner that meets or exceeds the latest revised standards and procedures established by AABB for parentage testing. Documentation verifying current accreditation by the AABB shall be attached to the proposal. The Contractor selected must maintain accreditation by the AABB and provide a certified copy of such accreditation when requested by DHHS during the term of this contract.

Response: DDC is one of the most accredited and certified laboratories in the DNA testing industry. We have received and currently hold all of the necessary accreditations and licensures to perform biological relationship testing in all 50 states and worldwide. All testing performed for the State of Nebraska will be in strict compliance with the current edition of the AABB's *Standards for Relationship Testing Laboratories*. DDC has maintained its AABB accreditation since 1996. In addition to our AABB accreditation, DDC holds additional accreditations and certifications from the following organizations: Clinical Laboratory Improvement Amendments (CLIA), ANSI National Accreditation Board (ANAB), College of American Pathologists (CAP), American Society of Crime Laboratory

Directors/Laboratory Accreditation Board (ASCLD/LAB), New York State Department of Health (NYDOH), Standards Council of Canada (SCC), the Ministry Of Justice (U.K.), and National Association of Testing Authorities (N.A.T.A.-Australia). Details of these accreditations are provided below:

a) Parentage Testing by the AABB (formerly the American Association of Blood Banks) since 1996.
b) CLIA Laboratory Certificate of Accreditation by the U.S. Department of Health & Human Services since 1996.
c) ISO 17025/IEC by ANSI National Accreditation Board (formerly ACLASS Accreditation Services). DDC has been certified to ISO standards since 2003, which are the international standards set for ensuring the technical competency of laboratories. ISO/IEC 17025 covers every aspect of laboratory management, ranging from sample preparation to analytical testing proficiency, to record keeping and reports.
d) Parentage Testing and other Molecular Pathology Testing by The College of American Pathologists (CAP) since 2004.
e) ASCLD/LAB-International by the American Society of Crime Laboratory Directors/Laboratory Accreditation Board since 2005. ASCLD/LAB-International is the most stringent accreditation program for forensic DNA laboratories.
f) Parentage/Identity Testing by the New York State Department of Health (NYDOH). The NYDOH monitors the overall quality of testing conducted on specimens obtained in New York State by out-of-state laboratories. The state's Clinical Laboratory Evaluation Program (CLEP) ensures the accuracy and reliability of analytical results obtained through on-site inspections, proficiency testing, and evaluation of personnel qualifications. DDC has been accredited by New York State since 1998 and undergoes an on-site assessment every two years by an external assessor.
g) Paternity/Family Relationship testing by the Standards Council of Canada (SCC). The SCC accredits laboratories performing forensic objective testing such as that involving parentage and familial relationships. Their accreditation verifies that an organization has the necessary competence to execute these functions. The SCC also conducts regular on-site assessments of DDC's laboratory and reviews its performance to ensure the facility is conforming to the Council's reporting requirements and quality expectations. Should your state have a paternity matter that includes Canada, this accreditation with DDC will help ensure the admissibility of the test results into their legal system.
h) Ministry of Justice (MOJ) is the ministerial department that works to protect the public and reduce reoffending while providing a more effective, transparent, and responsive criminal justice system for victims

and the public in the United Kingdom.

i) National Association of Testing Authorities (N.A.T.A.) is the authority that provides independent assurance of technical competence through a proven network of best practice industry experts. NATA provides assessment, accreditation and training services to laboratories and technical facilities throughout Australia and internationally.

DDC has a strong Quality Management System and consistently exceeds the standards set by its accrediting organizations. DDC will continue to maintain the necessary accreditations throughout the length of this agreement. A copy of each accreditation certificate appears in **Attachment 5**.

12. Quality Control

The Contractor shall utilize a program of quality control that ensures that equipment and personnel perform as required.

a. Proficiency Testing: The Contractor shall participate in available external proficiency testing programs.

b.. Procedures Manual: The Contractor shall maintain a manual detailing its procedures and policies pertaining to this Contract and the same shall be reviewed annually by the Contractor, and shall be available to DHHS upon request. Bidder should provide a copy of manual with its proposal.

Response:

Quality Control Procedures that Exceed AABB Standards

DDC recognizes that the accuracy of testing results produced in the laboratory is of utmost importance. All samples are handled, processed and analyzed in accordance with validated procedures and in a manner that ensures the accuracy and reliability of test results. DDC has made several investments in its testing process that significantly reduce the risk of sample swapping and other errors. These reduce the incidence of human error, which in the case of paternity testing, often leads to false paternity exclusions. Todd Lewis oversees DDC's Quality Management Program. The following is a summary of DDC's comprehensive and stringent quality control procedures, many of which exceed AABB minimum standards.

Dual Process™

DDC was commended by the AABB in 2004 for being the first laboratory to truly offer double blind testing. DNA Diagnostics Center is the only DNA testing

laboratory that performs every test twice, testing every genetic system in duplicate, not just exclusions, and not just a subset of the genetic markers. Our Dual Processing™ procedures ensure that each sample is tested in duplicate by two different teams working independently. Results from the two groups are compared upon completion of the analysis and must be in agreement for validation of the testing. This expensive and labor-intensive process is the most effective quality assurance program that ensures our testing is of the highest reliability and accuracy. This Dual Process™ is voluntary and far exceeds the industry standard. Every sample is independently logged-in, extracted, processed, and **all genetic systems are analyzed twice by two separate teams**. The two sets of results are reviewed by at least two DNA experts prior to a final review by a Ph.D. Director. This double blind testing on each sample ensures rapid turnaround times because there is no delay in repeating excluded alleged fathers. The standard battery and the additional validated systems will easily result in meeting the expected probabilities of paternity for alleged father inclusions and a minimum of three exclusions for alleged fathers that are not the biological father. The State of Nebraska will have a high level of confidence that the correct samples were tested and reported.

Color Coding of Specimen Envelopes

Each specimen collection kit consists of color-coded envelopes containing four (4) buccal swabs for each party to be tested. These features provide added measures to protect against the possibility of inadvertently switching samples at the time of sample collection. Blue envelopes are used for the alleged father, pink envelopes are used for the mother, and yellow envelopes are for the child(ren). DDC is one of the only DNA testing laboratories that provides color-coded specimen envelopes and chain of custody forms. The following photo represents the collection kits that are included with our proposal.

DDC's Specimen Collection Kit

Automated Processes Minimize Potential for Human Error

DDC utilizes automated processes and equipment whenever possible. By using sophisticated robotic sample handling equipment, the potential for human error in manipulating the layout and placement of samples during handling and the testing process is greatly reduced. This automation is not required by the AABB.

Bar Coding Samples at the Laboratory

All samples and chain of custody forms are bar coded with unique numerical identifiers. The bar code numbers are assigned using a proprietary software application, and each bar code is applied to the sample during the accessioning process. Prior to the testing process, the assigned bar codes are rescanned, and the system verifies the tested party name and bar code match. This auditing procedure ensures that each sample has been independently verified twice before entering the laboratory. At each additional step in the analysis procedure, these bar codes are scanned with a bar code reader and checked for concordance. If the bar codes do not match, laboratory processing is halted. Additionally, anytime a sample is transferred, a unique reference number is linked to that sample. This unique reference is thirty-two (32) digits represented by a 2D bar code, the unique reference number is known as a Globally Unique Identifier (GUID). There is no limit to the quantity of these unique linked numbers, thereby adding this quality process each time the sample is transferred. This concept in process control nearly eliminates the possibility of sample switching in the laboratory.

DDC's sample bar coding procedure goes far beyond AABB standards for sample identification. The barcode provides an additive quality feature after all names have been verified and checked for accuracy on the samples and chain of custody prior to linking with the GUID as described above. If there is an issue with any labeling involving a tested party name, laboratory analysis will not be conducted. The use of bar codes enhances quality assurance and in no way replaces the manual tested party name review for quality control purposes.

Multiple Exclusions

When laboratory data indicates exclusionary results**,** a minimum of three (3) exclusions will be required; however, most cases processed by DDC will have more than four (4) exclusions. AABB standards require a minimum of two (2) exclusions, but DDC has adopted a stricter policy, which realistically eliminates the possibility of false exclusions due to mutation events.

Gender Marker Amelogenin

The inclusion of the gender marker Amelogenin in the testing battery is an important quality control feature. This internal control helps confirm the identities of the tested parties (mother and father) and the identities of the children as well (especially in multiple-child cases) by verifying the gender of each party collected. If discrepancies exist between the gender identified on the chain of custody form and the test outcome (i.e., if two siblings of different gender have a sample switch), the software identifies this discrepancy during the Laboratory Director's review and further investigation will be required. No report will be generated until all issues have been resolved. Use of this marker to identify sample switching is not an AABB requirement.

Computer Verification of Sample Placement

DDC's software verifies testing results by analyzing all permutations of sample party identification within a case. In other words, the computer will show a color alert if the father is erroneously placed into the role of mother, the mother is put into the erroneous role of child, the child is put into the erroneous role of father, and all other permutations possible. Additionally, if testing results in a maternal exclusion, DDC's software will "red flag" all maternal exclusions. Additionally, DDC's software will alert the analyst to any cloning of samples within a case to prevent any possible sample duplications. The software also alerts the data analyst to any inclusions between the mother and father to prevent any potential mother/child switches within a case.

A. Proficiency Testing

To fulfill the competency requirements of the AABB, DDC participates in the CAP proficiency testing program and performs "blind" proficiency testing three times a year. The CAP survey samples are tested in the laboratory under the same conditions as all other samples. In addition, the laboratory receives and performs competency testing on samples received from the New York State Department of Health to comply with their competency testing requirement. Throughout the year, supervisors observe and complete a competency worksheet for each technical staff member (each technician is evaluated on bench techniques at least once annually). The results are reviewed by the Laboratory Director, and any non-conformances generated by this process are addressed with a personnel corrective action plan.

B. Procedures Manual

DDC maintains a Quality Assurance Manual and a comprehensive set of Standard Operating Procedures (SOPs) in accordance with the requirements of its accrediting agencies and to ensure accurate and reliable DNA testing results. All laboratory operations are governed by these written and approved policies and procedures. These documents are maintained electronically under strict document and version control. They undergo comprehensive review and approval by laboratory management annually or more often if necessary in order to ensure that they adhere to internal and external requirements and fulfill the needs of the organization and its clients. DDC's SOPs detail all aspects of our paternity operations including:

- Accessioning
- Contract Administration
- Shipment of Samples
- Chain of Custody
- Client Scheduling
- Reagent Preparation and Storage
- Laboratory Processing
- Data Review
- Case Management
- Interpretation of Results
- Process Validation
- Employee Training
- Safety Protocols

- Invoicing
- Customer Service
- Document Control
- Equipment Calibration and Maintenance
- Occurrence Management

All SOPs are reviewed periodically and modified as necessary. All standard operating procedures are maintained electronically under strict document and version control. Copies of DDC's Quality Assurance Manual is included as **Attachment #6** and Laboratory SOPs will be provided upon request.

13. Redrawing of Samples/Retesting/Reuse of Results

a. **The Contractor shall provide for any recollection of tissue specimens and/or retesting at no additional cost to DHHS when, for whatever reason, a specific case cannot be completed without recollecting one (1) or more additional specimens.**

Response: DDC recognizes the difficulty and time required to complete recollections and continually strives to keep the number of required recollections to a minimum. However, on occasion non-viable samples will be collected which can occur for a number of reasons, including insufficient collection of epithelial cells from the inside of the cheek, samples received at the laboratory for which the integrity of the packaging or the chain of custody has been compromised, or a sample received at the laboratory which has been contaminated or the DNA has degraded during shipment. Due to DDC's proven specimen collection technique, comprehensive training, extensive battery of STR markers, proven procedures, and the need for a very small amount of DNA, the necessity for recollections with buccal swab specimens is 0.20% which is well below many contracts' requirement of one percent (1%).

DDC's Standard Operating Procedures and Quality Management Program, managed by Dr. Todd Lewis, specify and enforce the measures necessary to minimize the incidence of recollected samples. The identification of non-conformances can occur within any process of the quality management system such as sample accessioning, sample processing, results reporting, quality control, equipment calibration, or facility operations. An identified non-conformance that necessitates a specimen recollection is addressed through immediate action and follow-up. Non-conformances are avoided through implementation of a preventive action program designed to monitor process indicators and act to

implement proactive measures that address non-conformances before they occur.

As stated above, Standard Operating Procedures that contribute to DDC's low recollection rate encompass the entire paternity testing process including comprehensive training of specimen collectors, color coding of sample kits, automated quality processes, internal laboratory protocols that prevent contamination, and facility procedures that protect the chain of custody. These procedures reinforce DDC's goals to exceed the minimum requirements outlined by the regulatory agencies, run an efficient operation, and provide consistent quality service that anticipates our customers' needs. By implementing a proactive approach to quality and requiring strict adherence to these procedures, through all departments and through all levels of personnel, DDC has greatly minimized the necessity for specimen recollections.

In the event that an additional sample is required, Nebraska's dedicated Customer Service Associate, Paula Cooper, will notify the appropriate agency representative of the reason for sample recollection and will make all the necessary arrangements for the recollection. DDC will be responsible for the recollection costs.

DDC will also perform any necessary retesting of specimens; such retesting will be at no charge to DHHS.

b. **When any individual has been previously tested (on the current or on another case) and the previous results are reused, but additional testing is neither required nor conducted, the Contractor shall not bill DHHS a fee for that reuse of test results.**

Response: As per the RFP, when any individual has been previously tested (on the current or on another case) and the previous results are reused, but additional testing is neither required nor conducted, DDC will not bill DHHS/CSE a fee for that reuse of test results. For all samples received under the terms of this contract, DDC will continue to store and reuse genetic testing results when requested for determining parentage in subsequent cases. For example, when a second alleged father is to be tested with a mother and child that has previously been tested, DDC will utilize the initial testing results for the mother and child with the testing results obtained for the new alleged father to complete the case. This retest procedure is now commonplace with many state and county child support agencies, and can be accomplished by submitting the request through our web portal DDC Direct Connect. DDC will maintain all testing data records for the State of Nebraska, and will match up a previously tested party in a new case.

DDC has an efficient process to complete these requests, and most requests are routinely processed within a few hours of receipt. The previous case numbers and names are validated and then matched and incorporated into the new case.

In addition, DDC's case information management software alerts the laboratory when a tested party that is scheduled has been sampled for a previous case. When scheduling parties to be tested, if any information received from DHHS/CSE such as the name, social security number, and/or the date of birth matches a previously tested subject, there is an alert. This will prevent unnecessary collection of individuals, will save time in the paternity establishment process, and will save the State of Nebraska money. This data reuse procedure will continue to save the State of Nebraska a significant amount of money if historical data can be utilized for determining parentage in subsequent cases and prevent the necessity to recollect samples.

There may be the need to perform additional testing in some circumstances to meet probability of paternity or exclusion requirements, but this would be very limited and infrequent. If there is a need for additional testing, DDC will recollect and test the new sample at no charge to the State of Nebraska.

c. When, in a new case, AABB protocol requires new testing of an individual who was tested in a previous case, completing the new testing qualifies for and will be paid by DHHS under the terms of the contract.

Response: DDC understands when, in a new case, AABB protocol requires new testing of an individual who was tested in a previous case, completing the new testing qualifies for and will be paid by DHHS under the terms of the contract

14. Waiver of Fees for Late Delivery of Test Results

The time for delivery of completed verified test results will be no later than twenty-four (24) calendar days following receipt by the Contractor of all needed samples or the fee shall be waived for that case. "Motherless" or Family Study type cases, which may require additional testing, and interstate cases will be allowed thirty (30) calendar days under the same provisions as stated above.

Response: DDC understands the liquidated damages provision stipulating the waiving of the testing fee for each case that exceeds the maximum turnaround time of twenty-four (24) or thirty (30) calendar days from the receipt of last collection as per the RFP.

DDC typically provides results in five (5) calendar days from the receipt of the last collection, with many reporting within 1-2 days. This expedient turnaround time allows for efficiency whereby cases are resolved more quickly, costs are reduced within the child support system by reducing the time that cases require TANF support, and very importantly, the stress on clients caused by any additional wait time and repeated phone calls from clients to caseworkers is diminished. DDC will accommodate special requests on a case-by-case basis for expedited results. If the DHHS encounters a special need, DDC is able to have results the next day or even the same day samples are received at the laboratory at no additional cost.

15. Payment of Interstate Cases

The Contractor shall comply with all relevant federal regulations, appearing at but not limited to 45 CFR 303.7 which state in part at (e)(1) that "the responding IV-D agency must pay the costs it incurs in processing intergovernmental IV-D cases, including the costs of genetic testing".

Response: DDC will continue to comply with all relevant federal regulations, appearing at but not limited to 45 CFR 303.7 which state in part at (e)(1) that "the responding IV-D agency must pay the costs it incurs in processing intergovernmental IV-D cases, including the costs of genetic testing". Below is detailed information regarding DDC's process for Interstate/Intergovernmental requests.

DDC's Scheduling Department, led by Kellie Bunch, will coordinate the efficient and timely collection of Intergovernmental/UIFSA and international samples using an extensive network of over four thousand five hundred (4,500) collectors and collection sites. In 2019 alone, DDC coordinated specimen collection appointments for well over thirty thousand (30,000) cases for interstate, institutional/incarcerated, international, and intrastate testing parties. These sites include: child support agencies, correctional facilities, clinical laboratories, hospitals, clinics, physicians, and health departments. Qualified individuals will perform all interstate and international sample collections according to current AABB standards. DDC will also coordinate the collection of specimens from parties who are in the military or are incarcerated. DDC will attempt to coordinate scheduling all parties for collection so that the samples arrive at the laboratory at approximately the same time.

For an individual requiring an interstate or international specimen collection, DDC will continue to be responsible for coordinating all aspects of the collection.

This includes, but is not limited to: scheduling the collection and following up to ensure that samples reach the laboratory and are analyzed and reported in a timely manner. DDC's dedicated Scheduling Department's primary function is to schedule interstate, intrastate cases, international, and institutional collections. As a whole, this group has many years of combined experience providing these services to clients, and has extensive experience with the coordination and scheduling of long-arm and absent party collections. They are familiar with the challenges of coordinating collections and ensure that arrangements are made regardless of area logistics. They are sensitive to special circumstances and will make arrangements to accommodate the needs of the customer.

All intrastate, interstate, and institutional collections generally have confirmed appointments within twenty-four (24) to forty-eight (48) hours after receiving the request. DDC is committed to continuing to maintain these metrics over the term of this contract. DDC believes the DHHS realizes significant financial benefits by accelerating paternity establishment and reducing the time many cases require TANF support.

DDC's secure, on-line scheduling tool- DDC Direct Connect - is typically the most efficient, accurate, and convenient way to schedule appointments. This tool alleviates the need for the caseworkers to re-enter contact or account information, increases communication accuracy, and can be accessed 24 hours per day, 7 days per week. DDC's web-based system for scheduling streamlines the ordering process for our customers. The site is accessed through https://contracts.dnacenter.com with the secure User ID and password set by each user. This process pre-populates customer data and notifies customers of schedules via e-mail, thus reducing request completion time and eliminating the inefficiencies that typically accompany a paper-based process.

When DDC receives an electronic scheduling request, we will locate a collection site convenient and accommodating to the absent party. The collection site will be equipped to perform court-legal DNA collections under strict chain of custody procedures. A date and time will be established within fifteen to twenty (15-20) working days depending upon the needs of the agency to allow the CSE sufficient time to notify the absent party. The confirmed appointment with the client names, case numbers, and collection site information is emailed back to the CSE representative. A collection kit with complete instructions, chain of custody form, and prepaid shipping materials will promptly be forwarded to the collection site.

DDC includes complete buccal swab collection instructions in each specimen collection kit that is dispatched for an interstate, intrastate, institutional, or

international collection. DDC will require that proper photo identification is presented at the time of specimen collection and that all other chain of custody protocols are followed. Adult parties will be required to provide government-issued photo identification. After the specimen collector verifies the identification, the identification number is recorded on the chain of custody form along with social security numbers (or last 4 digits) and dates of birth. DDC will ensure that no clients are collected without proper identification.

DDC has extensive experience with international collections, including those for related individuals located outside the U.S., active military personnel located in other countries, and immigration cases. DDC processes thousands of these types of international cases each year for customers in over one hundred seventy-three (173) countries worldwide. If DDC does not already have an established collection site within a particular country, it will locate one as necessary, so that the sample can be obtained in a timely manner, shipped to the laboratory to arrive at approximately the same time as the other samples, so that the case can be completed and paternity determined.

For international collections, DDC's Scheduling Department, led by Kellie Bunch, will contact the U.S. Embassy in the foreign country in question to discuss options for collecting a specimen. In general, hospital or clinical facilities are utilized, and DDC will forward all appropriate paperwork and a specimen collection kit to the designated site in order to facilitate collection. In addition, due to the prevalence of the use of buccal swabs, the collection and international shipment of this type of specimen is non-problematic, and even if there are unforeseen delays in customs or during shipment, degradation of the specimen is not of concern. DDC will assume all transportation charges for the shipment of international specimens to its laboratory. DDC will also be responsible for payment of the phlebotomists and/or specimen collectors in the responding country in accordance with 45 CFR 303.7.

Upon receipt of a request to collect a specimen from an incarcerated party, DDC's Scheduling Department will contact the institution to determine their site-specific procedures. DDC's Scheduling Department will work with the appropriate institution personnel and will collect the sample within a timely manner. If a specimen collector is not permitted access to a particular facility, DDC will provide a specimen collection kit and complete instructions to the institution so that their personnel can perform the collection. DDC maintains the same stringent specimen collection procedures for parties who are incarcerated as for any other collection (i.e., intergovernmental and local collections), including requirements for photographs (where permitted) and thumbprints. DDC will also assist in the

coordination of the release of tissue and/or blood specimens from deceased parties when requested by the DHHS.

Regarding collections for active military personnel, DDC's Scheduling Associate will send a copy of the court order or test request form, letter and specimen collection kit (complete with shipping supplies and instructions) to the military installation's Commanding Officer. Buccal swab specimens are collected by medical personnel at the infirmary or military hospital and are forwarded to DDC's laboratory for analysis.

DDC will make every effort to coordinate intergovernmental scheduling in a manner that maximizes the efficiency of specimen collections and ensures that all specimens required to complete a case arrive at the laboratory at approximately the same time. DDC will also provide notification of missed appointments and will reschedule them at no additional charge. To date, DDC has successfully managed well over one hundred thousand (100,000) absent party collections. DDC will be responsible for payment of specimen collectors in responding states per 45 CFR 303.7(E) (1).

16. Monthly Statistical Report

The Contractor shall provide DHHS's contract manager a monthly statistical report during the term of this contract. The report shall include the number of individuals receiving genetic tests during that month and the number of cases, tabulated by county of the referring office. The report shall also specify the number of paternities established, the number of alleged fathers excluded, the number of re-draws or re-samples requested, the total amount billed, and the number and name of cases in which the fee was waived. The reports shall be received by DHHS by the twentieth (20th) day of the following month.

Response: DDC will continue to provide Monthly Statistical Reports to DHHS via hard copy and/or electronically. Delivery of these reports will be coordinated and managed by Lori Neff. This summary report contains all of the data requested above and will be received by DHHS by the twentieth (20th) day of the following month. The Monthly Statistical Reports can be provided in hard copy format or electronically in a Microsoft Office format such as Excel or as a PDF document. DDC's Laboratory Information Management System (LIMS) is capable of automatically generating statistical reports that can be exported to standard software programs such as Microsoft Word of Excel. This report will be reviewed each month and will be provided to the DHHS within the specified time frame. If a hard copy is necessary versus an electronic version, that will be provided upon request. DDC has the ability to provide a variety of statistical data that can be customized to meet the agency's needs in the event that DHHS determines that

additional reporting parameters are necessary in the future. For example, DDC is able to extract data over any historical timeframe and provide reports such as open partial cases by county, average sample volume trends, and/or other customized requests. Not only will DDC provide the Monthly Statistical Reports, but we will exceed this requirement by offering additional statistical reports depicting such items as pending partials, quantity of samples collected, UIFSA and prison collections, all partitioned by county. A sample statistical report is provided in **Attachment #7.**

B. MANDATORY REQUIREMENTS

Bidder must submit a copy accreditation by College of American Pathologists, or any other national accrediting body or public agency which has requirements that are substantially equivalent to or more comprehensive than those of the college.

Response: Copies of DDC's accreditation certificates are provided in **Attachment #5.**

C. BIDDER REQUIREMENTS

1. Submit examples of reporting, including but not limited to test results and documentation of findings.
2. Describe customer services process including but not limited to lines of communication with DHHS complaint resolution and monthly reporting.
Bidder's response: Please refer to C-1 and C-2 below for DDC's response.
3. Provide information in regard to the ability to store and transmit scanned documents electronically including HIPAA and PHI information. If the bidder has this capability describe in detail how documents would be delivered electronically and how bidder complies with HIPAA and PHI requirements.
Bidder's response: Please refer to C-3 below for DDC's response and description of DDC Direct Connect.
4. Describe business processes to demonstrate that it will meet the timeframes set forth in the Scope of Work.

Bidder's response: Please refer to C-4 below for DDC's response.

Response:

C-1 Test Results and Reporting

DDC will continue to submit standard written reports including an interpretation of test results for each individual case in accordance with Nebraska state law and all applicable statutes. Paternity evaluation reports include clear, concise language to provide an understandable interpretation of testing results. Each paternity evaluation report will include, at a minimum, the following information:

- The tester's name, title and qualifications (including title of lab);
- Date of test;
- Donors' names (tested parties) and their relation to the child(ren);
- Racial origin(s) of the mother, alleged father, and any other necessary individuals (if applicable, such as in a family study):
- Child Support/DHHS case number and court or administrative order numbers;
- Type/description of test performed;
- Percentage probability of paternity;
- Power of exclusion;
- Combined paternity index (inclusions);
- Conclusions; and
- Donors' photographs and thumbprint (if required)
- Table of Results;
- Interpretation of the results;
- Effect of prior probability and likelihood of paternity; and
- Statement of exclusion, if applicable.
- Date(s) of specimen collection
- Signed Chain of Custody form
- Copy of judicial or administrative order for genetic testing, if provided
- Signature of Ph.D. Laboratory Director conducting case review
- Notary signature and seal

DDC is also able to provide, upon request, reports in Spanish and many other languages. Copies of sample inclusionary and exclusionary paternity reports are provided in **Attachment #3**. All paternity test reports will be issued to the CSE/DHHS office that requested the test. The personnel or agent of DHHS requesting

the test will receive a certified and notarized report plus two (2) photocopies of the same for each case. DDC will continue to store and transmit scanned secured documents electronically. Prior to the delivery of the test results by way of certified and notarized letter, DDC will offer the option for appropriate child support enforcement caseworkers to receive notification of the test results via email.

In addition, testing outcomes will be available to authorized CSE representatives via DDC's secure website. This website provides caseworkers with the ability to track and collect performance data on all cases received in our laboratory 24 hours a day. Our proprietary interface, https://contracts.dnacenter.com, offers a direct link to child support offices allowing immediate access to information stored in our database for paternity cases. This service feature provides our customers with the option of an almost paperless and convenient interface with our laboratory. An added feature allows for DDC to provide email notification that test results are completed, uploaded to the web interface, and ready to be viewed. Authorized CSE staff may print a fully completed report ensuring legibility accuracy,
and convenience. Like the traditional hard copy report, this electronic report includes the Ph.D. signature, report of findings, conclusions, chain of custody documentation, thumbprints, and photographic images of the tested parties. This notification feature is especially useful for lower volume offices, as they can opt to receive the alert, whereas higher volume offices often choose to log in and retrieve their results on a daily basis without the notification.

C-2 Communication, Complaint Resolution, and Monthly Reporting

Lines of Communication

DDC offers a highly trained and professional customer service organization who will answer questions regarding any Nebraska case. DDC's Customer Service and Scheduling Associates, managed by Tonya Williams-Powell, are available at the following toll-free number Monday through Friday during standard business hours 7:00 am to 6:00 pm Central Time: (800) 310-9868. In the event that technical consultation is required with one of DDC's Ph.D. staff, all eleven (11) can be accessed at the same toll-free number listed above.

DDC has assigned a dedicated Customer Service Associate to this account (versus requiring that CSE personnel contact a call center which may result in speaking with different people each time they require assistance). Ms. Paula Cooper has over twenty years of experience and has worked with Nebraska's CSE/DHHS offices during her tenure at Orchid Cellmark and DDC. Ms. Cooper will continue to serve as the point person for all day-to-day needs, and she is familiar with the CSE staff and their unique contractual requirements. During absences or if Paula is assisting other customers, DHHS/CSE calls will be routed to a designated back-up staff member - Sarah Ballard - who is also familiar with DHHS/CSE account specifics and will provide the same level of prompt service. As a previous and current provider of

genetic paternity testing services to the State of Nebraska, DDC currently has several individuals who are familiar with many Nebraska counties and can easily serve in a back-up role or in addition to Ms. Cooper during peak times. These Customer Service Associates and management personnel include Lori Neff, Diana Holland, Beth Potter, and Luann Wilcox, exemplary customer service to the State of Nebraska.

DDC also provides each county CSE with a contact list of contact staff along with daytime and mobile phone numbers for urgent matters or after-hours needs. DDC's Specimen Collection Network is also available twenty-four (24) hours per day, seven (7) days per week for specimen collection personnel to contact to ensure uninterrupted collection services in the event of emergency.

Complaint Resolution

DDC will continue to meet and exceed the requirements in place with this contract. We have not had any issues with the delivery of services under the existing contract with the State, and we pledge to continue to deliver the same level of prompt and reliable service under the new contract should it be re-awarded to us. This includes not only the items listed in the RFP but all phases of this contract. DDC prides itself with our professional staff and service-oriented behavior. DHHS and CSE associates throughout Nebraska have experienced our commitment to delivering the best possible level of service for DNA parentage testing. Many people can propose items on paper. We hope the State has experienced first- hand the very high level of prompt and reliable service that we have been providing to Nebraska for many years.

In the event that DDC receives a complaint, it is documented following DDC's internal quality procedures to ensure consistency with contractual requirements. The matter will be investigated as appropriate. Lori Neff or Tonya Powell will contact the CSE/DHHS associate who made the complaint for any needed followup. After the investigation and review, the initial incident will be resolved and procedures will be put into place addressing the root cause to prevent recurrence.

DDC will participate in meetings with the DHHS Project Director to discuss contract-related performance and administrative matters. As part of the Quality Management System at DDC, continuous improvement is an ongoing objective. DDC has an extensive occurrence management system to evaluate performance on a daily basis and implement appropriate corrective or preventive actions through a formal process as necessary. DDC develops and monitors key metrics through internal and external audits, direct observation of employees, assessments, trend analysis, and management review procedures. These metrics enable DDC to identify areas that can be improved.

Monthly Reporting

DDC will continue to provide Monthly Statistical Reports to DHHS via hard copy and/or electronically. Delivery of these reports will be coordinated and managed by Lori Neff. This summary report contains all of the data requested in the RFP and will be received by DHHS by the twentieth (20^{th}) day of the following month.. The Monthly Statistical Reports can be provided in hard copy format or electronically in a Microsoft Office format such as Excel or as a PDF document. DDC's Laboratory Information Management System (LIMS) is capable of automatically generating statistical reports that can be exported to standard software programs such as Microsoft Word of Excel. This report will be reviewed each month and will be provided to the DHHS within the specified time frame. If a hard copy is necessary versus an electronic version, that will be provided upon request. DDC has the ability to provide a variety of statistical data that can be customized to meet the agency's needs in the event that DHHS determines that additional reporting parameters are necessary in the future. For example, DDC is able to extract data over any historical timeframe and provide reports such as open partial cases by county, average sample volume trends, and/or other customized requests. Not only will DDC provide the Monthly Statistical Reports, but we will exceed this requirement by offering additional statistical reports depicting such items as pending partials, quantity of samples collected, UIFSA and prison collections, all partitioned by county. A sample statistical report is provided in **Attachment #7.**

C-3 DDC Direct Connect Web Site

All data regarding partial case and archived samples, case status, and test results is available electronically twenty-four (24) hours per day/7 days per week on DDC's secure web portal application (https://contracts.dnacenter.com) called DDC Direct Connect. DDC's on line case management and tracking system is a real time interface that provides access to:

- Case status information
- Information regarding partial cases
- Scheduling and appointment information
- Sample collection data
- On line case results (paternity test reports)
- Account summary information (statistics)

The secure web portal application also affords DDC's government customers the ability to:

- Print paternity test reports
- Enter scheduling requests
- Complete on line ordering of sample collection kits and supplies

- Complete retest authorizations for previously tested parties
- Download DDC's Specimen Collection Manual
- View DDC's Specimen Collection Training Video
- Perform a multitude of data queries; e.g. reports can be generated of all outstanding partial cases within a specified time period; all cases reported within a specific time period; all samples collected on a particular date, etc. Customized data can be exported by the user and sorted and customized to meet the individual needs of each CSE office.

Access to this web site provides customers with the ability to track and collect performance data on-demand for cases received in our laboratory. The site provides our customers with the option of an almost paperless and convenient interface with our paternity services division. Authorized CSE representatives may access all real-time appointment and scheduling data. Reports and results may be searched and accessed via CSE case number, docket or civil action number, tested party name (first and/or last), and by last four digits of social security numbers. In addition, DDC will provide email notification that test results are completed, uploaded to the web interface, and ready to be viewed. Authorized CSE staff may print a fully completed report ensuring legibility, accuracy and convenience. Like the traditional hard copy report, this electronic report includes the Ph.D. signature, report of findings, conclusions, chain of custody documentation, thumbprint, and photographic images of the clients. All completed paternity test results will be available within twelve (12) hours of the completion of testing. The user guide for DDC Direct Connect is provided in **Attachment #8.**

Website and Data Security

DDC's IT Infrastructure Team defines and monitors all IT security standards and prevents unauthorized access to electronic files and digital records. It ensures that the network and systems are properly protected against viruses, "mal-ware," security vulnerabilities, physical access, and that the network is protected against unauthorized access from other networks. It ensures that proper backup functions and measures are taken so that systems can be recovered in case of loss of data integrity or system failure, as well as ensures that necessary patches and or service packs are applied to systems when applicable. DDC's IT Infrastructure also maintains an awareness of trends in security threats, good practices and technology, and takes these into account when implementing and operating IT solutions to ensure optimum effectiveness and required security levels. Installation, engineering, maintenance, operation, and security of wired and/or wireless networks, serving company facilities and employees, on any property owned or tenanted by the company, are the sole responsibility of IT Infrastructure. DDC's IT infrastructure approves all communication networking products and/or technology or software before they are deployed. DDC Direct Connect has been used for years by Child Support offices nationwide and is compliant with HIPAA and PHI requirements.

Risk Management / Security

All information stored, processed, or transmitted by devices on DDC's network is considered confidential, and as such, all DDC managers and employees have responsibilities for the confidentiality, integrity, and restricted availability of information.

DDC has implemented several security protocols and electronic safeguards to its web-based reporting tool that will protect the confidentiality of client test results and will provide security to ensure that only authorized personnel are allowed access to case information. The DDC website is highly secure and data is protected by a user password and a 256-bit SSL Certificate.

Each authorized user for DHHS will be set up on DDC Direct Connect. Their username will be their email. The initial introductory email will have a temporary password. Once the user logs in for the first time, he/she will be prompted to change their temporary password to a unique password. They will be required to assign a complex password utilizing the protocols below:

A complex password of at least six (6) characters is automatically assigned. It must contain characters from two (2) of the following four (4) categories:

- Uppercase English letters (A to Z)
- Lowercase English letters (a to z)
- Number from 0 to 9
- Non-alphanumeric characters (!, @, #, $, etc.)
- Cannot contain the username

If the user forgets his/her password, he/she can select "Forgot Password." They will enter their email/username, and the system will automatically generate a new temporary password to the authorized user's email. The system will automatically log out a user after 30 minutes of inactivity.

The site uses Secure Socket Layer (SSL) encryption over HTTPS with a 256-bit SSL Certificate. Once an authorized user logs in, all traffic between the user and the web service in encrypted. Furthermore, the web server only communicates with internally firewalled servers.

Backups of Data

All of DDC's data is backed up throughout the day locally and offsite. All backups are encrypted using AES-256-bit Encryption. Offsite backups are stored at an SSAE-16 certified data center.

Firewall

DDC utilizes a SonicWall Firewall for its network infrastructure. The firewall is

partitioned into different zones for compliance reasons. We have two (2) appliances, one (1) for a PCI Zone and one (1) for an External Zone. Our Virtual Private Network (VPN) software also runs through the SonicWall firewall.

Security Breaches
In order to prevent security breaches, DDC has taken precautionary measures with its external results portal and internal environment with its users.

The external results portal is connected via a RESTful (Representational State Transfer) web service. This service will prompt users for their username and password to view results. If the service recognizes the user, it will make the results available; if not, it will deny the request. No session data is stored within the client's browser during the transaction.

Internally DDC stores data in a database that is accessible only via a secure interface encrypted with AES 256-bit encryption. A username and password is also required to access the database.

The encryption standards used at DDC meet and exceed the ITS-SEC-01 "Data Encryption and Cryptography" standards.

Threat Response
In the event that a threat has been detected on DDC's web environment at our hosted datacenter, notifications are immediately sent via email to the DDC IT Team. Upon receipt of the notification, the team responds by investigating and eliminating the threat. Steps taken to eliminate the threat include reviewing Firewall logs, identifying the IP address that is attempting to penetrate the server, identifying what the target is (host), and blocking/blacklisting the Internet Protocol (IP) address.

Telecommunication Security
DDC's telecommunications services span across nine (9) virtual servers, two (2) Session Initiation Protocol (SIP) lines, and 1 PRI. The virtual environment is secured behind our Firewall on a separate Virtual Local Area Networks (VLAN) that is for voice traffic only. The physical host that runs all virtual machines is secured in a data center with a badge reader limiting access to the secured room. Additionally, a camera takes a picture of each individual that enters into the datacenter. All faxes are transmitted over the Primary Rate Interface (PRI) through analog lines rather than SIP data lines.

C-4 Meeting of Timeframes for Scope of Work and Contract Implementation

As the current provider of genetic testing services to the State of Nebraska, there will be a seamless transition of services pursuant to the new contract if this project is

awarded to DNA Diagnostics Center. The State of Nebraska can continue to rely on DDC to provide all services specified in this Request for Proposal in a quality, competent, and professional manner. DDC understands that the contract terms and requirements for this would still get attention as if it were a completely new relationship to ensure a high level of satisfaction for the DHHS Program Manager and team. DDC does not take any existing relationship for granted. DDC will reach out to each DHHS/CSE office to verify satisfaction with existing collection arrangements and update or make any requested changes.

If re-awarded this contract, DDC will commence providing services to the State of Nebraska under the new contract on or before October 1, 2020. When DDC receives Notice of Award, we would like to set a time convenient to meet with DHHS Contract Management to review the contract requirements and resolve any service modifications. The following table displays the anticipated timeline for providing all specified services. These timelines are only a guide and will depend upon input from the DHHS once the Notice of Award is received. In summary, DDC will be fully functional and in compliance with all contract specifications and requirements prior to October 1, 2020.

Event	Timeline
Contract Award	TBD by DHHS
Contract Clarifications/Discussions/Negotiations	TBD by DHHS
Meeting with DDC Contract Implementation Team and DHHS representatives to discuss logistics and contractual matters. Meeting to be held via electronic medium within one week of contract award	TBD upon Notice of Award
Submit detailed final work plan to DHHS for controlled transition to implement new contract requirements.	DDC will provide this no later than 5 business days after meeting with DHHS representatives.
Identify and confirm collection site hours and locations. Make any necessary changes to the satisfaction of DHHS.	In conjunction with DHHS, DDC will develop a formalized collection schedule and collection sites to ensure all sites will meet the needs of DHHS prior to start date. To be completed on or before September 15, 2020.
Identify and train any new replacement specimen collectors for all sites highlighting key elements required for proper performance	DDC will train all specimen collectors. To be completed on or before September 15, 2020.

Event	Timeline
Continue to provide collection kits, shipping supplies, personal protective equipment, digital cameras, fingerprinting materials, and chain of custody forms to specimen collectors	DDC's Specimen Collection Network will ensure that all collectors and collection facilities have all necessary supplies to begin collecting specimens. This will be completed before September 15, 2020.
Maintain Customer Service Associates and back ups to service the Nebraska account	DDC will maintain personnel that have direct, first-hand experience working with the offices as well as and back-ups to provide scheduling and administrative services to DHHS. DDC will continue to provide a customer contact sheet to DHHS.
Update any DHHS contract specifications in DDC's Case Information Management System (i.e. collection sites, collectors, probability of paternity, billing requirements, etc.)	DDC will have all data entered, reviewed, and ready to implement before October 1, 2020.
Review and provide training to DDC's Customer Services and Scheduling staff regarding contract requirements.	Even as incumbent, DDC will hold a meeting with all staff supporting this contract to review all requirements, terms, and conditions. To be completed before September 15, 2020.
Customer Service Associates will contact each CSE/DHHS contact to re-introduce themselves and DDC and to confirm existing contact information and receive feedback on existing specimen collector(s) and make any necessary changes.	To be completed before September 15, 2020
Review DHHS specifications with laboratory and case reporting staff (probability of paternity, report format, statistical reports, specimen and file storage)	To be completed and implemented before September 15, 2020.
Review and amend specimen collection schedules as necessary.	To be completed before September 15, 2020, and ongoing throughout the life of the contract.
Provide adequate training to any DHHS offices regarding use of DDC's interactive secure website, as needed.	All authorized staff will be trained prior to October 1, 2020.
Review feedback from DHHS sites and make any necessary changes to existing specimen collectors based on satisfaction levels from inquiries listed previously.	To be completed prior to any collection appointments scheduled October 1, 2020 and on an ongoing basis throughout the life of the contract.
DDC will to prepare samples of statistical reports and invoices for DHHS review.	To be completed and approved prior to September 15, 2020.

Event	Timeline
Begin providing full service meeting all new contract requirements.	DDC will be fully operational with all contract requirements beginning October 1, 2020.
DDC Project/Contract Management Team to be in contact with DHHS Contract Manager to monitor service delivery and to ensure requirements are being met or exceeded. Any issues will be immediately addressed and corrected.	Ongoing throughout the life of the contract.
Provide monthly statistical reports and invoicing	Ongoing throughout the life of the contract.
Conduct monthly meetings with DHHS representatives to ensure satisfaction and that all contract requirements are being met or exceeded.	Ongoing throughout the life of the contract.

Contract Management

All facets of DDC's operations are governed by the requirements of its many accrediting organizations and though our Quality Assurance and Quality Control plans, which are managed and overseen by Dr. Todd Lewis. The validation, acceptance, and acknowledgement of DDC's Quality Plans are evidenced by our many accreditations and our ISO 17025 certification. Furthermore, as described in this proposal, DDC has implemented many stringent Quality Control procedures that exceed AABB standards to ensure the accuracy of all testing results produced in the laboratory. A copy of DDC's Quality Manual has been provided in **Attachment #6.**

DDC will continue to manage, control, and supervise all services provided to the State of Nebraska to ensure that the DHHS's expectations and all contractual obligations are met or exceeded. DDC prides itself on its reputation for exemplary contract management and excellent communication with its clients. As part of the Quality Management System at DDC, continuous improvement is an ongoing objective. To maintain these standards and continually improve the effectiveness of DDC's Quality System, we have an extensive occurrence management system to evaluate progress and performance on a routine basis and implement appropriate corrective or preventive actions as necessary. Through the use of process improvement initiatives, internal and external audits, direct observation of employees, assessments, quality assurance reporting, trend analysis, and management review procedures, DDC is able to effectively monitor its ability to meet internal and external standards and provide continuous improvement to anticipate our customer's needs and monitor our performance. We believe that our exceptionally strong focus on our customers and the maintenance of productive communication channels is of utmost importance.

DDC has multiple ongoing quality programs in place to ensure high performance standards and compliance with contractual requirements. With twenty-five (25) years of experience in genetic parentage testing, DDC has been exposed to many unique

contractual conditions, and we have used this vast experience to develop policies and procedures to handle issues in a professional and efficient manner. Our belief is that frequent communication with our customers is the key to anticipating and resolving any issues that may arise.

DDC evaluates the performance of its services in a number of ways. Contract and customer requirements are reviewed with all DDC staff in advance of the inception of a new contract. This allows for a thorough understanding by all of those involved for what is required to both meet and exceed client expectations prior to the commencement of services. After award of a contract, client requirements continue to be reviewed at routine intervals so that there is always a high level of awareness regarding client requirements.

On a daily basis, multiple reports are generated to monitor workflow, thus providing a snapshot of the state of the paternity operations. This information is used by the Departmental Managers and Directors to set priorities for the department areas in order to meet client requirements. This data is continually monitored and reviewed by Kathy Leis, Vice President, Operations, to identify and address any process bottlenecks that may arise. Ms. Leis reviews work status reports that summarize critical departmental metrics to ensure we are meeting or exceeding all performance standards. This information is communicated with management at the staff meetings and any corrective actions that are being taken are discussed.

Statistical reports are generated showing objective data for such items as turnaround time, scheduling activity, and other specific client specifications. Such reports are automated and are customized based on individual contract requirements. The assembly and distribution of these statistics provides information about our average turnaround time, the number of tests requiring more than the average turnaround time, and our minimum and average probability of paternity. These statistics are useful in ensuring that we are meeting or exceeding all contract requirements.

We encourage feedback from our clients on a daily basis through our Customer Service Department. DDC assigns a dedicated Customer Service Representative to each customer who is the "specialist" for that account. This ensures a high degree of knowledge regarding each customer's specific requirements. This feedback can be in the form of a suggestion regarding staff at a collection site, the design of our interactive web site or the design of our reports, to name a few. We take each and every comment from our clients to heart and will act upon it to improve our service. Our goal is to be flexible, innovative, proactive, and to respond promptly to any special circumstances.

DDC will periodically distribute a customer survey questionnaire as a tool to provide feedback to the laboratory and to ensure that we are providing and our customers are receiving the highest level of service. DDC utilizes this process as part of our commitment to customer satisfaction and to support the philosophy of continuous

improvement. Management will review feedback received from DHHS/CSE staff and make necessary changes to existing specimen collectors, sites, reports, internal support personnel, or other logistical areas based upon satisfaction levels from inquiries. In addition, DDC's Specimen Collection Network makes routine calls to customers to get feedback on specimen collector performance. Questions are posed relative to conduct, professionalism and quality of work.

DDC's facility and its personnel are fully qualified, competent, and adequate to continue to undertake and successfully manage the Nebraska Genetic Testing Services contract. As a fully licensed and accredited laboratory, all aspects of parentage testing performed at DDC are in strict compliance with or exceed the standards established by the AABB. DDC has previously provided and is the current provider of these services to the DHHS and is a current provider of genetic testing services to many states, efficiently and professionally managing projects of similar size and complexity to Nebraska. DDC currently holds state contracts for the performance of paternity testing for child support cases in the District of Columbia, Florida, Illinois, Kentucky, Michigan, Mississippi, Missouri, Ohio, Pennsylvania, Texas, and West Virginia. In addition, DDC performs genetic testing for county, local, and tribal child support offices in the states of Alabama, Alaska, California, Idaho, Indiana, Kansas, Louisiana, Maine, Minnesota, Montana, New York, North Dakota, Oklahoma, South Dakota, Washington, Wisconsin, and Wyoming. In the past year, DDC was awarded five (5) statewide paternity contracts similar in scope where DDC was also the incumbent vendor. These include: Florida, Michigan, Mississippi, West Virginia, and Pennsylvania. DDC was also awarded the contract for Washington D.C. and were also the incumbent vendor. DDC's highly experienced team successfully transitioned and executed each project. Contract requirements were incorporated and DDC continues to meet the contract deliverables and provide excellent service levels. DDC has proven it has the operational capacity, technical resources and expertly qualified personnel required to manage small, medium, and large paternity testing contracts, and the laboratory has the operational capacity and technical and administrative resources required to continue testing responsibilities for this contract by October 1, 2020.

Operational Capacity

DDC is one of the largest paternity testing providers in the country. We have contracts with numerous state and county entities under exclusive or multi-vendor terms. These contracts encompass all sizes of child support offices and programs, with varying levels of staffing, computerization, and technologies for testing. DDC can readily maintain the projected testing volume generated by the State of Nebraska. DDC is currently processing approximately 715,000 samples annually yet has the analytical capacity to process more than 1,120,000 samples annually. Even with the re-award of this contract, DDC has more than sufficient capacity, technical, and administrative resources to successfully manage this contract.

DDC is staffed with highly trained and qualified individuals dedicated to performing all

of the technical and administrative areas related to paternity testing. As a fully licensed and accredited laboratory, all aspects of parentage testing performed at DDC are in strict compliance with or exceed the standards established by the AABB. DDC has previously provided these services and is the current provider to DHHS and is a current provider of genetic testing services to many states, efficiently and professionally managing projects of similar size and complexity to Nebraska. DDC has proven it has the operational capacity, technical resources and expertly qualified personnel required to manage small, medium, and large paternity testing contracts, and the laboratory has the operational capacity and technical and administrative resources required to continue to maintain testing responsibilities for this contract.

VI. CORPORATE OVERVIEW

A. CONTRACTOR IDENTIFICATION AND INFORMATION

The bidder should provide the full company or corporate name, address of the company's headquarters, entity organization (corporation, partnership, proprietorship), state in which the bidder is incorporated or otherwise organized to do business, year in which the bidder first organized to do business and whether the name and form of organization has changed since first organized.

Response:

Full corporate name: DNA Diagnostics Center, Inc.
Address of headquarters: One DDC Way, Fairfield, OH 45014
Entity organization: Corporation
Incorporation: State of Ohio
Date established: June 17, 1994

Company Background and Relevant Experience

DDC is one of the world's largest and most experienced private DNA testing laboratories. Our laboratory was incorporated in the State of Ohio in 1994. In 1995, the headquarters moved to the current location and was renamed DNA Diagnostics Center (DDC). DDC has been providing quality genetic testing services for twenty-five (25) years to customers throughout the world.

As one of the nation's largest family relationship testing providers, DDC has developed a reputation for exceptional quality and legendary customer service. Its highly accredited laboratory provides DNA testing services for both government agencies and private customers to resolve the parentage of children and determine other family relationships. DDC is a market leader for the determination of paternity testing not only in the United States, but throughout

the world. Over the past twenty-five (25) years, DDC has analyzed well over ten million (10,000,000) family relationship samples in all fifty (50) states and over one hundred seventy-three (173) countries demonstrating our broad experience both domestically and internationally, and we are dedicated to the business of genetic identity testing. Our laboratory facility and its personnel are fully qualified, competent, and capable of implementing and maintaining the requirements of this contract. Throughout DDC's history and path to becoming a leading genetic testing services provider, we have retained the customer-oriented focus characteristic of a smaller organization. DDC prides itself in servicing accounts ranging from a limited number of samples to over sixty-five thousand (65,000) samples per year, and each customer is treated as a valued partner. This opinion is shared by our customers and is confirmed through positive customer surveys and through the references that are included with this proposal.

DDC offers comprehensive DNA testing services in several specialty areas: paternity and family relationship testing, forensics, and veterinary testing. DDC established the DNA Technology Park, a 7-acre campus located in Fairfield, Ohio, a suburb north of Cincinnati. DDC has state-of-the-art technology and instrumentation for performing DNA testing in this ultra-modern 66,000 square foot corporate headquarters and laboratory complex. The laboratory employs approximately two hundred forty (240) employees, comprised of management, laboratory staff, and customer service personnel dedicated solely to identity testing. Our eleven (11) Ph.D. scientists, together with our laboratory staff, have a combined experience level of more than two hundred fifty (250) years in DNA technology, paternity testing, forensic testing, and genetic studies. Additionally, DDC has three accredited satellite facilities located in Baltimore, Maryland; Minneapolis, Minnesota; Ridgewood, New Jersey; Chicago, Illinois: Boston, Massachusetts; Philadelphia, Pennsylvania; and Plantation, Florida.

DDC's Laboratory Facility in Fairfield, Ohio

Aerial View of DDC's Campus in Fairfield, Ohio

DDC's Service Offerings:
DDC provides a wide range of DNA testing services to individuals and organizations around the world. These include paternity and other family relationship testing, non-invasive prenatal testing, immigration testing, ancestry testing services, forensics, veterinary DNA testing and cell line authentication. DDC's scientists have the level of experience and depth of expertise required to solve difficult cases in each of these testing specialties. Additional information on all of DDC's service offerings can be found on our website: www.dnacenter.com.

Paternity and Family Relationship Testing

DDC is one of the most experienced private providers of paternity and family relationship testing. DDC will report findings of either a valid exclusion (minimum of three (3) direct exclusions) or inclusion that exceeds the AABB's minimum probability of paternity (greater than 99.0%; i.e. paternity index = 100). DDC's testing battery provides an average routine probability of paternity of 99.999999% (paternity index = 100,000,000) for standard cases. Our results are routinely recognized by courts and other government agencies in legal cases such as child support and Social Security benefit claims.

In the absence of an alleged father, DDC can provide other testing options in order to help establish the child's relationship including deceased sample testing, grandparentage testing, genetic reconstruction, and siblingship testing.

Non-Invasive Prenatal Testing

Available through DDC, this is one of the most accurate, non-invasive ways to establish paternity before a baby is born. The process is state-of-the-art, combining the latest in DNA SNP microarray technology and proprietary methods of preserving and analyzing the baby's DNA found naturally in the mother's bloodstream.

Immigration Testing

Many clients use DDC's DNA testing services to prove biological ties to a United States citizen who is sponsoring their immigration to the U.S. DDC's immigration specialists know the specific DNA testing standards and procedures for each country, having provided testing to more than 900 agencies and governments in over 173 countries worldwide.

Ancestry Testing Services

DDC offers ancestry testing services to help family historians, genealogists, and those interested in learning more about their heritage.

Forensics

DDC Forensics offers evidence screening, serological analysis, DNA testing, DNA expert testimony services, forensic paternity analysis, and DNA specimen matching services. We serve as a neutral laboratory providing accurate forensic DNA services to crime laboratories, law enforcement agencies, defense attorneys, and private investigators worldwide. DDC was honored at Ohio Innocence Project's (OIP) tenth Anniversary Gala, celebrating freedom for those exonerated and the organizations that have contributed to the effort. To date, DDC's testing for OIP includes more than 30 cases, resulting in the exonerations of Ohio residents, Robert Towler, Robert McClendon, and Dewey Jones. Working with other Innocence Projects on post-conviction cases throughout the United States, DDC has provided DNA testing that resulted in the exonerations of Florida citizens James Bains, Derrick Williams, and Cheydrick Britt, and Kentucky Innocence Project client, Kerry Porter.

Veterinary DNA Testing

DDC's subsidiary, Veterinary Diagnostics Center, provides innovative, quality DNA testing to breeders, veterinarians, and pet owners for companion and sport animals. We perform DNA profile tests required to register canine species, parentage tests for dogs and cats, bird sexing, and testing for genetic diseases in dogs and cats.

As a fully licensed and accredited laboratory, all aspects of parentage testing performed at DDC are in strict compliance with or exceed the standards established by the AABB and its other accrediting agencies. DDC has proven it has the operational capacity, technical resources and expertly qualified personnel required to manage the paternity genetic testing services contract for many small and large states and municipalities, and we will provide the highest quality services to the State of Nebraska for the duration of this contract.

States Currently Serviced by DDC's Government Contracts Division

In addition to private testing, DDC currently holds state contracts for the performance of paternity testing for child support cases in the District of Columbia, Florida, Illinois, Kentucky, Michigan, Mississippi, Missouri, Ohio, Pennsylvania, Texas, and West Virginia. In addition, DDC performs genetic testing for county, local, and tribal child support offices in the states of Alabama, Alaska, California, Idaho, Indiana, Kansas, Louisiana, Maine, Minnesota, Montana, New Jersey, New York, North Dakota, Oklahoma, South Dakota, Washington, Wisconsin, and Wyoming. DDC's highly experienced team successfully transitioned and executed each project. Contract requirements were incorporated and DDC continues to meet the contract deliverables and provide excellent service levels. The table below and depicts the annual testing volumes based on 2019 for DDC contracts and child support offices that DDC services:

State	Approximate Annual Sample Volume
Alabama	7,500
California	7,500
Florida	32,000
Illinois	14,500
Indiana	8,500
Kentucky	15,000
Louisiana	4,500
Michigan	22,000
Minnesota	4,000
Mississippi	15,000
Missouri	17,000
Nebraska	5,500
New Jersey	1,000
New York	7,000
Ohio	55,000
Pennsylvania	19,500
Texas	65,000
Tribal Native American	2,000
Washington DC	2,000
West Virginia	5,000
Wisconsin	20,000

In addition, the following highlights DDC's extensive experience in the field of genetic parentage testing:

- In 2019, DDC's laboratory provided results in over three hundred thousand (300,000) family relationship cases performing genetic testing and analyzing test results for nearly eight hundred thousand (800,000) individuals.

- DDC provides contract services to state and county agencies for programs of only a few samples per year to accounts submitting over sixty-five thousand (65,000) samples per year.

- DDC provides paternity testing services for the private sector as well. In 2019, DDC conducted testing for approximately five hundred thousand

(500,000) samples for various private sector clients, including attorneys, corporations, immigration agencies, and private individuals.

- DDC will perform DNA analysis exclusively and will provide results of solid exclusion or an average probability of paternity of 99.999999% or higher for standard cases, which exceeds both the AABB standard and the specifications of this solicitation.

- DDC will perform independent, confirmatory DNA analysis for all samples in all cases, not just exclusions, and not just excluded alleged fathers. All genetic markers in the routine test battery are tested in duplicate, not just an overlapping selected subset.

- DDC has many years of experience working with Child Support programs nationwide, and is the current supplier of genetic testing services to the State of Nebraska.

- DDC will provide highly skilled, experienced, reliable, and professional specimen collection services throughout the entire state of Nebraska, as well as nationwide and worldwide.

- DDC provides paternity testing using standard autosomal STR (Short Tandem Repeat) markers to resolve the vast majority of paternity analyses. DDC can also provide testing using Y-STRs (paternal lineage), and mitochondrial DNA testing (maternal lineage) as needed to resolve certain difficult cases.

- DDC can extract DNA from many biological materials including standard cheek swabs and blood samples, as well as more complicated tissue, fingernail, bone, teeth, pathology, and hair samples.

- DDC can provide paternity testing in more complicated situations when the mother is not available or when the alleged father is deceased. DDC can conduct complex kinship tests to determine a biological relationship between relatives other than a father and child (i.e. grandparents, aunts/uncles, or siblings).

- Test results will be furnished on average within five (5) calendar days of specimen collection, thus reducing the time necessary for paternity establishment.

- In addition to our extensive scientific experience in the human identity testing field, DDC also has a strong customer service team. This includes trained specialists who exclusively schedule UIFSA, long arm,

international, military, and prison draws, and Customer Service Associates dedicated to serving the needs of Nebraska Child Support.

- DDC's Chief Science Officer and Project Manager, Dr. Michael Baird, is currently serving the AABB as the Chairman of the Paternity Accreditation Standards Committee. In addition, DDC's Laboratory Director, Dr. Debra Davis has been a member of the AABB since 1998, and has been part of the AABB Assessor Program for Relationship Testing since 2007.

B. FINANCIAL STATEMENTS

The bidder should provide financial statements applicable to the firm. If publicly held, the bidder should provide a copy of the corporation's most recent audited financial reports and statements, and the name, address, and telephone number of the fiscally responsible representative of the bidder's financial or banking organization.

If the bidder is not a publicly held corporation, either the reports and statements required of a publicly held corporation, or a description of the organization, including size, longevity, client base, areas of specialization and expertise, and any other pertinent information, should be submitted in such a manner that proposal evaluators may reasonably formulate a determination about the stability and financial strength of the organization. Additionally, a non-publicly held firm should provide a banking reference.

The bidder must disclose any and all judgments, pending or expected litigation, or other real or potential financial reversals, which might materially affect the viability or stability of the organization, or state that no such condition is known to exist.

The State may elect to use a third party to conduct credit checks as part of the corporate overview evaluation.

Response: DNA Diagnostics Center is an Ohio incorporated entity established as a C Corporation. DDC is a wholly owned subsidiary of DDC-DNA Holdings, Inc. Based on our review of publicly available information regarding contract sizes and competitor activity, supplemented by industry publications and third party market assessment data, we believe that DDC is one of the largest providers of family relationship testing in the U.S., and we are a recognized and leading provider of such services worldwide. Based on our financial results, strong cash position, and future prospects for the business, DDC believes it will continue to be one of the leading providers of family relationship testing in the U.S. for years to come and has the financial viability and stability to efficiently and professionally manage the State of Ohio paternity testing contract.

DDC offers comprehensive DNA testing services in several specialty areas: paternity and family relationship testing, forensics, and veterinary testing. DDC established the DNA Technology Park, a 7-acre campus located in Fairfield, Ohio, a suburb north of Cincinnati. DDC has effectively and professionally managed many substantial state and county paternity testing contracts for many years.

As a privately held company, we do not publicly share our audited financials. DDC will provide audited financials to the evaluators upon request.

There are no judgments, pending or expected litigation, or other real or potential financial reversals, which might materially affect either the viability or stability of the organization or of our ability to perform the responsibilities of this contract.

Banking reference contact information is:

Huntington National Bank
P.O. Box 1558 EA1W37
Columbus, OH 43216-1558
Main account number 01651457739

Contact:

Mary Kay Mason, Senior Vice President, MBA, CTP, CRCR

Healthcare / Franchise / Corporate Treasury Management Advisor

The Huntington National Bank 525 Vine Street, 20th Floor, Cincinnati, OH 45202

Phone: 513.762.1880 | Mobile: 513.382.4810 | huntington.com

C. CHANGE OF OWNERSHIP

If any change in ownership or control of the company is anticipated during the twelve (12) months following the proposal due date, the bidder should describe the circumstances of such change and indicate when the change will likely occur. Any change of ownership to an awarded bidder(s) will require notification to the State.

Response: DDC does not anticipate a change of ownership or control of the company during the twelve (12) months following the proposal due date.

D. OFFICE LOCATION

The bidder's office location responsible for performance pursuant to an award of a contract with the State of Nebraska should be identified.

Response: DDC's office location and headquarters are located at One DDC Way, Fairfield, Ohio 45014.

E. RELATIONSHIPS WITH THE STATE

The bidder should describe any dealings with the State over the previous ten (10) years. If the organization, its predecessor, or any Party named in the bidder's proposal response has contracted with the State, the bidder should identify the contract number(s) and/or any other information available to identify such contract(s). If no such contracts exist, so declare.

Response: DDC is the current contract provider for DNA Genetic Paternity Testing with Nebraska DHHS. This contract was awarded in 2010 to Orchid Cellmark. In 2012, Orchid Cellmark's U.S. Child Support (IV-D) testing was divested to DNA Diagnostics Center, Inc. in addition to the transfer of clients throughout the nation, many of the same personnel, supervisors, managers, and laboratory directors also transitioned to DDC, thus maintaining the consistency and continuity of the same laboratory personnel working with the same Child Support accounts. The current contract # is 44727-04, Genetic Testing and Associated Services.

F. CONTRACTOR'S EMPLOYEE RELATIONS TO STATE

If any Party named in the contractor's proposal response is or was an employee of the State within the past sixty (60) months, identify the individual(s) by name, State agency with whom employed, job title or position held with the State, and separation date. If no such relationship exists or has existed, so declare.

If any employee of any agency of the State of Nebraska is employed by the contractor or is a Subcontractor to the contractor, as of the due date for proposal submission, identify all such persons by name, position held with the contractor, and position held with the State (including job title and agency). Describe the responsibilities of such persons within the proposing organization. If, after review of this information by the State, it is determined that a conflict of interest exists or may exist, the contractor may be disqualified from further consideration in this proposal. If no such relationship exists, so declare.

Response: DDC does not have any individuals who are or were ever employed by the State of Nebraska.

G. CONTRACT PERFORMANCE

If the contractor or any proposed Subcontractor has had a contract terminated for default during the past five (5) years, all such instances must be described as required below. Termination for default is defined as a notice to stop performance delivery due to the contractor's non-performance or poor performance, and the issue was either not litigated due to inaction on the part of the contractor or litigated and such litigation determined the contractor to be in default.

It is mandatory that the contractor submit full details of all termination for default experienced during the past five (5) years, including the other Party's name, address, and telephone number. The response to this section must present the contractor's position on the matter. The State will evaluate the facts and will score the contractor's proposal accordingly. If no such termination for default has been experienced by the contractor in the past five (5) years, so declare.

If at any time during the past five (5) years, the contractor has had a contract terminated for convenience, non-performance, non-allocation of funds, or any other reason, describe fully all circumstances surrounding such termination, including the name and address of the other contracting Party.

Response: DDC has not had any contract terminated in the past five (5) years for default, convenience, non-performance, non-allocation of funds, or any other reason.

H. SUMMARY OF CONTRACTOR'S CORPORATE EXPERIENCE

The bidder should provide a summary matrix listing the contractor's previous projects similar to this solicitation in size, scope, and complexity. The State will use no more than three (3) narrative project descriptions submitted by the contractor during its evaluation of the proposal.

The bidder should address the following:

i. **Provide narrative descriptions to highlight the similarities between the bidder's experience and this solicitation. These descriptions should include:**
   a) **The time period of the project;**
   b) **The scheduled and actual completion dates;**
   c) **The Contractor's responsibilities;**
   d) **For reference purposes, a customer name (including the name of a contact person, a current telephone number, a facsimile number, and e-mail address); and**
   e) **Each project description should identify whether the work was performed as the prime Contractor or as a Subcontractor. If a contractor performed as the prime Contractor, the description should provide the originally scheduled completion date and budget, as well as the actual (or currently planned) completion date and actual (or currently planned) budget.**

ii. **Contractor and Subcontractor(s) experience should be listed separately. Narrative descriptions submitted for Subcontractors should be specifically identified as Subcontractor projects.**
iii. **If the work was performed as a Subcontractor, the narrative description should identify the same information as requested for the Contractors above. In addition, Subcontractors should identify what share of contract costs, project responsibilities, and time period were performed as a Subcontractor.**
iv. **Experience with State(s) with similar geographic makeup.**
v. **Experience with any State's Child Support and legal system as it pertains to paternity establishment.**

Response: DDC's references from other Child Support contracts appear on the following two pages. In all contracts, DDC is the prime contractor and no portion of the analysis or management was subcontracted to another company. DDC has provided expert witness testimony and legal support to Child Support programs nationwide. However, like in Nebraska, the need for expert witness testimony and legal support is virtually non-existent now.

References:

Customer Company Name: State of Missouri	Contact: Sue Neeley, Contract Manager and John Ginwright, Deputy IV-D Director	
Address: 615 Howerton Court Jefferson City, MO 65102	Phone #: (573)526-5358 & (573)751-4995 E-mail: susan.k.neeley@dss.mo.gov john.b.ginwright@dss.mo.gov	
Project Name: Genetic Material Collection and Testing	Beginning Date of Project (Month/Year): 10/1/15	Ending Date of Project (Month/Year): 9/30/20

Description of project size, complexity and DDC's role in this project.

Project Dollar Value: $375,000 per year

DDC was awarded the State of Missouri contract in October 2015, which had been held by the incumbent provider since 1992. The current contract is effective until September 2016 with another four (4) years of renewal options extending to the year 2020. DDC provides the full spectrum of paternity testing services including, but not limited to, appointment scheduling, sample collection and transportation, laboratory testing, issuing genetic test reports, invoicing, customer service, expert witness services, and performance tracking. The approximate annual sample volume is 17,000.

Company Name: State of Louisiana	Contact Name:	
Address: 627 N. Fourth St. Baton Rouge, LA 70804	Phone Number: (225) 342-4789 E-Mail Address: Lydia.scales.DCFS@la.gov	
Project Name: Genetic Parentage Testing Services	Beginning Date of Project: (Month/Year) 1/1/16	Ending Date of Project:(Month/Year) 12/31/20

Description of project size, complexity and DDC's role in this project.

Project Dollar Value: $175,000 per year

DDC is one of two providers of genetic paternity testing services to the State of Louisiana. We have professionally managed the southern portion of this state contract since 2012. Services provided include but are not limited to, appointment scheduling, sample collection and transportation, laboratory testing, issuing genetic test reports, invoicing, customer service, expert witness services, and performance tracking. DDC also provides specimen collection services at the parishes being serviced by DDC. Approximate annual sample volume is 4,500. DDC was recently awarded the new contract that resulted from the RFP process that began in January 2016 extending through 2020.

This contract initially came to DDC in the Summer of 2012 after being with our corporate lineage (Orchid Cellmark and ReliaGene Technologies). Original testing services started in July 1992. After working with DDC through the remainder of the post-transition contract (2012-2015), the State of Louisiana selected DDC for a new contract term in 2015 (which runs through 12/31/2020).

Company Name: State of Mississippi	Contact Name:	
Address: P. O. Box 352, Jackson, MS 39205	Phone Number: (601) 359-4282 E-Mail Address: lyndsy.landry@mdhs.ms.gov	
Project Name: Genetic Parentage Testing Services	Beginning Date of Project: (Month/Year) 7/1/19	Ending Date of Project:(Month/Yea) 6/30/24

Description of project size, complexity and DDC's role in this project.

Project Dollar Value: $180,000 per year

Since 2012, DDC has provided paternity testing and all associated services for all 82 counties located in the State of Mississippi. This is another contract that initially came to DDC as a result of the transition in the Spring of 2012. This State had been working with the labs in the corporate lineage since 1990. After the initial two-year term (2012 through 2014), Mississippi issued its new RFP in the Spring of 2014. After success with DDC, the State of Mississippi awarded the new contract (July 1, 2014 through June 30, 2019) to DDC and then the current contract (July 1, 2019 through June 30, 2024).

Under the contracts, DDC helped Mississippi save a considerable amount of funds by transition from an old contract that utilized lab-furnished collectors at CSE offices and remote locations (similar to Ohio's Tier 1 and Tier 2) and implemented procedures where CSE associates have the clients swab themselves (similar to Ohio's Tier 3). DDC took an active role in the training of the collectors under the new procedures of the new contract.

Like all other Child Support accounts, DDC provides the full spectrum of paternity testing services including, but not limited to, appointment scheduling, furnishing supplies for sample collection and transportation, laboratory testing, issuing genetic test reports, invoicing, customer service, online case management website, expert witness services, and performance tracking. Approximate annual sample volume: 15,000.

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

The bidder should present a detailed description of its proposed approach to the management of the project including a staffing plan that addresses future needs as numbers tested increase or decrease.

Response: DDC's Project Management Team, led by Dr. Michael Baird, will participate in conference calls with the DHHS Contract Manager to discuss contract-related performance and administrative matters. As part of the Quality Management System at DDC, continuous improvement is an ongoing objective. DDC has an extensive occurrence management system to evaluate performance on a daily basis and implement appropriate corrective or preventive actions through a formal process as necessary. DDC develops and monitors key metrics through internal and external audits, direct observation of employees, assessments, trend analysis, and management review procedures. These metrics enable DDC to identify areas of improvement. These metrics will be reviewed with the DHHS Contract Manager at each meeting to ensure that DDC is meeting or exceeding the specifications of this contract. DDC has in the past and will continue to provide input and suggest potential solutions to identified problems ranging from our legal staff opinion to simple chain of custody modifications. DDC will be available at any interval that is needed in order to work with DHHS as a partner to improve the overall effectiveness of the program and address any outstanding issues.

DDC is one of the largest paternity testing providers in the country. We have contracts with numerous state and county entities under exclusive or multi-vendor terms. These contracts encompass all sizes of child support offices and programs, with varying levels of staffing, computerization, and technologies for testing. DDC can easily maintain the projected (and existing) testing volume generated by the State of Nebraska. DDC is currently processing approximately 715,000 samples annually yet has the analytical capacity to process more than 1,120,000 samples annually. Even with the re-award of this contract, DDC has more than sufficient capacity, technical, and administrative resources to successfully manage this contract.

The bidder should identify the specific professionals who will work on the State's project if their company is awarded the contract resulting from this solicitation. The names and titles of the team proposed for assignment to the State project should be identified in full, with a description of the team leadership, interface and support functions, and reporting relationships. The primary work assigned to each person should also be identified.

The caliber of DDC's staff is outstanding, and our team is one of the most tenured, competent, and experienced in the industry. Many of DDC's senior level staff have been employed with the company for more than a decade and have worked in the field of

genetic testing for well over twenty years. These individuals have worked with DHHS on the current contract and many of them have worked on prior contracts for extended periods of time. All laboratory staff are required to participate in internal and external training and proficiency programs and continuing education each year. These positions are considered key to contract implementation, facility operations, and the provision of services to the State of Nebraska. The following section provides a brief bio for each key staff individual, highlighting his/her responsibilities and experience. Detailed Curricula Vitae and References for key personnel are provided as **Attachment # 4.**

Michael Baird, Chief Scientific Officer and DHHS Project Manager

Dr. Baird, DDC's Laboratory Director and Chief Scientific Officer, has decades of experience in the field of DNA testing and has personally reviewed over 157,000 family relationship cases. In 1982, Dr. Baird was at the forefront of DNA testing as part of a team that pioneered identification through DNA and then offered it commercially. In 1987, he was the first DNA expert to testify in a U.S. court case and has since testified in hundreds of court cases involving DNA relationship testing and forensics. Dr. Baird has written and published numerous articles and manuscripts in the field of DNA technology, paternity testing, and forensics. Dr. Baird has appeared on several national TV shows that featured DNA testing. NBC News hired him as their on-air DNA expert during the OJ Simpson trial. He has also been interviewed on Larry King Live, Nancy Grace, Court TV, and others.

Dr. Baird has been with DDC for 18 years and is responsible for the development of the Standard Operating Procedures (SOPs) used by the laboratory, which cover the DNA testing, reporting, and customer service requirements. Dr. Baird is a pioneer in the use of DNA testing for relationship analysis and has over 35 years' experience in using DNA testing methods for relationship analysis. Dr. Baird is the first person to testify in the US in a forensic case using DNA test results he generated while at Lifecodes Corporation. Dr. Baird is approved by the AABB as the Laboratory Director. Dr. Baird has been involved as a volunteer with the AABB for the last 30 years and has been Chair of both the Relationship Testing Standards Committee and the Relationship Testing Accreditation Committee for the AABB. He has also been a volunteer assessor for the AABB and has assessed more than 15 laboratories seeking AABB accreditation for Relationship Testing. Dr. Baird is also a volunteer assessor for the College of American Pathologists (CAP) for molecular genetic testing and has inspected more than 10 laboratories seeking CAP accreditation. Many of these laboratories also obtained their CLIA certification bases on the CAP inspection. Dr. Baird is a native New Yorker and graduated high school in Warwick, NY. He attended Drew University in Madison, NJ for his bachelor's degree and The State University of New York for his master's degree. He attended The University of Chicago for his PhD in genetics and then completed a postdoctoral fellowship at The University of Michigan in the Department of Human Genetics where he studied sickle cell anemia. He then joined Columbia University as a Research Associate in the Department of Human Genetics and Medicine where he discovered the first splice junction mutation resulting in a genetic abnormality causing

beta thalassemia.

Dr. Baird next joined Lifecodes Corporation at its inception as a Senior Scientist where he led a Team that developed DNA test methods for the determination of paternity as well as forensic analysis. Dr. Baird was the first to present these methods for use in relationship analysis and forensics at a scientific meeting in 1985. Dr. Baird has published over 50 articles and chapters in books and has presented at dozens of scientific meeting during his career. Dr. Baird has testified in Court in over 300 cases in 35 different states involving paternity and forensic DNA testing he was involved in performing. Dr. Baird also helped develop DNA testing methods for HLA typing which many laboratories use today. Dr. Baird served on a panel of the Office of Technical Analysis of the US Government to provide information to Congress about DNA testing for relationship and forensic analysis. Dr. Baird is a member of numerous scientific societies and annually attends scientific conferences.

Led by Dr. Baird, our laboratory staff consists of eight (8) PhD-level Directors and a staff of Bachelor-degreed technologists and technicians. We have a dedicated and experienced on-site Quality Assurance Director, Todd Lewis, who oversees the laboratory's quality system and conducts monthly internal audits. Our Laboratory Directors and professional staff have combined experience of over three hundred fifty (350) years in DNA technology, paternity testing, forensic testing, immunogenetics, and genetic studies.

Kathy Leis, Vice President, Operations

Ms. Leis joined DDC in July 2012 after completing the oversight of the divestiture of Orchid Cellmark's IV-D government paternity business. She was employed at Orchid Cellmark for over 27 years, with over 35 years of laboratory experience. She has a Bachelor of Science degree in Medical Technology and is certified by the American Society of Clinical Pathologists. She has been directly involved in all aspects of paternity testing and is well versed in managing contracts. Ms. Leis not only has strong skill sets and experience in contract management, but also gained hands-on experience in all components of testing, including specimen collection and expert witness testimony as well as being intimately involved in quality processes. She has worked at the bench level in the laboratory, performed specimen collections, and has managed customer service. This allows her to better understand issues that arise in the field, as well as anticipate, prevent and solve problems.

Ms. Leis is responsible for overseeing the daily operations and for ensuring that both the laboratory and administrative operations meet or exceed the contractual requirements of the State of Nebraska DJFS. She has extensive experience since the mid-1980's working with Child Support, private industry and many other governmental agencies. She routinely participates in quarterly meetings to assess contract performance and is involved in all aspects of contract implementation and monitoring within the facility to ensure test results are issued accurately and in a timely manner. Other professional

positions held include the following: Director of Operations, Orchid Cellmark (formerly GeneScreen), 1998-2012, Paternity Laboratory Supervisor and Technologist, Orchid GeneScreen, 1985-1997, Staff Medical Technologist, St. Luke's Medical Center, 1984-1985, Staff Medical Technologist, Kettering Medical Center, 1981-1983 and Phlebotomist, Kettering Medical Center, 1979-1981.

Responsibilities/Functions:

- Directly responsible for coordination of resources, staffing, laboratory operations, and customer service. Ensure all operational requirements are achieved, maintain high customer satisfaction, and meet and exceed compliance with accrediting bodies and regulatory agencies.
- Ensures implementation and adherence to all task-specific Standard Operating Procedures.
- Approves all purchases for the facility and request approval according to task-specific Standard Operating Procedures.
- Ensures proper training and skill building of management staff in order to meet objectives.
- Oversight for tracking and monitoring workflow. Creates and designs new processes and systems to improve overall operations.
- Develops initiatives to enhance productivity, efficiency and improve profitability.
- Monitors operations through data collection, assessment of systems and success in obtaining the stated objectives.
- Provides data to be utilized in preparation of the annual capital and operating budget.
- Assists senior management in resource and strategic planning.
- Participates in the selection and evaluation of products and vendors.

Lori Neff, Director, Client Services and Government Contracts

Lori Neff, Director, Client Services and Government Contracts, is responsible for directing and maintaining consistent policies and procedures for the government contracts team to include: customer service, interstate/institutional scheduling, specimen collection network, and case processing and reporting while ensuring the highest levels of service, contract compliance, and satisfaction to DDC's customers. Ms. Neff has been involved in the paternity testing industry since 1992 and has worked directly with hundreds of child support agencies and staff, child protective services, tribal agencies, and other public social service agencies throughout the country. She started out as a Laboratory Technician for Orchid Cellmark when paternity testing was done with HLA and red cell antigen typing methods. She then assumed the role of Paternity Team Leader in 1994, then assumed the role of Bone Marrow Services Coordinator in January of 1997, was promoted to Manager of the Specimen Collection Network in 2002 and to Director of North American Customer Service in 2005. She joined DDC in 2012 as the Director of

Customer Service, and has since been promoted to the Director of Government Contracts, which includes all aspects of IV-D accounts nationwide. Her previous experience in multiple roles has allowed her to better understand the issues that may arise in the field, as well as anticipate, prevent and solve problems. Ms. Neff works directly with customers to ensure contract compliance and overall customer satisfaction. She has conducted many self-collection training seminars, web training, and general presentations for child support, court, and social services staff. Ms. Neff is certified by the American Society of Clinical Pathology, Board of Registry as a Medical Laboratory Technician. She earned her Associate of Applied Sciences degree in Medical Laboratory Technology from Clark State Community College.

Ms. Neff is located in DDC's headquarters in Fairfield, Nebraska (metropolitan Cincinnati). There, she manages the entire Customer Service and Scheduling teams within Government Contracts and works very closely with the laboratory directors.

Responsibilities/Functions:

- Ensures proper training and skill building of staff in order to meet objectives.
- Directly responsible for coordination of resources and customer staff to ensure that all contract requirements are achieved.
- Directs and supervises a staff with designated departmental responsibilities.
- Oversees the operation such that it is maintained in a professional and efficient manner.
- Monitors operations through data collection, assessment of systems and success in obtaining the stated contract-specific objectives.
- Evaluates current procedures and practices for accomplishing objectives and develop and implement improved practices.
- Tracks and monitors workflow. Creates and designs new processes and systems to improve overall operations.
- Serves as primary contact when new contracts are implemented. Schedules and facilitates customer quarterly review meetings to ensure that all contract objectives and customer expectations are being met.
- Provides statistics and data as requested to customers.
- Prepares materials for key events, presentations and contract proposals.
- Responsible for the transition of newly acquired contracts and accounts.
- Reviews staff performance evaluations.
- Routinely interacts and provides information and reports to Senior Management.
- Develops initiatives to enhance productivity, efficiency and improve cost efficiency.
- Represents DDC at Child Support conferences.

Debra Davis, Ph.D., Laboratory Director

Dr. Davis joined DDC in June 2012 and had been employed with Orchid Cellmark for over 13 years, serving as the Laboratory Director and previously as an Associate

Laboratory Director. Dr. Davis assumed the role of Laboratory Director at Orchid Cellmark-Dayton in June 2007 and has more than 21 years of experience in the field of Molecular Genetics. She has a Ph.D. in Biomedical Sciences with a concentration in Molecular Genetics from Wright State University in Dayton, Nebraska, an MBA in Finance, and a Bachelor of Science degree in Biology from the University of Cincinnati. She has over 6 years post-doctoral experience at the University of Cincinnati during which time she performed independent research using Polymerase Chain Reaction (PCR), Restriction Fragment Length Polymorphism (RFLP), cloning, and transgenic techniques.

Dr. Davis is currently responsible for reviewing and interpreting test results, reviewing paternity case files, and providing technical assistance. Dr. Davis is fully qualified to direct AABB accredited testing for the purposes of relationship and identity determination, and over the past seventeen years has had the opportunity to review well over 242,000 family relationship cases. She received her Certificate of Qualification from the New York State Department of Health as a Laboratory Director for Parentage/Identity Testing in 2004. She received specialized Training in Basic Population Genetics and Forensic Statistics in 2003. She has been a member of the AABB since 1998, and has been part of the AABB Assessor Program for Relationship Testing since 2007.

Dr. Davis has a strong commitment to all aspects of paternity and relationship testing, including assisting in the education and understanding of testing processes and outcomes. Dr. Davis is available to answer all questions that might arise involving paternity and relationship testing and also serves as an expert witness. Dr. Davis has testified in many diverse trials throughout the country. Dr. Davis has been an invited speaker at the Illinois Family Support Association's Twentieth Annual Members' Meeting and the Louisiana Support Enforcement Association 2009 Training Conference Workshop. Further, Dr. Davis is thoroughly committed to advancing the education and advancement for youth and is a past member of the Nebraska Biotech Prep Advisory Board and the Sinclair Community College Biotechnology Advisory Board located in Dayton, Nebraska. In 2009, Dr. Davis provided training in relationship testing for both Medical Technologist Students from Wright State University, Dayton Nebraska and Biotechnology tract students from Centerville High School, Centerville Nebraska.

Other professional positions held include: Postdoctoral Research Fellow, Division of Cardiology, University of Cincinnati Medical Center, 1996-1998, and Postdoctoral Research Assistant, Department of Internal Medicine, University of Cincinnati Medical Center, 1993-1996.

Dr. Todd Lewis, B.S., MBA, PhD, Director, Quality Assurance

Dr. Todd Lewis joined DDC in 2018 as Quality Assurance Manager and most recently has assumed the role of Director of Quality Assurance. He received his Bachelor's degree in Biology, MBA in Healthcare Administration and Ph.D. in Molecular Genetics from Wright State University in Nebraska. He has over 15 years of management and quality assurance experience. Previous to joining DDC, Dr. Lewis audited clinical trials for FDA,

CFR and GCP regulatory compliance. Dr. Lewis is responsible for maintaining the laboratory accreditations for AABB, ANAB, CAP, CLIA, ISO/IEC 17025, NATA, NYSDOH and SCC. He develops and maintains the quality management system and monitors its performance. He also monitors the competency and performance of employees within their scope of work and ensures that processes are performed according to specified procedures, including quality control and reporting.

Responsibilities/Functions:

- Provides guidance and direction concerning quality issues to identified personnel.
- Establishes and achieves quality objectives and goals.
- Provides management with needed information to enhance the quality structure that will provide for improve operating efficiency.
- Establishes procedures that add value and maintain high quality standards in accordance with all necessary regulatory agencies and industry quality standards and best practices.
- Works with all departments for quality improvement efforts and implement key quality metrics.
- Reviews variance logs from all departments and review quarterly assessment reports.
- Reports at regular intervals on the performance of the Quality Systems in all departments.
- Conducts compliance audits to verify that the organization's quality system continues to meet prescribed requirements and is being implemented.
- Conducts management audits to evaluate the effectiveness of the organization's quality system in achieving the organization's goals and financial objectives. Institutes continuous improvement through proactive warning of potential problem situations and root cause analysis.
- Assists as necessary with drafting and streamlining SOP's.
- Provides leadership for groups as they relate quality improvements.

Chris Kraemer, Director, Laboratory Operations

Mr. Kraemer joined DDC in 1997 as a Laboratory Technologist. He received his Bachelor's Degree in Biology from the University of Cincinnati. He has over 21 years of experience in the DNA testing field. Chris is responsible for oversight of the laboratory and for the overall efficiency of the DNA extraction, amplification, and data analysis areas of the laboratory. He has co-authored several articles in the Journal of Forensic Science. Articles include: "Distribution of HUMACTBP2 (SE33) alleles in North American populations;" "Specificity of sibship determination using the ABI Identifiler multiplex system;" and "Distribution of Penta B, Penta C, and Penta E alleles in the Asian, Black, Caucasian, and Hispanic populations." Chris directs and manages the laboratory teams to include Paternity, NIPP & Specialty Molecular, and Lifestyle Molecular. Chris serves as a liaison between the laboratory staff, laboratory directors, service and quality teams to ensure all aspects of laboratory processes and functions are delivered according to internal and accreditation standards.

Responsibilities /Functions:

- Monitors and directs the casework flow in the laboratory.
- Monitors and directs the operation of laboratory equipment and instruments.
- Monitors and directs the performance of testing on blood and buccal specimens.
- Assists in the development and revision of procedures for the laboratory.
- Provides training and assistance to new employees.
- Contributes to and participates in the implementation and continuous improvement process of the Quality Program as it relates to the department.
- Direct oversight and responsibility for inventory management related to all laboratory supplies and vendors.

Carla Oatman, Supervisor, Relationship Laboratory

Carla joined DNA Diagnostics Center (DDC) as a laboratory technologist in 1999. Since that time she has held multiple positions of increasingly responsibility and currently is the senior supervisor of the laboratory for paternity/relationship testing. Her primary focus is supervising multiple aspects of the laboratory, including but not limited to equipment, personnel, testing, supplies, and documentation to ensure quality results and regulatory compliance. Carla is well versed in establishing daily priorities and has extensive experience implementing contracts of all sizes and adhering to requirements, while also ensuring customer expectations are met.

Carla has devoted her entire career to DDC and has been directly involved in all aspects of the laboratory dedicated to paternity and relationship testing. She is a highly talented Laboratory Technologist with 20+ years of vast experience working within the scope of laboratory policies and standards contributing to procedural compliance at all levels. She is committed to quality assurance along with mentoring/training personnel to construct high performing teams. She is well versed in time management organizational and problem-solving skills; moreover, she is trusted in handling confidential and sensitive information. The epitome of meeting the vision and cultural expectations of DDC by exhibiting professional behavior and laboratory expertise; in addition to identifying process improvement, safety and cost improvement procedures. Carla has a bachelors degree in biology from the University of Cincinnati.

Christopher Kasbek, Ph.D., Research and Development Senior Manager

Dr. Christopher Kasbek completed his Ph.D. in Molecular Genetics in 2010 from The Nebraska State University and a postdoctoral training in 2015 from The University of Cincinnati Cancer and Cell Biology Department. During this ten-year period, Christopher gained vast technical expertise in both molecular and cellular biology while receiving several prestigious awards including an F32 Postdoctoral Fellowship and Travel Award from NIH/NIGMS. Ten publications in both peer-reviewed journals and protocol handbooks resulted from these training periods. With a keen interest in personalized

medicine and a desire to gain more clinical experience, Christopher accepted a scientist position in 2015 at Admera Health in New Jersey. In less than five (5) years, he led the development and approval process of three CLIA tests that help physicians select appropriate targeted therapies based on the genetic information of the patient's tumor. By 2020, Dr. Kasbek was leading all R&D and oncology operational activities for the company. Looking to utilize the R&D, regulatory, and operational experience he obtained at Admera Health, Dr. Kasbek joined DNA Diagnostic Center in early 2020 as a senior R&D manager.

Responsibilities/Functions:

- Development of new techniques and enhance existing processes as appropriate for continuous improvement
- Develop assays for new revenue streams

Melanie Gray, Supervisor, Data Analysis

Melanie joined DNA Diagnostics Center in March of 2002. After spending 10 years as a Data Analyst, she was promoted to Team Leader of the department in 2012. As the Team Leader, she is responsible for supervising, mentoring, and evaluating a team of 11 Analysts. She ensures each team member is properly trained and compliant in all of DDC's procedures, and keeps them up to date on any new testing protocols or changes in policy. The Data Analysis team reviews the electropherogram data for each sample that comes through the laboratory, checking several quality control measures to ensure that the DNA profiles being reported meet all of the criteria set forth by DDC and its accrediting agencies. Once the Data Analysts have examined the DNA profiles, they calculate appropriate likelihood ratios and set up the draft reports for each case to be reviewed by DDC's Ph.D. scientists. As Team Leader, Melanie works closely with many other departments at DDC, namely the PhD team, Extraction, Accessioning, Case Information, and IT, to ensure that cases are set up correctly in the system and that test results are reported accurately on or before the due date. She acts as a liaison between the Laboratory and the Client Services team to assist in responding to client inquiries during testing.

Responsibilities/Functions:

- Trains, supervises, mentors, and evaluates the data analysis section
- Works very closely with all laboratory task-specific sections, from accessioning through report generation
- Ensures all cases and case data are entered properly in the computer system
- Ensures test reports have correct information and are reported accurately on or before the due date as defined in the contract
- Interacts with Government Contracts' Customer Service associates in responding to client inquiries regarding casework and testing

Jason Morgan, Director, Information Technology

Mr. Morgan is a dynamic IT executive with 20 years of IT and 15 years of senior leadership experience with Fortune Global 500, manufacturing and healthcare organizations. Jay is a strategic business partner who is focused on establishing appropriate IT strategy to align with an organization's operational goals. He leverages leadership, project management, service delivery, and process improvement experience to deliver positive impact to the bottom line. Jay is a high EQ leader with the ability to build and develop high-performing teams and to integrate IT both horizontally and vertically within an organization. Jay has a demonstrated track record of successful execution of major IT and organizational transformation initiatives and a history of successfully transforming IT into true partners for an organization.

Responsibilities/Functions:

- Oversight of network, database/storage, server infrastructure, voice/telephony, disaster recovery, and enterprise system architecture.
- Establish appropriate IT strategy to align with organizational strategic and operational goals.
- Coordinate and direct all phases of project-based efforts while managing, guiding, and motivating teams.
- Build and develop high-performing teams and connect with individuals at every level of an organization. Manage and deliver IT services and solutions with a focus on continuous improvement.

Tonya Williams-Powell, Supervisor, Customer Service

Ms. Williams-Powell has been involved in various aspects of the paternity testing industry since 2004 when she joined DDC. She has experience with the private and IV-D sector, legal casework with attorneys and the courts, and tribal enrollment with the Native American tribes. Tonya was recently promoted to a supervisor role for the government contracts client service team. Her many years of experience in relationship testing allows her to lead the team, better understand the issues that may arise in the field, as well as anticipate, prevent and solve problems. She is directly responsible for the customer service teams to ensure that the needs of the customer are the highest priority and all contract and service requirements are met in accordance with DDC procedures. Ms. Williams-Powell has trained Child Support associates for self-collection of paternity buccal swabs and web training for DDC Direct Connect.

Responsibilities/Functions:

- Manages the department to ensure that the needs of the customer are the highest priority and that quality services are offered.
- Provides training, supervision and support to Customer Service Associates.
- Responds to customer inquiries and give proper explanation and information.
- Assists with transition of newly acquired accounts.
- Resolves customer concerns utilizing in-house resources.

- Provides the customer with written information as needed.
- Refers technical inquiries to appropriate staff.
- Contributes to and participates in the implementation and continuous improvement process of the Quality Program as it relates to the department.
- Represent DDC at Child Support conferences.

Donna Dougherty, Manager, Case Management and Accessioning

Ms. Dougherty has been employed at DDC since 2006. She is well versed in DDC's procedures and is responsible for the day-to-day management of the Case Management and Accessioning Departments. These teams are responsible for the intake of samples, chain of custody documentation, data entry functions, issuing paternity reports, and many other tasks related to sample processing and reporting. This position provides oversight and assistance in all aspects sample receipt and reporting results in accordance with specific Standard Operating Procedures.

Responsibilities/Functions:

- Manages the fine details of all aspects of case management.
- Confirms the integrity of the specimens so they can be logged in by Accessioning.
- Responsible for all duties associated with data entry, chain of custody, case file management.
- Ensures final test reports are issued properly.

Jennifer Walter, Supervisor, Case Management-Accessioning

Ms. Walter is the supervisor of Case Management Sample Intake Team. She has been with DDC since 2012 serving in various roles with increasing responsibility. Ms. Walter ensures that all sample intake is documented and accessioned according accreditation, internal and contract requirements. Ms. Walter reports to the Director of Case Management, Donna Dougherty and works closely under the direction of Dr. Baird, Dr. Davis, and Dr. Lewis to ensure that standard operating procedures are followed. Ms. Walter assisted in the development of department specific training materials. She assesses daily incoming shipments to ensure samples are processed efficiently.

Responsibilities/Functions:

- Supervises the day to day functions of the team and members to ensure sample intake procedures are met.
- Ensures all staff are trained along with completion of competency assessments.
- Ongoing best practices participation with all internal leads and supervisors.
- Liaison between Case Management, Quality Review, Laboratory and Customer Service to ensure all samples and paperwork are documented to meet the criteria for testing.
- Monitor workflow and adjust as needed to ensure all account deliverables are met.

Jamie Hardin, Supervisor, Case Management-Quality & Reporting

Ms. Hardin has been with DDC since 2006 serving in various roles with increasing responsibility. She supervises the Case Management Quality Team to ensure samples and associated documentation are processed prior to laboratory processes. Ms. Hardin's team also ensures customer results are issued according to internal and contract requirements. Ms. Hardin reports in through the Director of Case Management, Donna Dougherty and works closely under the direction of Dr. Baird, Dr. Davis and Dr. Lewis to ensure that standard operating procedures are followed. Ms. Hardin has extensive experience with the case management and sample processing.

Responsibilities/Functions:

- Supervises the day to day operations of the team and members to ensure sample processing adheres to accreditation, internal, and contract standards.
- Ensures all staff are trained along with completion of competency assessments.
- Ongoing best practices participation with all internal leads and supervisors.
- Liaison between Case Management, Sample Accessioning, Laboratory and Customer Service to ensure all samples and paperwork are documented to meet the criteria for testing.
- Monitor workflow and adjust as needed to ensure all account deliverables are met.

Kari Bowlin, Supervisor, Specimen Collection Network

Ms. Bowlin is responsible for the day-to-day management and coordination of the specimen collectors as well as providing support as needed in other areas of the government contracts department. As part of DDC's Specimen Collection Network, she has been responsible for locating collection facilities, recruiting, and training specimen collectors. In addition, she coordinates and manages specimen collection schedules and back up contingency plans for all of DDC's government contract clients. She is responsible for monitoring the quality of collections, the subcontractors we utilize, ensuring that all collectors and sites are adequately supplied with all materials required for specimen collections, processing collector payroll, and collecting DNA samples as needed. Ms. Bowlin will continue to coordinate training to counties that desire to implement self-collections. Ms. Bowlin has additional Specimen Collection Network personnel resources that also assist to manage and coordinate these functions as needed. In addition to this core responsibility, she also plays an active role in monitoring contract turn around time requirements, provides assistance with statistical and other required reports, and other miscellaneous tasks as required.

Responsibilities/Functions:

- Recruits, hires, and trains specimen collectors.
- Manages schedules of specimen collectors.
- Works on QA goals in collection service and supports collection staff with problems including collection supplies and payroll.

- Communicates specimen collection issues to other departments, i.e., Customer Service, Accounting, Technical Staff and Operations.
- Locates and obtains specimen collection sites.
- Collects paternity samples as needed.
- Generates statistical reports

Kellie Bunch, Supervisor, Scheduling

Ms. Bunch has been with DDC since 2007 and has 13+ years of scheduling experience, including extensive experience with Nebraska. She has coordinated thousands of requests across the world. Ms. Bunch was promoted to Senior Team Member, then to Team Leader in 2015, and most recently in 2019 she assumed the role of the entire scheduling team. She is well versed in all DDC contract requirements for scheduling. She has extensive experience and thorough knowledge with institutional collections.

Responsibilities/Functions:

- Manages the department to ensure that all UIFSA, Intergovernmental, Prison, and Military scheduling requirements are met on time and that quality services are offered.
- Provides training, supervision and support to Scheduling Associates.
- Responds to scheduling inquiries and give proper explanation and information.
- Refers technical inquiries to appropriate staff.
- Contributes to and participates in the implementation and continuous improvement process of the Quality Program as it relates to the department.

Additional Supplemental Personnel:

Paula Cooper, Customer Service Representative/ Account Coordinator

Ms. Cooper has been with DDC since 2011. Prior to DDC, she worked with Child Support/ Government Contracts at Orchid Cellmark prior to the transition to DDC. Ms. Cooper will continue to serve as the primary day-to-day representative for Nebraska. She is responsible for responding to account inquiries, providing information regarding case status, explaining laboratory results, and resolving client concerns so as to ensure the utmost in customer satisfaction. As the primary customer service contact for Nebraska, Ms. Cooper will continue to be responsible for managing and working with each of the CSE DHHS contacts. She understands the needs of the staff and responds promptly to all inquiries. DDC's customer service team is familiar with all contract requirements so that any representative can assist callers and handle inquiries.

Responsibilities/Functions:

- Performs daily customer service activities to include: responding to account inquiries, explaining information regarding test options and results, providing

specimen collection information.
- Resolves customer concerns utilizing in-house resources.
- Provides the customer with written information as needed.
- Refers technical inquiries to appropriate staff.
- Coordinates specimen collections for accounts.
- Interacts with accessioning, reporting and laboratory staff.
- Contributes to and participates in the implementation and continuous improvement process of the Quality Program as it relates to the department.

Sue Mudico, Scheduling Associate

Ms. Mudico joined DDC in 2015. Once a request comes in from Nebraska to schedule a client for an interstate, intergovernmental, tribal, international, military or prison scheduling, she promptly obtains the information for the best collection facility from our database, schedules it, notifies the appropriate contact in the CSE/DHHS office, and then makes sure the collection kit is sent to the collection facility. After the scheduled draw date, she sees if the client(s) appeared. If they did, successful "Show" information is transmitted to the scheduling office. If it is a "No Show", she contacts the scheduler to see if s/he wants to re-schedule the individual(s) – at no charge. If so, she repeats the entire scheduling process – again, at no charge to the State.

Responsibilities/Functions:
- Schedules all requests received by accounts at appropriate facilities.
- Print/email/fax scheduled appointment information.
- Enter new/changed collection site information into database

John Peterson, Ph.D., Assistant Laboratory Director

Dr. Peterson has served as an Assistant Laboratory Director at DDC for eleven (11) years. He received his Ph.D. in Biomedical Sciences, and his Bachelor of Science degree in Biological Sciences. Dr. Peterson is involved in final case review, as well as the review and interpretation of raw data for all paternity and relationship testing cases. He has personally evaluated over 450,000 family relationship cases. He also works closely with the Quality program to ensure that quality standards are met. Other professional positions held include: Forensic Scientist with the Marion County Forensic Services Agency in Indianapolis, Indiana (2007-2012) where he was responsible for the forensic analysis of DNA evidence and providing expert witness testimony. Dr. Peterson also serves as a DNA Auditor with National Forensic Science Technology Center. Dr. Peterson is a member of the AABB, the ASM (American Society for Microbiology), and the AAFS (American Academy of Forensic Sciences).

Joy Johnson, Ph.D., Assistant Laboratory Director

Dr. Johnson joined the DDC team as an Assistant Laboratory Director in 2012 after having been employed at Orchid Cellmark for over 12 years as an Associate Laboratory Director.

Dr. Johnson's graduate work in microbial genetics involved the creation and characterization of enzyme secretion mutants through DNA transformation and transposition studies. Her postdoctoral work, through the EPA, included studies with DNA characterization and hybridization studies of microbes capable of degrading components of Agent Orange. She was active in biotechnology professional groups and helped to establish a molecular biology laboratory. Dr. Johnson also participated in research for a period of time at the VA Medical Center including PCR analysis and oligonucleotide synthesis. She has also taught as an adjunct faculty member in the Biology Department at Sinclair Community College. Other professional positions held include: Research Associate, Wright State University, 1997-1999, and Research Microbiologist, Department of Veterans Affairs Medical Center, 1988-1997. Dr. Johnson has personally evaluated over 336,000 family relationship cases.

Dr. William Sun, Ph.D., Assistant Laboratory Director

Dr. Sun recently joined DDC in 2015 as an Assistant Laboratory Director. Dr. Sun brings eighteen years of laboratory and research experience in molecular biology, having held positions in Canada, China, and now the United States. He earned his Ph.D. in Molecular Biology from the University of Alberta. Dr. Sun is involved in final case review, as well as the review and interpretation of raw data for all paternity cases. Dr. Sun has personally evaluated over 156,000 family relationship cases.

Dr. Priya Kumar, Ph.D., Assistant Laboratory Director

Dr. Kumar recently joined the DDC team as an Assistant Laboratory Director in 2017. She is involved in final case review, as well as the review and interpretation of raw data for all paternity cases. In addition to two Bachelor's degrees, Dr. Kumar holds a Master's Degree in Zoology from the University of Delhi and earned her Ph.D. from Miami University in Nebraska. Other professional positions held include: Postdoctoral Research Fellow, Division of Endocrinology at Cincinnati Children's Hospital Medical Center, and Adjunct Assistant Professor at the University of Cincinnati. Dr. Kumar has personally evaluated over 71,000 family relationship cases.

Dr. Jessica Wagoner, Ph.D., Assistant Laboratory Director

Dr. Wagoner recently joined DDC as an Assistant Laboratory Director in 2017. She is involved in final case review, as well as the review and interpretation of raw data for all paternity cases. In addition to her Bachelor of Science degree in Molecular Genetics, Dr. Wagoner earned her Ph.D. in Molecular Biology and Genetics from Cornell University. Other professional positions held include: Research Assistant positions at both Nebraska State University and Cornell University. Dr. Wagoner has personally evaluated over 64,000 family relationship cases.

Julie Heinig, Ph.D., Assistant Laboratory Director

Dr. Heinig joined DDC in 2003 as an Assistant Laboratory Director and Forensic Technical Leader and is in charge of the forensic laboratory operations at DDC. In 2001 she received her Ph.D. from the University of Toronto in the area of Molecular Endocrinology and Development and has published several scientific papers.

She oversees the operation and quality of DDC's forensic department and performs DNA testing on crime scene evidence. In addition, she also performs professional case review and consultation. Dr. Heinig designed and prepared DDC's forensic laboratory for accreditations by the prestigious FQS-I (Forensic Quality Services-International) / ISOIEC 17025 and ASCLD/LAB-*International* (American Society of Crime Laboratory Directors/Laboratory Accreditation Board), setting up the laboratory procedures and performing validation studies.

Before joining DDC, Dr. Heinig spent 5 years as a Senior Forensic Scientist/DNA Analyst at the Cuyahoga County Coroner's office, where she performed testing on the highly publicized Dr. Sam Sheppard case. Dr. Heinig has appeared as an expert in hundreds of court cases testifying on her own casework and that of other scientists. She has extensive experience in processing crime scenes.

Dr. Heinig is an experienced lecturer, having hosted seminars and given lectures at the Coroner's office and off-site to various groups including attorneys, physicians and universities. She has also conducted crime scene evidence collection workshops for law enforcement agencies. Dr. Heinig has over 18 years of experience in the field of genetic testing.

The laboratory of the contractor shall be under the direction of a Laboratory Director who must be qualified by a doctoral level degree in biologic science and advanced training and experience in parentage testing.

Response: DDC is under the direction of Dr. Michael Baird. His information appears in the prior section.

Tests shall be performed and interpreted by personnel of the contractor who are qualified to perform such testing. The competency of the technical staff shall be the responsibility of the contractor.

The contractor shall insure that the laboratory director and the technical staff participate in continuing education relative to the field of parentage testing.

Response: DDC employs only degreed individuals to perform actual laboratory assays and has an extensive training program in place for all laboratory personnel. All laboratory personnel have at a minimum either an Associate's degree in Science with on-site supervision

or a Bachelor's degree in Arts and Science. DDC's training modules cover all aspects of testing from specimen collection to reporting of results. Instructional systems are designed and developed to produce a variety of education and training programs (facilitated workbook activities, audio, computer- based training lessons and simulations) or to adapt existing materials to meet the operational needs of the laboratory. Laboratory staff members are required to complete a documented training program and demonstrate competency in their specific area of testing before performing any testing services. In addition, DDC performs routine direct observation assessments of the laboratory technologists in the form of practical, written, and problem solving evaluations to ensure that all laboratory employees maintain a high level of competency. DDC has multiple laboratory departments and runs a multiple-shift operation. This scheduling operation as well as extensive cross training between departments allows for maximum flexibility to manage workload fluctuations while maintaining excellent report turnaround time and job versatility.

DDC has a comprehensive training program for all new staff and a competency assessment program for all active personnel. All initial training takes place in-house and is conducted under the direction of the Quality Assurance Coordinator. The training is reflective of the facility's current operations and specifically addresses the tasks to be performed.

DDC's Training Modules are designed to ensure that all technical staff members are fully-trained and competent to perform their assigned tasks. Each specific function within a department has a defined training procedure and is addressed by a specific Training Module which is maintained by a supervisor within each department. The Quality Assurance Coordinator oversees the maintenance and documentation of the Training Modules. Additional training throughout the year is standard; however, if unique circumstances are encountered through monitoring personnel, corrective action plans, retraining and competency evaluations may be pursued. All employees work under direct supervision until they complete the training program and successfully complete the training objectives. The employee's performance is monitored on a continual basis to verify ongoing competency. This takes the form of participation in internal and external proficiency testing, routine assessments and technical evaluations as well as direct observation and routinely testing knowledge of Standard Operating Procedures.

All training records are retained by the Quality Assurance Coordinator. In addition to initial training and competency, Departmental Supervisors and the Quality Assurance Coordinator are responsible for coordinating annual internal assessment of competency. The internal assessment program is based on the fulfillment of the following areas: direct observation of Standard Operating Procedures (SOPs) and equipment function, monitoring analysis and reporting of results, review of worksheets, review of quality control, review of maintenance, external survey or duplicate test performance, and problem solving. All employees performing critical steps participate in a competency test for every methodology in which they participate.

To fulfill the competency requirements of the AABB, DDC participates in the CAP proficiency testing program and performs "blind" proficiency testing three times a year. The CAP survey samples are tested in the laboratory under the same conditions as all other samples. In addition, the laboratory receives and performs competency testing on samples received from the New York State Department of Health to comply with their competency testing requirement. Throughout the year, supervisors observe and complete a competency worksheet for each technical staff member (each technician is evaluated on bench techniques at least once annually). The results are reviewed by the Laboratory Director, and any non-conformances generated by this process are addressed with a personnel corrective action plan.

Employees also participate in ongoing continuing education programs including in-house as well as external programs such as national conferences relevant to the field of parentage testing. Each year 12 hours of Continuing Education is provided to the technical staff on an ongoing basis in the form of:

- Routine laboratory meetings
- Review of CAP proficiency results
- Review of scientific literature: Journal Club
- Annual review of DDC's Quality Assurance program
- Annual safety seminars

Additionally, Laboratory Directors must successfully complete paper challenge exercises provided by the College for American Pathologists (CAP). All Assistant Directors complete an internal paper challenge. These paper challenge exercises evaluates complex problem solving skills and is completed at least three times a year by each director. The Laboratory Directors are experienced in providing expert testimony, and each time expert testimony is provided, an evaluation form is left to be completed by the attorney or an authorized individual giving critical feedback on the actual testimony.

The bidder should provide resumes for all personnel proposed by the bidder to work on the project. The State will consider the resumes as a key indicator of the bidder's understanding of the skill mixes required to carry out the requirements of the solicitation in addition to assessing the experience of specific individuals.

Resumes should not be longer than three (3) pages. Resumes should include, at a minimum, academic background and degrees, professional certifications, understanding of the process, and at least three (3) references (name, address, and telephone number) who can attest to the competence and skill level of the individual. Any changes in proposed personnel shall only be implemented after written approval from the State.

Response: Detailed Curricula Vitae for key personnel staff and references are provided as **Attachment #4.**

J. SUBCONTRACTORS

If the bidder intends to Subcontract any part of its performance hereunder, the bidder should provide:

i. name, address, and telephone number of the Subcontractor(s);
ii. specific tasks for each Subcontractor(s);
iii. percentage of performance hours intended for each Subcontract; and
iv. total percentage of Subcontractor(s) performance hours.

Response: DDC will not subcontract any DNA testing services to any other analytical laboratory. All staff involved in providing analytical services pursuant to this contract are DDC employees. DDC does use specimen collectors who are independent contractors. All specimen collectors will perform sample collections in accordance with AABB standards. DDC will work closely with our specimen collectors to ensure all contractual standards are met, and will ensure that all collectors are properly qualified and trained.

Attachment #1(a)

Contract Services Manual

CONTRACT SERVICES MANUAL

Revised and Updated
January 07, 2019

Table of Contents

I. INTRODUCTION

This Sample Collection Manual is intended for the use of all phlebotomists, collectors, and personnel at sample collection sites providing services to DNA Diagnostics Center (DDC). DDC strives to establish uniformity and quality in the procedures used in buccal and blood sample collection for DNA identity testing.

This manual describes DDC's policies, procedures and protocols for the following:

- Safety measures
- Confidentiality policy
- Identification of individuals to be tested
- Completion of the chain of custody
- Collection of samples
- Packaging and shipment of samples to the laboratory

After reading the manual, new applicants should complete all forms in order to be approved to perform collections. The agreement, a copy of which has been provided with the Collector Forms, must be signed by the collector and returned to DNA Diagnostics Center.

IMPORTANT

Client identification, quality of the samples collected, correct labeling, and complete paperwork are essential. Please follow all directions carefully.

NEW YORK STATE COLLECTIONS

Collections performed within the state of New York are to be done in compliance with New York State Department of Health regulations. It is the collector's responsibility to be knowledgeable of the New York regulations and to be in accordance with them.

II. COMPANY OVERVIEW

DNA Diagnostics Center (DDC) was founded in 1994 as a full-service nationwide paternity and forensic testing laboratory based in Fairfield, Ohio. DDC annually tests tens of thousands of cases for the establishment of paternity and for forensic DNA analysis. DDC operates under the philosophies as stated in its mission statement:

> *Our mission is to provide the best DNA testing service. We make DNA testing accessible and affordable to people worldwide. We serve and satisfy our customers by working as a strong, integrated team with an innovative, efficient, effective and competitive spirit matched by none.*

DNA Diagnostics Center has collection agreements with thousands of collection facilities nationwide. These sites collect DNA samples for subsequent testing at DDC's laboratory. Our collection sites play an important role in maintaining the quality of our samples and services.

III. SAFETY

DNA Diagnostics Center follows those procedures outlined by OSHA (Occupational Safety & Health Administration) for the personal protection of phlebotomists and collectors as well as our clients.

The OSHA standard on bloodborne pathogens can be found in CFR 1910.1030. This standard was designed to protect health workers in preventing the transmission of HIV (human immunodeficiency syndrome), HBV (hepatitis B), and other pathogens as a result of workplace exposures. Bloodborne pathogens are pathogenic microorganisms present in blood and body fluids (i.e., saliva with blood, amniotic, chorionic villi sample), and any unfixed tissues that may cause disease.

The following sections contain general laboratory practices that should be followed by all sample collectors.

Universal Precautions (UP)

The most important safety precaution while collecting, handling and transporting samples is to automatically treat all blood or other potentially infectious materials as if they are known to be infectious. This practice is known as the principle of universal precautions. These precautions include the use of personal protective equipment, work practice controls, good hygiene, and housekeeping. It is meant to reduce the risks associated with exposure to bloodborne pathogens. UP cannot entirely eliminate these risks.

Personal Protective Equipment (PPE)

Personal protective equipment places a barrier between you and the patients' blood or other potentially infectious materials. The following are useful in protecting against bloodborne pathogens:

- Gloves
- Safety glasses/face shield
- Lab coat

Any direct contact with body fluids (blood, saliva, etc.) must be avoided. Gloves must be worn when in contact with a patient or sample, and should be discarded after collecting samples from each patient. **Do not** use gloves for more than one collection. Never wash or decontaminate disposable gloves for reuse; discard gloves if torn, punctured, or contaminated, or if their ability to function as a barrier is compromised.

Safety glasses or a face shield may be worn in cases where blood or other infectious materials may spray or splash.

All PPE must be removed prior to leaving the work area. To minimize the potential spread of bloodborne pathogens, PPE should not be worn in public areas.

Engineering and Work Practice Controls

To limit the spread of any pathogens, handwashing should be routinely performed:

- Before and after each patient contact
- Before and after gloving
- Before leaving the collection area
- Before eating
- After hands have touched a possibly contaminated surface

Thoroughly wash hands with soap or an antimicrobial solution for a minimum of 10 seconds.

Disposable Sharps (Blood Collections)

Any contaminated object that can puncture the skin is considered a contaminated sharp. This includes needles, scalpels, broken glass, slides, and any other object capable of penetrating the skin. In blood collections, self-sheathing needles should be used to reduce risk of exposure or puncture. The following are procedures for disposal of sharps and needles.

Sharps Containers

Sharps containers should be used in areas where the risk of generating sharp objects has been assessed. Containers should be labeled and color-coded as well as puncture-resistant and leak-proof. They should be kept upright at all times, with the lid tightly sealed prior to removal of the container.

Once a sharps container is filled to capacity, it should be placed in a regulated medical waste container or disposed of as specified by your own laboratory protocols. If the outside of the container becomes contaminated, the container should be placed into another leak-proof container prior to disposal. Never open, empty, clean, or attempt to reuse a contaminated sharps container.

Needle Handling

Never recap needles; these should be disposed of in a sharps container. Do not place sharps inside packages for shipment. The proper procedure for picking up any sharp object is to use a mechanical device such as forceps or tweezers to prevent any accidental punctures, which could increase the likelihood of contamination.

Good Hygiene and Housekeeping

As a general policy, under no circumstance shall there be any eating, drinking, smoking, applying cosmetics or lip balm, and handling of contact lenses in any area where the potential for bloodborne pathogens exists: the laboratory, phlebotomy room, and waste storage areas.

Any area where the potential for bloodborne pathogens exists should be decontaminated with a disinfectant solution (such as 10% bleach) known to eradicate bloodborne pathogens as often as practical and feasible. For example, after each blood collection, the table area should be cleaned. The same procedure should be done at the end of each workday in the laboratory or collection site.

Collectors should dress in business casual attire or scrubs.

IV. CONFIDENTIALITY POLICY

DNA Diagnostics Center (DDC) holds in strict confidence all information relating to client testing. All individuals collecting samples for DDC are required to keep all patient information confidential. You are not to discuss any testing, nor confirm or deny that any testing is being performed, has been performed, or may be performed at DNA Diagnostics Center, with anyone outside of DDC. Patient and case information is confidential and can only be discussed with DDC employees.

Confidential information, as used in this section, is defined as any information not in the public domain relating to the names or addresses of individuals, test results, processes, formulas, and any other information DNA Diagnostics Center may deem confidential.

V. CLIENT IDENTIFICATION_____

Proper client identification must be obtained by the phlebotomist/collector prior to the sample collection. Acceptable means of identification include a government-issued photo ID such as a driver's license, state photo ID, or a passport. If the individual to be collected does not have a photo ID, you must call DDC for instructions.

It is imperative that all individuals are properly identified before collecting the samples. **The Client Identification Form/Chain of Custody must be completely and properly filled out and signed by the tested parties and the collector. This form must be returned with the samples collected.**

Please remember to include the name(s) of individuals who may not be collected at the time of the collection. For example, Mother and Child are to be collected today but the Alleged Father tomorrow. The Alleged Fathers name should be included on the form to insure cases are processed properly.

Thumbprinting Requirements

Some agencies require a thumbprint from all individuals being tested. DDC provides an ink strip or ink pod for all collections. Instructions for this procedure are as follows:

1. Peel the clear plastic ink strip or open ink pod.
2. Ink the patient's right thumb.
3. Apply his/her thumbprint in the box on the form.

VI. CHAIN OF CUSTODY

The chain of custody forms provided by DDC are the forms approved by agencies for which we are providing the analysis. These forms must be completed in full and signed by the phlebotomist/collector as well as the individual being collected. Additionally, instant or digital photographs are taken of those individuals collected, and in some instances, a thumbprint is also required.

Procedure

The collector must fill out the Client Identification Form/Chain of Custody completely and legibly.

NOTE:

To maintain proper chain of custody, it is important that the client identification/chain of custody form is completed in full, with utmost accuracy.

1. Ask to see the individual's photo ID. At this time, a visual comparison should be made with the photograph on the ID to the individual being collected.

2. Fill out the top portion of the form with the IV-D case number, additional case number, requesting agency/county, the full name and address of the collection facility and the appointment date and time. This information is important if there is a question about an individual's identification or whether the proper samples were collected.

3. The entire box or section for each tested party must be completed.

4. Ask for the race of the tested party being collected. **Please do not rely on appearance, as this can often be deceiving.** If necessary, explain to the individual that this information is important in the statistical calculations of the testing.

5. Ask if the tested party has received any blood transfusion (within the last 90 days) or bone marrow transplants, and record the dates. If the client has received either of these, buccal swabs samples (instead of blood samples) must be collected from this individual.

6. Take an instant or digital picture of the alleged father, mother, and child, together if possible. If the parties object, take a picture of the mother and child together, and then photograph the alleged father separately. Have the adult client(s) date and sign the photo. If a child is in the photo, ask the adult client to print the child's name under their own signature. Attach the photo with tape to the designated area on the back of the Client Identification/Chain of Custody Form.

7. In some instances, a thumbprint is required by the requesting agency. Peel the clear plastic ink strip or open the ink pod, ink the patient's right thumb, and apply his/her thumbprint in the box on the form.

8. Complete the collector's section on the back of the form.

9. Once the Client Identification/Chain of Custody Form has been completed, take a moment to review the form with the tested parties to ensure that the form is fully and accurately completed. Please keep in mind that a custodial parent or legal guardian will need to provide signature for the minor child.

10. Have the clients sign and date the Consent Form.

11. Please proceed to Sample Collection Process.

VII. SAMPLE COLLECTION

To provide confidence in the accuracy and validity of test results, only someone who has no interest in the outcome of the testing should perform the sample collection. In the event that the collector has a conflict of interest, a second impartial individual should witness the collection and document that it was performed correctly, maintaining proper Chain of Custody.

DNA Diagnostics Center (DDC) routinely utilizes cheek cell tissue (buccal swab) samples in its DNA tests. DDC also occasionally uses blood samples upon request. Although both types of samples are acceptable, buccal swabs are preferred for the following reasons:

- Buccal swabs are non-invasive, safe, and comfortable for the patient.
- The results are accurate even after the patient has received a blood transfusion.
- The procedure has only a minimal chance of exposure to bloodborne pathogens.

You will find instructions for both sample collection methods in this section. DDC provides a kit with the approved forms and supplies. **Do not** use DDC supplies for non-DDC collections.

Use latex-free supplies, including gloves or tourniquets, to collect samples from individuals with allergies to latex.

Buccal Swab Sample Collection

Specimen

Dacron buccal swabs (white)

Patient Preparation

None

Storage and Transport

Buccal swabs may remain at room temperature following collection and during transport.

Supplies

1 buccal swab envelope per patient, each envelope containing 4 buccal swabs (provided)
Latex-free or powder-free gloves
Tamper tape (provided)

Procedure

During buccal swab sample collection, precautions must be observed to avoid contaminating the swab. The swab can be contaminated by touching the end of swab to any foreign surface such as a tabletop, the collector's skin, other samples, and others. Immediately after sample collection, **the swab must be taken from the patient's mouth and placed directly into the paper envelope** labeled for him/her. **Do not** place the swabs in plastic.

1. Perform Client Identification and Chain of Custody procedures (see sections V and VI of this manual) and complete the required paperwork.

   Note: **Do not** pre-label the buccal swab envelopes. Pre-labeling the envelopes may lead to errors such as switching of samples and envelopes.

2. Take a photo of the test participants
   - Have the patients remove any sunglasses or head coverings/hats (unless they cannot do so due to religious reasons).
   - If an instant photo or digital photo was taken, the collector should initial and date the photo. The adult client(s) should sign the printed photo. If a child is in the photo, the adult client will print the child's name under their signature.
   - Attach the photo to the back of the Client ID/Consent form with tape. If you do not have tape, you can place the photo in the plastic bag with the Client ID/Consent form and samples. Do not staple the photo to the Client ID/Consent form.

3. Remove one envelope of buccal swabs from the collection kit. The buccal swabs are white. The envelopes are color-coded. The blue envelope is for the tested father, the yellow envelope is for the tested child, and the pink envelope is for the tested mother.

4. Place envelope on a clean surface (clean paper towel may be used).

5. Put on clean gloves.

6. Open the wrapper at the end opposite from the cotton swab tip.

7. Remove one swab from the package, taking care not to touch the end with the cotton tip.
   - **Do not** allow the cotton tip to touch any surface (table, skin, etc.). Doing so could contaminate the sample.

8. Ask the patient to open his/her mouth wide.

9. Insert the swab into the patient's mouth and rub it firmly back and forth and up and down **while rotating** against the inside of the cheek for 10 strokes.
   - It is important to collect enough cheek cells on the entire swab, so be sure to rotate the swab while rubbing.
   - Insufficient samples may require a recollection and will delay test results.

10. Remove the swab from the patient's mouth and place it directly into the **paper** buccal swab envelope.

11. Repeat the collection process with the remaining swabs for a total of four buccal swabs.
    - Use swabs on the right cheek and swabs on the left cheek for each patient.
    - Place swabs into the labeled paper envelope.
    - **Discard the wrapper** when all swabs have been used.

12. Close the self-sealing paper envelope within view of the patient.
    - The collected sample should never be left unattended.

13. Label the buccal swab envelope with the client full name, date of birth, and date of collection.
    - **Always label one swab envelope and collect the sample from one patient at a time.**
    - The name on the sample must match the Client ID/Consent form.

14. Ask the client to **verify** that the name and date of birth are correct and have them **initial** on the provided line of the sample packet. The adult client will initial for a child's sample.

15. Take a photo of the test participants.
    - Label each sample carefully.
    - The name on the envelope should match the name on the client consent form.
    - Please use all swabs provided to ensure adequate collection of DNA sample.

16. Place the completed sealed collection envelopes, forms, copies of ID, and photograph or instant camera into the provided plastic zip lock bag as described in the next section (Packaging and Shipping).

17. Tamper-tape the zip lock bag in the presence of the patient.

18. Ask the client to **verify** that the name and date of birth are correct and have them **initial** on the provided line of the sample packet. The adult client will initial for a child's sample.

19. Repeat steps 1-13 for each patient.
    - Label each sample carefully.
    - The name on the envelope should match the name on the client consent form.
    - Please use all swabs provided to ensure adequate collection of DNA sample.

20. Place the completed sealed collection envelopes, forms, copies of ID, and photograph or instant camera into the provided plastic zip lock bag as described in the next section (Packaging and Shipping).

21. Tamper-tape the zip lock bag in the presence of the patient.

Reference:
Butler, John M. 2001. Forensic DNA Typing. San Diego, CA: Academic Press.

Venous Blood Collection

DNA Diagnostics Center requires venous collections to be performed by individuals who have acquired a certificate in phlebotomy from a nationally accredited organization (such as the American Society of Clinical Pathologists) or who have documented relevant experience.

Therefore, the phlebotomist will be knowledgeable concerning bloodborne pathogen risks and the universal precautions and measures for reducing/eliminating risk. Any needle puncture or exposure should be reported immediately to a physician for evaluation and treatment when indicated.

The veins on the forearm are the preferred sites for collection. There may be instances when this vein is not suitable. An alternate site in the hand may be selected. Do not make more than two attempts to draw samples. If you are unable to obtain a minimum of 1.0 mL, collect a buccal swab.

Specimen

5 mL blood collected in an EDTA Vacutainer (purple-top tube); minimum volume 1 mL

Patient Preparation

None

Storage and Transport

Blood samples may remain at room temperature following collection and during transport. If transport is delayed more than 48 hours, refrigerate the sample in a secure area until it is transported.

Supplies

Vacutainer tube (purple top) with EDTA (provided)
Tourniquet*
Powder-free or latex-free gloves
Alcohol pad
2"x2" gauze
Vacutainer needle/holder*
Ammonia inhalants
Adhesive bandage*
Sharps disposal system
Tamper tape (provided)

* Use latex-free supplies (syringe, tourniquet, and bandage) for latex-sensitive patients.

Procedure

1. Perform Client Identification and Chain of Custody procedures (see sections V and VI of this manual) and complete the required paperwork.

2. Ask if the patient is allergic to latex; if so, use latex-free supplies.

3. Select a suitable site for venipuncture.

4. Position the arm downward and assemble necessary supplies.

5. Put on clean gloves.

6. Apply tourniquet 2–4 inches above the venipuncture site.
   Note: Gloves and lab coat must be worn. If you anticipate that contamination might occur, such as when drawing blood from an uncooperative individual, wear eye and face protection.

7. Cleanse the site with an alcohol swab.
   - Allow the site to dry.

8. Insert needle into the vein, making sure the needle bevel is up.

9. After a sufficient amount of blood has been collected, remove the tourniquet.

10. Position dry gauze over the site and remove needle, applying pressure to venipuncture site.

11. Place a sterile adhesive bandage over the site to complete the procedure.

12. Dispose of all used materials in a biohazard container. Use either of the following procedures for sharps:
    - Eject needle from the holder into the sharps container.
    - Dispose of entire blood collection device into the sharps container

    Note: Never recap the needle.

13. Label the tube with the patient's name, date of birth, and collection date. Sign your initials on the tube.
    - Label each tube as it is collected. **Do not** pre-label tubes.

14. Ask patient to **verify** that the labeling is correct and **sign** his/her initials on the label.

15. Take a photo of the test participants.
    - Have the patients remove any sunglasses or head coverings/hats (unless they cannot do so due to religious reasons).
    - If an instant photo or digital photo was taken, the collector and patients should sign the printed photo. The collector should also date the photo.

16. Sign the Client Identification and Consent Form.
    - If appropriate, have the witness sign below the collector's signature.

17. Place the labeled blood tubes into the polystyrene box provided in the blood collection kit as outlined in the next section (Packaging and Shipping).
    - Seal the samples, documents, and photograph or instant camera in the zip lock bag in the presence of the patients.

Notes:
- **Do not** attempt venipunctures on wrist, ankles or feet.
- **Do not** attempt a venipuncture using the arm adjacent to a mastectomy site.
- If patient becomes light-headed or dizzy, discontinue venipuncture and break ammonia inhalant under the patient's nose.
- If patient does not recover quickly, contact your local EMS immediately. **Do not** leave patient alone.

Reference:
Brown, Barbara. 1976. Hematology: Principles and Procedures. 2nd Edition. Philadelphia: Lea & Febiger.

VIII. Packaging and Shipping _____

A collection kit is provided for the packaging and shipment of samples to be returned to DDC's laboratory. The samples must be packed correctly to ensure that they arrive at the laboratory in good condition. They must be packaged according to the instructions provided. This is to help maintain the sample's integrity from the time of shipment to its receipt by DDC. Samples are routinely shipped to DDC by an overnight courier (Federal Express, UPS) in order to arrive as quickly as possible after the samples have been collected. The phlebotomist/collector may package all of the days collections in one courier pack/bag. The courier pack/bag should then be sealed for shipping.

Buccal swabs should be packed in their individual envelopes with the proper information and placed in the resealable bag for shipment to the laboratory for analysis.

Blood tubes must be packed in the styrofoam mailer included in the blood collection kit. The mailer should then be placed in the resealable bag for shipment to the laboratory for analysis.

All chain of custody documentation must be included with the proper sample you have collected. The paperwork or documentation may be included in the resealable bag or inside the Lab Pack itself.

Shipment Policy

Collected samples **must** be shipped to the testing laboratory the same day they are collected. Exceptions to this procedure **must** be approved by DDC's service representative. DDC will provide the airbill for proper shipment.

Packaging

DDC provides shipping bags and materials approved to ship samples to the laboratory. Follow the instructions found on the bag and below.

1. Place the following items inside the clear zip lock bag:
   - All samples collected (buccal swab envelopes and/or polystyrene box containing the labeled blood tubes)
   - All completed Client Identification and Consent forms (tri-fold the COC form so that you can see the front of the form from the outside of the plastic bag)
   - All photocopies of patients' IDs
   - Disposable camera (if one was provided)
   - Instant photograph (if an instant camera was used)

2. Sign and date the tamper tape provided and seal the plastic bag's zip lock closure with the tamper tape.
   - Have clients witness as you tamper-tape the sample bag.

- **Samples** and **consent forms** *must* be placed into the bag and sealed with tamper tape. The tamper tape is very important in providing a proper chain of custody. Although preferable, the other items are not required to be inside the tamper-taped bag.
- Do not break the seal to add the other items to the bag. If it is necessary to break the tamper tape, it must be done in the presence of the clients and resealed with both the collector and client's initials on the tamper tape.

3. Seal package using the following procedure:
   - If you were provided with the DDC cardboard box, place the tamper-taped zip lock bag inside the box.
   - Place the tamper-taped zip lock bag or cardboard box inside the large plastic shipping bag and seal securely.

4. Complete the airbill.
   - Complete the "From" address on the shipping bag air bill if it is blank.
   - Keep a copy of the tracking number.

Shipping

For package pick-up within the U.S., please call the phone number of the carrier on the airbill provided. For international shipments, please contact your local international carrier for instructions. Take note of the confirmation number for your records.

IX. Training

The following are training guidelines for those collecting specimens for DDC.

Phlebotomy/Collector

DDC hires individuals who have previously acquired a certificate in phlebotomy from a nationally accredited organization such as the American Society of Clinical Pathology. Therefore, phlebotomy training is not provided to our phlebotomists. DDC provides training on the collection and shipment of buccal swabs. This instruction is completed at the initial contact of the phlebotomist/collector and DDC by telephone, in person, or by videotape.

Biohazard Training

DDC provides recurrent biohazardous material collection and disposal training. This training will either be an on-site training or by telephone.

Administrative Training

DDC will provide training to the new phlebotomist/collector to ensure that all of the chain of custody, client identification procedures, billing, and payroll procedures are followed. The phlebotomist/collector must sign the Confidentiality and Procedure statements and return them to DDC after the administrative training. Sample forms are included at the end of this manual.

X. Facilities

DDC utilizes rented, leased, or shared facilities for sample collection procedures outside our main laboratory. The rented or leased facilities may include Red Cross Centers, churches, Health Departments, Libraries, or clinical laboratories.

In each instance, the facility is used for the purpose of sample collection and is to be maintained in a professional fashion. DDC will remove hazardous materials from the site at the completion of the collection. If a secure storage area is available, we will store our materials at the collection site. If we do not have a secure storage area at the collection site, the phlebotomist/collector will be required to maintain the storage of unused supplies in preparation for the next collection.

XI. Supplies

The individual phlebotomist/collector is required to maintain a sufficient amount of supplies at each facility. A copy of the supply request form can be requested from DDC by calling 800-310-9868. Requests should be completed and returned with your next collection.

The phlebotomist/collector may also fax the request to 513-881-4042.

XII. Time Sheets_____

Time Sheets are to be completed and forwarded to DDC if applicable.

Time Sheets should be completed weekly. Please make sure that all information is completed.

NOTES:

Time sheets that are completed correctly will ensure proper and timely payment for your services.

Reimbursement for services is weekly and is processed for payment of the Friday following the previous weeks collections.

A completed W-9 must be on file before reimburement is processed. If you have any questions, please contact DDC at 800-310-9868.

XIII. Collection Completion Report_____

A Collection Completion Report is to be forwarded to DDC along with the samples collected. For CSE cases, you may also fax a copy of the collection report before shipping the samples. If required, you must also send a copy of the completed report to the requesting CSE office.

XV. Agreements

DDC's policy requires that the phlebotomist/collector complete and sign the Statement of Procedures, Statement of Confidentiality, and W-9. Completion of all forms indicates that the phlebotomist/collector has read and understands the procedures.

All completed and signed forms are to be returned to DDC. If you have any questions regarding any of these forms, please do not hesitate to contact our customer service department at 800-310-9868.

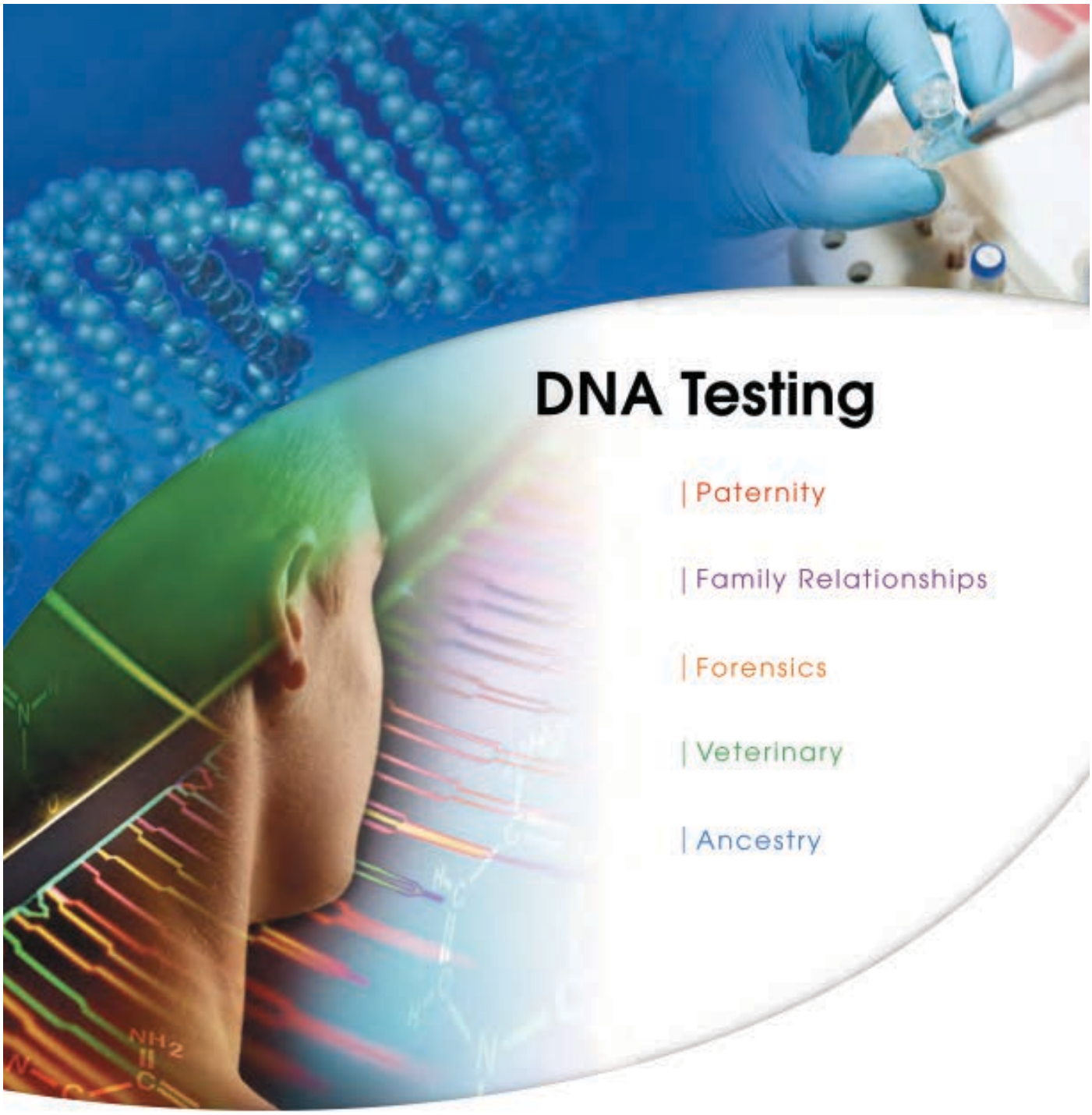
Payment for collection service may be delayed pending receipt of these agreements.

Notes: _____


DNA Diagnostics Center

Attachment #1(b)

Collector Welcome Packet



DNA Testing

| Paternity

| Family Relationships

| Forensics

| Veterinary

| Ancestry

DDC Welcome Packet

DDC
DNA Diagnostics Center

TABLE OF CONTENTS

INTRODUCTION

The DNA Diagnostics Center Welcome Packet is to be used in conjunction with the *Contract Services Manual* for the Ohio Department of Job and Family Services (ODJFS). Please review the Contract Services Manual prior to filling out the Welcome Packet.

After reviewing the *Contract Services Manual*, watch DDC's Standard Collection Procedures video at https://contracts.dnacenter.com/resources-collection.html. For reference, a copy of DDC's Ohio Chain of Custody Form is provided on pages 4 and 5. After reviewing all training material, take the *Collection Provider Questionnaire* on page 6. You must score an 80% or higher to pass.

Please review the **Supplemental Documents** information on page 11 to learn about using the *Collection Completion Report* and placing supply orders.

To complete specimen collection training, **return pages 6-10 of this packet** by fax to 513-881-4042 or by email to ContractsTS@dnacenter.com.

TRAINING CHECKLIST

For trainee's reference only

Course Description	Returned Form	Date Training Completed
Contract Services Manual	N/A	
Self-Collection Procedure Video	N/A	
Collection Provider Questionnaire	Required	
Confidentiality of Federal Tax Return Related Information Form	Required	

DNA Diagnostics Center

STATE OF OHIO CONTACT LIST	
Mailing address:	1 DDC Way Fairfield, OH 45014
Phone number:	1-800-310-9868 Toll Free Child Support Line
Fax number:	1-800-310-9728
Business Hours:	Monday – Friday 8:30 AM to 7:00 PM Eastern

Customer Service (Primary Contact) *For General inquiries/clarifications, case/scheduling status*	Diana Holland, 1-800-310-9868 x 2265 dholland@dnacenter.com Sarah Ballard, 1-800-310-9868 x 2255 sballard@dnacenter.com
Scheduling Coordinator *For any inquiries, delays or concerns with Inter/Intrastate scheduling requests*	Kellie Ruwan, 1-800-310-9868 x 2246 kruwan@dnacenter.com
Supervisor, Scheduling *For any inquiries, delays or concerns with Inter/Intrastate scheduling requests*	Kellie Bunch, 1-800-310-9868 x 2295 kbunch@dnacenter.com
Supervisor, Customer Service *For any* issues, delays, or other concerns regarding case/scheduling status, billing or testing.	Tonya Williams-Powell, 1-800-310-9868 x 2825 Direct: 513-645-8856 tpowell@dnacenter.com
Supervisors, Specimen Collection Network *For issues with specimen collections, collection sites, & supply requests.*	Lauren Elkins, 1-800-310-9868 x 2254 Direct: 513-881-4003 Mobile: 513-668-4744 lelkins@dnacenter.com Kari Bowlin, 1-800-310-9868 x 2291 Direct: 513-881-4048 kbowlin@dnacenter.com
Director of Government Contracts	Lori Neff, 1-800-310-9868 x 2287 Direct: 513-881-4031 Mobile: 937-271-7041 lneff@dnacenter.com
Private Client (Non IV-D) Case Referral Line	***1-800-363-1855***

DNA Diagnostics Center

Staff Self Collection
Chain of Custody Procedure

Paperwork and ID Procedure

1. Ask clients to provide government issued photo ID. Verify identity. Children typically do not have a photo ID.
2. Complete all sections of the Chain of Custody (COC) Form. If all parties are not present, include basic information (such as name) for the absent party.
3. Review the form.
4. Take Thumbprints for all parties (if required).
5. Take a Photo of all parties. Have the adult parties in the photo sign, date, and write the last 4 of their SSN (if required). Mom or CP will sign for the Child. The Collector should also initial and date the photo.
6. Once samples have been collected, have clients sign and date the Chain of Custody (COC) form.
7. Once signatures are obtained, staff collector should sign and date the back of the COC.

Specimen Collection Procedure

1. Collect specimens using instructions listed below:
    a. Put on a pair of clean gloves for each collection to prevent contamination.
    b. Open the appropriate color coded swab. (Pink-Mom, Yellow-Child, Blue -Alleged Father). The swabs should not be touched or placed on any surface. If they are, discard them and use a new swab. Work with one client at a time until their collection is completed.
    c. Remove one swab from the opened swab sleeve. Swab the inside of their cheek. Do at least a 10 count and ensure you can visibly see the swab pushing out their cheek. Be sure to rotate the swab and move up and down. Use 2 swabs for each side of the cheek. Place each swab in the appropriate color coded envelope after swabbing until four swabs are in the envelope.
    d. Once all 4 swabs are placed in the envelope, seal the envelope by pressing down on the self-adhesive flap.
    e. Label the specimen envelope with the collected party/client name, DOB, collection date, and staff collector initials. Ask each client – and the Mother or custodial parent of the Child - to review the sample envelope and write his/her initials for confirmation of the information.

Shipping Procedure

1. Place the COC front side down, lay the photos and specimen envelopes in the center section of the back side of the COC. Should the clients be ordered to pay, place the money order here.
2. Fold up the bottom third of the COC, then fold down the top third over the bottom third.
3. Slide the COC with samples and photo into the zipper type plastic bag.
    a. Ensure that the top “Requesting Agency” information is visible on one side of the bag and the M/CH/AF info is visible when the other side of the bag is viewed.
    b. Remove the excess air and seal the bag.
4. Sign/Date the tamper tape and place it over the zipper mouth of the bag. Once the tamper proof seal has been placed over the bag, the client is then free to leave.
5. Place each sealed bag inside the return shipping UPS bag. Maintain security for these samples. Once all specimens have been collected for the day, remove the strip for the adhesive seal for the UPS bag and seal securely.
6. Prepare package for courier pick up depending upon site specific procedures. UPS can be contacted for a pick up by calling 800-823-7459 or call DDC at 800-310-9868 with questions.
7. Record the tracking number.

DNA Diagnostics Center

One DDC Way • Fairfield, OH 45014
1-800-310-9868 • 1-800-310-9728 (fax)

Check Box if Private Case ☐

Client Identification Form/Chain of Custody

IV-D Case #: _____

Additional Case #: _____

Requesting Agency / County: _____

Collection Site: _____
Facility

_____
Address

_____
City *State* *Zip*

Appointment Date & Time: _____

To Collector: Please print clearly. Entire box must be completed on each party collected.

MOTHER

Last Name, First Name | **Middle Initial** | **Date of Birth** | Place Right Thumbprint Here

Social Security No.

Form of Photo ID Used and ID Number:
☐ Driver's License # _____ ☐ Military ID # _____
☐ School ID # _____ ☐ Other *(type and #)*: _____

Race *(check one)*: ☐ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other *(specify)*:

Have you had a blood transfusion within the past 3 months? ☐ Yes ☐ No

Have you ever had a bone marrow or stem cell transplant? ☐ Yes ☐ No

DDC USE ONLY

(if required)

CHILD

Last Name, First Name | **Middle Initial** | **Date of Birth** | Place Right Thumbprint Here

Social Security No.

Sex: ☐ M ☐ F

Form of Photo ID Used and ID Number:
☐ Driver's License # _____ ☐ Military ID # _____
☐ School ID # _____ ☐ Other *(type and #)*: _____

Have you had a blood transfusion within the past 3 months? ☐ Yes ☐ No

Have you ever had a bone marrow or stem cell transplant? ☐ Yes ☐ No

DDC USE ONLY

(if required)

ALLEGED FATHER

Last Name, First Name | **Middle Initial** | **Date of Birth** | Place Right Thumbprint Here

Social Security No.

Form of Photo ID Used and ID Number:
☐ Driver's License # _____ ☐ Military ID # _____
☐ School ID # _____ ☐ Other *(type and #)*: _____

Race *(check one)*: ☐ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other *(specify)*:

Have you had a blood transfusion within the past 3 months? ☐ Yes ☐ No

Have you ever had a bone marrow or stem cell transplant? ☐ Yes ☐ No

DDC USE ONLY

(if required)

ADDITIONAL PARTY

Relationship:

Last Name, First Name | **Middle Initial** | **Date of Birth** | Place Right Thumbprint Here

Social Security No.

Sex: ☐ M ☐ F

Form of Photo ID Used and ID Number:
☐ Driver's License # _____ ☐ Military ID # _____
☐ School ID # _____ ☐ Other *(type and #)*: _____

Race *(check one)*: ☐ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other *(specify)*:

Have you had a blood transfusion within the past 3 months? ☐ Yes ☐ No

Have you ever had a bone marrow or stem cell transplant? ☐ Yes ☐ No

DDC USE ONLY

(if required)

STATEMENT OF CONSENT AND RELEASE

I hereby consent to procurement of biological samples, photographs and fingerprints for myself and as a representative of the minor child in this case, if applicable, and release DDC from any liability relating to any misrepresentation on my part. I hereby agree to indemnify and hold DDC harmless from any losses and expenses as a result of any such misrepresentation. I understand that the biological samples provided will be used for DNA testing and the results may be used in a court of law to assist in the determination of parentage of the applicable child(ren), that the results may be stored for possible future use, and may be disclosed as required by law or legal process, including in connection with the determination of parentage. I hereby consent to the use of the results for any such purpose without requiring further approval from me, and I have initialed the label(s) on the specimen container(s) confirming the container(s) are correctly identified as containing my or my child(ren)'s specimen(s).

Sign Here **Mother's Signature:** _____ Date: _____

Sign Here **Custodian's Signature:** _____ *Relationship to the child:* _____ Date: _____

Sign Here **Alleged Father's Signature:** _____ Date: _____

Sign Here **Additional Party's Signature:** _____ Date: _____

Form Continues on Reverse

SPECIMEN COLLECTOR'S STATEMENT
(must be completed by collector)

I have positively identified the parties and have collected, packaged and sealed the specimens and have witnessed the preceding signatures:

on _____ at _____ ☐ AM ☐ PM.
Month Day Year Time

I affirm, under penalties for perjury, that no tampering with the specimens occurred while the specimens were in my control.

Sign Here

Signature: _____

Print Name: _____

Is the collector a Child Support Employee? ☐ Yes ☐ No

Company Affiliation: _____

ADDRESSES
(if additional results are to be mailed)

MOTHER _____

_____
Address

_____
City State Zip

FATHER _____

_____
Address

_____
City State Zip

TAPE PHOTO HERE

TAPE PHOTO HERE

DNA DIAGNOSTICS CENTER LABORATORY USE ONLY

Was the Package Received Sealed and Secure: ☐ Yes ☐ No **Sample Type if Other Than buccal:** _____

I hereby affirm that I received the specimens for the individuals named on this form and found no evidence that the specimens had been tampered with or that the package had been opened prior to our receipt.

Recipient's Initials & Date: _____

Laboratory Notes: _____

_____

DNA Diagnostics Center

Collection Provider Questionnaire

Name: Date:

Title: County/Agency/Tribe:

Please take a moment to review the Contracts Collection Manual and answer these questions. Please only answer with one response for each question by marking the appropriate circle. When submitting the answers, please "reply to" the email you received and your score will be calculated by DDC. We will contact you if you have more than 3 incorrect responses and require further assistance.

Q1: Which of the following best describes the principal of Universal Precautions?

- ☐ Handle all patient specimens as if infectious.
- ☐ Use handling precautions only with specimens containing blood borne pathogens
- ☐ All samples are safe unless tested positive for HIV and/or HBV
- ☐ Gloves universally protect the collector from exposure to pathogens

Q2: Confidential information, as defined by DDC, is described as:

- ☐ Information that can be given to anyone not related to the patients
- ☐ Information that cannot be given to the patients directly
- ☐ Information that is shared only with your coworker
- ☐ Information not in the public domain relating to the names or addresses of individuals, test results, processes, formulas, and other information DDC may deem confidential

Q3: Acceptable Identification can be obtained by which method:

- ☐ Government issued, photo identification
- ☐ State Identification
- ☐ Passport
- ☐ All of the above

Q4: To maintain proper chain of custody, it is important that:

- ☐ Ask to see the individual's photo ID
- ☐ Complete the client identification form with required information
- ☐ All tested parties and the collector sign and date the form
- ☐ A photo is taken of all tested parties
- ☐ A thumbprint is provided (if required)
- ☐ All of the above

Q5: What information on the consent form is needed for statistical calculation of the adult clients?

- ☐ Age
- ☐ Date of Collection
- ☐ Race
- ☐ All of the above

Q6: During the sample collection, contamination can occur by:

- ☐ Touching the end of the swab to any foreign surface
- ☐ Touching the collectors skin
- ☐ Coming in contact with other samples
- ☐ All of the above

Q7: What measures are to be taken to prevent sample mix-ups?

- ☐ Label and collect one client sample at a time
- ☐ Seal the buccal envelope and ask client to verify the sample labeling immediately
- ☐ Never pre-label the buccal envelopes with patient's names or information
- ☐ All of the above

Q8: The total number of swabs to be used on each client is?

- ☐ Three
- ☐ One on each cheek
- ☐ Two
- ☐ Four...two on inside of each cheek.

Q9: What should you remember to do when photographing patients?

- ☐ Have the patients remove any sunglasses or hats/scarves (unless worn for religious reasons.
- ☐ Have the patients sign the instant photo
- ☐ As the collector, initial and date the instant photo
- ☐ All of the above

Q10: When shipping the samples back to DDC, place which items in the clear zipper type bag:

- ☐ All samples collected
- ☐ All completed Client ID and Consent forms
- ☐ Any photocopies of patient identification
- ☐ Disposable camera (if one was provided) or instant photograph (if an instant camera was used
- ☐ All of the above

Q11: If you have forgotten to include the paperwork in the clear zipper type bag once you have sealed it with tamper tape, you should:

- ☐ Rip open the bag and put the paperwork in before shipping
- ☐ Carefully cut the bag with scissors as to not destroy the tamper tape and insert the paperwork
- ☐ Open a new kit and use the bag from it
- ☐ As long as the samples are in the zipper type bag, the paper work can be sent along with the sealed samples. It is not necessary to seal up the paperwork as long as samples are sealed and tamper taped prior to shipping

Q12: As a collector providing services to DDC, which of the following should be avoided:

- ☐ Maintain confidentiality
- ☐ Provide a clean and neat collection facility or area
- ☐ Minimize errors by reviewing procedures regularly
- ☐ Collect anywhere you can find a table, regardless of clutter or dirt

DNA Diagnostics Center

CONFIDENTIALITY OF FEDERAL TAX RETURN RELATED INFORMATION

As a vendor for various governmental agencies, employees, agents, or subcontractors of DNA Diagnostics Center may have access to Federal Tax Return related confidential information. I am fully aware that federal tax returns and return information (whether original, hard copy, photocopy, magnetic tape, or other form) received from Internal Revenue Service in the course of my performance of services for government contracts are to be treated as confidential as defined in Section 6103 of the Internal Revenue Code. In my capacity as such, information will be used solely for the purpose of the administration of the child support program. I am aware that if I unlawfully disclose willfully any return information, criminal action could be brought against me and upon conviction I could be fined in any amount not exceeding $5000, or imprisonment of not more than 5 years, or both, together with the cost of prosecution. Additionally, in cases of willful unlawful disclosure, a civil action may be brought for actual and (or) punitive damages of not less than $1,000 and the costs of the action.

I acknowledge that I have read and agree to be bound by the attached excerpts from section 6103, 7213, 7213(A), and 7431 Internal Revenue Code of 1954, as amended by the Tax Reform Act of 1976, to the extent applicable to my performance of the services for DHS. I further acknowledge that said excerpts are available for my future reference. Please refer to the Federal link for further assistance.
http://www.irsvideos.gov/Governments/Safeguards/SafeguardsSecurityAwarenessTraining

I affirm that I have reviewed the *Safeguards Security Awareness Training* video. I further affirm that I will not disclose any federal tax return, return information, or social security account number in any manner whatever, except to the extent and in the manner specifically permitted by applicable State or Federal laws, rules or regulations. I am aware that any violation of the above may be grounds for immediate dismissal from State service and/or other penalties as outlined above.

_____
Name (please print)

_____ _____
Signature Date

SUPPLEMENTAL DOCUMENTS

The collector will fill out a *Collection Completion Report* for each collection event. The collector will write the client name, testing role (M, C, AF), CSE case number and docket number (if applicable) for each client that is collected. The report should be completed as clients are collected. Make sure to fill out the information at the top of the report prior to sending a copy to DDC. A tracking number must be included on every report. The tracking number should be written down in the "Shipment Tracking Number" field. The report must be faxed to 513-881-4042 after the collection event is completed. After the report is faxed, it can be placed in the shipping bag with samples. Provide a copy to the county if requested.

Collectors must keep a copy of the tracking number for each package that is shipped to DDC. The tracking number is located on the shipping label. If your samples are not received, we start an investigation with the shipping company. We cannot start an investigation without a tracking number. Collectors should keep record of all tracking numbers used. In the event that a completion report is not received by DDC, we will reach out to the collector to request the tracking number.

The *Specimen Collection Supply Order Form* lists the supplies that DDC regularly sends to our collectors. DDC will send your initial supply order automatically. If you need to order supplies, please do so monthly. You can fax the supply order form to 513-881-4042 or email it to ContractsTS@dnacenter.com. Orders are typically shipped on the day after they are received. If you have a rush order, please indicate that in the "Special Instructions" field.

DNA Diagnostics Center

Collection Completion Report

Please Fax To: 1-513-881-4042

Collector's Name: _____ Date of Collections: _____

County: _____ Collection Location: _____

Collector's Phone: _____ Collector's Signature: _____

Shipment Tracking Number: _____

NAME OF CLIENT	M	C	AF	CASE #	Docket / Other
1.	◯	◯	◯		
2.	◯	◯	◯		
3.	◯	◯	◯		
4.	◯	◯	◯		
5.	◯	◯	◯		
6.	◯	◯	◯		
7.	◯	◯	◯		
8.	◯	◯	◯		
9.	◯	◯	◯		
10.	◯	◯	◯		
11.	◯	◯	◯		
12.	◯	◯	◯		
13.	◯	◯	◯		
14.	◯	◯	◯		
15.	◯	◯	◯		
16.	◯	◯	◯		
17.	◯	◯	◯		
18.	◯	◯	◯		
19.	◯	◯	◯		
20.	◯	◯	◯		
21.	◯	◯	◯		
22.	◯	◯	◯		
23.	◯	◯	◯		
24.	◯	◯	◯		
25.	◯	◯	◯		

TABLE KEY: AF = Alleged Father C = Child M = Mother

NOTES: _____

_____

CCR-4000-CS 120906-AH

DNA Diagnostics Center

Specimen Collection Supply Order Form

Item	Packaged	Item #	Quantity Requested
Pink Envelopes and White Buccals	50	SP1014	
Yellow Envelopes and White Buccals	50	SP1015	
Blue Envelopes and White Buccals	50	SP1016	
Chain of Custody Forms	50	SP1013	
Clear Plastic Bags	50	SP1019	
Tamper Tape	50	SP1020	
Small Non-Latex Gloves	75 Pairs / Box	SP1022	
Medium Non-Latex Gloves	75 Pairs / Box	SP1023	
Large Non-Latex Gloves	75 Pairs / Box	SP1024	
Extra Large Non-Latex Gloves	45 Pairs / Box	SP1025	
1-Day Return Shipping Airbills & Bags	1	SP1066	
2-Day Return Shipping Airbills & Bags	1	SP1067	
USPS Mailer (Standard US Mail)	1	SP1064	
Fuji Camera	1	SP1000	
Fuji Film WIDE	10 Pics / Pack	SP1001	
Fuji Film MINI	10 Pics / Pack	SP1080	
Batteries	2 / Pack	SP1045	
Thumbprint Ink Pod	1	SP1018	
Thumbprint Ink Strip	1	SP1065	
Contract Kit	1	SP1033	
Prison Kit	1	SP1041	

Shipping Information _____

Name: _____ **Attention to:** _____

Address: _____

City, State, Zip: _____

Phone #: _____ **Fax #:** _____

Email: _____

Special Instructions:

Orders can be faxed to 513-881-4042 or emailed to ContractsTS@dnacenter.com. You can also turn this form in with samples.

All supply orders should be received by DDC no less than 2 weeks prior to your next collection date to ensure accurate and timely delivery. Please order enough supplies to last 30 calendar days.

JAIL PAPERWORK

If you are asked to do a jail collection, there are a few special things that you need to know. Once we get a jail collection request from one of our accounts, DDC will find the closest collector to that jail. We will always provide the collector with the inmate's name, birthday, and court order. Sometimes, we are also able to secure inmate numbers and booking photos. DDC expects for jail collections to be completed as soon as possible. If there are any special circumstances surrounding the collection, let us know so that we can notify the requesting account.

In order to schedule a date and time for the collection, the collector needs to call the jail to request entrance for a court-ordered DNA collection. DDC cannot call the jail to do this since you are the one who needs access. If you have any issues with your contact, please inform the DDC scheduler.

On the date of your scheduled jail collection, please call the jail prior to leaving your house to verify that the inmate is still present. **Make sure to bring the inmate's court order, Scheduling Confirmation sheet, and any collection supplies needed to the jail.**

DDC provides prison kits for collectors to keep on hand. If you do not have any prison kits at the time of collection, you can use your regular supplies. Keep in mind that you will need to have pages 15-17 with you if you do not have prison kits.

The *Non-Collection Statement* is for situations where you arrive at the jail at your scheduled time and the inmate cannot be produced. They may have been transferred, released, on work duty, or in SHU. You must fill out all applicable information on the statement and have a prison official sign it.

The *Refusal Form* is required when the inmate refused DNA collection. The inmate needs to print their name under "I _____, am hereby refusing…" and sign and date under that. The collector needs fill out the top portion of the form and sign and date under the inmate's signature. Lastly, prison official signs and dates at the bottom.

The *Photo Exempt Statement* is to be used if the jail won't let you bring in a camera to take the photo. If that's the case, ask the jail for a copy of the inmate's booking photo. If they refuse, please fill out the Photo Exempt Statement and include it with the sample.

If a prison official is unavailable or refuses to sign any of the forms, call the DDC customer service line while you're still at the jail. You can reach us Monday-Friday from 8 AM – 8 PM at 1-800-310-9868.

If you do not supply the required forms to DDC, you will not be paid for your attempt.

The forms must be emailed to the scheduler, faxed to 513-881-4042 or emailed to contractsts@dnacenter.com.

DNA Diagnostics Center

DNA Non-Collection Statement

For DNA Parentage Testing

To be Completed by the Collector and Prison Official

I, _____, attempted to collect DNA samples
Name of Collector

today, _____, from inmate _____/
Date of Appointment *(mm/dd/yyyy)* Inmate's Name

_____, for the purpose of having his/her DNA samples collected as
Inmate's Number

directed by the attached court order/administration order.

According to the prison official whose name is listed below, the inmate is unavailable for sample collection due to the following reason(s):

- ❑ Inmate was released on: _____
  Date of Release *(mm/dd/yyyy)*
- ❑ Inmate was transferred to: _____ on _____/_____/_____
  Name of Prison Date of Transfer *(mm/dd/yyyy)*
- ❑ Other (please specify): _____

Sign Here

X _____ _____/_____/_____
Signature of Collector Date *(mm/dd/yyyy)*

_____ _____
Printed Name and Title of Prison Official Name of Prison Facility

Sign Here

X _____ _____/_____/_____
Signature of Prison Official Date *(mm/dd/yyyy)*

DNA Diagnostics Center

DNA Specimen Collection Refusal Form

For DNA Parentage Testing

Chain of Custody Documentation

Case Information

Today's Date: *(mm/dd/yyyy)* _____/_____/_____ Agency Case #: _____

Requesting Agency: _____

I, _____, am hereby refusing

to consent to a DNA specimen collection to be used for DNA parentage testing.

Sign Here

X_____ X_____/_____/_____

Signature Date *(mm/dd/yyyy)*

Sign Here

X_____ X_____/_____/_____

Signature of Collector Date *(mm/dd/yyyy)*

Sign Here

X_____ X_____/_____/_____

Signature of Witness* *(if available)* Date *(mm/dd/yyyy)*

Witness may be the CSE Staff, Prison Official, etc.

Please fax this form to DNA Diagnostics Center at **1-800-310-9728**.
Attach this original form to the Client Identification and Consent Form and return to:

DNA Diagnostics Center
ATTN: Government Contracts
One DDC Way
Fairfield, OH 45014

DNA Diagnostics Center

Photo Exempt Statement

Prison Only

Please complete this form **ONLY** if the facility does not allow the use of a camera or to obtain a copy of the inmate identification during the collection process. If available, please have the inmate sign and date a photocopy of a booking photo.

I,_____, was present and positively identified the collected
(name of collector or witness)

individual listed below. I witnessed the completion of the Chain of Custody form and his/her signature.

Verification of Identity for: _____

Type of Identification: _____

Signature of Collector / Witness: _____

Printed Name: _____ Date: _____ / _____ / _____

Title or Position: _____

NOTE: This form MUST be returned with specimens and Chain of Custody. Should you require assistance or have questions regarding this collection, contact DDC Customer Service at 1-800-310-9868.

Attachment #1(c)

Specimen Collection
Customer Service

Customer Service

The DDC Difference

Specimen Collection

DNA Diagnostics Center

Objectives

- To be able to understand the role that the DDC Specimen Collector plays in assisting the state and/or county IVD program to establish parentage services.
- To understand the importance of professionalism and confidentiality when dealing directly with the clients/testing parties.
- To allow DDC to provide services according to contract requirements.

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Customer Service

- DDC is contracted with state and local child support agencies to perform paternity testing services.
  - Every state offers a Title IVD (child support) program to assist families.
  - As part of these services, each state, county, or tribal agency contracts with genetic test providers who are accredited to perform paternity testing services to include the following services; Testing, Results Issuance, Customer Service and Support, Interstate/ Institutional Scheduling, and Specimen Collection.

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Customer Service

- Who are our customers?
  - Contract Management Staff
  - State/County Child Support Staff
  - Attorneys
  - Judges
  - The testing parties/clients
    - The Specimen Collector has direct/face to face interaction with the ODJFS/CSEA customer

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The Value of Great Service by the Specimen Collector

- The customer is delighted with the DDC experience.
- DDC can exceed customer expectations and ensure contract compliance.
- DDC customers can then provide their clients/ tested parties with great service.
- Clients/Tested parties can feel a sense of comfort knowing their samples were collected in a confidential and professional manner.

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Customer Expectations

- That DDC will deliver quality parentage testing results in the specified timeframes
- That DDC will provide prompt, efficient, and professional service
- That DDC will deliver on the services contracted from initial referral to specimen collection and issuance of results

Customer Service-Specimen Collection

- Understand the requirements of the Specimen Collection Process
  - Follow all procedures provided by DDC
  - All information obtained from the Client/State/Local Agency, DDC, and the tested parties themselves is confidential.
    - The specimen collector is not to share any appointment information for any tested party.
    - Personal information on any tested party is not to be shared.
    - All inquiries regarding their case should be directed to the Ohio child support program at 800-686-1556.

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Customer Service-Specimen Collection

- Collect samples from the scheduled parties
  - For example, if the Mom is marked for collection, she should be collected. Many times the moms will assume they are not being collected
  - If parties appear and are not scheduled, please call DDC at 800-310-9868 for confirmation.
- Do not provide any client/tested party opinion, guidance, support, or input relating to any case.
  - State that you are only providing the sample collection. All inquiries should be directed to the Ohio child support program at 800-686-1556.

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The Basics

- The client/tested party will appear at the designated date/time for specimen collection.
  - Acknowledge the customer.
  - Once the client/tested party is in the collection room/area, let them know you will collect their sample and ship to the laboratory for testing.
  - Do not confirm any testing turn around times.
    - Let them know the CSEA will provide their results.
  - Once the samples are collected and all paperwork is completed, thank the client/tested party and dismiss them.

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The Basics Continued

- Typical questions that may be asked during a collection.
  - Can you tell me if the other party appeared?
  - I know that “he/she” has an appointment here today. Has he shown yet?
  - I was tested a few years ago, why do I have to be tested again?
  - I know this baby is his, why do I have to do the test?
  - When will I get my results?

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The Basics Continued

- Sample Responses
  - If you have any questions about your case, you will need to speak to the child support office/caseworker.
  - I'm sorry, but I am only performing the Specimen Collection process. The child support office will need to answer any questions you may have.
  - I know that it must be frustrating, but the child support office will be able to assist you.

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The Basics Continued

- Procedural side of customer service
  - Know the collection procedures
  - Be courteous to the clients/tested parties
  - Keep “small talk” and general conversations to a minimum
  - Complete sample collection process in an efficient manner
  - Thank the client/tested party and dismiss them

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Tense/Escalated Situations

- If a situation becomes escalated for whatever reason, try to separate the individuals if it is relating to disputes between the parties
  - Notify your immediate supervisor or in house staff to determine next steps.
    - If the situation is not remedied and appears to escalate, contact police or security.
  - Contact DDC at 800-310-9868 as soon as logical so the matter can be documented and reported to the child support program.

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Critical points to remember

- Do not give out any information on any party for any case regardless of the circumstances.
- Provide the state child support program assistance number to any client/tested party as requested.
- Let them know you are only performing the specimen collection process and do not have any case specifics, turn around times, or other information.

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Skills for Success

- List the skills needed to be a successful DDC Specimen Collector
  - Be professional and courteous to the client/tested party
  - Follow the specimen collection procedures
  - _____
  - _____
  - _____

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Professionalism

- If the client/tested party has questions, refer them to the 800 child support program number.
- Do not share opinions, negative stories, or derogatory comments about tested parties, the child support program or the testing laboratory.
- Do not criticize others.
- Avoid inappropriate humor or language.

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Professionalism Cont'd

- Speak professionally and quietly with the clients/tested parties.
  - Conversation should be held to a minimum.
  - Client names or reasons for appointments should not be overheard by others awaiting appointments.
  - Acknowledge delays and apologize if there is a wait.

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Plan to overcome challenges

- We all have workloads that can become overwhelming very quickly on any given day.
  - List some skills to handle those challenges
    - _____
    - _____

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Challenges we face

- List specific challenges we may encounter during any given day
  - Clients that appear for appointments at the wrong date/time
  - _____
  - _____
  - _____

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DDC Dedication to Service

- DDC maintains customer focus and productive communication channels with its customers. We believe that our exceptionally strong concentration on our clients and the preservation of dynamic interaction is of utmost importance.

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Review

- What are some of our customers' expectations?
- What are your biggest challenges?
- How do you handle questions from a client/testing party?
- How can you diffuse an escalated situation?
- Name some benefits of providing good service?

Attachment #1(d)

Assisted Buccal Specimen Collection

Assisted Buccal Specimen Collection
Chain of Custody Procedure
(Revised and adapted as a result of the COVID-19 Pandemic)

Table of Contents

A. Introduction

This process is effective May 1, 2020 and will continue indefinitely in order to conduct buccal swab specimen collections with little to no direct physical customer contact. It is intended for use within the governmental agency facility and may be performed by either the IV-D agency staff or DNA Diagnostics (DDC) staff, referred to throughout as "collector". The process must be in adherence with **all** local- and/or state-mandated safety and social distancing requirements, and must meet the accreditation standards for the American Association of Blood Banks (AABB). AABB is the accrediting body that dictates laboratory requirements and standards for parentage testing. **No deviation from this procedure is acceptable that may result in direct physical contact with the customer and/or within a six foot distance.**

"Assisting" the customer involves giving proper instruction to ensure collection of a suitable buccal sample for paternity testing, while directly witnessing the collection. The intention is to:

1. Eliminate physical contact between the "collector" and the customer; while adhering to social distancing requirements, and

2. Eliminate any paperwork exchange where possible.

Chain of custody must be maintained and documented, while providing instructions to the customer for the buccal swab collection procedure and witnessing the entire process.

B. Supplies Needed

1. The collector will need to provide:

    a. Face covering-home made cloth mask, scarf, bandanna or disposable mask;
    b. Pen

2. DDC to provide:

    a. Gloves
    b. Chain of Custody forms
    c. Buccal swabs & sample envelopes

3. Local agency to provide:

    a. Appropriate space as outlined in section C;
    b. Sanitizing surface cleaner in accordance with facility accepted procedures;

Note: Gloves must be removed and discarded in regular trash between customers, and surfaces should be sanitized using the protocols that are in place for that local facility.

4. The customer will need to arrive with:

    a. Face covering;
    b. Pen;
    c. Government issued photo id

****The following sections C, D, and E are the responsibility of the IV-D agency****

When planning for collections one must take into account, but not limited to the following considerations:

C. Prepare the Space

1. Coordinate designated seating in advance so that it is clear where the customers should sit during the collection process. Maintain social distancing between the collector and other customers.

2. Identify a location to place paperwork to ensure a distance of 6 feet between the staff member/collector and customers. It will be necessary to establish a routine that follows the agency/facility protocols for outside visitors and meeting with

customers on-site. It may be helpful to install a Plexiglas shield with a cutout at the bottom to pass paperwork under.

3. If the facility lends itself to conducting collections outdoors and/or in a drive-up setting there must be an agreed upon procedure and proper planning in place in order to facilitate outdoor/drive-up collection. Such a procedure will require the agency completing 100% of the paperwork in advance, with the exception of the customer consent. DDC can work with you to determine if this is an option and to customize an acceptable protocol if appropriate.

D. Schedule Customers

1. Communicate in advance to all customers, instructing them to remain home in the event they are experiencing any symptoms of illness.

2. Schedule customers that do not reside together at separate times; customers must have individual appointment times to avoid a gathering of people in any waiting areas. Emphasize the importance of being prompt.

3. Inform customers that they must wear a covering over their nose and mouth to enter the building. This covering may be a homemade mask, scarf, bandana, or handkerchief. Also instruct customers to bring their own pen.

E. Prepare for Customer Arrival

1. Complete facility sanitizing protocols before the arrival of customers and in between customers.

2. Wherever possible, pre-populate as much of the known information on the Chain of Custody form in advance of the customer arrival. This will reduce contact time during the process. DDC can provide an electronic version of the Chain of Custody form, if needed.

   Note: It will be helpful if the agency can pre-populate the Chain of Custody form even if DDC is supplying a collector for the “Collector Assisted Process.” This could be done by phone much like a “pre-registration” for a medical procedure and provide the completed or partially completed form at the time of collection.

3. Depending on the circumstances, you may establish a process where you can call or text customers when you are ready for them to enter the building.

4. Put on clean gloves prior to the customers entering the space. Observe social distancing and/or have a Plexiglass divider between yourself and the customer.

F. Verify the ID and Complete Paperwork

1. Verify the identity of individual(s) by viewing a government- issued photo ID. Children typically do not have a photo ID. Instruct the customer to place the ID in the designated location and have them return to their seat while you view the ID and confirm their identity.

2. Complete all or any remaining sections of the Chain of Custody form by asking questions to the customer. Obtain basic information (such as first and last name) for parties who are absent. Fingerprints will **not** be obtained for this procedure, leave this section blank.

3. Ask the parties to lower their face coverings and take a photo of all parties.

4. Write the first and last name of the tested party at the bottom of the photo, along with the date. Repeat the name back to the party to ensure that it is correct.

G. Specimen Collection Procedure

1. Open the wrapper at the end opposite from the swab tip. You can peel apart the paper ends or break the paper using the stick end of the swabs. Leave the stick exposed for the customer and place them in the designated location. It is also acceptable to instruct the customer to open the swab packets while receiving proper instruction from the collector.

Note: The actual cotton portion of the swab should not be touched or placed on any surface. If they are, discard them and use a new swab. Work with one customer at a time until their collection is completed.

2. Let the customer remove one swab from the opened swab sleeve. Ask them to swab the inside of their cheek taking precaution to stay away from the gum line and keep the swab in the middle section of the cheek. Conduct swabbing while counting to at least 10 for each swab. Ensure you can visibly see the

swab pushing out their cheek. They should be rotating the swab and moving up and down. Use 2 swabs for each side of the cheek.

3. Have the customer place each swab in the appropriate color-coded envelope after swabbing until four swabs are in the envelope. The mother or custodial parent should swab the child.

4. Once all four swabs are placed in the envelope, have the customer seal the envelope by pressing down on the self-adhesive flap.

5. Have the customer label the specimen envelope with the collected party/customer name, date of birth, and collection date. Ask each customer – and the Mother or custodial parent of the child -- to review the sample envelope and write his/her initials to confirm the information. Have them place completed labeled envelope with swabs in the designated location. Initial and date the swab envelope and place it into the plastic sleeve.

H. Prepare to Send the Specimen and Paperwork

1. Once samples have been collected, have customers sign and date the Chain of Custody consent statement.

2. Ask the customer to place the completed sample envelope and signed consent statement in the designated paperwork area while maintaining appropriate social distance.

3. Obtain the sample envelope and consent statement, review for completion, and sign and date the back of the Chain of Custody form.

4. Place the Chain of Custody form front-side down. Lay the photos and specimen envelopes in the center section of the back side of the Chain of Custody form. If customers are ordered to pay, place the money order here.

5. Fold up the bottom third of the Chain of Custody form, then fold down the top third over the bottom third.

6. Slide the Chain of Custody form with the samples and photo into the zipper-type plastic bag.

7. Ensure that the top “Requesting Agency” information is visible on one side of the bag and the M/CH/AF info is visible when the other side of the bag is viewed.

8. Remove the excess air and seal the bag.

9. Sign/Date the tamper tape and place it over the zipped closure of the bag. Once the tamper-proof seal has been placed over the bag, the customer is free to leave.

10. Place each sealed bag inside the return shipping courier bag. Maintain security for these samples. Once all specimens have been collected for the day, remove the strip for the adhesive seal for the courier bag and seal it securely.

I. Shipping Procedure

1. Prepare the package for courier pick-up depending upon site-specific procedures. If a pick-up is needed, call FedEX at 800-463-3339. Call DDC at 800-310-9868 if you have questions.

2. Record the tracking number.

Attachment #2

Chain of Custody Form

DNA Diagnostics Center

One DDC Way • Fairfield, OH 45014
1-800-310-9868 • 1-800-310-9728 (fax)

Client Identification Form/Chain of Custody

IV-D Case #: _____

Additional Case #: _____

Requesting Agency / County: _____

Collection Site: _____
Facility

_____
Address

_____
City *State* *Zip*

Appointment Date & Time: _____

Check Box if Private Case ☐

Kentucky Child Support Enforcement
☐ **K-TAP** **or** ☐ **Non-K-TAP**

To Collector: Please print clearly. Entire box must be completed on each party collected.

MOTHER

Last Name, First Name | **Middle Initial** | **Date of Birth** | Place Right Thumbprint Here

Social Security No.

Form of Photo ID Used and ID Number:
☐ Driver's License # _____ ☐ Military ID # _____
☐ School ID # _____ ☐ Other *(type and #)*: _____

Race *(Please check one)*: ☐ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Other *(specify)*:

Have you had a blood transfusion within the past 3 months? ☐ Yes ☐ No

Have you ever had a bone marrow or stem cell transplant? ☐ Yes ☐ No

DDC USE ONLY

(if required)

CHILD

Last Name, First Name | **Middle Initial** | **Date of Birth** | Place Right Thumbprint Here

Social Security No.

Sex: ☐ M ☐ F

Form of Photo ID Used and ID Number:
☐ Driver's License # _____ ☐ Military ID # _____
☐ School ID # _____ ☐ Other *(type and #)*: _____

Race *(Please check one)*: ☐ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Other *(specify)*:

Have you had a blood transfusion within the past 3 months? ☐ Yes ☐ No

Have you ever had a bone marrow or stem cell transplant? ☐ Yes ☐ No

DDC USE ONLY

(if required)

ALLEGED FATHER

Last Name, First Name | **Middle Initial** | **Date of Birth** | Place Right Thumbprint Here

Social Security No.

Form of Photo ID Used and ID Number:
☐ Driver's License # _____ ☐ Military ID # _____
☐ School ID # _____ ☐ Other *(type and #)*: _____

Race *(Please check one)*: ☐ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Other *(specify)*:

Have you had a blood transfusion within the past 3 months? ☐ Yes ☐ No

Have you ever had a bone marrow or stem cell transplant? ☐ Yes ☐ No

DDC USE ONLY

(if required)

ADDITIONAL PARTY
Relationship:

Last Name, First Name | **Middle Initial** | **Date of Birth** | Place Right Thumbprint Here

Social Security No.

Sex: ☐ M ☐ F

Form of Photo ID Used and ID Number:
☐ Driver's License # _____ ☐ Military ID # _____
☐ School ID # _____ ☐ Other *(type and #)*: _____

Race *(Please check one)*: ☐ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Other *(specify)*:

Have you had a blood transfusion within the past 3 months? ☐ Yes ☐ No

Have you ever had a bone marrow or stem cell transplant? ☐ Yes ☐ No

DDC USE ONLY

(if required)

STATEMENT OF CONSENT AND RELEASE

I acknowledge, consent, and agree to the following: As a tested party to this disputed paternity case and/or representative of the child(ren) in said case, I hereby authorize and consent to the procurement of my/the child(ren)'s specimens, photographs, and identification. I have witnessed the labeling of the specimens and affirm that they have been correctly identified. The results of this test are court-admissible and may be used to determine paternity. I understand that the biological specimens will be used for genetic testing and may be stored for future testing, if necessary.

Sign Here **Mother's Signature:** _____ Date: _____

Sign Here **Custodian's Signature:** _____ *Relationship to the child:* _____ Date: _____

Sign Here **Alleged Father's Signature:** _____ Date: _____

Sign Here **Additional Party's Signature:** _____ Date: _____

Form Continues on Reverse

SPECIMEN COLLECTOR'S STATEMENT
(must be completed by collector)

I have positively identified the parties and have collected, packaged and sealed the specimens and have witnessed the preceding signatures:

on _____ at _____ ☐ AM ☐ PM.
Month Day Year Time

I affirm, under penalties for perjury, that no tampering with the specimens occurred while the specimens were in my control.

Sign Here

Signature: _____

Print Name: _____

Is the collector a Child Support Employee? ☐ Yes ☐ No

Company Affiliation: _____

ADDRESSES
(if additional results are to be mailed)

MOTHER _____

_____
Address

_____
City State Zip

FATHER _____

_____
Address

_____
City State Zip

TAPE PHOTO HERE

TAPE PHOTO HERE

DNA DIAGNOSTICS CENTER LABORATORY USE ONLY

Was the Package Received Sealed and Secure: ☐ Yes ☐ No **Sample Type if Other Than buccal:** _____

I hereby affirm that I received the specimens for the individuals named on this form and found no evidence that the specimens had been tampered with or that the package had been opened prior to our receipt.

Recipient's Initials & Date: _____

Laboratory Notes: _____

_____

Attachment #3

Sample Reports

DNA Diagnostics Center

DNA Test Report

North Platte-DHHS CSE NE

DDC is accredited/certified by AABB, CAP, ISO/IEC 17025 by ANAB, CLIA & NYSDOH.

Case 1998650	MOTHER	CHILD	Alleged FATHER
Name			
Race	Caucasian		Caucasian
Sample Type	Buccal	Buccal	Buccal
Date Collected	10/4/2019	10/4/2019	7/25/2019
Test No.			

Locus	PI	Allele Sizes		Allele Sizes		Allele Sizes	
D3S1358	3.36	15	16	16	18	16	18
vWA	9.71	14	17	15	17	15	
D16S539	1.69	11		11	12	11	12
CSF1PO	3.12	11		11	12	12	
TPOX	8.38	8	11	10	11	10	11
D8S1179	2.43	13	14	14		14	15
D21S11	2.36	28	32.2	29	32.2	29	32.2
D18S51	3.39	13	17	13	15	13	15
D2S441	1.47	10	14	10	11	11	14
D19S433	2.73	13	16	15	16	15	15.2
TH01	5.24	9.3	10	7	10	7	
FGA	5.96	20	21	20	25	22	25
D22S1045	2.84	15	16	16		16	
D5S818	6.18	10	12	12	13	13	
D13S317	1.78	9	11	9	12	11	12
D7S820	3.12	7	9	8	9	8	10
SE33	8.33	21.2	27.2	21.2	29.2	27.2	29.2
D10S1248	2.89	13	14	14	15	14	15
D1S1656	3.88	14.3	17.3	17.3		13	17.3
D2S1338	2.32	24	25	17	25	17	20
Amelogenin		X		X		X	Y

Interpretation:

Combined Paternity Index: **74,750,486,272**

Probability of Paternity: **99.999999998%**

The alleged father is not excluded as the biological father of the tested child. Based on testing results obtained from analyses of the DNA loci listed, the probability of paternity is 99.999999998%. This probability of paternity is calculated by comparing to an untested, unrelated, random individual of the Caucasian population (assumes prior probability equals 0.50).

Subscribed and sworn before me on October 10, 2019

Jennifer Walter
Notary Public, State of Ohio
My Commission Expires May 10, 2021

I, the undersigned Laboratory Director, verify that the interpretation of the results is correct as reported on 10/10/2019.

Alejandra Gutierrez, Ph.D.

End of Report

DNA Diagnostics Center

DNA Test Report

Douglas-Omaha County CSE NE

DDC is accredited/certified by AABB, CAP, ISO/IEC 17025 by ANAB, CLIA & NYSDOH.

Case 2065894		MOTHER		CHILD		Alleged FATHER	
Name							
Race		Unspecified				Black	
Sample Type		Buccal		Buccal		Buccal	
Date Collected		3/11/2020		3/11/2020		3/6/2020	
Test No.							
Locus	PI	Allele Sizes		Allele Sizes		Allele Sizes	
D3S1358	0.00	14	16	15	16	14	
vWA	1.48	15	18	15	18	15	17
D16S539	0.00	11	12	12		11	
CSF1PO	0.00	10	12	11	12	10	
D8S1179	0.00	12	13	12	14	11	13
D21S11	0.00	31	31.2	31.2	35	28	29
D18S51	0.00	13	15	13	19	14	20
D19S433	1.79	12.2	14	12.2	13	12.2	13
TH01	0.00	7	9	9		9.3	
FGA	2.80	21	25	23	25	23	28
D22S1045	0.00	15	17	16	17	14	17
D5S818	1.39	13		12	13	12	13
D13S317	0.00	8	11	8	11	12	14
D7S820	0.93	8	10	8	10	9	10
SE33	0.00	20	25.2	19	25.2	17	31.2
D10S1248	1.81	14		14		12	14
D1S1656	0.00	13	15.3	13	15.3	15	17.3
D2S1338	0.00	17	22	19	22	16	21
Amelogenin		X		X	Y	X	Y

Interpretation:

Combined Paternity Index: **0**

Probability of Paternity: **0%**

The alleged father is excluded as the biological father of the tested child. This conclusion is based on the non-matching alleles observed at the loci listed above with a PI equal to 0. The alleged father lacks the genetic markers that must be contributed to the child by the biological father. The probability of paternity is 0%.

Subscribed and sworn before me on March 17, 2020

NOTARIAL SEAL

Donna L. Dougherty

Donna L. Dougherty
Notary Public, State of Ohio
My Commission Expires May 8, 2022

I, the undersigned Laboratory Director, verify that the interpretation of the results is correct as reported on 3/17/2020.

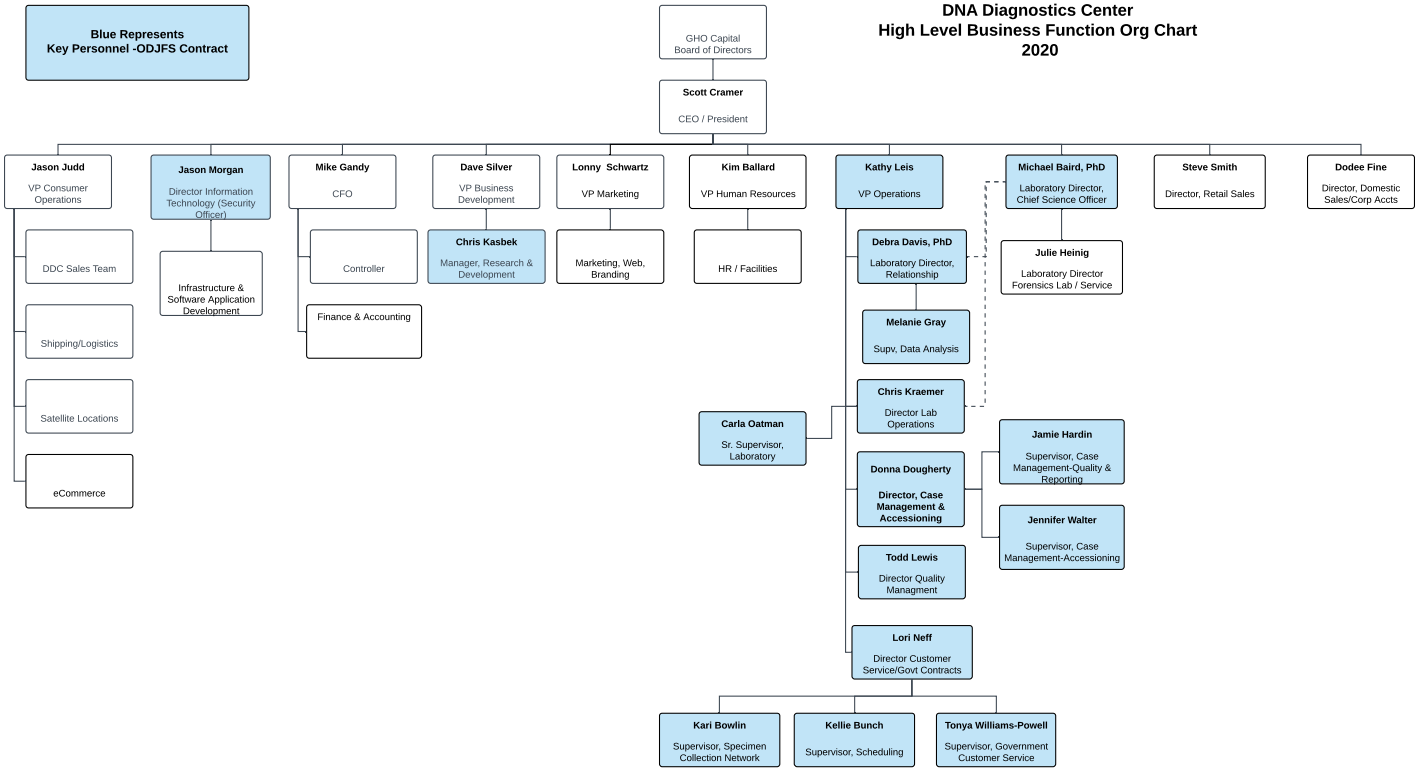
William Sun, Ph.D.

End of Report

Attachment #4

Key Personnel

CV's and References


Blue Represents
Key Personnel -ODJFS Contract
DNA Diagnostics Center
High Level Business Function Org Chart
2020
GHO Capital
Board of Directors
Scott Cramer
CEO / President
Jason Judd
VP Consumer Operations
DDC Sales Team
Shipping/Logistics
Satellite Locations
eCommerce
Jason Morgan
Director Information Technology (Security Officer)
Infrastructure & Software Application Development
Mike Gandy
CFO
Controller
Finance & Accounting
Dave Silver
VP Business Development
Chris Kasbek
Manager, Research & Development
Lonny Schwartz
VP Marketing
Marketing, Web, Branding
Kim Ballard
VP Human Resources
HR / Facilities
Kathy Leis
VP Operations
Carla Oatman
Sr. Supervisor, Laboratory
Debra Davis, PhD
Laboratory Director, Relationship
Melanie Gray
Supv, Data Analysis
Chris Kraemer
Director Lab Operations
Donna Dougherty
Director, Case Management & Accessioning
Todd Lewis
Director Quality Managment
Lori Neff
Director Customer Service/Govt Contracts
Kari Bowlin
Supervisor, Specimen Collection Network
Kellie Bunch
Supervisor, Scheduling
Tonya Williams-Powell
Supervisor, Government Customer Service
Michael Baird, PhD
Laboratory Director, Chief Science Officer
Julie Heinig
Laboratory Director Forensics Lab / Service
Jamie Hardin
Supervisor, Case Management-Quality & Reporting
Jennifer Walter
Supervisor, Case Management-Accessioning
Steve Smith
Director, Retail Sales
Dodee Fine
Director, Domestic Sales/Corp Accts

CURRICULUM VITAE

MICHAEL LEONARD BAIRD, Ph.D.

EDUCATION

Ph.D. – Genetics The University of Chicago Chicago, IL	1978
M.A. - Biology State University of New York New Paltz, NY	1973
B.A. - Biology State University of New York Madison, NY	1971

PROFESSIONAL EXPERIENCE

Chief Science Officer DNA Diagnostics Center (DDC) Fairfield, OH	2010-Present
Associate Vice President & Laboratory Director DNA Diagnostics Center Fairfield, OH	2008 - 2009
Laboratory Director DNA Diagnostics Center Fairfield, OH	2002 - 2008
Senior Director, Laboratory Operations Orchid Diagnostics Stamford, CT	2001 - 2002
Vice President, Laboratory Operations Lifecodes Corporation Stamford, CT	1992 - 2001
Director Business Development Lifecodes Corporation Stamford, CT	1990 - 1992

Director of Forensics & Paternity 1986 - 1990
Lifecodes Corporation
Stamford, CT

Senior Scientist 1982 - 1986
Lifecodes Corporation
Stamford, CT

Adjunct Assistant Professor 1986 - 1992
New York Medical College
New York, NY

Research Associate 1979 - 1982
Columbia University

Postdoctoral Fellow 1978 - 1979
University of Michigan
Ann Arbor, MI

PROFESSIONAL ASSOCIATIONS

- The American Academy of Forensic Sciences
- American Association for the Advancement of Science
- American Association of Blood Banks (AABB)
- American Society of Hematology
- American Society of Human Genetics
- Sigma Chi Society
- International Society for Forensic Genetics
- American Society of Crime Laboratory Directors
- American Society of Histocompatibility and Immunogenetics
- International Association for Identification

LICENSES AND CERTIFICATIONS

New York State Department of Health
Certificate of Qualification Number B 3447
Histocompatibility (HLA typing with DNA probes) Paternity/Identity Analysis

State of Connecticut Department of Health
Certificate of Qualification Number 381
Clinical Laboratory Director

Department of Health & Human Services
Laboratory Registration Certificate

CLIA ID #36D0910013

American Society of Histocompatibility and Immunogenetics
Laboratory Director of Histocompatibility Laboratory

PROFESSIONAL SOCIETY POSITIONS

- AABB: Chair Parentage Testing Accreditation Program Unit, Liaison to Parentage Testing Standards Committee, Member of Accreditation Program Committee, Assessor of Parentage Testing Laboratories for AABB
- Human Identity Trade Association, President
- American Society of Histocompatibility and Immunogenetics, Inspector

PUBLICATIONS

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3. Catrall, M. E., M. L. Baird, and E. D. Garber. 1978. Genetics of Ustilago violacea. III. Crossing over and nondisjunction. Botanical Gazette. 139:266-270.

4. Baird, M. L. and E. D. Garber. 1979. Genetics of Ustilago violacea. IV. An electrophoretic survey for urease variants in wild strains. Botanical Gazette. 140:84-88.

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15. Bank, A., S. E. Spence, P. G. Pergolizzi, M. C. Driscoll, and M. Baird. 1983. Gene defects in beta thalassemia. In Goldwasser, E. (Ed.): Regulation of Hemoglobin Biosynthesis. Elsevier/Holland.

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17. Beldjord, C., C. Lapourmourlie, M. Baird, R. Girot, L. Adjrad, G. Lenoir, M. Benabadji, and D. Labie. 1983. Four new haplotypes observed in Algerian beta thalassemia patients. Human Genetics. 65:204-206.

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20. Balazs, I., K. Wexler, L. Nicholas, L. Miyazaki, A. Giusti, M. Baird, P. Rubinstein, F. Allen, and L. Sussman. 1986. Application of DNA polymorphisms to the determination of paternity. In Brinkmann, B. and Henningsen, K. (Eds): Advances in Forensic Haemogenetics. pp 196-200.

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CURRICULUM VITAE

KATHY L. LEIS

EDUCATION

B.S. – Medical Technology — 1983
University of Dayton
Dayton, OH

A.S. - Medical Laboratory Technology — 1981
Kettering College of Medical Arts
Kettering, OH

PROFESSIONAL EXPERIENCE

Vice President, Operations — 2014 - Present
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Director of Operations — 2012 - 2014
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Director of Operations — 1997 - 2012
Orchid Cellmark Inc.
Dayton, OH

Paternity Laboratory Supervisor — 1985 - 1997
GeneScreen
Dayton, OH

Staff Medical Technologist/Generalist — 1984 - 1985
St. Luke's Medical Center
Maumee, OH

Staff Medical Technologist, Transfusion Service — 1981 - 1983
Kettering Medical Center
Kettering, OH

Phlebotomist — 1979 - 1981
Kettering Medical Center
Kettering, OH

PROFESSIONAL AFFILIATIONS

- American Society of Medical Technologists
- Ohio Society of Medical Technologists
- American Association of Blood Banks
- American Society of Clinical Pathologists
- American Society for Histocompatibility and Immunogenetics

PUBLICATIONS

Miller Raymond D ; Phillips Michael S ; JO Inho ; Donaldson Miriam A ; Studebaker Joel F. ; Addleman Nicholas ; Alfisi Steven V. ; M Wendy ; Bhatti Hamid A. ; Callahan Chad E. ; Carey Benjamin J. ; Conley Cheryl L. ; Cyr Justin M. ; Derohannessian Vram ; Donaldson Rachel A. ; Elosua Carolina ; Ford Stacey E. ; Forman Angela M. ; Gelfand Craig A ; Grecco Nicole M. ; Gutendorf Susan M.; Hock Cricket R. ; Hozza Mark J.; H Soyoung ; Sun Miin ; Jackson Diana L. ; Sangmeeahn Jo ; Jung Sung-Chul ; Kim Sook ; Kimm Kuchan ; Kloss Ellen F. ; KOBOLDT Daniel C. ; KUEBLER Jennifer M. ; KUO Feng-Shen ; LATHROP Jessica A. ; LEE Jong-Keuk ; Leis Kathy L. ; Livingston Stephanie A. ; Lovins Elizabeth G. ; Lundy Maria L.; Maggan Sima ; Minton Matthew ; Mockler Michael A. ; Morris David W. ; Nachtman Eric P. ; Oh Bermseok ; Park Chan ; Park Chang-Wook ; Pavelka Nicholas ; Perkins Adrienne B. ; Restine Stephanie L ; Sachidanandam Ravi ; Reinhart Andrew J. ; Scott Kathryn E. ; Shah Gira J. ; Tate Jatana M. ; Varde Shobha A. ; Walters Amy ; White J. Rebecca ; Yoo Yeon-Kyeong ; "**High-Density Single-Nucleotide Polymorphism Maps of the Human Genome**", Genomics ISSN 0888-7543, 2005, vol. 86, n°2, pp. 117-126.

Gutendorf, R. W. and K. Leis, "**An Apparent Maternal Exclusion Resolved by Family Studies**", OABB/IABB, 1986.

Gutendorf, R. W., K. Leis, and L. Frabotta, "**Exclusion of Paternity Without Testing the Mother**", OABB, 1987.

Yates, J., P. Chapman, and K. Leis, "**Evaluations of Indirect Exclusions**", OABB, 1991.

Gutendorf, R. W., R. Smith, K. Leis, and J. Yates, "**Paternity Inclusion in the Presence of Multiple Exclusions**", Annal. of Clin. and Lab Sci., Vol. 21, No. 4, 1991.

CURRICULUM VITAE

LORI NEFF

EDUCATION

Associate of Applied Science, Medical Laboratory Technology — 1991
Clark State Community College
Beavercreek, OH

PROFESSIONAL EXPERIENCE

Director, Government Contracts — 2015 - Present
DNA Diagnostics Center Inc. (DDC)
Fairfield, OH

Director Customer Service — 2012 - 2015
DNA Diagnostics Center Inc. (DDC)
Fairfield, OH

Director, North American Customer Service — 2005 - 2012
Orchid Cellmark Inc.
Dayton, OH

Manager, Specimen Collection Network — 2002 - 2005
Orchid Cellmark Inc.
Dayton, OH

Bone Marrow Services Supervisor — 1997 - 2002
Orchid Cellmark Inc.
Dayton, OH

Paternity Team Leader — 1994 - 1997
Orchid GeneScreen
Dayton, OH

Laboratory Technician — 1992 - 1994
Orchid GeneScreen
Dayton, OH

Medical Laboratory Technician — 1991 – 1992
Mercer County Joint Township
Coldwater, OH

CERTIFICATIONS

American Society of Clinical Pathology
Board of Registry
Medical Laboratory Technician

MILITARY SERVICE

Hospital Corpsman, HM3 1989 - 1997
United States Naval Reserve
(Honorable Discharge)

CURRICULUM VITAE

DEBRA DAVIS, PH.D.

EDUCATION

M.B.A. – Finance — 2001
University of Cincinnati
Cincinnati, OH

Ph.D. - Biomedical Sciences (Molecular Genetics) — 1993
Wright State University
Dayton, OH

B.S. – Biology — 1987
University of Cincinnati
Cincinnati, OH

PROFESSIONAL EXPERIENCE

Laboratory Director — 2012 - Present
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Laboratory Director — 2007 - 2012
Orchid Cellmark Inc.
Dayton, OH

Associate Laboratory Director — 1998 - 2007
Orchid Cellmark Inc.
Dayton, OH

PROFESSIONAL AFFILIATIONS

Certification of Qualification New York State Department of Health: Laboratory Director for Parentage /Identity Testing and DNA Testing (2004 to present)

AABB (American Association of Blood Banks) Member since 1998

Member AABB Relationship Testing Standards Subcommittee 2010-2010

Member AABB Assessor Program 2007-Present

POST DOCTORAL EDUCATION

Specialized Training in Basic Population Genetics and Forensic Statistics. 14th International Symposium on Human Identification (2003)

Postdoctoral Research Fellow, Department of Internal Medicine, Division of Cardiology, University of Cincinnati Medical Center, Cincinnati, Ohio
Supervisors: Muthu Periasamy, Ph.D. and Michael Ritchie, M.D.
"Overexpression of the SR Ca2+ ATPase in transgenic mice"
*Performed both RFLP and PCR genotype analysis of transgenic mice (1996 – 1998)

1993-1996 Postdoctoral Research Assistant, Department of Internal Medicine, Division of Cardiology, University of Cincinnati Medical Center, Cincinnati, Ohio
Supervisors: Muthu Periasamy, Ph.D. "Transcriptional regulation of the cardiac/slow-twitch muscle SR Ca2+ ATPase (SERCA2) gene. (1993 – 1996)

GRADUATE RESEARCH/TEACHING EXPERIENCE

Graduate Research Assistant, Department of Biochemistry, Wright State University, Dayton, Ohio (1987-1993)
Supervisor: John Paietta, PhD. "Molecular Characterization of the arylsulfatase gene of *Neurospora crassa."*

Graduate Teaching Assistant, Undergraduate Biology Laboratory, Wright State University, Dayton, Ohio. (1998)

Graduate Teaching Assistant, Honors Biology Laboratory, Wright State University, Dayton, Ohio (1989)

Graduate Teaching Assistant, Clinical Chemistry (lecture and laboratory)
Wright State University, Dayton, Ohio (1989)

Research Support:

Individual National Research Service Award (NRSA) Postdoctoral Fellowship, "Molecular analysis of SR Ca2+ ATPase gene expression." 3-yrs./ ($25,600, 26,900, 28,900) August 1, 1995- July 31, 1998

American Heart Association, Postdoctoral Fellowship, "Transcriptional regulation of the cardiac SR Ca2+ ATPase gene." 1-yr./ ($30,000) July 1, 1995- June 30, 1996 ***declined

INVITED SPEAKER

12th International Symposium on Human Identification- Speaker Paternity Section October 2001 "Interesting Cases / Obstacles in Parentage Testing"

Illinois Family Support Association's Twentieth Annual Members' Meeting and Conference – Speaker October 2008 "DNA Testing"

Louisiana Support Enforcement Association 2009 Training Conference March 11, 2009 Workshop "Utilization of Paternity DNA Testing in Court: The Goof, The Bad and The Unacceptable."

Prosecuting Attorneys of Michigan 2010 Meeting and Conference. March 18, 2010 Workshop "DNA Testing".

Eastern Regional Child Support Association 2010 Meeting and Conference. May 4,2010 Workshop Speaker "DNA Testing".

Indiana Child Support Enforcement 2010 Meeting and Conference. June 3, 2010 Workshop Speaker " DNA Testing".

PUBLICATIONS

D.L. Baker and Paietta J.V. Characterization of the arylsulfatase gene of *Neurospora crassa. FASEB Journal,* 5, 6694 (1991).

D.L. Baker and Paietta J.V. Analysis of the regulated expression of the *Neurospora crassa* arylsulfatase gene. *Abstracts of the General Meeting of the American Society for Microbiology,* 1953 (1992).

D.L. Baker, Shabbeer J., Larsen J., Walsh R.A., and Periasamy, M. Characterization of multiple cis-acting elements regulating SERCA2 expression in cardiac and skeletal muscle cells. *J Cellular Biochemistry.* Suppl. 18D: W201 (1994).

D.L. Baker, Aria M., Matsui h., Sukovich D., Shabbeer J., Dave V., Walsh RA., and Periasamy M. Regulation of sacroplasmic reticulum gene expression during cardiac hypertrophy and heat failure. (in Dhalla W.S., Singal P.K. Beamlish R.E., eds.) *Heart Hypertrophy and Failure,* Kluwer Academic Publishers, Boston. (1995).

Baker, Dave V., Reed T., and Periasamy M. Multiple SP1 binding sites in the cardiac/slow-twitch muscle Ca2+ ATPase (SERCA2) gene promoter are required for expression in Sol8 muscle cells. *J Biol. Chem.* 271: 5921-5928(1996).

D.L. Baker, Dave V., Reed T., and Periasamy M. SP1 plays an essential role in the transcriptional regulation of the SERCA gene. *Keystone Symposia: Molecular Biology of the Cardiovascular System.* 200 (1996).

T. Reed, Baker DL, Dave V., and Periasamy M. Muscle specific transcriptional regulation of the

cardiac/slow-twitch SERCA2 gene. *Circulation.* 94:1324 (1996).

D.L. Baker, .Loukianov E, Bhagwat A, Hoit B, Walsh RA, and Periasamy M. Overexpression of the SR Ca2+ in transgenic mouse hearts. *ISHR Meeting,* Vancouver, British Columbia, Canada, (1997)

D.L. Baker, Dave V., Reed T., and Periasamy M. A Novel E-box/AT-rich element is required for the muscle specific expression of the sarcoplasmic reticulum Ca2+ ATPase (SERCA2) gene . *Nucleic acids Res.* 26:1092-1098 (1998).

D.L. Baker, Reed T, Grupp IL, Grupp G, Bhagwat A, Hoit B, Walsh RA, and Periasamy M. Overexpression of the cardiac SR Ca2+ ATPase increases myocardial performance. *American Heart Association—70th session,* (1997).

Rishi AK, Wu JT, Yu M, Belani JP, Fontana JA, Baker DL, Periasamy M, and Hussain A. Regulation of the sacro/endoplasmic reticulum Ca2+ transport ATPase in thapsigargin- resistant Syrian hamster smooth muscle cells. *Nucleic acids Res.* (1998).

Loukianov E, Ji Y, Grupp IL, Kirkpatrick D, Baker DL, Loukianova T, Grupp G, Lytton J, Walsh RA, Periasamy M. Enhanced myocardial contractility and increased Ca2+ transport function in transgenic hearts expressing the fast-twitch skeletal muscle sarcoplasmic reticulum Ca2+ ATPase. *Circ.Res.* 83: 889-897 (1998).

Loukianov E, Ji Y, Baker DL, Reed T., Babu, J, Loukianov T, Greene A, Shull G, and Periasamy M. Sarco(endo)plasmic reticulum Ca2+ ATPase isoforms and their role in muscle physiology and pathology. “Cardiac sarcoplasmic reticulum function and regulation of contractility.” *Annuals of New York Academy of Science* (1998).

D.L. Baker, Grupp IL, Ji Y, Reed T, Loukianov E, Grupp G, Bhagwat A, Hoit B, Walsh RA, and Periasamy M. Targeted overexpression of the sarcoplasmic reticulum Ca2+ ATPase increases cardiac contractility in transgenic mouse hearts *Circ. Res.* 83:1205-1214 (1998).

CURRICULUM VITAE

Todd W. Lewis, Ph.D., MBA

EDUCATION

Ph.D. – Biomedical Sciences — 2017
Wright State University
Dayton, OH

Master of Business Administration — 2015
Wright State University
Dayton, OH

Bachelor of Science – Biology — 2010
Wright State University
Dayton, OH

PROFESSIONAL EXPERIENCE

Director, Quality Assurance — 2018-Present
DNA Diagnostics Center (DDC)
Fairfield, OH

Clinical Research Associate — *2016-2018*
Medpace
Cincinnati, OH

Graduate Research Assistant — 2010-2016
Wright State University
Dayton, OH

PROFESSIONAL AFFILIATIONS

Member of American Society For Quality

PUBLICATIONS

Gadgil RY, Rider SD Jr, Lewis T, Barthelemy J, Leffak M. Analysis of Trinucleotide Repeat Stability by Integration at a Chromosomal Ectopic Site. Methods Mol Biol. 2020:2056:121-136. doi:10.1007/978-1-4939-9784-8_8

Lewis T, Barthelemy J, Virts E, et al. Deficiency of the Fanconi anemia E2 ubiqitin conjugase UBE2T only partially abrogates Alu-mediated recombination in a new model of homology dependent recombination. Nucleic Acids Res. 2019;47(7):3503-3520. Doi:10,1093/nar/gkz026

Gadgil R, Barthelemy J, Lewis T, Leffak M Replication stalling and DNA microsatellite instability. Biophys Chem. 2017;225:38-48. Doi:10.1016/j.bpc.2016.11.007

Virts EL, Jankowska A, Mackay C, Lewis T, et al. Alu Y-mediated germline deletion, duplication and somatic stem cell reversion in UBE2T defines a new subtype of Fanconi anemia. Hum Mol Genet. 2015;24(18):5093-5108. Doi:10.1093/hmg/ddv227

Liu G, Chen X, Gao Y, Lewis T, Barthelemy J, Leffak M. Altered replication in human cells promotes DMPK (CTG)(n). (CAG)(n) repeat instability. Mol Cell Biol. 2012;32(9):1618-1632. Doi:10.1128/MCB.06727-11

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CURRICULUM VITAE

CHRISTOPHER M. KRAEMER

EDUCATION

B.S. – Biology — 2001
University of Cincinnati
Cincinnati, OH

PROFESSIONAL EXPERIENCE

Director, Laboratory Operations — 2018 - Present
DNA Diagnostics Center (DDC)
Fairfield, OH

Manager, Laboratory, Corporate Compliance and Safety — 2016 - 2018
DNA Diagnostics Center (DDC)
Fairfield, OH

Senior Laboratory Manager — 2012 - 2016
DNA Diagnostics Center (DDC)
Fairfield, OH

Technical Supervisor — 2002 - 2012
DNA Diagnostics Center (DDC)
Fairfield, OH

Lead Technologist — 2001 – 2002
DNA Diagnostics Center (DDC)
Fairfield, OH

Laboratory Technologist — 1998 – 2001
DNA Diagnostics Center (DDC)
Fairfield, OH

Laboratory Technician — 1997 – 1998
DNA Diagnostics Center (DDC)
Fairfield, OH

PUBLICATIONS

Reid, T.M., Ingala, D.A., Kraemer, C.M., Dage, W.M., Dieckhoner, C., Fortman, J.F., Hodge, D.M., Johnson, K.L., Oatman, C., Schlotman, H., Schuh, C., and Baird, M.L. Distribution of

HUMACTBP2 (SE33) alleles in three North American populations. J. Forensic Science, 48: 1422-1423, 2003.

Reid, T.M., Wolf, C.A., Kraemer, C.M., Lee, S.C., Baird, M.L., and Lee, R.F. Specificity of sibship determination using the ABI Identifiler multiplex system. J. Forensic Science, 49: 1262-1264, 2004.

Peterson, J.W., Reid, T.M., Kraemer, C.M., Ingala, D.A., Baird, M.L., Lee, S.C., and Lee, R.F. Distribution of Penta B, Penta C, and Penta E alleles in Asian, Black, Caucasian, and Hispanic populations. J. Forensic Science, 50: 966-968, 2005.

Curriculum Vitae

CARLA OATMAN

Education

B.S-Biology University of Cincinnati Cincinnati, OH	1999

Professional Experience

Senior Supervisor- Paternity Lab DNA Diagnostics Center (DDC) Fairfield, OH	2019-Present
Supervisor- Paternity Lab DNA Diagnostics Center (DDC) Fairfield, OH	2017-2019
Senior Team Member- Paternity Lab DNA Diagnostics Center (DDC) Fairfield, OH	2014-2017
Laboratory Technologist DNA Diagnostics Center (DDC) Fairfield, OH	2000-2014
Laboratory Technician DNA Diagnostics Center (DDC) Fairfield, OH	1999-2000

Publications

Reid, T.M., Ingala, D.A., Kraemer, C.M., Dage, W.M., Dieckhoner, C., Fortman, J.P., Hodge, D.M., Johnson, K.L., Oatman, C., Schlotman, H., Schuh, C and Baird, M.L. Distribution of HUMACTBP2 (SE33) alleles in three North American populations. J. Forensic Science, 48: 1422-1423, 2003.

CURRICULUM VITAE

Christopher Kasbek, Ph.D.

EDUCATION

Ph.D. – Molecular Genetics — 2010
The Ohio State University
Columbus, OH

B.A. – Biology — 2004
Case Western Reserve University
Cleveland, OH

PROFESSIONAL EXPERIENCE

Research and Development, Senior Manager — 2020
DNA Diagnostics Center (DDC)
Fairfield, OH

Clinical Manager, Research and Development — *2018-2019*
Admera Health
South Plainfield, NJ

Senior Scientist, Research and Development — 2017-2018
Admera Health
South Plainfield, NJ

Scientist, Research and Development — 2016-2017
Admera Health
South Plainfield, NJ

PATENTS

Huang, JT, Kasbek, C, Hu, G, Song, Q. Nucleic Acid Preparation and Analysis. PCT/US2017/018052. August 24,2017.

PUBLICATIONS

Feng, X, Hsu, SJ, Kasbek, C, Chaiken, MF, and Price, CM. CTC1-mediated C-strand fill-in is an essential step in telomere length maintenance. Nucleic Acids Research, 45(8): 4281-4293, May 2017.

CURRICULUM VITAE

MELANIE GRAY

EDUCATION

B.A. Psychology — 2001
Ohio University
Athens, OH

PROFESSIONAL EXPERIENCE

Team Leader, Data Analysis — 2012 – Present
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Data Analysis Senior Team Member — 2005 – 2011
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Data Analyst — 2002 - 2005
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Kasbek, C, Wang, F, and Price, CM Human TEN1 maintains telomere integrity and functions in genome-wide replication restart. Journal of Biological Chemistry, 288(42): 30139-30150, October 2013.

Wang, F, Stewart, JA, Kasbek, C, Zhao, Y, Wright, WE, and Price, CM. Human CST has independent functions during telomere duplex replication and C-strand fill-in. Cell Reports, 2: 1096-1103, November 2012.

Stewart, JA, Wang, F, Chaiken, MF, Kasbek, C, et al. Human CST promotes telomere duplex replication and general replication restart after fork stalling. EMBO, 31: 3537-49, August 2012.

Yang, CH, Kasbek, C, Majumder, S, Yusof, AM, and Fisk, HA. Mps1 Phosphorylation Sites Regulate the Function of Centrin 2 in Centriole Assembly. Mol Biol Cell, 21: 4361-72, December 2010.

Kasbek, C, Yang, CH, and Fisk, H.A. Antizyme Restrains Centrosome Amplification by Regulating the Accumulation of Mps1 at Centrosomes. Mol Biol Cell, 21: 3878-89, November 2010.

Kasbek, C, Yang, CH, and Fisk, HA. Mps1 as a link between centrosomes and genomic instability. Environ Mol Mutagen, 50(8): 654-65, March 2009.

Kasbek, C, Yang, CH, and Fisk, HA. The use of infrared fluorescent dyes in immunofluorescence microscopy. Chapter 81 in the Protein Protocols Handbook, 2rd Ed. 2009.

Kasbek, C, et al. Preventing the Degradation of Mps1 at Centrosomes is Sufficient to Cause Centrosome Re-duplication in Human Cells. Mol Biol Cell, 18: 4457-69, November 2007.

CURRICULUM VITAE

Jason Morgan

EDUCATION

B.S. Information Technology
University of Cincinnati
Cincinnati, OH

PROFESSIONAL EXPERIENCE

Information Technology Director — 2020
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

IT Management & Advisory Services Consulting — 2016-2019
Thyssenkrupp Bilstein of America Inc.
Hamilton, OH

Director of Information Technology — 2013-2016
The Marmon Group
Harrison, OH

Manager, Information Technology — 2008-2013
The Wornick Company
Cincinnati, OH

IT Team Lead — 2000-2005
Episcopal Retirement Homes, Inc.
Cincinnati, OH

CERTIFICATIONS

Project Management Certification
Xavier University
Cincinnati, OH

CURRICULUM VITAE

Tonya Williams-Powell

EDUCATION

Criminal Justice Major — 1980-1982
Florida State University
Tallahassee, Florida

PROFESSIONAL EXPERIENCE

Supervisor, Government Contracts — 2019- Present
DNA Diagnostics Center Inc. (DDC)
Fairfield, OH

Floor Coach- Contact Center — 2017 - 2019
DNA Diagnostics Center Inc. (DDC)
Fairfield, OH

Client Service/ Native American Services Representative — 2017
DNA Diagnostics Center Inc. (DDC)
Fairfield, OH

Corporate Accounts Representative — 2017
DNA Diagnostics Center Inc. (DDC)
Fairfield, OH

Legal/Native American Representative — *2014-2017*
DNA Diagnostics Center (DDC)
Fairfield, OH

Ancestry/Lineage Representative — *2012-2015*
DNA Diagnostics Center (DDC)
Fairfield, OH

Forensics Services Coordinator — 2007 – 2012
DNA Diagnostics Center (DDC)
Fairfield, OH

PROFESSIONAL EXPERIENCE

Customer Service Representative- Web DNA Diagnostics Center (DDC) Fairfield, OH	2004- 2007
Customer Service Representative DNA Diagnostics Center (DDC) Fairfield, OH	2004

CURRICULUM VITAE

DONNA DOUGHERTY

EDUCATION

High School Diploma — 1993
Preble Shawnee High School

PROFESSIONAL EXPERIENCE

Director, Case Management & Accessioning — 2017 – Present
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Manager Case Management & Accessioning — 2013 – 2017
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Team Leader, Case Management, Government Contracts — 2006 – 2013
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Owner — 2005 – 2006
DLD Marketing
Fairfleld, OH

Mortgage Loan Processor — 2002 – 2005
Tri-State Mortgage
Blue Ash, OH

Manager — 1998 - 2000
Check Mart
Hamilton, OH

Manager, Photo Lab — 1993 - 1997
Kroger
Oxford, OH

OTHER

Notary Public — 2000 - Present
State of Ohio

CURRICULUM VITAE

JENNIFER WALTER

EDUCATION

High School Diploma **1998**
Fairfield Senior High School

PROFESSIONAL EXPERIENCE

Supervisor, Case Management -Accessioning *2018-Present*
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH 45014

Supervisor, Collection Network *2018*
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH 45014

Team Lead, Government Contracts *2016-2018*
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH 45014

Senior Team Member, Government Contracts *2014-2068*
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH 45014

Data Entry Specialist, Government Contracts *2012-2014*
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH 45014

Sears Dental *2010-2012*
Office Assistant
Mason, OH

Laurel Grocery *2008-2010*
Office Assistant
London, KY

DuraFloors *2001-2006*
Office Assistant
West Chester, OH

Other
Notary Public *2016-Present*
State of Ohio

CURRICULUM VITAE

JAMIE HARDIN

EDUCATION

Butler Tech, Medical/ Legal Secretary, Certificate	2004-2005
Talawanda High School, Diploma	1997

PROFESSIONAL EXPERIENCE

Supervisor, Case Management-Quality & Reporting DNA Diagnostics Center Fairfield, OH 45014	2019- Present
Supervisor, DTC and Accessioning DNA Diagnostics Center Fairfield, OH 45014	2017-2019
Team Leader, Direct to Consumer DNA Diagnostics Center Fairfield, OH 45014	2016-2017
Senior Team Member, Case Management DNA Diagnostics Center Fairfield, OH 45014	2008- 2016
Specimen Collector DNA Diagnostics Center Fairfield, OH 45014	2007-2014
Case Management Specialist DNA Diagnostics Center Fairfield, OH 45014	2006-2008

PROFESSIONAL AFFILIATIONS

PUBLICATIONS

CURRICULUM VITAE

KARI BOWLIN

EDUCATION

High School Diploma **2014**
Edgewood High School

PROFESSIONAL EXPERIENCE

Supervisor, Collection Network ***2019-Present***
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH 45014

Contract Services Coordinator ***2018-2019***
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH 45014

Senior Team Member, Government Contracts ***2016-2018***
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH 45014

Data Entry Specialist, Government Contracts ***2014-2016***
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH 45014

Other

Notary Public ***2016-Present***
State of Ohio

Key Personnel References

CURRICULUM VITAE

KELLIE BUNCH

EDUCATION

High School Diploma — 1992
Princeton High School
Cincinnati, OH

Scarlet Oaks Career Development Center — 1992
Certification in Business/Executive Administrative Assistant
Cincinnati, OH

PROFESSIONAL EXPERIENCE

Supervisor, Scheduling — **2019 - Present**
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Team Leader, Scheduling — **2015 - 2019**
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Senior Team Member, Scheduling — **2013 – 2015**
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Customer Service and Scheduling Representative — **2009 – 2013**
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Case Management Specialist — **2007 - 2009**
DNA Diagnostics Center, Inc. (DDC)
Fairfield, OH

Customer Service/Order Entry/Payroll Representative — **1998 - 2006**
Overhead Door Service
Cincinnati, OH

Inventory Control/ Accounts Payable/Receivable — **1993 - 1998**
Robert James Sales
Cincinnati, OH

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Dr. Michael L. Baird

Candidate's Proposed Position: Project Leader / Chief Science Officer

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: Mayo Clinic	Contact Name: Linda B. Baughn, PhD	
Address: 200 First Street, SW Rochester, MN 55905	Phone Number: 507-538-7151 E-mail: Baughn.Linda@mayo.edu	
Project Name: SNP Genotyping	Beginning Date of Project: Month/Year 09/17	Ending Date of Project: Ongoing
Description of project size, complexity, and the candidate's role in this project. Project size –Large-scale project to test more than 1,000 multiple myeloma patients with the Precision Medicine Research Array (PMRA) to generate SNP genotypes at over 900,000 genetic locations Complexity – High complexity. DDC generated SNP genotype data from a cohort of multiple myeloma patients to help determine the underlying genetic basis for patient reaction to therapy. The data was generated using the Affymetrix Precision Medicine Research Array that interrogates over 900,000 SNPs. In addition, the ethnicity of each patient was determined bases on the percentage of 42 population groups present in the genome. Timeline: started 9/17 – ongoing The results of the first study were presented at the American Society of Hematology annual meeting in 2018 and an article published in the Blood Cancer Journal, volume 8, pages 1 – 19. An additional study of multiple myeloma patients is currently underway using the same approach of SNP genotyping with the PMRA and providing data and ethnicity to Dr. Baughn. Candidate's role – Project Leader		
Company Name: Natera, Inc.	Contact Name: Dr. Mathew Rabinowitz	
Address: 201 Industrial Road, Suite 410 San Carlos, CA 94070	Phone Number: 650-249-9090 Email: mrabinowitz@natera.com	
Project Name: Non-invasive prenatal paternity test development and validation	Beginning Date of Project: Month/Year 06/14	Ending Date of Project: Ongoing
Description of project size, complexity, and the candidate's role in this project. Project size – Large-scale project to develop and validate the non-invasive prenatal paternity test. Complexity – high complexity. Dr. Baird and the DDC team worked with Dr. Rabinowitz and his Team to develop and validate a non-invasive prenatal paternity (NIPP) test that can be administered as early as 8 weeks gestation. The test currently utilizes next generation sequencing technology to examine 2688 SNPs. A bioinformatics algorithm developed by Natera is utilized to analyze the data to determine whether or not the alleged father is the biological father of the fetus. Timeline: Started 6/14; Ongoing relationship with Natera to provide NIPP. More recently, the bioinformatics pipeline has been updated to incorporate best practices and learning in the generation of paternity. The pipeline now allows the confirmation of tested alleged fathers. Scatter plots of the data are now routinely available to review. As a result of the updated pipeline, the AABB granted accreditation to the NIPP test in 2019. Candidate's role – Project Leader		
Company Name: The University of Colorado	Contact Name: Andrew Smolen, Ph.D.	
Address: Institute of Behavioral Genetics Campus Box 447 Boulder, CO 80309	Phone Number: 303-817-1817 Email: Andrew.Smolen@Colorado.edu	

Description of project size, complexity, and the candidate's role in this project.

Project size –Large-scale project to test more than 1,000 DNA samples with the Precision Medicine Research Array (PMRA) to generate SNP genotypes at over 900,000 genetic locations

Complexity – High complexity.

DNA samples were provided by Dr Smolen for DNA SNP genotyping using the Affymetrix Precision Medicine Research Array (PMRA). DNA samples were provided in a 96 well format at a know concentration and volume. Many of the DNA samples were over 20 years old. The data generated will be used by researchers for studies in behavioral genetics.

Candidate's role – Project Leader

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Kathy Leis

Candidate's Proposed Position: Vice President, Operations

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: State of Texas, Office of Attorney General	Contact Name: Marijes Brownell	
Address: 5500 E. Oltorf Austin, TX 78741	Phone Number: 512-460-6527 Email: marijes.brownell@texasattorneygeneral.gov	
Project Name: Genetic Paternity Testing Contract Implementation	Beginning Date of Project: Month/Year July 2014	Ending Date of Project: Month/Year August 2020
Description of project size, complexity, and the candidate's role in this project. DDC was awarded the State of Texas contract in July 2014. There was a planned six (6) month implementation phase, which included extensive document and procedure creation in accordance with contract requirements. Services provided under this contract were fully operational in January 2015. The contract has a term of 6 years, ending in August 2020. The annual sample volume is approximately 65,000 samples. I am the contracts manager for this contract and during the implementation phase I worked almost daily with their implementation on the many phases. This project has several similarities to the State of Ohio in volume and scope. DDC provides a large network of Vendor (DDC) sites throughout the State of Texas. This is similar to a Tier 1 service level in the State of Texas. In addition to this, DDC also provides an equally large network of subcontracted specimen collectors that collect samples at designated courthouses throughout the state, similar to the Tier 2 requirement for the State of Ohio. The OAG also conducts staff/agency self-collections in designated Child support office locations throughout the state similar to a Tier 3 in Ohio. DDC developed all of the training protocols and conducted statewide training to OAG staff. I am involved in the review meetings and provide oversight to ensure that DDC is meeting the contract deliverables throughout the term of the contract.		

Client Company Name: Any Lab Test Now	Client's Project Supervisor Contact Name: Clarissa Bradstock, CEO	
Address: 5815 Windward Parkway, Suite 205, Alpharetta, GA 30005	Phone Number: 678-431-0623 E-Mail: cwbradstock@anylabtestnow.com	
Project Name: Paternity Genetic Testing Services	Beginning Date of Project: Month/Year October 2013	Ending Date of Project: Month/Year Current-Ongoing
Description of the related services provided: DDC has an ongoing relationship with Any Lab Test Now (ALTN) providing paternity and relationship testing services. We provide customer service with dedicated account managers as well as a self service portal to allow secure access to issue results. Clarissa Bradstock is the CEO and can attest to my role in providing the leadership to ensure high quality testing as well as exemplary service. DDC provides services to the majority of the 160+ ALTN franchises and annually provides paternity testing for over 35,000 samples annually.		

Company Name: Pennsylvania Department of Welfare	Contact Name: Crystal Zelenski, Commodity Specialist	
Address: Department of General Services | Bureau of Procurement 555 Walnut Street, 6th Floor Forum Place | Harrisburg, PA 17101	Phone Number: 717.346.8112 Email: czelenski@pa.gov	
Project Name: Genetic Testing for Parentage	Beginning Date of Project: Month/Year Oct 2019	Ending Date of Project: Month/Year Current
Description of project size, complexity, and the candidate's role in this project. I was the contract manager for state of Pennsylvania genetic testing paternity contract awarded in 2014. DDC was awarded the contract in October of 2014 and most recently re-awarded a new contract in October 2019. I worked with the DDC team and those at the state level in Pennsylvania to ensure that all of the counties understood their service levels and come up with solutions that were mutually agreeable with everyone. I now interact as necessary when issues arise as she has handed it off to child support program teams. This contract involves full service from sample collection to report and there are approximately 20,000 samples/year.		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Lori Neff

Candidate's Proposed Position: Director, Government Contracts

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: State of Texas Office of the Attorney General	Contact Name: Marijes Brownell	
Address: 5500 East Oltorf, Austin, TX 78741	Phone Number: 512-460-6527 E-mail: marijes.brownell@texasattorneygeneral.gov	
Project Name: Implementation and maintenance of the Parentage Testing Services Contract	Beginning Date of Project: Month/Year 07/2014	Ending Date of Project: Month/Year 8/2020
Description of project size, complexity, and the candidate's role in this project. DDC has held the contract for Parentage Testing Services for the State of Texas since July of 2014. There are approximately 65,000 samples collected under for this contract per year. I have been the primary representative from DDC to work with the OAG and ensure continuous adherence to contract requirements. This contract requires several customized features including daily inbound and outbound files. I have worked with Ms. Brownell since the initial award from all stages of planning, launch, and maintenance. In addition to ongoing interaction, I prepare monthly statistical reports, quarterly reports, ongoing monitoring and feedback to ensure all contract deliverables are met. I also monitor the OAG training system to ensure all DDC staff complete all scheduled new and ongoing training. All formal communication is documented as controlled correspondence. I oversaw a successful desktop disaster exercise with the OAG in June 2019.		
Company Name: Michigan DHS-Office of Child Support	Contact Name: Pratin Trivedi	
Address: 201 N. Washington Sq., Victor Center, 4th Floor, Lansing, MI 48933	Phone Number: 517-334-6560 E-mail: TrivediP@michigan.gov	
Project Name: Genetic Paternity Testing Services	Beginning Date of Project: Month/Year 10/2019	Ending Date of Project: Month/Year 09/2028
Description of project size, complexity, and the candidate's role in this project. DDC has held the State of Michigan-Paternity Testing Services contract since 2012. In 2019, the original DDC contract ended and DDC was again awarded the new contract that began in November 2019. There are approximately 22,000 samples collected per year. I have been involved with Mr. Trivedi and several prior and subsequent contacts at the Michigan DHS-Office of Child Support. DDC successfully manages all aspects of in state schedules for the specimen collectors. I am involved in the day to day management of this contract. The state of Michigan also has an Expungement law for all excluded alleged fathers and I also oversee this process to ensure compliance with the law. Under my direction, the DDC Contracts team is processing all cases, intrastate collections, interstate appointments and institutional collections. I have presented to the Office of Child Support team and stayed in close communication with Mr. Trivedi to ensure satisfaction with DDC Services.		
Company Name: State of West Virginia	Contact Name: Kimberly Bentley	
Address: 350 Capitol Street, Room 147, Charleston, WV 25301	Phone Number: 304-586-1508 E-mail: Kimberly.d.bentley@wv.gov	
Project Name: Genetic Testing	Beginning Date of Project: Month/Year 10/5/2019	Ending Date of Project: Month/Year 10/4/2022
Description of project size, complexity, and the candidate's role in this project. I have been involved with the State of West Virginia since 2015. As the primary contact for the this contract, I have worked with Ms. Bentley to ensure satisfaction with DDC services and meet all contract deliverables. The State of West Virginia contract requires the vendor to provide all collection sites in the State, where approximately 5,000 samples are collected per year. I have worked closely with Ms. Bentley when there are special cases, collection sites, or other needs relating to genetic testing services for the State of West Virginia.		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Debra L. Davis, PhD, MBA

Candidate's Proposed Position: Laboratory Director

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: AABB	Contact Name: Mary Mount, past chairman AABB RT	
Address: 4550 Montgomery Ave #700, Bethesda, MD 20814	Phone Number: E-mail:	
Project Name: 13th Edition of Standards for Relationship testing	Beginning Date of Project: Month/Year 1/2017	Ending Date of Project: Month/Year 12/2018
Description of project size, complexity, and the candidate's role in this project. Revision of the Standards for Relationship Testing. Debra Davis is a member of the AABB Relationship Testing Standards Program Unit (RT SPU)and has actively participated in the revision for the 13th edition of Relationship Standards. The SPC role is the creation, development and revision of AABB Standards, that guide the policies, processes and procedures that accredited laboratories use to provide acceptable results and a safe work environment for laboratory personnel.		
Company Name: Natera	Contact Name: Joshua Layne	
Address: 201 Industrial Road, Suite 410, San Carlos, California 94070	Phone Number: E-mail:	
Project Name: : Accreditation of Non-invasive Paternity Testing	Beginning Date of Project: Month/Year 1/2018	Ending Date of Project: Month/Year 6/2019
Description of project size, complexity, and the candidate's role in this project. Accreditation of Non-invasive Parentage Testing. The goal of the project was to successfully obtain Accreditation for the Non-invasive Prenatal Parentage Testing though the AABB and then to implement this into operations at DNA Diagnostics Center. Debra Davis was critical part of the team that successfully collaborated with Natera to see this project into operation within the specified time frame. Dr. Davis ensured that the members of her staff were appropriately trained and that the proposed testing process would meet the requirements of the contract and appropriate standards.		
Company Name: DDC/Transfusion	Contact Name: Robert Wenk	
Address: :	Phone Number E-mail: rwenk1@verizon.net	
Project Name: Transfusion – Paternity calculations for Chimeric alleged fathers-Manuscript ID Trans-2017-0408	Beginning Date of Project: Month/Year 6/2017	Ending Date of Project: Month/Year 8/2017
Description of project size, complexity, and the candidate's role in this project. Paternity calculations for chimeric alleged fathers. The goal of the project was to successfully develop paternity calculations for Alleged Fathers exhibiting a chimeric profile and then to implement this into operations at DNA Diagnostics Center. Debra Davis was critical part of the team that successfully collaborated with Dr. Robert Wenk to develop these calculations. A manuscript detailing these calculations entitled "Paternity Probabilities When a Child is a Congenital Chimera" was accepted for publication in Transfusion.		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Dr. Todd Lewis

Candidate's Proposed Position: Quality Assurance Director

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: DNA Diagnostics Center	Contact Name: Kathy Leis	
Address: One DDC Way, Fairfield, OH 45014	Phone Number: (513) 881-7800 x2257 E-mail: kleis@dnacenter.com	
Project Name: MediaLab integration project	Beginning Date of Project: Month/Year Oct 2019	Ending Date of Project: on-going
Description of project size, complexity, and the candidate's role in this project. This project involved migrating over all company policies, procedures and forms, in addition to formatting training, competency, safety and corrective action modules. Once the program is staged and validated, all employees will be trained on how to use the system. This is a large sized, medium complexity project with Todd serving as lead project manager.		
Company Name: DNA Diagnostics Center	Contact Name: Dr. Debra Davis	
Address: One DDC Way, Fairfield, OH 45014	Phone Number: (513) 881-7800 x2258 E-mail: ddavis1@dnacenter.com	
Project Name: QA monitoring and reporting process improvement	Beginning Date of Project: Month/Year Sep 2019	Ending Date of Project: Jan 2020
Description of project size, complexity, and the candidate's role in this project. Process improvement involved re-evaluating the quality assurance monitors to enable more meaningful actionable items. Redefined the QA monitors to encompass more activities and changed the reporting structure to a more visible output. The QA reports are now reviewed with a larger team on a regular basis. This was a medium sized, medium complexity project with Todd serving as lead project manager.		
Company Name: DNA Diagnostics Center	Contact Name: Dr. Michael Baird	
Address: One DDC Way, Fairfield, OH 45014	Phone Number: (513) 881-7800 x2276 E-mail: mbaird@dnacenter.com	
Project Name: SpermCheck device FDA clearance project	Beginning Date of Project: Month/Year Jun 2019	Ending Date of Project: Ongoing
Description of project size, complexity, and the candidate's role in this project. As a member of the implementation team I reviewed contract requirements, assuring the appropriate quality monitors were in place and compliance was provided. I reviewed any variances requested concerning the DDC Quality System policies and practices. I actively participated in the research and development of the increased sensitivity assay. This project is a large sized, large complexity project with Todd serving as co-lead project manager.		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Chris Kraemer

Candidate's Proposed Position: Director, Laboratory Operations

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: DNA Diagnostics Center	Contact Name: Dr. Michael Baird	
Address: One DDC Way, Fairfield, OH 45014	Phone Number: 513-881-4026 Email: mbaird@dnacenter.com	
Project Name: Weight Loss SNP Test with Partner Company	Beginning Date of Project: Month/Year 7/2019	Ending Date of Project: Month/Year 8/2019
Description of project size, complexity, and the candidate's role in this project. This project added will result in an additional 30,000 samples per year. High complexity As Director of Laboratory Operations, Chris was responsible for hiring and training new staff. He was responsible for validation of the new test, for the overall data quality and turnaround time for all testing. Chris was also in charge of getting new instrumentation ordered and validated and ordering additional reagents and consumables required for testing. Involved as the technical resource for troubleshooting and problem solving any process or instrument issues.		
Company Name: DNA Diagnostics Center	Contact Name: Kathy Leis	
Address: One DDC Way, Fairfield, OH 45014	Phone Number:513-881-4005 Email: kleis@dnacenter.com	
Project Name: AABB Accreditation for Non-Invasive Prenatal Paternity Testing	Beginning Date of Project: Month/Year 6/2019	Ending Date of Project: Month/Year 6/2019
Description of project size, complexity, and the candidate's role in this project. High complexity As Director of Laboratory Operations, Chris was responsible for writing the validation plan and executing the plan. He was responsible for the overall data quality and turnaround time for all testing. Chris was also in charge of ordering additional reagents and consumables required for testing. Involved as the technical resource for troubleshooting and problem solving any process or instrument issues.		
Company Name: DNA Diagnostics Center	Contact Name: Kathy Leis	
Address: One DDC Way, Fairfield, OH 45014	Phone Number:513-881-4005 Email: kleis@dnacenter.com	
Project Name: Validation of alternate sample types for Non-Invasive Prenatal Paternity Testing	Beginning Date of Project: Month/Year 8/2019	Ending Date of Project: Month/Year 12/2019
Description of project size, complexity, and the candidate's role in this project. High complexity As Director of Laboratory Operations, Chris was responsible for writing the validation plan and executing the plan. He was responsible for the overall data quality and turnaround time for all testing. Chris was also in charge of ordering additional reagents and consumables required for testing. Involved as the technical resource for troubleshooting and problem solving any process or instrument issues		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Carla Oatman

Candidate's Proposed Position: Senior Supervisor- Paternity Lab

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: DNA Diagnostics Center	Contact Name: Kathy Leis	
Address: One DDC Way, Fairfield, OH 45014	Phone Number: 513-881-4005 Email: kleis@dnacenter.com	
Project Name: Shorter Kinship Turn Around Time	Beginning Date of Project: Month/Year 1/2017	Ending Date of Project: Month/Year 3/2017
Description of project size, complexity, and the candidate's role in this project. High Complexity As Supervisor of the Paternity Lab, Carla was responsible for training staff and overall workload. She executed quality control and quality assurance measures to stay compliant with accreditation. Carla was involved in maintenance, troubleshooting, and problem solving with laboratory instrumentation. She also accounted for and maintained all critical reagents necessary for testing.		
Company Name: DNA Diagnostics Center	Contact Name: Dr. Michael Baird	
Address: One DDC Way, Fairfield, OH 45014	Phone Number: 513-881-7806x2276 E-mail: mbaird@dnacenter.com	
Project Name: Standardizing Controls	Beginning Date of Project: Month/Year 9/2017	Ending Date of Project: Month/Year 11/2017
Description of project size, complexity, and the candidate's role in this project. Medium Complexity As Supervisor of the Paternity Lab, Carla was responsible for training staff members, overall workload, and turnaround time for testing. She executed quality control and quality assurance measures to stay compliant with accreditation. Carla was involved in maintenance, troubleshooting, and problem solving with laboratory instrumentation. She also accounted for and maintained all critical reagents necessary for testing.		
Company Name: DNA Diagnostics Center	Contact Name: Dr. Todd Lewis	
Address: One DDC Way, Fairfield, OH 45014	Phone Number: 513-881-7806x2270 E-mail: tlewis@dnacenter.com	
Project Name: QA/QC Document Control	Beginning Date of Project: Month/Year 1/2019	Ending Date of Project: Month/Year 6/2019
Description of project size, complexity, and the candidate's role in this project. Medium Complexity As Senior Supervisor of the Paternity Lab, Carla was responsible for transitioning documentation and forms from paper copies into an electronic format. She was also responsible for the implementation of new forms and training staff on the new format. Carla maintained all proper documentation during the transition in order to stay compliant with accreditation.		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Christopher Kasbek

Candidate's Proposed Position: Sr. Manager, Research & Development

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: Novartis	Contact Name: Ying Li	
Address: 250 Massachusetts Ave Cambridge, MA 02139	Phone Number: 617-871-8000 E-mail: ying-8.li@novartis.com	
Project Name: Utility of RNA analysis for liquid biopsy clinical trials	Beginning Date of Project: Month/Year 01/18	Ending Date of Project: Month/Year 09/18
Description of project size, complexity, and the candidate's role in this project. High Complexity Chris was the project manager of an approximately $100K clinical trial feasibility study based on liquid biopsy technology developed by his team. Novartis wanted to explore a clinical trial using RNA to provide additional benefit to cancer patients undergoing liquid biopsy. Chris managed lab staff to run the assay on the samples, communicated the progress, and assured deliverables were provided in the agreed turn-around-time.		
Company Name: Perthera	Contact Name: Edik Blais	
Address: 8200 Greensboro Dr, Suite #350 McLean, VA 22102	Phone Number: 833-781-7810 E-mail: eblais@perthera.com	
Project Name: OncoGxOne® solid tumor profiling	Beginning Date of Project: Month/Year 04/19	Ending Date of Project: Month/Year 01/20
Description of project size, complexity, and the candidate's role in this project. High Complexity Chris was the project manager in an effort to outsource the sales/marketing and bioinformatics components of his OncoGxOne® solid tumor profiling assay to Perthera. Chris performed R&D to develop an NGS panel, led a team in attaining CLIA approval for the test, and led communications with Perthera to help integrate them into the Admera infrastructure. The partnership is expected to service 5,000 patients in 2020.		
Company Name: Admera Health	Contact Name: Yun Zhao	
Address: 126 Corporate Blvd. South Plainfield, NJ 07080	Phone Number: 908-222-0533 E-mail: yun.zhao@admerahealth.com	
Project Name: Nucleic Acid Extraction for Large Revenue Projects	Beginning Date of Project: Month/Year 09/2015	Ending Date of Project: Month/Year 06/2019

Description of project size, complexity, and the candidate's role in this project.

Moderate Complexity

Chris performed complex DNA/RNA extractions in a high pressure environment for >2000 samples and >10 different clients. In addition to performing technical lab work, Chris was involved in communication with the project management team and result delivery.

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Melanie Gray

Candidate's Proposed Position: Sr. Supervisor, Data Analysis

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: DNA Diagnostics Center	Contact Name: Kathy Leis	
Address: One DDC Way, Fairfield, OH 45014	Phone Number:513-881-4005 Email:kleis@dnacenter.com	
Project Name: Decreased TAT for Kinship cases	Beginning Date of Project: Month/Year 1/2017	Ending Date of Project: 3/2017
Description of project size, complexity, and the candidate's role in this project. Complexity= medium Melanie was responsible for training third shift analysts on how to process kinship plates, in order to decrease the turn-around-time on kinship cases. Having third shift staff process these plates helps to move the cases through testing more efficiently. As a result, the decrease in turn-around-time allows DDC to compete in the market.		
Company Name: DNA Diagnostics Center	Contact Name: Debra Davis	
Address: One DDC Way, Fairfield, OH 45014	Phone Number: 513-881-7806 ext. 2258 Email: ddavis1@dnacenter.com	
Project Name: Plate Worksheet update	Beginning Date of Project: Month/Year 6/2019	Ending Date of Project: Month/Year 7/2019
Description of project size, complexity, and the candidate's role in this project. Complexity= low Melanie worked with the IT department to update the Plate Worksheet. She re-designed the Control recording section, to be in accordance with our updated Control policy. In addition, she added the State display for each case, which helps staff identify cases that must be given priority.		
Company Name: DNA Diagnostics Center	Contact Name: Todd Lewis	
Address: One DDC Way, Fairfield, OH 45014	Phone Number:513-881-7806 x2270 Email:tlewis@dnacenter.com	
Project Name: Quality Assurance Monitor	Beginning Date of Project: Month/Year 4/2018	Ending Date of Project: 7/2018
Description of project size, complexity, and the candidate's role in this project. Complexity= medium As Sr. Supervisor of the Data Analysis department, Melanie assists the QA Manager with Quality Assurance monitors daily. In 2018 Melanie implemented various QA spreadsheets, and maintains them daily. The spreadsheets are used for data mining and to record events that occur during the testing process.		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Jason Morgan

Candidate's Proposed Position: Director, IT

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: thyssenkrupp Bilstein of America	Contact Name: Roman Chulsky	
Address:	Phone Number: 513.600.8188 E-mail: romik.chulsky@hotmail.com	
Project Name: Enterprise MES Implementation	Beginning Date of Project: 03/2017	Ending Date of Project: 11/2018
I led the implementation of the manufacturing execution system for the US plant for thyssenkrupp Bilstein. I acted as the PM on this project which entailed replacing dozens of custom developed applications that were used for production and quality recording and reporting purposes. This project involved a high degree of complexity due to the existing landscape of custom developed applications. Furthermore, this system was required to integrate with two additional enterprise systems; ERP platform (SAP) as well as a system used for material and finished goods traceability. The scope of this project included a single manufacturing plant with over 800 employees and nearly 50 different production lines/work cells.		
Company Name: thyssenkrupp Bilstein of America	Contact Name: Roman Chulsky	
Address:	Phone Number: 513.600.8188 E-mail: romik.chulsky@hotmail.com	
Project Name: BI Analytics Toolset	Beginning Date of Project: 06/2017	Ending Date of Project: 04/2018
I acted as executive sponsor of this project which involved the implementation of an enterprise-class Business Intelligence toolset (Qliksense). This project had a higher degree of difficulty due to the number of data sources (6) utilized to analyze information from. The initial scope was limited to the US operations of tk Bilstein and about 1000 employees but quickly grew to include worldwide operations for tk Bilstein which included an additional 3500 employees.		
Company Name: thyssenkrupp Bilstein of America	Contact Name: Roman Chulsky	
Address:	Phone Number: 513.600.8188 E-mail: romik.chulsky@hotmail.com	
Project Name: Connected Factory – Industry 4.0	Beginning Date of Project: 01/2019	Ending Date of Project: 05/2019
I acted as the US IT lead on this global project for tk Bilstein. which was kicked off to provide an implementation template for the rest of the manufacturing plants around the globe for tk Bilstein. This project had a very high degree of complexity as it included connecting shop-floor, machine level data with cloud-based platforms and tools for analysis. Security considerations were a top concern with architecting this solution.		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Tonya Williams Powell

Candidate's Proposed Position: Client Service Supervisor – Government Contracts

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: Puyullap Tribe	Contact Name: Barbara Richards	
Address: 3009 Portland Ave E. Tacoma WA 98404	Phone Number 253-573-7800 Email: Barbara.Richards@PuyallupTribe-nsn.gov	
Project Name: Native American Services	Beginning Date of Project: 06/2012	Ending Date of Project: Current
Description of project size, complexity, and the candidate's role in this project. In 2012, I joined the Native American Department and assisted with case setup, scheduling and case maintenance related to DDC's ongoing relationship with the Puyallup Tribe. In 2017 I became the lead representative for the Native American Department. I work closely with representatives of the tribe and provide answers to questions related to DNA testing, assisting with current cases, provide information of any new products, and handling any escalated issues. I am responsible for handling any billing issues, scheduling of meetings between our company and the tribal board, and maintaining the Native American database		
Company Name: Morongo Tribe	Contact Name: Leighann Reyes	
Address: 12700 Pumarra Rd., Banning CA 92220	Phone Number: 951-849-4697 Email: lreyes@morongo-nsn.gov	
Project Name: Native American Services	Beginning Date of Project: June 2012	Ending Date of Project: Current
Description of project size, complexity, and the candidate's role in this project. With the Morongo Band of Mission Indians, I am responsible for maintaining the day to day communication with the Tribal Administration which can range from, verifying pricing, assisting with access to our training collection process, invoicing, and any contract questions. I am responsible for scheduling any of meetings between our company and the tribal board, answer any lineage questions, testing alternatives, and maintaining the Native American database		
Company Name: Nottawassepi Huron Band of Potawatomi	Contact Name: Larysa Hill	
Address: 1485 Mno-Bmadzewen Way, Fulton, MI 49052	Phone Number: 269-704-8391 Email: lhill@nhbpi.com	
Project Name: Nottawaseppi Contract Award/Service	Beginning Date of Project: June 2016	Ending Date of Project: Current
Description of project size, complexity, and the candidate's role in this project. DDC was awarded this contract in June 2016. I work with the then director of Native American Services to set up pricing, testing times and testing services to that were offered to the Nottawassepi Tribe for enrollment purposes. I was the main contact for the tribes' Government Records Manager who assisted with their tribe's enrollment process. I was responsible for explaining the process, assisting with crafting a letter the tribe would present to their members advising of the testing process, and explain results. If needed, I spoke to the board in explaining the results and alternative testing options.		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Donna Dougherty

Candidate's Proposed Position: Director, Case Management

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: SelfDecode/SelfHacked	Contact Name: Eliana Ferdman	
Address: 3400 Corte Martin Newport Beach, CA 92660	Phone Number: Email: eliana@selfdecode.com	
Project Name: PMDA Project – SelfDecode/SelfHacked	Beginning Date of Project: Month/Year 1/2019	Ending Date of Project: Month/Year 7/2019
Description of project size, complexity, and the candidate's role in this project. Assisted in implementation of PMDA project. Donna was able to coordinate directly with key contacts internally and externally to ensure delivery of requested data. Donna was able to provide workflow to IT teams internally to make sure API documentation was accurately created to support this new account. Donna continues to work directly with Eliana to fulfill request for kits, data or any other day to day questions.		
Company Name: DNACode	Contact Name: Ron Hanerfield	
Address: 200 Jalan Eunos, Euhabitat 01-37 Singapore 419544	Phone Number: 011-65-96902127 Email: ron@dnacode.com	
Project Name: Healthy Weight DNA Code	Beginning Date of Project: Month/Year 1/2018	Ending Date of Project: Month/Year 8/2018
Donna has been the point of contact for several key members of the DNACode account. Donna has been able to provide excellent customer service to ensure that reports. Donna was able to create a streamlined process to ensure timely accessioning of all samples and reporting.		
Company Name: DB Services	Contact Name: Mike Westendorf	
Address: 8604 Allisonville Road #231 Indianapolis, IN 46250	Phone Number: Email: mwestendorf@dbservices.com	
Project Name: Distributor Portal	Beginning Date of Project: Month/Year 06/2017	Ending Date of Project: Month/Year 3/2019
Description of project size, complexity, and the candidate's role in this project. Donna was a key member of the distributor portal project. Donna worked directly with developers internally and externally to create a state of the art portal for our distributors to access. This project allowed for distributors to submit cases through an API or directly through the web, allowed them to see all case status and retrieve results when they were ready. This portal also allowed distributors to quickly have access to forms, F&Q, key contacts, company announcements and draw site availability. Donna continues to be a point of contact for outside resources as needed.		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Jennifer Walter

Candidate's Proposed Position: Supervisor, Case Management Accessioning

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: DNA Diagnostics Center	Contact Name: Chris Kraemer	
Address: One DDC Way Fairfield, OH 45014	Phone Number: 888-362-9778 x2268 E-mail: ckraemer@dnacenter.com	
Project Name: Genetic Testing: Healthy Lifestyle	Beginning Date of Project: Month/Year May 2019	Ending Date of Project: Month/Year Current
Description of project size, complexity, and the candidate's role in this project. Jennifer assisted senior management in developing a plan to accept and accession single profile samples. As supervisor of Case Management, Jennifer was responsible for hiring/training new and existing staff in order to fulfill the increased sample/case volume. Jennifer is a point of contact for the healthy lifestyle contacts. This contract has added an additional 200-600 single profile samples per day.		
Company Name: DNA Diagnostics Center	Contact Name: Lori Neff	
Address: One DDC Way Fairfield, OH 45014	Phone Number 513- 881-4031 E-mail: lneff@dnacenter.com	
Project Name: OH State Contract for Paternity	Beginning Date of Project: Month/Year July 2016	Ending Date of Project: Month/Year - Current
Description of project size, complexity, and the candidate's role in this project. As Case Management Supervisor, Jennifer was responsible for learning and understanding the Ohio state contract requirements and guidelines. Jennifer was also responsible for training new and existing staff to accept and accession the samples received proficiently and efficiently following the state requirements/guidelines.		
Company Name: DNA Diagnostics Center	Contact Name: Donna Dougherty	
Address: One DDC Way Fairfield, OH 45014	Phone Number: 513-881-8025 E-mail: ddougherty@dnacenter.com	
Project Name: Case Management Restructure	Beginning Date of Project: Month/Year July 2019	Ending Date of Project: Month/Year Dec 2019
Description of project size, complexity, and the candidate's role in this project. Jennifer assisted senior management in developing a plan to merge all divisions into one large team. Divisions are Government Contracts, Retail, Corporate accounts, and Direct to Consumer. As supervisor, Jennifer was responsible for hiring/training new and existing employees to be cross-trained in all divisions. Staff went through months of intense training to ensure they can process all samples at a precise level. All of Case Management staff can accurately accept and accession all samples received. Unfailingly, staff is able to distinguish between customers and samples.		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Jamie Hardin

Candidate's Proposed Position: Supervisor, Case Management

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name DNA Diagnostics Center	Contact Name: Chris Kraemer	
Address: One DDC Way Fairfield, OH 45014	Phone Number: 888-362-9778 x2268 E-mail: ckraemer@dnacenter.com	
Project Name: Genetic Testing: Healthy Lifestyle	Beginning Date of Project: Month/Year- May 2019	Ending Date of Project: Month/Year-Current
Description of project size, complexity, and the candidate's role in this project. Jamie assisted senior management in developing a plan to accept and accession single profile samples. As supervisor of Case Management, Jamie was responsible for hiring/training new and existing staff in order to fulfill the increased sample/case volume. Jamie is a point of contact for the healthy lifestyle contacts. This contract has added an additional 200-800 genetic profile samples per day.		
Company Name: DNA Diagnostics Center	Contact Name: Lori Neff	
Address: One DDC Way Fairfield, OH 45014	Phone Number 513-881-4031 E-mail: lneff@dnacenter.com	
Project Name: OH State Contract for Paternity	Beginning Date of Project: Month/Year July 2016	Ending Date of Project: Month/Year Current
Description of project size, complexity, and the candidate's role in this project. As Case Management Supervisor, Jamie was responsible for learning and understanding the Ohio state contract requirements and guidelines. Jamie was also responsible for training new and existing staff to accept and accession the samples received proficiently and efficiently following the state requirements/guidelines.		
Company Name: DNA Diagnostics Center	Contact Name: Donna Dougherty	
Address: : One DDC Way Fairfield, OH 45014	Phone Number: 513-881-8025 E-mail: ddougherty@dnacenter.com	
Project Name: Case Management Restructure	Beginning Date of Project: Month/Year July 2019	Ending Date of Project: Month/Year Dec 2019
Description of project size, complexity, and the candidate's role in this project. Jamie assisted senior management in developing a plan to merge all divisions into one large team. Divisions are Government Contracts, Retail, Corporate accounts, and Direct to Consumer. As supervisor, Jamie was responsible for hiring/training new and existing employees to be cross-trained in all divisions. Staff went through months of intense training to ensure they can process all samples at a precise level. All of Case Management staff can accurately accept and accession all samples received.		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Kari Bowlin

Candidate's Proposed Position: Supervisor, Collection Network

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: DNA Diagnostics Center	Contact Name: Jessica Cress	
Address: One DDC Way Fairfield, OH 45014	Phone Number: 513-881-7806 Ext 2857 E-mail:	
Project Name: Genetic Testing: Shipping Transition	Beginning Date of Project: 7/2018	Ending Date of Project: 9/2018
Description of project size, complexity, and the candidate's role in this project. Kari assisted the collection network in developing a plan to transition all collection sites and collectors to a new shipping vendor. Kari was responsible for submitting new orders with the new vendor supplies including directions on how each individual collection site and all collectors should transition. Kari transitioned around 200 collectors and 100 collection sites to the new shipping vendor.		
Company Name: DNA Diagnostics Center	Contact Name: Lori Neff	
Address: One DDC Way Fairfield, OH 45014	Phone Number: 513-881-4031 E-mail:	
Project Name: Tier Project	Beginning Date of Project: 3/2018	Ending Date of Project: 4/2019
Description of project size, complexity, and the candidate's role in this project. As Collection Network Supervisor, Kari assisted to enhance our tier process. Kari worked closely with a contractor by the name of DB Services. Kari was responsible for accurately verifying all collectors' tiers when they are collecting at different locations to ensure billing is done efficiently. Kari associated over 300 collectors to their coordinating collection sites to identify the correct tiers per each collection they perform.		
Company Name: DNA Diagnostics Center	Contact Name: Donna Dougherty	
Address: One DDC Way Fairfield, OH 45014	Phone Number: 513-881-8025 E-mail:	
Project Name: Michigan Expungement	Beginning Date of Project: 12/2018	Ending Date of Project: Present
Description of project size, complexity, and the candidate's role in this project. Kari successfully learned the Michigan Expungement process. Kari is responsible for ensuring all of the Alleged Father's information from the state of Michigan is expunged 90 days after it has been deemed they are not the father of the child the test was performed for. Kari has to remove the information from several different areas of our testing process. Kari successfully completed her first Michigan audit in June of 2019.		

OFFEROR'S CANDIDATE REFERENCES

Candidate's Name: Kellie Bunch

Candidate's Proposed Position: Supervisor – DDC Contact Center Scheduling

Three (3) professional references who have received services from the candidate in the past three (3) years

Company Name: Clarion County Domestic Relations	Contact Name: Heather Reiner	
Address: 17 South 14th Avenue Clarion, PA 16214	Phone Number: 814-226-1033 Email: heather.reiner@pacses.com	
Project Name: PA Contract Award	Beginning Date of Project: 2/1/2020	Ending Date of Project: Current
Description of project size, complexity, and the candidate's role in this project. This DR office is just one of the 67 counties within the state of PA that DDC services and schedules for on a daily basis. DDC has been working with the state of PA since the Orchid Cellmark acquisition in 2012. The new contract that DDC was recently awarded begins on 2/1/2020. DDC is responsible for completing all intrastate, interstate, and incarcerated appointments. All scheduling is completed within 24-48 hours from the day it is requested. I supervise the schedulers for all Government Contract accounts with DDC.		
Company Name: Boone County BCSE	Contact Name: Selena Slone	
Address: 156 Resource Lane Foster, WV 25081	Phone Number: 304-369-7828 Email: selena.k.slone@wv.gov	
Project Name: WV Contract Award	Beginning Date of Project: August 2015	Ending Date of Project: Current
Description of project size, complexity, and the candidate's role in this project. This BCSE office is just one of the 55 counties within the state of WV that DDC services and schedules for on a daily basis. DDC has been the vendor for the state of WV since 2015. The new contract that DDC was awarded began in September/October 2019. DDC is responsible for completing all intrastate, interstate, and incarcerated appointments. All scheduling is completed within 24-48 hours from the day it is requested. DDC is required to maintain collection dockets for some of the instate collection sites. Those dockets are supplied to the collectors and/or collection sites weekly. I supervise the schedulers for all Government Contract accounts with DDC.		
Company Name: Marion County DR	Contact Name: Lissette Klusman	
Address: 5431 East Silver Springs Blvd. Silver Springs, FL 34488	Phone Number: 352-438-0912 Email: lissette.klusman@floridarevenue.com	
Project Name: FL Contract Award	Beginning Date of Project: March 2019	Ending Date of Project: Current
Description of project size, complexity, and the candidate's role in this project. This DOR office is just one of the 67 counties within the state of FL that DDC services and schedules for on a daily basis. DDC has been working with the state of FL since the Orchid Cellmark acquisition in 2012. The new contract that DDC was recently awarded began in March 2019. DDC is responsible for all out of state and incarcerated appointments. All scheduling is completed within 24-48 hours from the day it is requested. I supervise the schedulers for all Government Contract accounts with DDC.		

Attachment #5

Accreditation Certificates

COLLEGE of AMERICAN PATHOLOGISTS

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

The College of American Pathologists
certifies that the laboratory named below

DDC/DNA Diagnostics Center
Laboratory
Fairfield, Ohio
Michael L. Baird, PhD

CAP Number: 6701701
AU-ID: 1109722
CLIA Number: 36D0910013

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 August 31, 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

R. Bruce Williams, MD, FCAP

President, College of American Pathologists

AABB Accreditation

DDC/DNA Diagnostics Center - Fairfield

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, 2018 - September 30, 2020

ADVANCING TRANSFUSION AND CELLULAR THERAPIES WORLDWIDE • AABB Est. 1947

Mary Beth Bassett

President, AABB

Darrell J. Triulzi MD

Chair, Accreditation Program Committee

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
DNA DIAGNOSTICS CENTER
205 CORPORATE COURT
FAIRFIELD, OH 45014

CLIA ID NUMBER
36D0910013

EFFECTIVE DATE
04/13/2020

LABORATORY DIRECTOR
MICHAEL L BAIRD Ph.D.

EXPIRATION DATE
04/12/2022

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.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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

185 Certs2_031720

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

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
HISTOCOMPATIBILTY (010)	03/16/2018		

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.

New York State Department of Health

PFI: 5894

Clinical Laboratory Permit

CLIA: 36D0910013

DNA Diagnostics Center
One DDC Way
Fairfield OH 45014

Director:
Michael L. Baird, Ph.D.

Owner:
DNA Diagnostics Center, Inc

is hereby authorized to perform laboratory procedures at the above location in the following categories in accordance with Article 5, Title V, Section 575 of the Public Health Law. This permit shall become void upon a change in the director, owner or location of the laboratory, and an application for a new permit shall be made to the Department.

Parentage/Identity Testing

Renewal
Effective Date: July 1, 2019
Expiration Date: June 30, 2020

Subject to Revocation
Permit Not Transferable

POST CONSPICUOUSLY

Serial: LAP 114111

CERTIFICATE OF ACCREDITATION

ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

This is to certify that

DNA Diagnostics Center / DDC
One DDC Way
Fairfield, OH 45014

has been assessed by ANAB and meets the requirements of international standard

ISO/IEC 17025:2017

while demonstrating technical competence in the field of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of activities to which this accreditation applies

AT-1299
Certificate Number

ANAB Approval

Certificate Valid Through: 12/21/2021
Version No. 004 Issued: 10/24/2019

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

DNA Diagnostics Center / DDC

One DDC Way
Fairfield, OH 45014

Todd Lewis 513-881-7800 Ext. 2270
Dr. Michael Baird 513-881-7800 Ext. 2276
contact@dnacenter.com www.dnacenter.com

TESTING

Valid to: **December 21, 2021** Certificate Number: **AT-1299**

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Paternity / Biological Relationship Testing DNA Testing-STR Analysis	DNA extraction Amplification by Polymerase Chain Reaction (PCR) Capillary electrophoresis	Biological Samples, Non-biological samples containing cellular material and DNA	Thermal Cycler ABI 3730 Genetic Analyzer
Mitochondrial Analysis Sequence analysis SNP analysis	DNA extraction Amplification by PCR Sequencing by chain termination Capillary electrophoresis	Buccal Swabs	Thermal Cycler ABI 3730 Genetic Analyzer
Y-STR DNA Analysis DNA Testing-STR Analysis	DNA extraction Amplification by PCR Capillary electrophoresis	Biological Samples, Non-biological samples containing cellular material and DNA	Thermal Cycler ABI 3730 Genetic Analyzer

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
X-STR DNA Analysis DNA Testing-STR Analysis	DNA extraction Amplification by PCR Capillary electrophoresis	Biological Samples, Non-biological samples containing cellular material and DNA	Thermal Cycler ABI 3730 Genetic Analyzer

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1299.

Standards Council of Canada
Conseil canadien des normes

SCOPE OF ACCREDITATION

DDC/DNA DIAGNOSTICS CENTER
1 DDC Way
Fairfield, OH
45014 USA

Accredited Laboratory No. 730
(Conforms with requirements of ISO/IEC 17025:2017, RG-FORENSIC)

CONTACT:	Todd Lewis
TEL:	+1 513 881 7800
FAX:	+1 513 881 7803
EMAIL:	tlewis1@dnacenter.com
URL:	https://www.dnacenter.com/

FIELDS OF TESTING:	DNA Relationship, Forensic
FORENSICS DISCIPLINE(S):	Forensic Biology / DNA
PROGRAM SPECIALTY AREA:	Forensic
INITIAL ACCREDITATION DATE:	2012-01-05
MOST RECENT ACCREDITATION:	2019-07-10
ACCREDITATION VALID TO:	2022-01-05

FORENSICS

Forensic Biology / DNA

Description of Activities:
Parentage and other familial relationship testing

The following are incorporated: item handling, item preparation, DNA extraction, PCR amplification, capillary electrophoresis, analysis, genotyping (autosomal STR, Y STR), interpretation and reporting.

Standards Council of Canada
Conseil canadien des normes

Techniques for which laboratory is accredited:

a. Capillary electrophoresis
b. Human DNA Testing services for Paternity cases and other Familial Relationship cases using autosomal STR and Y STR
c. Manual DNA extraction
d. Robotic and manual PCR amplification set-up

Notes:

RG-FORENSIC: SCC Requirements and Guidance for the Accreditation for Forensic Testing Laboratories
ISO/IEC 17025:2017: General Requirements for the Competence of Testing and Calibration Laboratories

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Elias Rafoul, Vice President
Accreditation Services

Date: 2019-07-10

Number of Forensic Techniques: 4
SCC 1003-15/912
Partner File #0
Partner:

Attachment #6

Quality Manual

Contents

1. Scope

1.1 This ISO 17025 conforming Quality Manual specifies the competence, impartiality and operational requirements that have been adopted and implemented by DNA Diagnostics Center.

1.2 This Quality Manual is applicable to all laboratory activities identified in EIR-022-01: Scope of Laboratory Activities.

1.3 Laboratory customers, regulatory authorities, peer-assessments, accreditation bodies, and others shall use this Quality Manual to confirm and recognize the competence of DNA Diagnostics Center to perform testing and calibration activities.

2. Normative References

2.1 This Quality Manual has been developed to conform with the requirements of ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories in addition to requirements set forth by AABB, ANAB, CAP, CLIA, MOJ, NATA, NYSDOH and SCC.

3. Management System Structure

3.1 This management system has been systematically designed to enable users to easily cross reference the various elements. The basic architecture is illustrated in Figure 1.

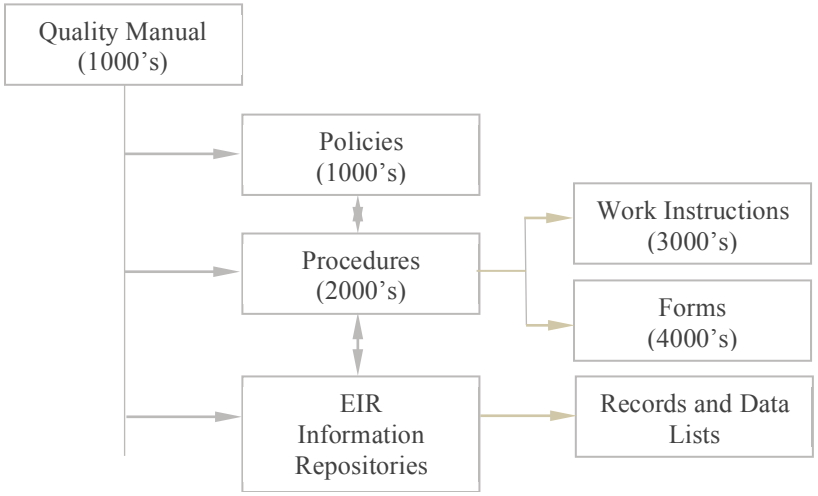


Figure 1: Management System Document Structure

4. General

4.1 Impartiality

4.1.1 It is the policy and commitment of DNA Diagnostics Center to appropriately structure and manage activities in a manner that protects and preserves impartiality.

4.1.2 Our lab demonstrates commitment to impartiality by:

4.1.2.1 Providing a policy statement that explicitly expresses our commitment (clause 4.1.1 of this quality manual).

4.1.2.2 Providing a Code of Conduct (QMS-1001) for members of management and all laboratory personnel.

4.1.2.3 Establishing procedures for ensuring impartiality, evaluating risks, and periodically reevaluating the risks. Refer to QMS-2012: Ensuring Impartiality for more information.

4.1.2.4 Maintaining records of risk assessments and by implementing countermeasures to prevent or minimize the identified risks.

4.1.2.5 Systematically incorporating steps, throughout the relevant policies and procedures, that prevent or minimize identified risks and expose situations when impartiality is compromised.

4.1.2.6 Ensuring all laboratory personnel are aware, through orientation and ongoing training of:

4.1.2.6.1 QMS-1001: Code of Conduct Policy

4.1.2.6.2 QMS-2012: Ensuring Impartiality Procedure

4.1.2.6.3 The risks they may face by reviewing the Risk Assessment

4.1.2.7 Providing personnel with access to top management to report behaviors or incidents thought to compromise impartiality.

4.1.3 DNA Diagnostics Center assumes full responsibility for being impartial and for preventing commercial, financial, and other pressures.

4.1.4 DNA Diagnostics Center identifies, reassess, prevents and minimizes risks to impartiality according to QMS-2012: Ensuring Impartiality.

4.2 Confidentiality

4.2.1 DNA Diagnostics Center assumes full responsibility for the confidentiality of all information obtained through laboratory activities. We express our commitment to members of management and laboratory personnel through QMS-1001: Code of Conduct. DNA Diagnostics Center is legally bound to maintain confidentiality through various non-disclosure agreements, confidentiality agreements, and other similar agreements as required by our customers. QMS-2013: Handling Confidential Information shall be followed when a customer's information is released to the public.

4.2.2 QMS-2013: Handling Confidential Information shall be followed when releasing confidential information.

4.2.3 QMS-2013 Handling Confidential Information shall be followed when obtaining confidential information about customers from other sources such as complainants, regulators, etc.

4.2.4 All personnel, including external resources, shall keep information obtained through laboratory activities confidential and shall follow QMS-2013.

5. Structural Requirements

5.1 DNA Diagnostics Center is organized as a C corporation in The United States of America and is headquartered in Fairfield, Ohio. Our Articles of Incorporation explains the specifics of our corporation.

5.2 The management having overall responsibility for the laboratory are identified in the following organizational chart.

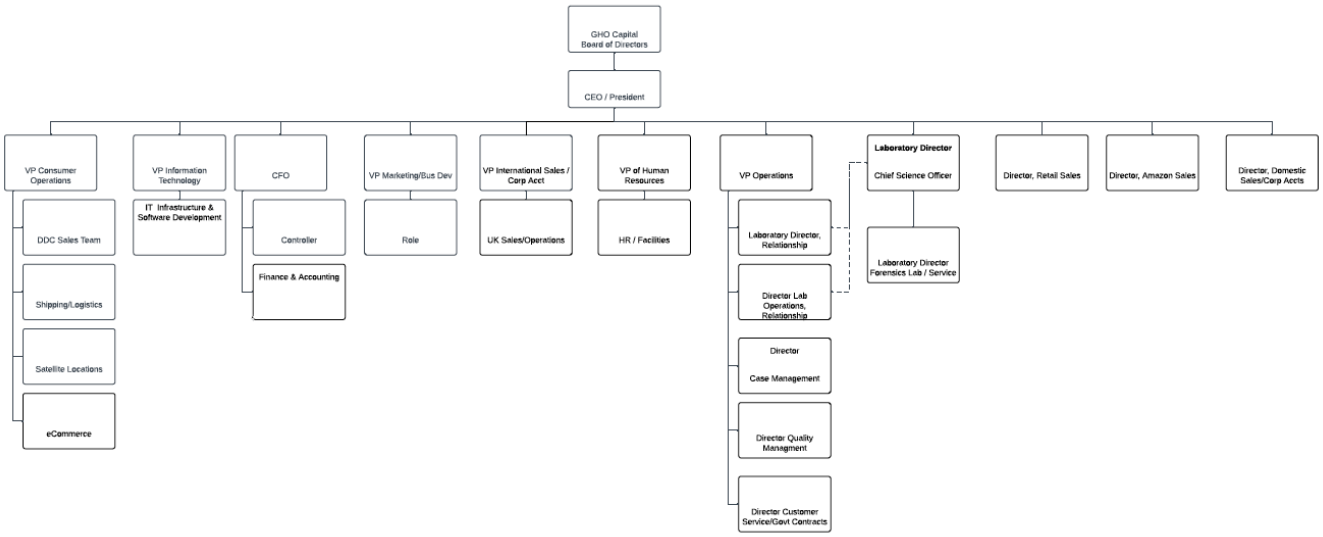


Figure 2: Organizational Chart

5.3 Range of Activities (Scope)

5.3.1 DNA Diagnostics Center provides Testing services in the Biological / Forensics field. The complete list of activities covered by this management system is provided in EIR-022: Scope of Laboratory Activities.

5.3.2 DNA Diagnostics Center only claims conformity with ISO 17025 and our accrediting bodies for the activities recorded on an ongoing basis in EIR-022: Scope of Laboratory Activities. This excludes activities that are provided externally.

5.4 DNA Diagnostics Center is committed to conducting testing services that satisfy our customer requirements, the requirements of ISO 17025 and requirements of our accrediting bodies.

5.4.1 The management system as outlined within this quality manual applies and will be followed regardless of where services are rendered (on or offsite).

5.4.2 It is critical that all personnel conform to the requirements of ISO 17025, with our customer requirements as well as the relevant accrediting bodies and regulatory authorities providing recognition. To support this, all employees shall receive basic training about the quality system and customer expectations specified in EIR-019-01: Competence Requirements.

5.5 The organization and management structure of DNA Diagnostics Center are provided in the organizational chart referenced in clause 5.2 of this Quality Manual.

5.5.1 The organizational chart displays this laboratory's place in the parent organization, and the relationships between management, technical operations and support services.

5.5.2 The organizational chart displays the interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities. Specific responsibility and authority for laboratory activities are provided throughout this management system. General authority and responsibility follows:

5.5.2.1 Top Management has ultimate authority over the management system and all activities of the laboratory. Top management is responsible for:

5.5.2.1.1 following the appropriate policies, procedures, work instructions, and methods when performing laboratory activities;

5.5.2.1.2 reporting to management when departures from standard work or the customer's requirements occur;

5.5.2.1.3 requesting additional resources when needed to carry out activities in accordance with this management system or the customer's requirements;

5.5.2.1.4 participate in training and various courses to meet the ongoing technical requirements for performing laboratory activities;

5.5.2.1.5 identifying opportunities and making proposals for improvement.

5.5.2.2 Laboratory Personnel are responsible for:

5.5.2.2.1 following the appropriate policies, procedures, work instructions, and methods when performing laboratory activities;

5.5.2.2.2 reporting to management when departures from standard work or the customer's requirements occur;

5.5.2.2.3 requesting additional resources when needed to carry out activities in accordance with this management system or the customer's requirements;

5.5.2.2.4 participate in training and various courses to meet the ongoing technical requirements for performing laboratory activities;

5.5.2.2.5 identifying opportunities and making proposals for improvement.

5.6 This management system is designed to conform with ISO 17025:2017. It is comprised of this Quality Manual, Policies, Procedures, Lists, Records and more to enable consistent performance of laboratory activities and yield valid results.

5.7 The managerial and laboratory personnel have the authority and resources to carry out their duties; including:

5.7.1 implementing, maintaining, and improving this management system (ex. site org. charts, budgets, workload metrics and capital plans);

5.7.2 identifying departures from this management system, our accrediting body's requirements;

5.7.3 testing procedures and customer requirements;

5.7.4 initiating preventive and corrective actions to minimize potential for deviation;

5.7.5 monitoring and reporting the performance of the management system and recommending improvements;

5.7.6 ensuring the effectiveness of all laboratory activities.

5.8 The effectiveness of the management system is reviewed and communicated during Management Reviews. Management review meeting minutes are recorded for laboratory personnel to reference.

5.9 QMS-1002: Quality Policy addresses the importance of meeting customers' and other requirements.

5.10 During changes and improvements to the management system, the leadership team shall monitor the system and results as appropriate to ensure that the overall integrity is maintained.

6. Resource Requirements

6.1 General

6.1.1 It is the policy of this laboratory to have appropriate personnel, facilities, equipment, systems and support services required to perform activities included in EIR-022: Scope of Laboratory Activities.

6.1.2 This policy is fulfilled through the procedures provided by following clauses of this quality manual:

6.1.2.1 6.2. Personnel

6.1.2.2 6.3. Facilities and environmental conditions

6.1.2.3 6.4. Equipment

6.1.2.4 6.6. Externally provided products and services

6.1.2.5 6.5. Metrological traceability

6.2 Personnel

6.2.1 DNA Diagnostics Center ensures impartiality as described in QMS-1000 clause 4.1: Impartiality. Only personnel who are employed by or contracted to DNA Diagnostics Center shall perform testing activities. DNA Diagnostics Center ensures the competence of all personnel performing testing activities as described in 6.2.3. All testing activities are supervised and shall be carried out in accordance with stated methods, our customers' requirements, and our laboratory's management system.

6.2.2 The competence requirements for laboratory personnel are recorded in EIR-019-01: Competence Requirements.

6.2.3 Prior to new personnel performing laboratory activities or existing personnel performing new activities, the laboratory management shall assess the competence of all personnel (internal and external) and record the assessment in EIR-012-01: Activity Authorization Matrix. Any gaps between the demonstrated and required competence shall be recorded in the Activity Authorization Matrix.

6.2.4 EIR-019 Competence Requirements and Job Description documents contains job descriptions that communicate duties, responsibilities, and authorities for specific laboratory functions (roles). Job descriptions are accessible to all laboratory personnel. At a minimum, job descriptions include:

6.2.4.1 Required education, expertise, and experience;

6.2.4.2 Required qualifications and training;

6.2.4.3 Responsibilities for performing activities within the ISO 17025 management system;

6.2.4.4 Responsibilities while performing testing activities;

6.2.4.5 Responsibilities while planning tests and evaluating results;

6.2.4.6 Responsibilities for reporting opinions and interpretations;

6.2.4.7 Responsibilities for developing, modifying and validating new methods;

6.2.4.8 Managerial duties (if any).

6.2.5 QMS-2014: Ensuring Competent Personnel contains the procedures for determining competence requirements, selecting, training, supervising, authorizing and monitoring the competence of laboratory personnel.

6.2.6 QMS-2014: Ensuring Competent Personnel contains the procedure for authorizing personnel to carry out specific laboratory activities.

6.3 Facilities and Environmental Conditions Policy and Procedure

Purpose:

The purpose of environmental conditions policy and procedure is to create and maintain an environment that is suitable for testing and ensure that it meets the requirements of the governing standards.

Scope:

Includes all areas where testing activities are performed.

Responsibility:

Quality Manager:	Ensure the requirements of this procedure are met.
All Personnel:	Monitor and record pertinent environmental conditions as outlined in this procedure.

6.3.1 The DNA Diagnostics Center facility provides an environment that facilitates the correct performance of tests. Our facility is supplied with reliable electrical service, overhead fluorescent lighting, and an HVAC system capable of sustaining the environmental conditions specified by governing standards.

6.3.2 Unless otherwise specified, the following facility and environmental conditions are maintained in controlled areas:

6.3.2.1 Temperature: 74°F (+/- 10°F)

6.3.2.2 Relative humidity: <70%

6.3.3 Environment and Facility requirements are identified for each activity recorded in EIR-022-01: Scope of Laboratory Activities. The relevant environmental conditions shall be monitored and recorded at the time activities are performed and when periodic observations are made.

6.3.4 DNA Diagnostics Center controls, monitors and records the relevant environmental conditions as required by governing standards. All testing shall be paused when environmental conditions are present that threaten accurate test results. Threatening environmental conditions may include:

6.3.4.1 Biological sterility

6.3.4.2 Dust

6.3.4.3 Temperature and Humidity

6.3.4.4 Electrical supply

6.3.5 DNA Diagnostics Center's facility is secure from unauthorized access and isolated from neighboring areas with incompatible activities. The appropriate countermeasures have been implemented to prevent cross contamination.

6.3.6 Access to the testing facility is controlled to maintain confidentiality and prevent unauthorized modification of tests.

6.3.7 Good housekeeping is maintained to prevent contamination, in addition to ensuring a safe, efficient and productive work environment.

6.3.8 The laboratory is effectively separated from incompatible activities. Activity separation requirements, if any, are recorded in EIR-021-01: Scope of Laboratory Activities.

6.3.9 When performing activities at locations outside of the laboratory's control, DNA Diagnostics Center will ensure that the facility and environmental requirements of ISO 17025, this procedure, the requirements of the methods, and the requirements of the customer are met. All relevant facility and environmental conditions shall be recorded at the time the activity is performed and when periodic observations are made.

6.4 Equipment

6.4.1 DNA Diagnostics Center either owns or has access to all equipment and supplies required to correctly perform all activities included in EIR-021-01: Scope of Laboratory Activities. Equipment used for testing is selected based on its capability to meet the test standard's and customer's requirements. Equipment and supplies include, but are not limited to:

6.4.1.1 Machines;

6.4.1.2 Measuring Instruments;

6.4.1.3 Software;

6.4.1.4 Measurement Standards;

6.4.1.5 Reference Materials;

6.4.1.6 Reference Data;

6.4.1.7 Reagents

6.4.2 Only equipment that is under permanent control of DNA Diagnostics Center and contained in EIR-014: Tools and Equipment List is used for testing activities included in EIR-021-01: Scope of Laboratory Activities. Refer to EIR-014: Tools and Equipment List for a complete listing of equipment and specifications used for testing and calibration purposes.

6.4.2.1 DNA Diagnostics Center will ensure that the ISO 17025 requirements are met under any circumstance that the lab uses equipment that is not permanently controlled.

6.4.3 In general, all equipment (including reference standards and reference materials) shall be carefully handled and transported to prevent contamination, damage, deterioration, and to ensure proper functioning. Equipment shall be used only within its specified range of capability. All equipment will be maintained in suitable environments conforming with QMS-1000, Clause 6.3 and/or relevant standards.

6.4.3.1 Work instructions shall be written for specific equipment that requires special handling, transportation or storage beyond the general accommodations.

6.4.4 Verification of Conformance

6.4.4.1 Consumable Supplies shall be verified to conform with the requirements specified in the item's Product and Service Requirements (PSR) document, prior to initial use. The item shall be assessed for conformance according to QMS-2015: Ensuring Quality of External Products and Services.

6.4.4.2 Tools and Equipment shall be verified to conform with the specified requirements in the item's Tool and Equipment Requirement's (TER) document, prior to initial use and when being placed back into service. The item shall be assessed for conformance according to QMS-2015: Ensuring Quality of External Products and Services.

6.4.5 Measurement equipment requirements for accuracy and uncertainty shall be recorded in the item's Measuring Equipment Requirements (TER) document. The item's conformance record, which includes the item's actual values compared to the specified values shall be recorded in EIR-014: Tools, Equipment and Software under the specific folder.

6.4.6 EIR-014: Equipment and Tools List references the specifications for measuring equipment that affects the validity of results or when metrological traceability is required for reported results. All equipment recorded in EIR-014 shall be verified to conform to the applicable requirements prior to initial use and at specified intervals as required by the item's Tool and Equipment Requirements (TER) document.

6.4.7 DNA Diagnostics Center's calibration program monitors and adjusts all significant aspects of equipment at a frequency appropriate to maintain confidence that the applicable requirements are met.

6.4.7.1 The effectiveness of the overall calibration program is reviewed during the annual Management Review.

6.4.7.2 Adjustments to the calibration program are made based on the resulting actions from the annual Management Review.

6.4.8 As far as practical, all equipment under the control of the lab and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the last date calibrated and date or expiration criteria for the next calibration.

6.4.8.1 Internal calibrations: QMS-4029: Calibration Tag shall be used to comply with the requirements of Clause 6.4.8.

6.4.8.2 External calibrations: Calibration tags shall conform with section 6.4.8 and our accrediting body's requirements.

6.4.8.3 External calibration tags shall include the accrediting body's scope logo and certificate number or other reference to its scope of accreditation.

6.4.8.4 Refer to QMS-1000, Clauses 6.4.4 to 6.4.7 for additional information.

6.4.9 Equipment that has been subjected to overloading or mishandling, gives suspect results, is shown to be defective or outside of specification limits shall be immediately removed from service. The equipment will be quarantined and labeled with QMS-4030: Out of Service Tag.

6.4.9.1 The quality manager and/or technical manager shall be promptly notified and initiate the appropriate action as specified by QMS-1000, Clause 7.10 for Nonconforming Work.

6.4.10 Intermediate checks shall be performed according to the specifications provided in the item's Tool and Equipment Requirements (TER) and follow the same procedure a routine calibrations and inspections.

6.4.11 Correction factors resulting from calibrations shall be recorded in the appropriate conformity assessment record. The corrected output shall be confirmed during the calibration process.

6.4.12 Test and calibration equipment (including both hardware and software), shall be safeguarded from adjustments which would invalidate the test and/or calibration results.

6.4.13 Each tool, equipment, and software significant to the outcome of test and calibration is uniquely identified with a TEQ- and number. Refer to the EIR-014: Tools and Equipment List.

6.4.14 The following details are summarized in EIR-014 Tools and Equipment List

6.4.14.1 Unique identification number of the equipment and/or software;

6.4.14.2 The item's Tool and Equipment Requirements document identification (e.g., TER-XXXX);

6.4.14.3 The items status and if used for testing included in EIR-022-10 Scope of Laboratory Activities;

6.4.14.4 Description of the equipment and/or software, including software/firmware version;

6.4.14.5 Manufacture's name, type/model identification and serial number;

6.4.14.6 Equipment accuracy and uncertainty specifications from the item's TER;

6.4.14.7 Normal storage location (as appropriate);

6.4.14.8 Dates last calibrated, date of next calibration, and most recent conformity assessment record identification number.

6.4.14.9 Date last serviced according to the maintenance identified in the item's TER, date of next maintenance, frequency of maintenance.

6.4.14.10 Manufacturer instructions and specifications;

6.4.15 Additional requirements and records are stored and retained as follows:

6.4.15.1 Product and Service Requirements (PSR's) contain the specifications and acceptance criteria for consumable supplies and reference materials. PSR's are stored in EIR-015: Provided Products and Services under the specific folder. Conformity assessment results, relevant dates, and the period of validity; are recorded as PSRA's and stored in EIR-015: Provided Products and Services under the specific folder

6.4.15.2 By reference to the item's conformance assessment id; any damage, malfunction, modification, adjustment, or repair to the equipment;

6.4.15.3 Calibration certificates and reports are stored in EIR-014: Tools, Equipment and Software under the specific folder. Maintenance and inspection records are stored and retained in EIR-014: Tools, Equipment and Software under the specific folder.

6.4.16 Calibration, Verification and Maintenance Intervals

6.4.16.1 Calibration, verification and maintenance due dates have a 30 day total grace period, unless otherwise specified. In other words, the date the actual service shall occur within a window that is 15 days before or after the due date for internally sourced calibrations or verifications. Externally sourced calibrations and maintenance will attempt to follow the same due date parameters, but may alter due to availability of the service company.

6.4.16.2 Historical calibration results shall be used to demonstrate that the calibration grace period is appropriate and ensures the device conforms with the applicable requirements.

6.5 Metrological Traceability

6.5.1 All equipment (including reference standards and reference materials) used for activities included in EIR-022-10: Scope of Laboratory Activities shall maintain metrological traceability of its measurement results through an unbroken chain of calibrations, with recorded uncertainties, that are linked to an appropriate reference.

6.5.2 All equipment (including reference standards and reference materials) used for activities included in EIR-022-10: Scope of Laboratory Activities shall be traceable to the International System of Units (SI). All test calibration results and uncertainty estimates shall be linked to SI units either directly or through universally accepted physical constants and/or transformations. Traceability is achieved by:

6.5.2.1 Obtaining calibrations by authorized laboratories that:

6.5.2.1.1 Are accredited by a recognized authority to ISO 17025;

6.5.2.1.2 Include the required calibrations in their scope of accreditation.

6.5.2.2 Using certified values of certified reference materials that are provided by a reference material producer that conforms to the requirements of ISO 17034.

6.5.2.3 Comparing measurement results, directly or indirectly, with national or international standards.

6.5.3 When metrological traceability to the SI units is not technically possible, DNA Diagnostics Center shall establish metrological traceability to an appropriate reference by:

6.5.3.1 Using certified values of certified reference materials that are provided by a reference material producer that conforms to the requirements of ISO 17034.

6.5.3.2 Using reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

6.6 Externally Provided Products and Services

6.6.1 DNA Diagnostics Center ensures only suitable products and services are supplied to the laboratory through QMS-2015: Ensuring Quality of External Products and Services.

6.6.2 Procedures and records for externally provided products and services

6.6.2.1 QMS-2015: Ensuring Quality of External Products and Services shall be followed when defining, reviewing, and approving requirements for externally provided products and services.

6.6.2.2 QMS-2015: Ensuring Quality of External Products and Services shall be followed when defining criteria for evaluation, selection, monitoring performance, and re-evaluation of external providers.

6.6.2.3 QMS-2015: Ensuring Quality of External Products and Services shall be followed to ensure externally provided products and services conform to the applicable requirements.

6.6.2.4 QMS-2015: Ensuring Quality of External Products and Services shall be followed when authorizing the use of externally provided products and services and when responding to non-conforming products and services.

6.6.3 Requirements are communicated to authorized providers according to QMS-2009: Procuring Products and Services.

7. Process Requirements

7.1 Review of Requests, Tenders and Contracts Procedure

Purpose:

The purpose of the review procedure is to ensure that the methods and customer requirements are adequately defined and understood, to ensure that the laboratory has the appropriate resources and capability to conduct the test and the method(s) selected is appropriate and meets the customer's requirements. This policy pertains to new requests, revisions and projects that do not exist on the current testing menu.

Scope:

This procedure applies to all new and existing requests, tenders and/or contracts.

Responsibility:

Quality Manager:	Ensure the requirements of this procedure are met.
Reviewer:	Reviews request for the appropriate information and offers input in a timely manner. Accepts requests and contracts upon satisfactory review. Notifies affected personnel of changes to the original request or contract.

All Personnel: Promptly notify the customer of any deviations from the request or contract.

7.1.1 Process

7.1.1.1 A new request is created by the customer liaison according to QMS-2018: New Project Request Procedure.

7.1.1.2 The laboratory's designated Project Request reviewer is notified of the new Project Request.

7.1.1.3 The reviewer verifies that the laboratory possesses the competence, capability and resources and determined if anything needs to be subcontracted.

7.1.1.4 The Project Request is submitted to the customer for review and acceptance. A purchasing document from the customer is sufficient evidence of acceptance and authorization for the project as recorded in the Project Request.

7.1.1.5 The laboratory reviewer compares the purchasing documents to the Project Request. Differences are identified and resolved.

7.1.1.6 The designated reviewer completes the determination checklist at the end of the Project Request and selects the appropriate authorization based on the results of the review.

7.1.2 All requests, shall be recorded according to QMS-2018: New Project Request Procedure and assigned a new REQ number.

7.1.2.1 Activities that are intended to be provided externally shall be communicated to the customer using QMS-2008: Authorization Request to Subcontract Form.

7.1.2.2 Upon receipt of authorization, the authorization record shall be stored in EIR-000: Project Files with the respective project folder.

7.1.3 DNA Diagnostics Center shall inform the customer either written or verbally when a selected method is inappropriate or out of date.

7.1.4 Statement of conformity requests shall identify the activities requiring a statement of conformance, the acceptance criteria source and the decision rule source. Conformity assessment details shall be recorded in the Project Request Form, QMS-2023.

7.1.5 Upon receipt of tenders / contracts/ purchasing documents, the designated laboratory reviewer shall compare the documents to the REQ generated for the project. Any differences shall be highlighted and discussed with the customer prior to accepting the project. Any deviations requested by the customer shall be reviewed and determined to produce valid results and to preserve this laboratory's integrity. Records of these assessments are recorded in the Project Request (REQ).

7.1.6 DNA Diagnostics Center shall inform the customer in writing of any laboratory deviations from the contract.

7.1.7 It is the policy of this laboratory to maintain healthy relationships with the customer by cooperating with them or their representatives in clarifying request, monitoring results of activities included in the Project Request, and general progress of the project.

7.1.8 Records of reviews, significant changes, and discussions shall be recorded and retained in EIR-000: Project Files within the designated project folder.

7.2 Selection, Verification and Validation of Methods

7.2.1 Selection and Verification of Methods

7.2.1.1 DNA Diagnostics Center uses methods and procedures that are appropriate for all the calibration and testing activities and, where appropriate, for the evaluation of measurement uncertainty as well as statistical techniques for data analysis.

7.2.1.2 Work instructions, standards, manuals and reference data are maintained in a current state and are available to laboratory personnel by electronic access through laboratory supplied computers.

7.2.1.3 Unless otherwise specified, only the latest version of methods shall be used. As appropriate, methods will be supplemented with additional details to ensure consistent application and interpretation. These supplemental methods may be in the form of supplemental methods and/or laboratory work instructions.

7.2.1.4 Unless otherwise specified, DNA Diagnostics Center only uses internationally, nationally or regionally accepted standards. Any methods selected by the laboratory shall be approved for use by the customer prior to test.

7.2.1.5 As specified under Clause 7.1.1.3, DNA Diagnostics Center's Project Request reviewer will verify that the laboratory possesses the required competence, capability and resources prior to recommending methods to the customer. The verification record is included in the Project Request and retained in EIR-000: Project Files within the designated project folder.

7.2.1.6 If a new revision of the selected method becomes available prior to performing the testing activity, then the laboratory will re-verify its capability and inform the customer of the revised method prior to performing the activity.

7.2.1.7 DNA Diagnostics Center designates Laboratory Developed Tests for its own use within EIR-022-01: Scope of Laboratory Activities.

7.2.1.8 All planned deviations and justifications from the specified methods are recorded in the Project Request. Planned method deviations are considered authorized and accepted by the customer according to Clause 7.1.5.

7.2.2 Validation of Methods

7.2.2.1 DNA Diagnostics Center performs non-standard methods, laboratory-developed methods, or standards methods outside of their intended scope within EIR-022-01: Scope of Laboratory Activities, those methods will be validated in accordance with QMS-2025 Validation of Test Methods.

7.2.2.2 The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

7.2.2.3 The techniques used for method validation can be one of, or a combination of, the following:

7.2.2.3.1 calibration or evaluation of bias and precision using reference standards or reference materials;

7.2.2.3.2 systematic assessment of the factors influencing the result;

7.2.2.3.3 testing method robustness through variation of controlled parameters, such as incubator temperature,

7.2.2.3.4 volume dispensed;

7.2.2.3.5 comparison of results achieved with other validated methods;

7.2.2.3.6 interlaboratory comparisons;

7.2.2.3.7 evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles

7.2.2.3.8 of the method and practical experience of the performance of the sampling or test method.

7.2.2.4 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.

7.2.2.5 The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements

7.2.2.6 The laboratory shall retain the following records of validation:

7.2.2.6.1 the validation procedure used;

7.2.2.6.2 specification of the requirements;

7.2.2.6.3 determination of the performance characteristics of the method;

7.2.2.6.4 results obtained;

7.2.2.6.5 a statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling

7.3.1 DNA Diagnostics Center does not perform sampling within EIR-022-01: Scope of Laboratory Activities.

7.4 Handling Test Items

7.4.1 QMS-2024: Handling Test Items specifies the procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.

7.4.2 QMS-2024: Handling Test Items specifies the precautions needed to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing.

7.4.3 Each test item is uniquely identifiable through the combination of the Group Case Number, sample number and a unique barcode for each item within in a group of items. Items are labeled upon receipt using an appropriate method to protect against loss of identification.

7.4.4 Test items are visually inspected for defect upon arrival to the lab. Any defects or abnormalities shall be recorded and explicitly noted in the test report. The customer will be consulted under any circumstances that the item is not suitable for testing. The customer shall be consulted for additional information pertaining to the Chain of Custody or case requirements if the information provided is inadequate. The results of discussions shall be recorded in the LIMS.

7.4.5 DNA Diagnostics Center stores items according to the specified environmental conditions. The actual storage conditions are monitored and recorded along with the duration of conditioning. Records of the storage conditions are retained in EIR-000: Project Files within the designated project folder.

7.5 Technical Records

7.5.1 Technical records are retained for each project and included in EIR-000: Project Files and grouped by REQ number. Technical records include the activity report, activity results, raw data, calculations, media, and handwritten notes and observations. QMS-4024: Technical Record Template may be used as a starting point for activity specific data forms. The requirements for all records include for each activity:

7.5.1.1 The date or range of dates the activity was performed;

7.5.1.2 The name of the personnel responsible for performing the activity;

7.5.1.3 The name of the personnel responsible for checking the results;

7.5.1.4 Original observations, data, and calculations;

7.5.1.5 Sufficient information to facilitate, if possible, identification of factors affecting measurement uncertainty;

7.5.1.6 Sufficient information to repeat the activity under conditions as close as possible to the original;

7.5.2 Amendments may be made to technical records by hand or electronically. Amendments to technical records shall be clearly identified and traceable to previous revisions and to the original observations. The altered aspects of the records shall be clearly recorded and display the name or initials of the personnel responsible for the alterations.

7.5.3 Both the amended records and original records shall be retained in EIR-000: Project Files within the designated project file, identified with the REQ number.

7.6 Evaluating Measurement Uncertainty

7.6.1 DNA Diagnostics Center estimates uncertainty according to QMS-2001: Estimating Measurement Uncertainty.

7.6.2 The uncertainty is assessed for internal calibration methods that affect activities identified in EIR-022-01: Scope of Laboratory Activities according to QMS-2001: Estimating Measurement Uncertainty.

7.6.3 The uncertainty is assessed for all test methods included in EIR-022-01: Scope of Laboratory Activities according to QMS-2001: Estimating Measurement Uncertainty.

7.6.4 DNA Diagnostics Center currently provides DNA STR and SNP Analysis testing under Scope of Laboratory Activities. The output of the testing is provided in the form of a report that provides a qualitative interpretation. When following the flow chart for determining measurement uncertainty in QMS-2001 2.2, it is determined that DDC is following published methods that provides qualitative results and therefore falls under Category 1. This Category 1 classification does not require a measurement uncertainty budget.

7.7 Ensuring the Validity of Results

7.7.1 DDC ensures the validity of results by actively participating in proficiency tests, external assessments, internal audits and competency review of employees.

7.7.2 QMS-2019: Ensuring the Validity of Results shall be used to specify the assessment procedures for monitoring the validity of results. Records of resulting method assessment plans shall be retained in EIR-023: Method Assessments within the method's designated folder.

7.7.3 Other performance monitoring schemes, such as, proficiency testing and interlaboratory comparisons, shall be identified according to QMS-2005: Proficiency Testing Plan

7.7.4 Data, analysis and results from method assessments shall be recorded as specified by the Method Assessment Procedures.

7.7.5 The criteria for successful method assessments are defined in QMS-2005: Proficiency Testing Plan.

7.7.6 Nonconforming results and negative trends that require corrective action will follow QMS-1000 Clause 8.7.

7.7.7 Nonconforming results and negative trends that require an update to the Method Assessment Procedure will be revised according to QMS-2019: Ensuring the Validity of Results.

7.7.8 Monitoring Program

7.7.8.1 The C.S.O./Laboratory Director and Laboratory Directors select quality indicators to be monitored monthly. These indicators will insure the overall effectiveness of the current operational quality, safety policies and procedures. Any indicators outside the established thresholds will be reviewed and corrective action will be taken. A monthly QA monitor report will be summarized and presented to members of the laboratory management team.

7.7.8.2 Periodically, the laboratory staff will discuss areas of the laboratory operation that they feel could benefit by a monitoring plan. Monitoring will be open to anything that the laboratory staff perceives to be a problem area or an opportunity for improvement.

7.7.8.3 Monitoring of various areas of the laboratory operation will occur as needed and continue for a length of time deemed suitable to complete the monitoring process.

7.7.8.4 Areas that may be monitored for quality assurance include, but are not limited to, sample types, sample age, extraction and PCR methods, data entry, as well as patient complaints and reports of non-conformances.

7.7.8.5 Each monitoring will be proceeded by a written plan as to what is being monitored, what are the goals of the monitoring, and a summary of the outcome. The written plan will be followed by the actual data collected during the monitoring period.

7.7.8.6 Summary information obtained through monitoring will be used to shape the direction of the testing program in the laboratory and to set guidelines pertaining to various aspects of the laboratory process. Any process improvement will be monitored following implementation for improvement.

7.7.8.7 Annually, DDC will participate in a review of internal and external assessment with proficiency testing, competency, redraw rate, completeness of record and annual review of program with the Laboratory Executive Management Team and staff.

7.8 Reporting Results

7.8.1 General

7.8.1.1 All test results shall be reviewed and authorized for release by Assistant Laboratory Director or Laboratory Director only.

7.8.1.2 The results are provided accurately, clearly, unambiguously and objectively, and include all the information required by the customer, as necessary for the interpretation of the results, as required by the method used.

7.8.1.3 When agreed with customer, the results may be reported in a simplified way. All reports shall be retained as technical records in the LIMS and/or Hard copy folders in the Testing Records Center.

7.8.1.4 All technical records pertaining to the project shall be readily available

7.8.2 Common Requirements for Reports

7.8.2.1 All reports shall contain the content specified by ISO 17025:2017, Clause 7.8.2. and accrediting bodies, when appropriate. Refer to QMS-2023 Test Report Content and Issuance

7.8.2.2 DNA Diagnostics Center assumes full responsibility for all the information provided in the report, except when information is provided by the customer.

7.8.2.3 Data provided by a customer shall be clearly identified in the report.

7.8.2.4 When the information is supplied by the customer that has potential to affect the validity of results the report shall include a statement such that DNA Diagnostics Center is reporting customer supplied data and cannot confirm its validity.

7.8.2.5 When the customer has supplied test items, the report shall include a statement that the results apply to the sample as received.

7.8.3 Specific requirements for test reports

7.8.3.1 All test reports, where necessary for the interpretation of results, shall contain the applicable content specified by ISO 17025:2017, Clause 7.8.3, accrediting body specifications and conform to the requirements of Clause 7.8.1 of this quality manual.

7.8.3.2 DNA Diagnostics Center does issue sampling reports.

7.8.4 Specific requirements for calibration certificates

7.8.4.1 DNA Diagnostics Center does not perform calibration services.

7.8.5 Reporting sampling – specific requirements

7.8.5.1 DNA Diagnostics Center does issue sampling reports.

7.8.6 Reporting statements of conformity

7.8.6.1 In general, DNA Diagnostics Center does not issue statements of conformity.

7.8.6.2 If a statement of conformity is included in a report, it shall conform to ISO 17025:2017, Clause 7.8.6.

7.8.7 Reporting opinions and interpretations

7.8.7.1 Only Assistant Laboratory Director or Laboratory Director are authorized to express opinions and interpretations in reports.

7.8.7.2 Opinions and interpretations shall be expressed solely based on the results of the items tested.

7.8.7.3 Official opinions and interpretations from DNA Diagnostics Center shall only be rendered in the form of a report.

7.8.8 Amendments to Reports Procedure

7.8.8.1 Amendments to a report are made only in the form of a new report, which includes a reference to the change in the report and the statement that the new report is amended and supersedes the previous report including the appropriate case number and dates.

7.8.8.2 Amended reports shall be reviewed, authorized and reissued following QMS-2023: Test Report Content and Issuance.

7.8.8.3 The reissued report shall be redistributed to all individuals and/or libraries that received the original report.

7.8.8.4 Report amendments typically occur as the result of incomplete or erroneous information, typographical errors, or editorial changes.

7.8.8.5 Amended reports shall conform to the applicable requirements identified under Clause 7.8 of this Quality Manual.

7.9 Complaint Handling Procedure

Purpose:

The purpose of the Complaint Handling Procedure is to define a standard approach for recording, investigating and responding to customer complaints.

Scope:

This procedure applies to customer complaints and internal complaints regarding the quality and technical aspects of testing. Examples include accuracy, report content and implementation of the quality system. This procedure is not intended to apply to non-technical aspects such as lead time, hours of operation, and interpersonal conflict.

Responsibility:

Quality Manager:	Investigate the complaint and need for action. If appropriate, promptly issue a corrective action for the complaint. Validate corrective action is implemented and effective.
Lab Director:	Investigate the technical aspects and adjudicate the complaint. Document any required changes in corrective action document, if required.

7.9.1 The complaint handling process shall be provided to stakeholders upon request. The internal complaint procedure is outlined in QMS-2006: Handling Complaints and Concerns. The external complaint procedure is explained in the following text.

7.9.2 Complaints, either internal or external, shall be handled in a timely manner.

7.9.3 DNA Diagnostics Center assumes full responsibility for all decisions when handling complaints.

7.9.4 Complaints shall be directed to the Quality Assurance department and logged into EIR-018-01: Complaints Log. The Quality Manager or designee will gather evidence regarding the complaint and present to the Lab Director to determine the appropriate course of action.

7.9.5 If the investigation shows that the complaint is invalid, the originator of the complaint shall be notified of the findings and that this issue is closed. If a complaint is appealed, a new investigation will commence.

7.9.6 If the investigation reveals a valid problem, the Quality Assurance department shall be immediately notified, a corrective action shall be initiated per Clause 8.7 of this Quality Manual and the Nonconforming Work Procedure shall be followed per Clause 7.10. of this Quality Manual.

7.9.7 A written response or verbal communication formally detailing the findings of the investigation and ensuing actions shall be sent to the originator of the complaint and appropriate stakeholders.

7.9.8 Complaints shall be summarized and reviewed during management review sessions.

7.10 Nonconforming Work Procedure

Purpose:

The purpose of the control of nonconforming work procedure is to ensure reliable test results and to provide a standard procedure for containing and correcting results that do not conform to the agreed requirements of the customer.

Scope:

This procedure applies to all testing activities.

Definitions:

Nonconforming Work: Any work that does not conform to the applicable requirements of the method, specifications, standards, customer requirements or the requirements of this management system.

Responsibility:

Lab Director:	Determine if nonconforming work warrants halting work or issuance of test reports. Resumes any halted activities.
Quality Manager:	Investigate the situation and need for action. If appropriate, promptly issue a corrective action for the complaint. Validate corrective action is implemented and effective.

Technical Manager:	Investigate the technical aspects of the situation and initiate changes to permanently correct the situation. Document change in corrective action document.
All Personnel:	Responsible for halting nonconforming work and following this procedure.

7.10.1 When deciding what nonconforming work warrants a corrective action DDC has established the following guidelines:

7.10.1.1 Process: For a process nonconformance that did not result in a defective product being released, DDC will track trends and account for employees involved to determine if it is a process, training or personnel issue. After an investigation, a preventative or corrective action may be initiated. After any error is discovered, the product is quarantined from release and offending employee is notified. Retraining will be performed if warranted.

7.10.1.2 Product: For a product nonconformance the established quality controls for the system as a whole were not adequate and the defective product (report or device) was released. A corrective action plan must be initiated for this situation.

7.10.1.3 Regulatory: Any regulatory nonconformance must have a corrective action plan to ensure regulatory standards are met.

7.10.2 Any testing activities that do not or are suspected of not conforming to the appropriate requirements shall be reported to and promptly investigated by the quality manager or designee.

7.10.2.1 All laboratory personnel involved in testing activities have the authority and are responsible for halting work and withholding test reports when nonconforming work is identified. Whether all work is halted, depends on the severity of the situation and if the problem is systemic.

7.10.2.2 The individual halting the work shall promptly report the situation to their Manager.

7.10.2.3 Together, the individual halting the work, the Department Manager and Quality Manager shall evaluate the risk, significance and/or acceptability of nonconformance and the extent of nonconformance on previous testing. The Lab Director shall decide if a corrective action is necessary.

7.10.2.4 A corrective action shall be immediately initiated per Clause 8.7 of this Quality Manual, if warranted.

7.10.2.5 The Quality Manager or designee shall notify the affected parties, as appropriate, and recall nonconforming work.

7.10.2.6 Once the corrective action is implemented and verified effective, the Lab Director shall authorize resumption of work, if it was halted.

7.10.3 The correction action procedure per Clause 8.7 of this Quality Manual shall be followed when nonconforming work may recur or when internal policies and procedures are suspect, per Clause 7.10.1.

7.10.4 When personnel discover a problem that could possibly lead to non-conforming work, but the error has yet to occur, a preventative action form QMS-4005 may be completed, depending on the level of risk.

7.11 Control of Data and Information Management

7.11.1 DNA Diagnostics Center assumes responsibility for obtaining access to all information needed to perform the activities identified in EIR-022-01: Scope of Laboratory Activities.

7.11.2 DNA Diagnostics Center validates the functionality of information systems used for the collection, processing, recording, reporting, storage, and retrieval of data before introducing such systems for use. DNA Diagnostics Center follows this process when validating data systems and software.

7.11.2.1 Information system requirements are defined and recorded.

7.11.2.2 An assessment of the information system is performed against the requirements.

7.11.2.3 The assessment results are recorded and retained.

7.11.2.4 Information systems and software that meet the applicable requirements, as specified by DNA Diagnostics Center, are authorized for use.

7.11.3 In addition to the requirement of DNA Diagnostics Center, information systems shall conform to the following requirements of ISO 17025:2017. Information systems shall:

7.11.3.1 Be protected from unauthorized access.

7.11.3.2 be safeguarded against tampering and loss;

7.11.3.3 be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

7.11.3.4 be maintained in a manner that ensures the integrity of the data and information;

7.11.3.5 include recording system failures and the appropriate immediate and corrective actions.

7.11.4 Information systems that are managed by an external provider shall conform to the process and requirements included in Clause 7.11. of this Quality Manual.

7.11.5 Laboratory personnel are provided access to instructions, manuals and reference data that are relevant to the laboratory information management system.

7.11.6 QMS-2003: Control of Data specifies the process for validating calculations and data transfers in a systematic manner.

8. Management System

8.1 General

8.1.1 DNA Diagnostics Center's Management System is designed, documented, implemented, and maintained to fulfill the requirements of ISO 17025 and additional accrediting bodies, to ensure the quality and validity of results.

8.1.2 DNA Diagnostics Center's Management System is intended to be self-contained and conforms to the requirements of ISO 17025:2017, Clause 8.1.2 Option A.

8.2 Management System Documentation

8.2.1 DNA Diagnostics Center assumes responsibility for establishing, documenting, and maintaining policies and objectives and ensures they are acknowledged and implemented at all levels of the laboratory's organization. DNA Diagnostics Center demonstrates ownership as follows:

8.2.1.1 By documenting this Quality Manual and all referenced policies, procedures, forms, lists, etc.

8.2.1.2 By requiring all laboratory personnel to be familiar with DNA Diagnostics Center's ISO 17025 Management System. Refer to QMS-2014: Ensuring Competent Personnel.

8.2.1.3 By requiring all laboratory personnel, including members of management, to read and agree to DDC's Code of Conduct.

8.2.2 DNA Diagnostics Center's ISO 17025 Management System addresses competence, impartiality, and consistent operation of the laboratory as follows:

8.2.2.1 Competence - QMS-2014: Ensuring Competent Personnel

8.2.2.2 Impartiality - QMS-1000: Clause 4.1

8.2.2.3 Consistent Operation of the Laboratory - QMS-1000 and all referenced policies, procedures, etc.

8.2.3 Further evidence of DNA Diagnostics Center's commitment can be observed in the records collected though daily work and structured activities. Typical records include, but are not limited to:

8.2.3.1 Management Review Records

8.2.3.2 Competence Assessments in the Activity Authorization Matrix

8.2.3.3 Internal Audit Records

8.2.3.4 Preventative Actions

8.2.3.5 Corrective Actions

8.2.3.6 Customer Surveys

8.2.4 All relevant Management System documents are referenced either directly by QMS-1000: Quality Manual or indirectly through a referenced Policy, Procedure, or other documents. A complete list of Management System Documents is recorded in EIR-013: Records and Documents List.

8.2.5 Laboratory personnel are provided access to the Management System Documents and related information that are applicable to their responsibilities.

8.3 Management System Document Control Procedure

Purpose

The purpose of the document control procedure is to define the system of control for approving, issuing, changing and distributing documents that form the management system.

Scope:

The scope of documents covered by this section includes those that pertain to the management system. Refer to QMS-2020: Management System Documents for an outline of Management System documents. Note: control of data related to testing is covered under Clause 8.4: Control of Records.

Responsibility:

Quality Manager	The quality manager is responsible for document control and has the responsibility to review, control and maintain the management system documents.
Originator	Creates and modifies documents as needed.
Reviewer	Reviews and offers input in a timely manner.
Approver	Review and approves documents in a timely manner.
User	Ensures that the latest approved version of the document is being used, responds to the need for new documents and proposes changes to approved documents as appropriate.
Technical Manager:	Investigate the technical aspects of the situation and initiate changes to permanently correct the situation. Document change in the corrective action document.

8.3.1 QMS-2020: Management System Documents specifies the categories of documents in DNA Diagnostics Center's ISO 17025 Management System.

8.3.2 Document control procedure for Level 1 normative documents

8.3.2.1 The content of normative documents is externally controlled and disseminated. Refer to section QMS-2020: Management System Documents for a description of normative documents.

8.3.2.1.1 Level 1: Normative documents are maintained and disseminated by the associated organization. The controlled copies of these documents are maintained in a combination of hard copy and electronic format. The latest versions of these documents may be confirmed by accessing the associated organizations website. A complete listing of documents and their latest versions may be found in EIR-013: Records and Documents List.

8.3.3 Document Control Procedure for Level 2-5 documents

8.3.3.1 The content of level 2-5 documents is internally controlled and disseminated.

8.3.3.1.1 Level 2-5 documents are created, maintained, changed, approved, issued and disseminated in an electronic format. The electronic copy is the only controlled copy of the document. A complete listing of documents and their latest versions may be found in EIR-013: Records and Documents List. All printed copies are not controlled.

8.3.4 Document Approval and Issue

8.3.4.1 All documents in the management system shall be reviewed and approved by the Lab Director, quality manager and/or the designed deputy prior to issue. The master list of documents is contained within EIR-013: Records and Documents List used within the quality system.

8.3.5 Ensuring Document Integrity

8.3.5.1 Authorized versions of the documents are identified EIR-013: Records and Documents List. This list and all documents are available to all authorized personnel as needed.

8.3.5.2 The documents are reviewed annually and revised as needed to ensure continuing suitability with applicable requirements.

8.3.5.3 Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use.

8.3.5.4 Obsolete documents (electronic and hard copies) retained for legal or knowledge preservation purposes are suitably marked as “OBSOLETE” and stored in a quarantined area

8.3.6 Document Identification

8.3.6.1 Management system document types shall be determined based on QMS-2020: Management System Documents.

8.3.6.2 Documents shall be uniquely identified with the appropriate prefix and a three-digit suffix. For example:

QMS-XXXX	Where QMS designates a Quality Management System Procedure and XXXX represents the unique 4-digit document number.
Example:	QMS-2001 Estimating Measurement Uncertainty

8.3.6.3 Each document shall contain a change control section that includes the document version, revision date, change control comments and document and authorizer's digital signature.

8.3.6.4 Each document page shall be numbered with the current page number as well as the total number of pages within the document.

8.3.6.5 Each page of the document shall contain the document version number.

8.3.7 Document Changes

8.3.7.1 Changes to documents shall be reviewed and approved by the Quality Assurance Manager or designee. The originator of the new document or change shall provide an appropriate amount of background information in the change control comments of the document to provide appropriate context.

8.3.7.2 The altered document text or section shall be explicitly noted in the change control comments.

8.3.7.3 In general, written amendments to a controlled document are encouraged. Amendments to document by hand, prior to reissue are acceptable providing that the amendment is clearly marked, dated and initialed by the Quality Assurance Manager or designee. The Quality Assurance Manager or designee is responsible for promptly reissuing the document.

8.3.7.4 Electronically controlled documents shall be protected against inadvertent/unauthorized changes by password protecting the documents against change. The Quality Assurance Manager and/or designee shall maintain a confidential password for altering document content.

8.3.8 Notification of New or Modified Documents

8.3.8.1 A change notification, using QMS-4006: Change Notification and Review Record or electronic equivalent, is sent to all affected personnel once a new document version is authorized. The change notification and training can be a Manager review with personnel or a larger company group meeting when warranted.

8.3.8.2 The Quality Assurance Department maintains review records of change notifications

8.4 Control of Records

8.4.1 Records shall be uniquely identified, collected, indexed, disposed and stored with appropriate security to protect against breaches in confidentiality and damage. Records are located in the secure Document Center or within the designated electronic repository.

8.4.1.1 Refer to QMS-2004: Records Maintenance and Retention Procedure for a complete listing of record types, associated forms, retention times, transmission, and handling procedures.

8.4.1.2 Records shall be legible and are stored according to Clause 8.4.1.1 of this Quality Manual. This procedure was developed to prevent damage, deterioration, and loss. Retention times are assigned per according to QMS-2004: Records Maintenance and Retention Procedure.

8.4.1.3 All records are stored in a secure location as specified by QMS-2004: Records Maintenance and Retention Procedure and are accessible to authorized personnel only.

8.4.1.4 Electronic records are maintained on a secure server as specified by QMS-2004: Records Maintenance and Retention Procedure and are backed up real time and protected against unauthorized access and amendment by a secure password protected network.

8.4.2 Technical Records

8.4.2.1 The procedure for storing Technical records such as original observations, derived data, calibration records, staff records, test reports and calibration certificates are maintained based on QMS-2004: Records Maintenance and Retention Procedure.

8.4.2.2 The required information by record type is provided in the associated form. This required information shall be enough to identify sources of uncertainty and enable the test to be repeated under conditions similar to the original.

8.5 Actions to Address Risks and Opportunities

8.5.1 QMS-2022: Risks Opportunities and Actions Assessment shall be followed to identify risks and opportunities for improvement.

8.5.2 Actions to address risks and opportunities are identified in RA-002: Process Risks and Opportunities Assessment.

8.5.3 Actions shall be prioritized as specified by QMS-2022: Risks Opportunities and Actions Assessment and shall be proportional to the potential impact of the effects.

8.5.4 Plans to implement prioritized actions shall be created as specified by QMS-2022: Risks Opportunities and Actions Assessment.

8.6 Improvement

8.6.1 DNA Diagnostics Center shall regularly monitor and continuously improve the effectiveness of the management system. Monitoring activities shall include:

8.6.1.1 Quality objectives;

8.6.1.2 Customer feedback;

8.6.1.3 Complaints;

8.6.1.4 Audit results;

8.6.1.5 Proficiency testing;

8.6.1.6 Review of Corrective and Preventative Actions;

8.6.1.7 Management Review

8.6.2 QMS-2021: Customer Service specifies the periodic solicitation of customer feedback. The feedback is reviewed and used to improve the management system, laboratory activities and customer service.

8.6.3 QMS-2022: Risks Opportunities and Actions Assessment shall be followed when opportunities for improvement are identified.

8.6.4 Additions and changes to the management system are disseminated to laboratory personnel as outlined in QMS-2008: Document Change Notification.

8.7 Corrective Action Procedure

Purpose:

The purpose of the corrective action policy and procedure is to define a standard approach for identifying problems, investigating causes, implementing countermeasures, recording the results, and preventing problems from recurring.

Scope:

The Corrective Action Procedure applies to all problems identified while completing day to day tasks or performing laboratory activities. Typical problems involve deficiencies with the management system, audit findings, customer complaints and nonconforming work.

Definitions:

Countermeasure	One possible solution in a set of possible solutions to a problem.
Problem	Nonconformance with the management system, ISO requirements, test or calibration specification, accrediting body requirements or customer requirements.

Responsibility:

Lab Director	Review, approve and adjudicate corrective actions. Determine the magnitude of the error and whether work needs halted. If work was halted, notify personnel when work can resume.
Quality Manager	Evaluate need for corrective action. Maintain a record of and log of corrective actions. Verify and monitor the effectiveness of corrective actions.
Originator	Initiate and follow this procedure when solving problems within the scope of this policy.

8.7.1 A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, and feedback from customers and staff observations.

8.7.2 All personnel have the authority and responsibility for initiating a corrective action when nonconforming work (section 4.9) or departures from the policies and procedures in the management system or technical operations have been identified. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3 The originator of the corrective action shall notify the Quality Manager. The Quality Manager shall evaluate the situation and the need for corrective action.

8.7.4 Each corrective action shall be documented using QMS-4004: Corrective Action Report. Each CAR shall be uniquely identified and retained in EIR-005: Corrective Action Repository. The following naming convention shall be used for Corrective Action Reports.

CAR-YY-XXX	Where CAR designates a Corrective Action Report, YY is year and XXX represents the unique 3-digit document number.
Example:	CAR-19-003 [optional descriptor text]

8.7.5 A scientific approach to problem solving shall be used for the corrective action process. The Plan, Do, Check, Act problem solving method is preferred.

8.7.6 PLAN: The originator of the CAR shall complete a thorough root cause analysis of the problem. There are various approaches to root cause analysis that depend on the situation. The preferred approach is the "5 why" approach that addresses why the problem was caused and why the problem was allowed to persist. Effective use of this approach isolates one problem with one cause that can be turned on and off.

8.7.7 DO: Possible countermeasures shall be identified (hypotheses) and experimentally evaluated.

8.7.8 CHECK: Experimental results are evaluated against hypothesis. The quality manager or designees shall monitor the experiment for an appropriate period of time to determine if the countermeasure is effective.

8.7.9 ACT: Upon satisfactory completion of this process the appropriate steps are taken to adopt the countermeasure as new standard practice and the appropriate personnel are notified. This would include updating risks and opportunities and any required changes to the management system.

8.7.10 An additional internal audit shall promptly occur for identified activities, to ensure conformance with the management system, lab policies, ISO 17025 and our accrediting body's requirements.

8.7.10.1 ISO 17025 Note: Such additional audits often follow the implementation of the corrective actions (during the ACT process) to confirm their effectiveness. An additional audit should be necessary only when a serious risk to the business is identified.

8.8 Internal Audits

Purpose:

The purpose of the internal audit procedure is to define a standard approach and frequency for auditing the management system and laboratory activities.

Scope:

Internal audits assess the management system and laboratory activities included in EIR-022-01: Scope of Laboratory Activities.

Definitions:

Assessor	Individual conducting the audit.

Responsibility:

Lab Director	Review internal audits and ensure corrective/preventative actions are implemented.
Quality Manager	Ensure that internal audits are completed on a timely basis, at the frequency specified by the management system, by qualified personnel.
Assessor	Perform an audit of the management. Document concerns and nonconformance and supply an assessment report.

8.8.1 Internal audits of the Management System shall be performed using DDC's Quality Management System requirements, ISO/IEC 17025:2017 and accrediting body normative documents as the basis for the audit. Whenever possible, internal audits shall be conducted by an independent and impartial third party. The lab shall provide appropriate accommodations for auditing activities. Internal quality system audits shall be conducted annually between the months of March and November

8.8.2 The Quality Assurance Manager will:

8.8.2.1 Define the criteria and scope for each audit,

8.8.2.2 Plan, establish, implement and maintain the audit program

8.8.2.3 Define the frequency, methods, responsibilities, planning requirements and reporting

8.8.2.4 Will take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory and the results of previous audits when planning an audit.

8.8.2.5 Ensure that the results of the audits are reported to relevant management.

8.8.3 Internal audits of laboratory activities identified in EIR-022-01: Scope of Laboratory activities shall use the specified methods as the basis for audits of those activities and will follow the guidelines in QMS-2010.

8.8.4 Internal audits shall be surveillance type audits that adhere to a monthly rotation schedule to assure that all tests, within the scope of accreditation, are audited on a yearly basis. The schedule is recorded on IQA-4002 and archived in EIR-008: Internal Audits.

8.8.5 The Quality Manager is responsible for initiating and completing corrective and/or preventive actions per Clause 8.7. of this Quality Manual without undue delay. If nonconforming work is discovered, Clause 7.10: Control of Nonconforming Work shall be followed.

8.8.6 The results of any audit performed shall be submitted in writing to the Quality Manager, reviewed by the Lab Director or appropriate level of management.

8.8.7 A follow up audit will be conducted at the appropriate time in the corrective action process to validate effectiveness of the corrective action(s).

8.8.8 Any update in regulatory or normative guidelines will be assessed at the time of release to DDC's current documents and practices to ensure compliance.

8.8.9 Records of the Audits are located in EIR-008

8.9 Management Reviews

Purpose:

The purpose of the management review policy and procedure is to provide a standard approach and frequency conducting management reviews.

Scope:

Management reviews consider the management system and laboratory activities included in EIR-022-01: Scope of Laboratory Activities.

Responsibility:

Quality Manager	Ensure that management reviews are completed on a timely basis, at the frequency specified by the management system, with the appropriate personnel.
Lab Director	Review and evaluate the management review for completeness and the need for corrective action or revisions

Top Management	Review and evaluate the management review for completeness and the need for corrective action or revisions

8.9.1 Management reviews shall be conducted on an annual basis by the end of the second quarter.

8.9.2 QMS-4007: Management Review Form shall be used to document the management review agenda and meeting minutes. At a minimum the form shall include:

- 8.9.2.1 Changes in internal and external business environment that are relevant to the laboratory;
- 8.9.2.2 Fulfilment of objectives;
- 8.9.2.3 Suitability of policies and procedures;
- 8.9.2.4 Status of actions from previous management reviews;
- 8.9.2.5 Outcome of recent internal audits;
- 8.9.2.6 Corrective actions;
- 8.9.2.7 Assessments by external bodies;
- 8.9.2.8 Changes in the volume and type of the work or in the range of laboratory activities;
- 8.9.2.9 Customer and personnel feedback;
- 8.9.2.10 Complaints;
- 8.9.2.11 Effectiveness of any implemented improvements;
- 8.9.2.12 Adequacy of resources and training;
- 8.9.2.13 Results of risk identification;
- 8.9.2.14 Outcomes of the assurance of the validity of results and other relevant factors, such as monitoring activities and training;
- 8.9.2.15 Reports from managerial and supervisory personnel;
- 8.9.2.16 Results of interlaboratory comparisons and proficiency testing;
- 8.9.2.17 Recommendations for new improvement;
- 8.9.2.18 Quality control activities;
- 8.9.2.19 Resulting assignments;

8.9.3 Findings and resulting actions shall be recorded and completed within an appropriate timeframe. Assignment time frames shall be established during the management review.

8.9.4 Outcomes of the Management Review shall include:

- 8.9.4.1 the effectiveness of the management system and its processes;

8.9.4.2 improvement of the laboratory activities related to the fulfillment of the requirements of this document;

8.9.4.3 provision of required resources;

8.9.4.4 any need for change.

9. Authorization

9.1 This procedure has been reviewed and determined to conform with the requirements of ISO 17025, this laboratory's accrediting bodies, and the requirements of the ISO 17025 Management System. This procedure is authorized for use.

Authorization		
Approved by	Approval Date	Signature
Dr. Michael Baird	4/24/2019	

Revision Table			
Version	Effective Date	Revised by	Document Changes
V1	5/1/2019	Dr. Todd Lewis	Created new document

Quality Policy

Mission Statement

The mission and vision of the DNA Diagnostics Center laboratory is to be recognized by customers and the scientific community as the leader in providing innovative DNA Testing services. Our vision is to focus on exceeding customer expectations and deliver quality DNA services in an innovative, team-oriented environment. It is our objective to serve our clients with courtesy, professionalism and confidentiality and to provide the highest quality service and accurate testing results within the expected time frame or less.

1. Purpose

DNA Diagnostics Center (DDC) recognizes that our customers' success depends on timely, accurate, and impartial information. Providing such information depends on a commitment to our customers and our management system that is based on ISO 17025. Policies and procedures supporting the management system are provided through the quality manual and in referenced documents.

The purpose of this policy is to communicate the importance of meeting customers and other stakeholder requirements. Additionally, this policy will conform to ISO 17025, this laboratory's management system and accrediting body requirements.

2. Scope

This policy applies to the ISO 17025 Management System and includes activities performed by the testing laboratory and DDC off-site service centers.

3. Quality Policy

3.1 DDC is committed to providing customers with professional high-quality service.

3.2 To fulfill this commitment, DDC shall create, maintain, and continuously improve our management system according to the latest revision of the ISO 17025 standard and our accrediting body's requirements.

3.3 The purpose of the management system is to define a standard approach for providing the highest quality service to our customers thereby building customer confidence in the validity of results our laboratory provides. Moreover, the management system ensures continuity despite changes in personnel or management. The quality manual serves as a communication tool as well as a training tool for new employees.

3.4 Laboratory personnel must be competent to perform laboratory activities and demonstrate impartiality on a consistent basis.

3.5 It is critical that all personnel conform with the requirements of this laboratory's ISO 17025 Management System, our customer requirements, as well as the relevant regulatory authority's and accrediting body requirements. Therefore, all personnel performing laboratory activities shall be familiar with ISO 17025, customer requirements, the quality manual as well as other procedures and work instructions that affect the quality of work.

3.6 Accrediting bodies will be notified according to each accrediting body's requirements for, but not limited to:

3.6.1 Investigation of the laboratory by a government entity or adverse media attention related to laboratory performance; including any complaint investigations conducted or warning letters issued by any oversight agency.

3.6.2 When lab is subject to a validation inspection

3.6.3 Discovery of actions by laboratory personnel that violate national, state or local regulations

3.6.4 Change in laboratory test menu prior to starting a new patient testing or the laboratory permanently or temporarily discontinues some or all testing.

3.6.5 Change in location, ownership, directorship, name, insolvency or bankruptcy of the laboratory.

3.6.6 Proficiency test failure.

3.7 All promotional materials shall conform to all applicable accrediting body requirements. The C.S.O./Laboratory Director will review both written and internet promotional materials for compliance.

3.8 All testing activities shall be carried out in accordance with this laboratory's ISO 17025 Management System, stated methods and our customers' requirements. Our standard for service will exceed our customer expectations for accurate, repeatable and impartial test results.

3.9 Top management is committed to conforming with ISO 17025 and our accrediting body's requirements. We will continually assess and improve the effectiveness of this management system as appropriate.

3.10 Our commitment is demonstrated through ongoing participation in activities that assess and ensure the integrity of this system and through providing the appropriate resources. Evidence of meeting this commitment includes management review records, preventative actions, corrective actions, and customer surveys/reviews.

4. Departures from the Management System

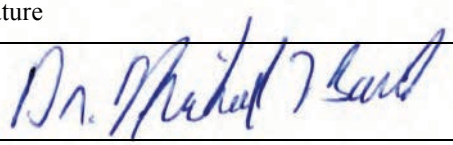
4.1 Although DDC is committed to making reasonable attempts to prevent and minimize departures from the management system, procedures, methods, and customer requirements, we recognize that departures will occasionally occur. Therefore, it is our policy that any departures shall be explicitly documented and promptly reported to the appropriate stakeholders including accrediting bodies.

4.2 If appropriate, the cause for departure shall be reported and investigated. Corrective or preventive actions shall be recorded and implemented to prevent future departures.

4.3 Every member of the laboratory is responsible for following the quality assurance plan as outlined in QMS-1000. Quality assurance training is completed during Orientation and specific procedural quality control is completed during procedural training, if applicable.

5. Authorization

5.1 This procedure has been reviewed and determined to conform with the requirements of ISO 17025, this laboratory's accrediting bodies, and the requirements of the ISO 17025 Management System. This procedure is authorized for use.

Authorization		
Approved by	Approval Date	Signature
Dr. Michael Baird	4/24/2019	

Revision Table			
Version	Effective Date	Revised by	Document Changes
V1	5/1/2019	Dr. Todd Lewis	Created new document

Attachment #7

Sample Statistical Report

DNA Diagnostics Center

Nebraska Monthly Statistics

Month October Year 2019

County	Samples	Caess Reported	Inc	Exc	% Exc	AVG TAT	Re-Use Samples	Re-Collects
Buffalo County Attorney CS Office NE	12	4	2	2	50%	3.0	0	0
Custer County Attorney's Office - CSE	6	2	2		0%	2.0	1	0
Dawson County CSE	3	1		1	100%	2.0	0	0
Dodge County CSE Office	12	4	3	1	25%	2.0	0	0
Douglas-Omaha County CSE	141	47	40	7	15%	2.0	15	0
Gage County Attorney, CSE NE	3	1		1	100%	3.0	0	0
Hall County Attorney's Office CSE	21	7	7		0%	3.0	2	0
Hastings HHS Child Support-NE	30	10	8	2	20%	2.0	0	0
Jefferson County HHS NE	15	5	4	1	20%	2.0	1	0
Johnson County Attorney's Office	3	1	1		0%	3.0	0	0
Lancaster Co Attorney's Office	21	7	5	2	29%	3.0	2	0
Lincoln-DHHS CSE NE	72	24	15	9	38%	2.0	11	0
Norfolk CSE	21	7	6	1	14%	2.0	0	0
North Platte-DHHS CSE NE	18	6	4	2	33%	2.0	3	0
Phelps County	3	1		1	100%	2.0	0	0
Sarpy County Attorney	6	2	1	1	50%	3.0	0	0
Sarpy-DHHS-CSE NE	3	1	1		0%	5.0	0	0
Saunders County CSE	12	4		4	100%	2.0	2	0
Scotts Bluff County Child Support NE	18	6	6		0%	2.0	0	0
Winnebago Tribe of Nebraska	3	1	1		0%	2.0	0	0
Totals	**423**	**141**	**106**	**35**	**25%**	**2.45**	**37**	**0**

Attachment #8

Direct Connect User Manual

DNA Diagnostics Center

DDC Direct Connect

DDC Direct Connect: Overview

DDC Direct Connect is DDC's online case management system which provides a means of accessing DNA testing information.

DDC Direct Connect
contracts.dnacenter.com

Added Features:

- Single login for Case status, DNA test reports, documents and scheduling
- Simplified navigation
- Excellent searching capability
- Interactive Retest Authorization process

DDC Direct Connect: Home Page

DNA Diagnostics Center

DNA Diagnostics Center

1-800-310-9868

Direct Connect Login

Home | About Us | Laboratory | Resources

Government Contracts

DDC Direct Connect

DDC's online case management and tracking system. This real time interface provides access to the following:

- Case Status and Appointment Information
- eDocuments Download.
- Scheduling Request Entry
- Retest Authorization
- Online Supply Order
- Access to Specimen Collection Manual
- Agency Account Summary Information

All of the above are accomplished with one log in. Access will be set by DDC and requires an individual user ID and password entry, thus ensuring the confidentiality of stored data.

Log into the DDC Direct Connect Portal with username and password.

Login Now

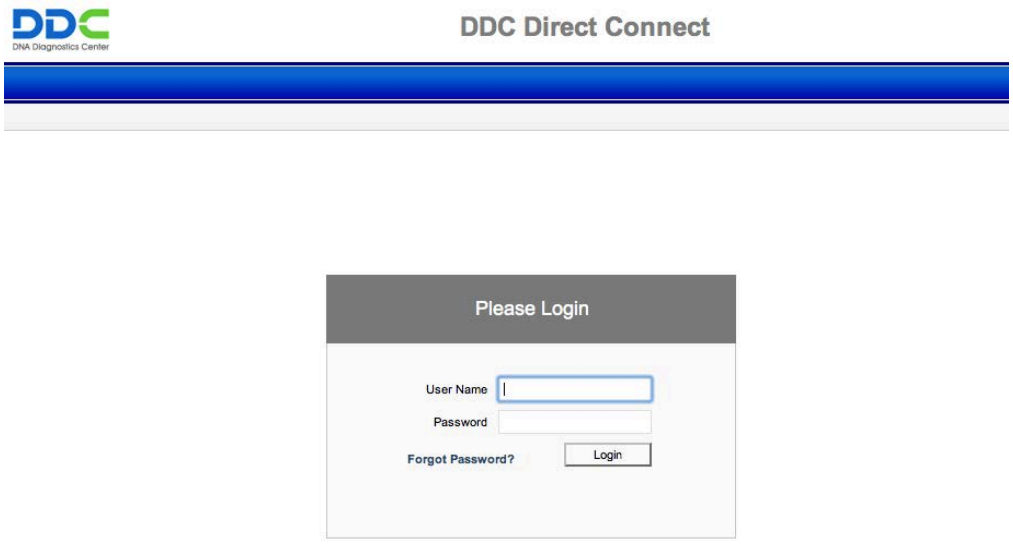
308

DDC Direct Connect: Login

Enter User ID and Password received in your Welcome email into the appropriate fields on the login page.

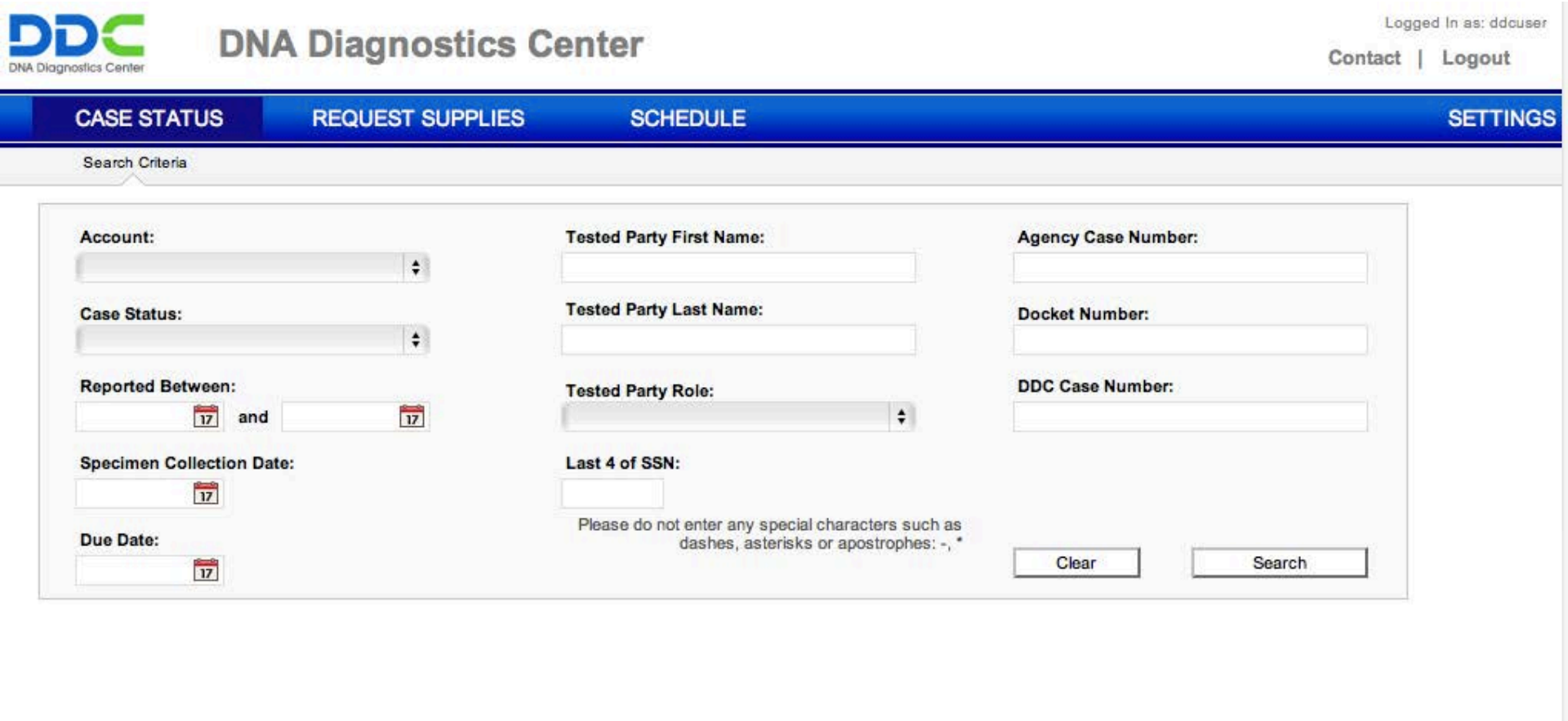
Note: User ID and passwords are case sensitive.

- On the first login, a window will prompt to reset your password. This is a new security feature for enhanced protection of your account. Please follow all steps. All passwords must contain 6 characters, at least one letter and one number and a special character such as *, $ or #.



DDC Direct Connect: Case Status / Search Criteria

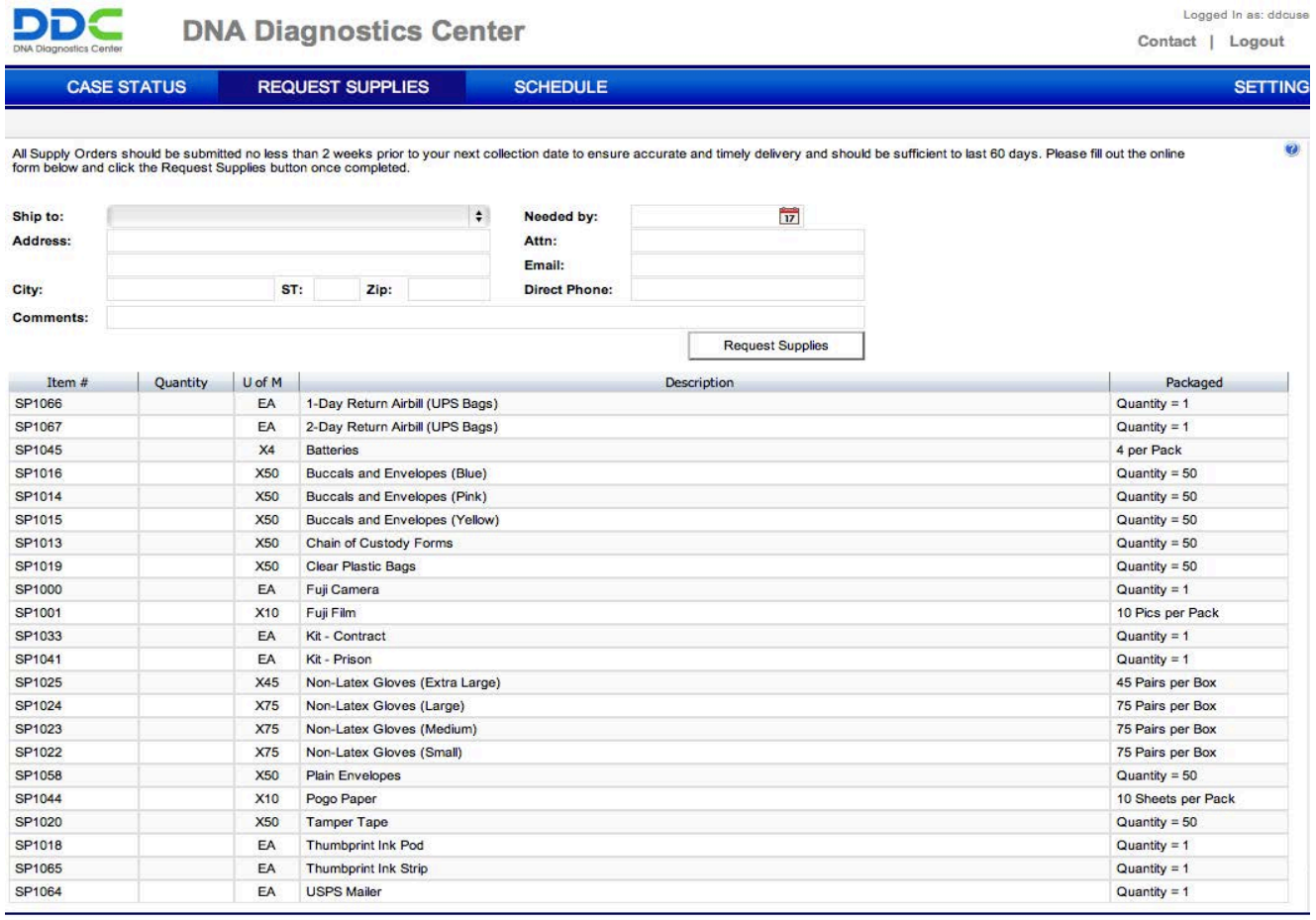
Tested Party and Case Information can be searched from the Case Status Screen. Searches are performed by entering the data and clicking on the Search button. A minimum of one search criteria is needed to perform a search.



DDC Direct Connect: Request Supplies

The **Request Supplies tab** allows access to order your supplies online.

Fill out the fields located at the top portion of the online form, enter the items needed and click "Request Supplies".



DNA Diagnostics Center

Logged In as: ddcuse

Contact | Logout

CASE STATUS | REQUEST SUPPLIES | SCHEDULE | SETTING

All Supply Orders should be submitted no less than 2 weeks prior to your next collection date to ensure accurate and timely delivery and should be sufficient to last 60 days. Please fill out the online form below and click the Request Supplies button once completed.

Ship to: | Needed by:
Address: | Attn:
Email:
City: | ST: | Zip: | Direct Phone:
Comments:

Request Supplies

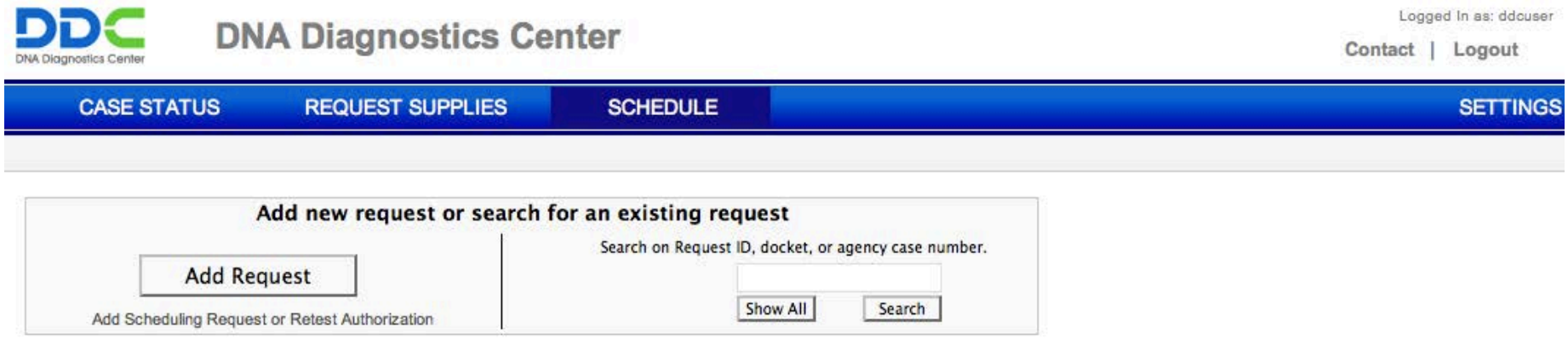
Item #	Quantity	U of M	Description	Packaged
SP1066		EA	1-Day Return Airbill (UPS Bags)	Quantity = 1
SP1067		EA	2-Day Return Airbill (UPS Bags)	Quantity = 1
SP1045		X4	Batteries	4 per Pack
SP1016		X50	Buccals and Envelopes (Blue)	Quantity = 50
SP1014		X50	Buccals and Envelopes (Pink)	Quantity = 50
SP1015		X50	Buccals and Envelopes (Yellow)	Quantity = 50
SP1013		X50	Chain of Custody Forms	Quantity = 50
SP1019		X50	Clear Plastic Bags	Quantity = 50
SP1000		EA	Fuji Camera	Quantity = 1
SP1001		X10	Fuji Film	10 Pics per Pack
SP1033		EA	Kit - Contract	Quantity = 1
SP1041		EA	Kit - Prison	Quantity = 1
SP1025		X45	Non-Latex Gloves (Extra Large)	45 Pairs per Box
SP1024		X75	Non-Latex Gloves (Large)	75 Pairs per Box
SP1023		X75	Non-Latex Gloves (Medium)	75 Pairs per Box
SP1022		X75	Non-Latex Gloves (Small)	75 Pairs per Box
SP1058		X50	Plain Envelopes	Quantity = 50
SP1044		X10	Pogo Paper	10 Sheets per Pack
SP1020		X50	Tamper Tape	Quantity = 50
SP1018		EA	Thumbprint Ink Pod	Quantity = 1
SP1065		EA	Thumbprint Ink Strip	Quantity = 1
SP1064		EA	USPS Mailer	Quantity = 1

Scheduling Requests

To enter a new scheduling request, click on the Schedule Tab on the navigator bar.

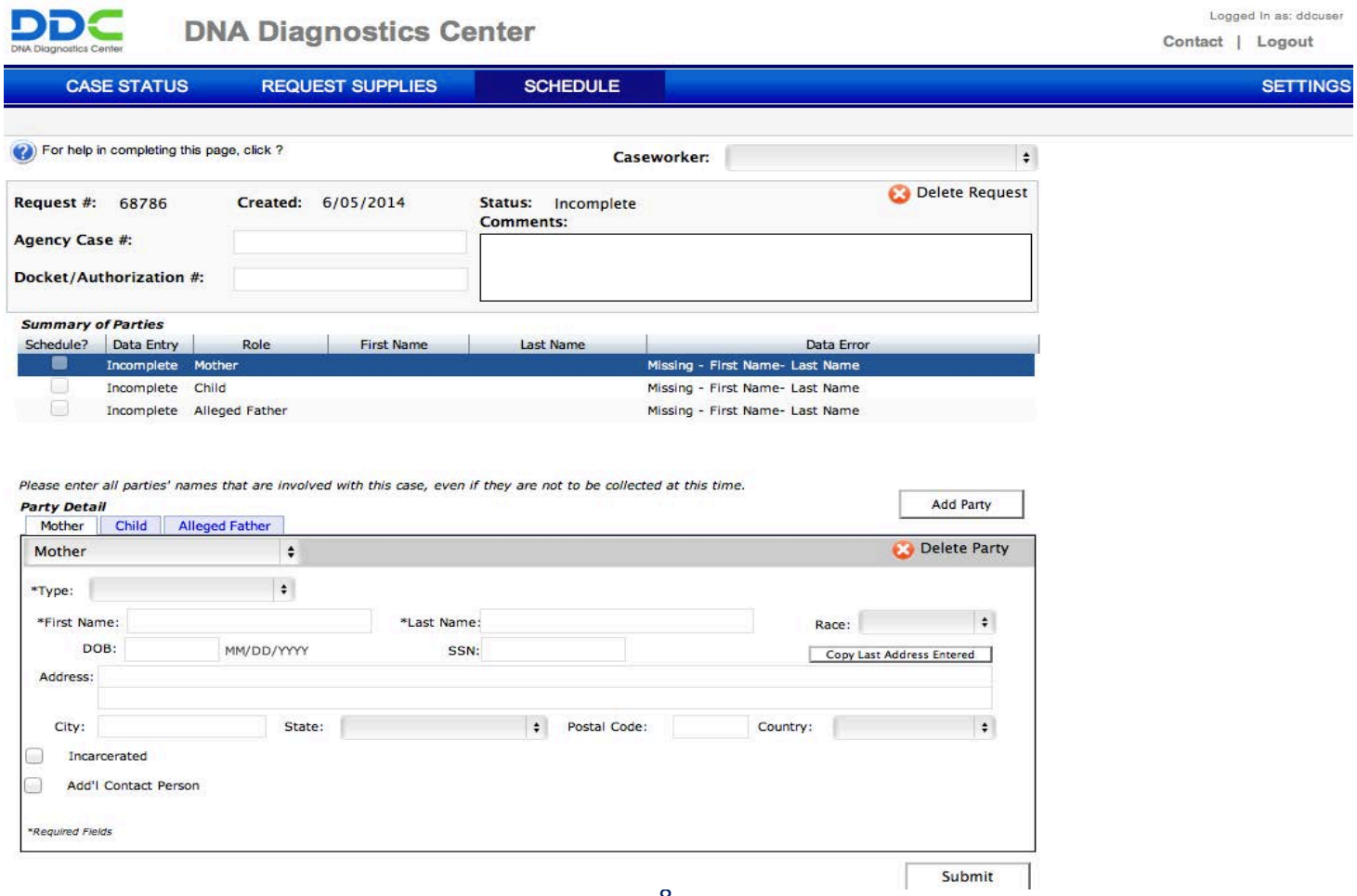
On this screen, you can add a new request or search for an existing one. Under "Add Request", you have the ability to add a new request and/or request a Retest Authorization on a previously tested sample.

If you have access to multiple agencies, after clicking Add Request, you will be prompted to choose the requesting agency.



Scheduling: New Request

To enter a new request, fill in all appropriate information starting with the Agency Case Number and/or Docket number. All required fields are marked with an asterisk (*). If required fields are missing, the request will not be submitted. A pop up message will appear indicating what information is missing.



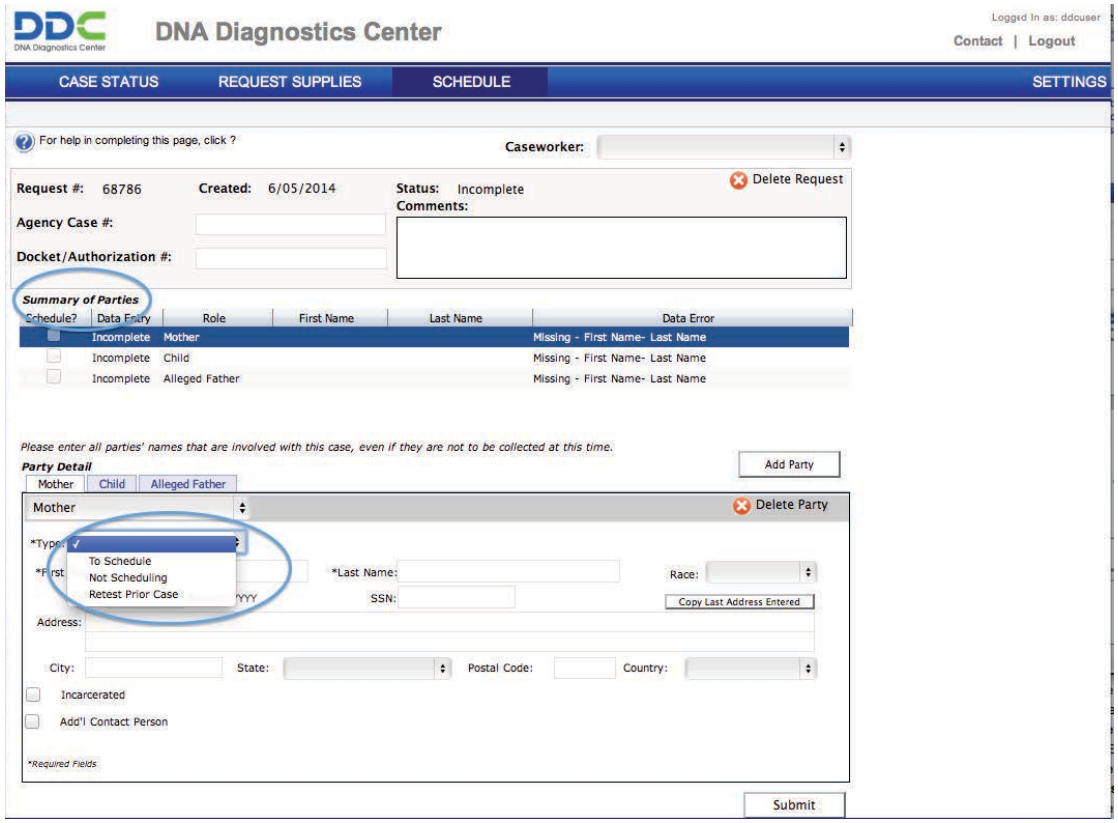
Scheduling: New Request

The Summary of Parties information is READ ONLY and will update as the Party Detail is completed. There are 3 types of requests for each tested party:

1.To Schedule: This should be selected when DDC is scheduling the appointment (interstate cases or institutional collections).

2.Not Scheduling: This should be selected when DDC is not scheduling the appointment so that we have the complete case information for each party.

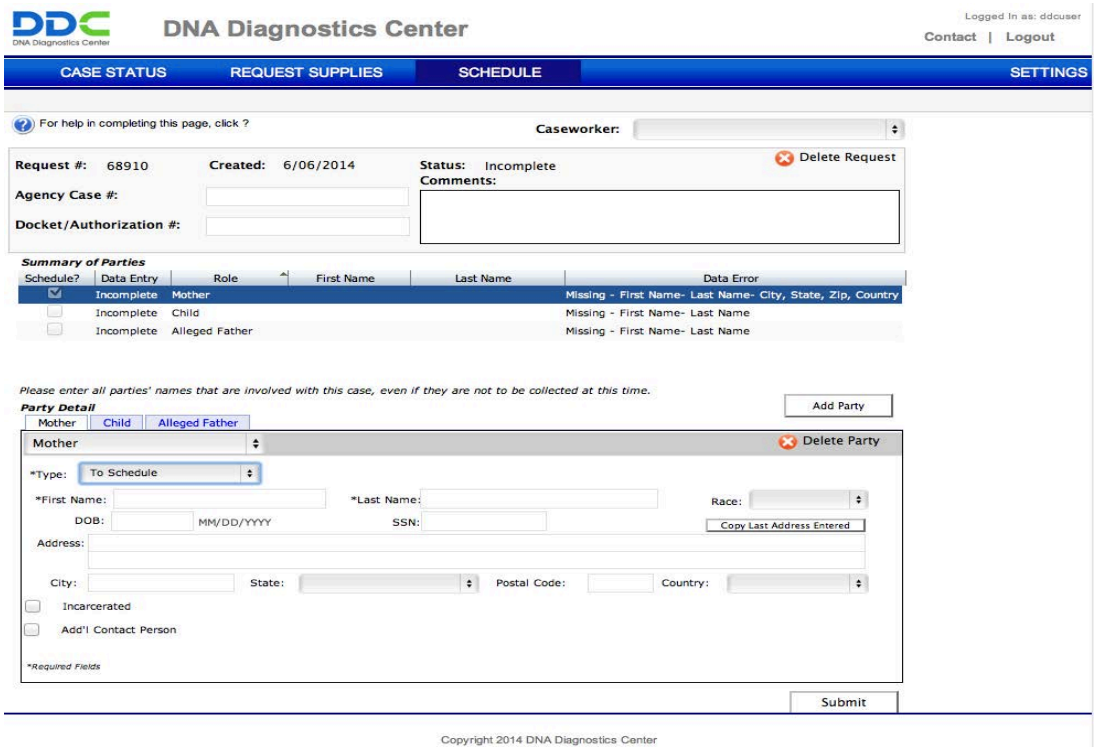
3.Retest Prior Case: This type should be chosen when requesting that a previously tested sample be used rather than collecting a new sample



Scheduling: To Schedule

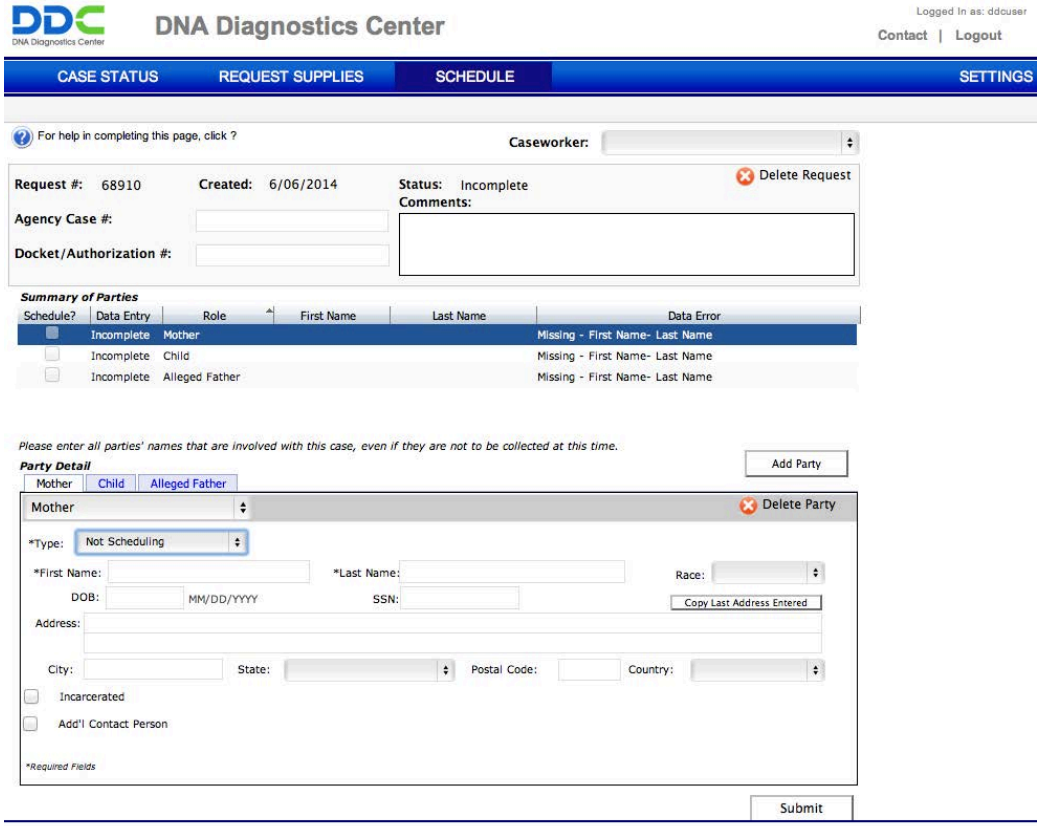
Enter all client information such as name, race, date of birth and social security number (if applicable)

1. Enter Address information - When providing address information for the child, if it is the same address as the mother, select "Copy Last Address Entered" and the system will auto-populate that information
2. Indicate if this tested party is Incarcerated. If so, additional information will appear to enter the Correctional Facility in which they are located, Inmate Number, and release date.
3. Click Submit



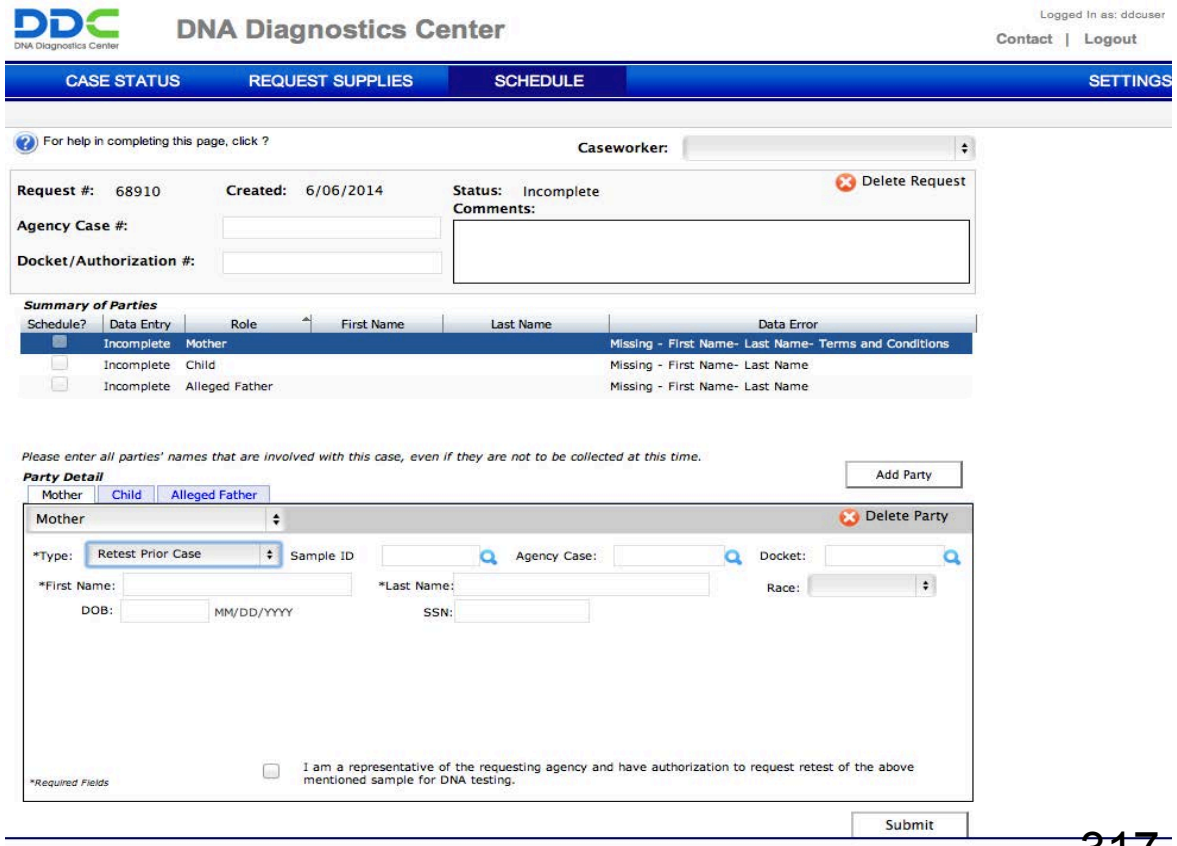
Scheduling: Not Scheduling

1. Although DDC may not be scheduling the appointment for a particular tested party, we still need the information for the case. Having this information ensures that DDC knows who to test in each case.
2. Enter all client information such as name, race, date of birth and social security number (if applicable)
3. Address information is not required for an individual that DDC is not scheduling
4. Click Submit



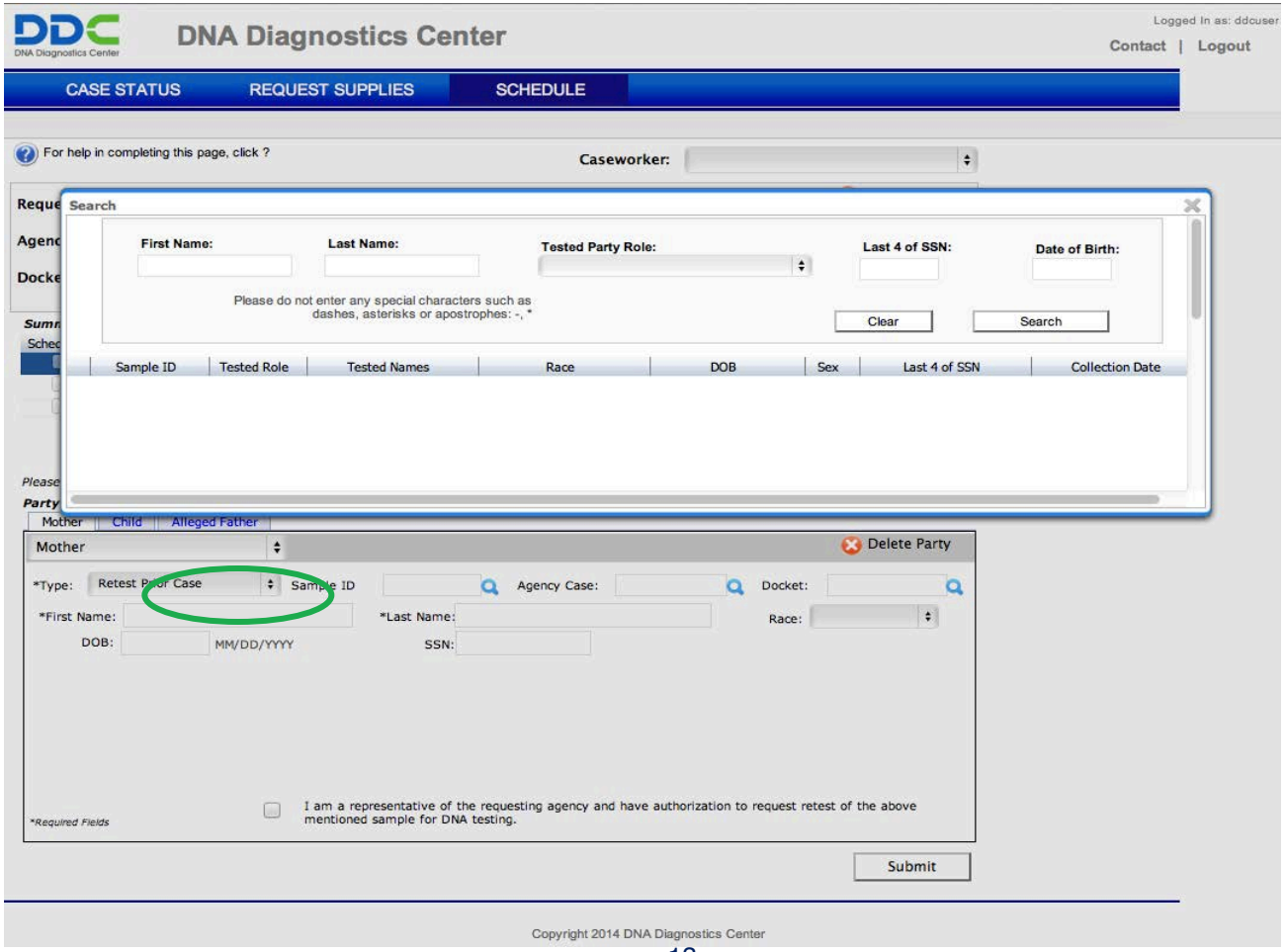
Scheduling: Retest Prior Case

1. Rather than recollecting an individual, DDC can use the DNA profile from a previously tested sample (where permitted by contract)
2. A tool is provided to search for a previously tested client by searching for the previous Sample ID, agency case number or docket number
3. Client Information will auto-populate when the sample has been found in our system.
4. Address information is not required, or displayed, as DDC will not be scheduling a DNA collection



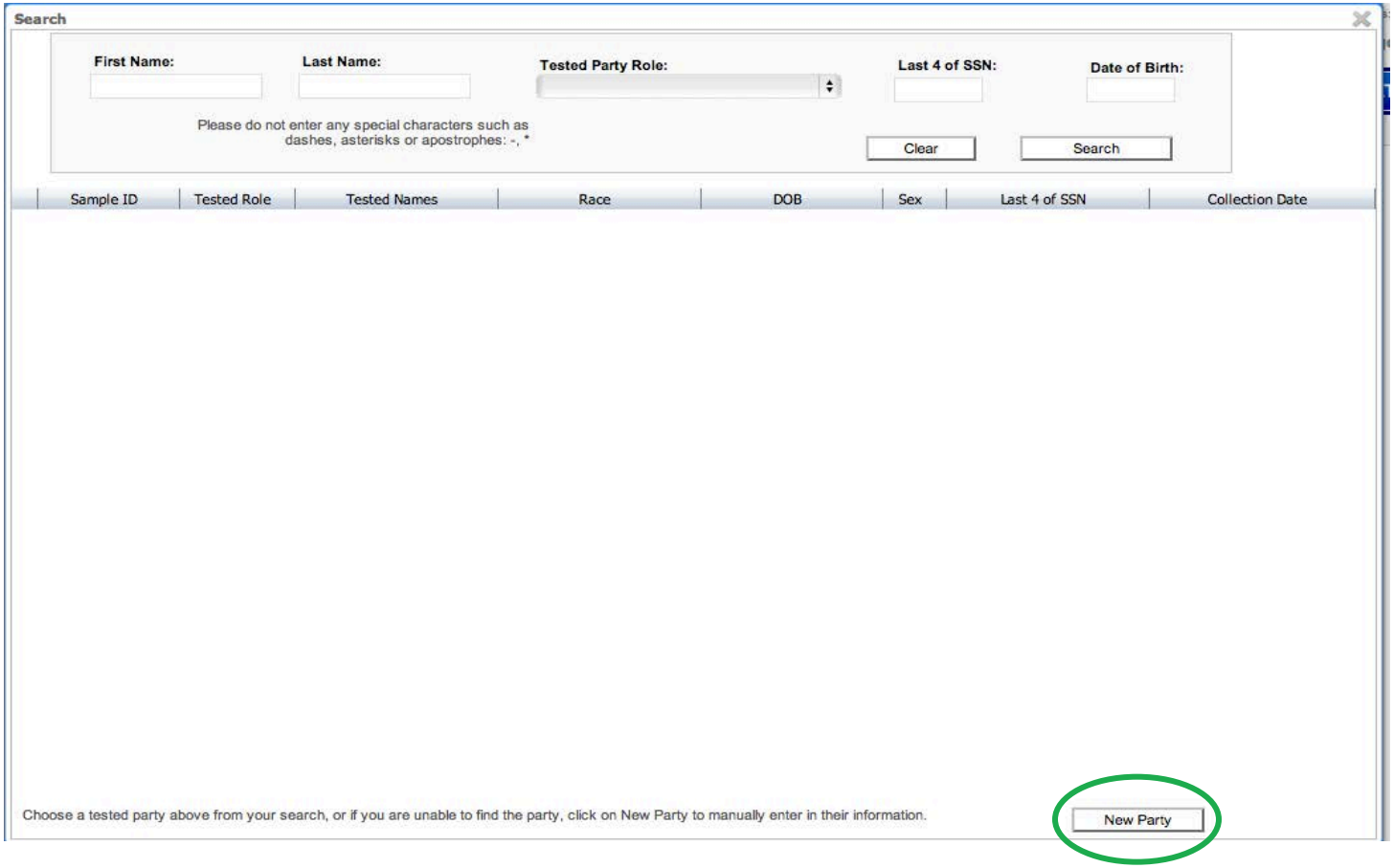
Scheduling: Retest Prior Case

1. Choose Retest Prior Case
2. Search by Sample ID, Agency Case Number or Docket Number
3. Click on the magnifying glass icon to show the search screen
4. Attached is a search by Sample ID
5. Enter First and Last Name, Tested Party Role, Last 4 of SSN, and/or Date of Birth



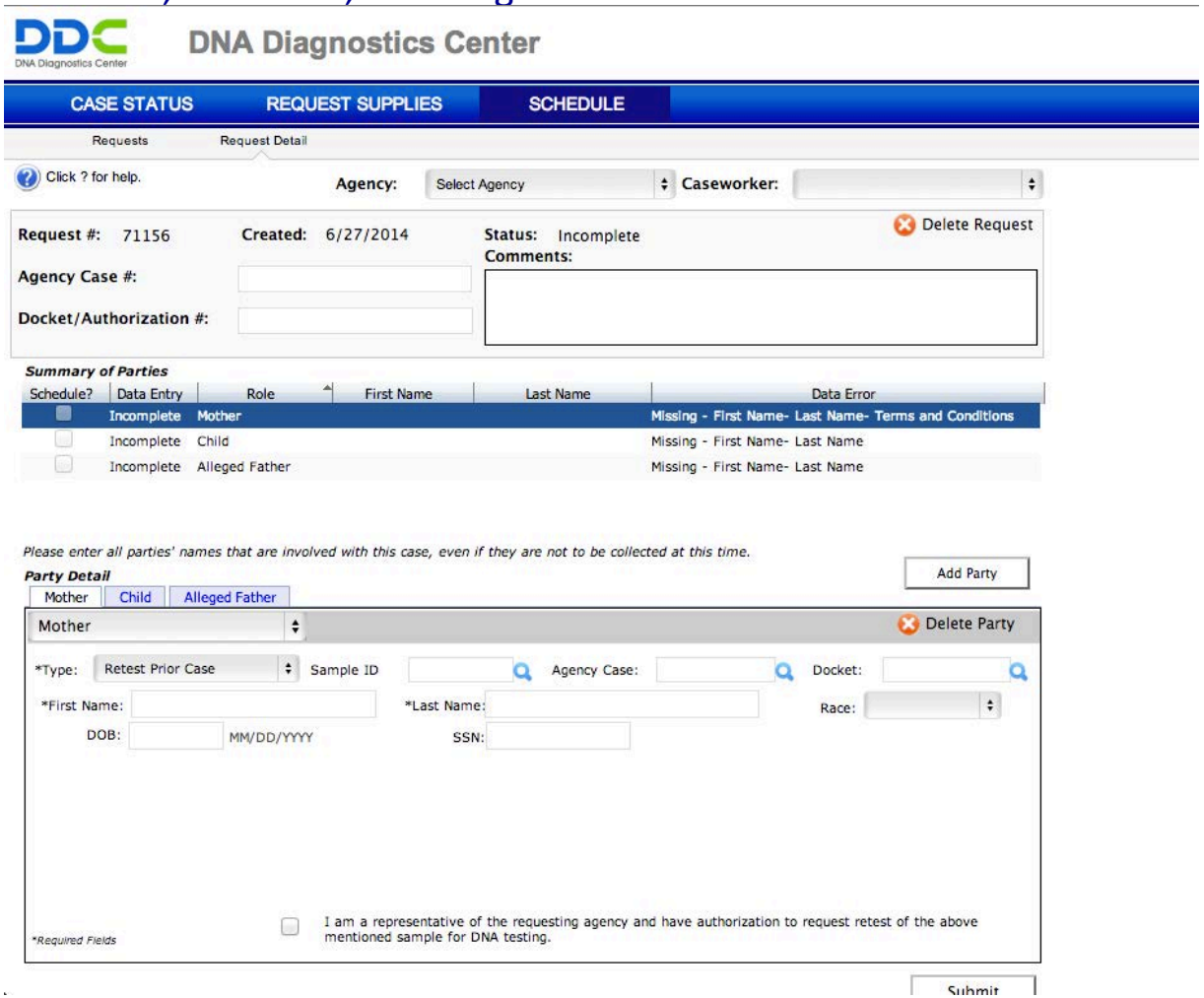
Scheduling: Retest Prior Case

If you are unable to locate a previously tested sample, there is an option to add this person by clicking "NEW PARTY" at the bottom of the page. This will allow you to manually add the person's name, date of birth, social security number, etc.



Scheduling: Retest Prior Case

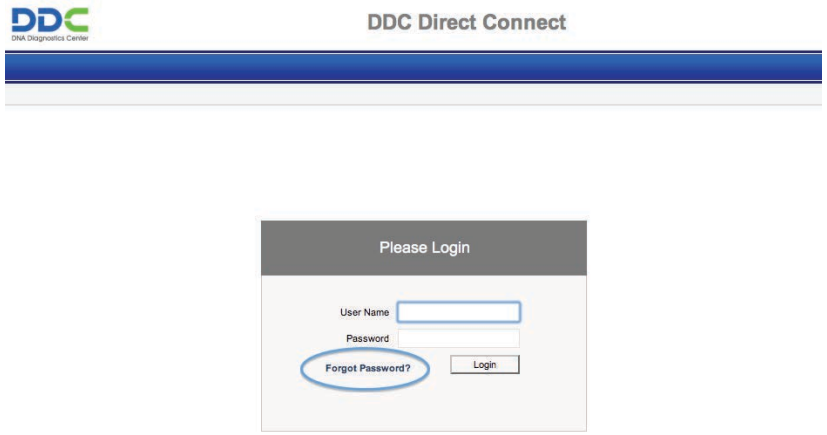
If your search is by Agency Case Number, you will find the appropriate case and select into your request. At this point, you have chosen the case but not the person to retest. To find the person needed, click in the Sample ID field to show all individuals tested within that case. The sample ID's are as follows: -10: Mother, -20: Child, -30 Alleged Father.



Password Reset

Expired Password: Every 90 days the system will require a new password. Upon the first login after 90 days has passed, a prompt will indicate "Your password has expired. Please enter a new password below." Once the existing password is entered and confirmed, a message will prompt you to enter your user name and new password.

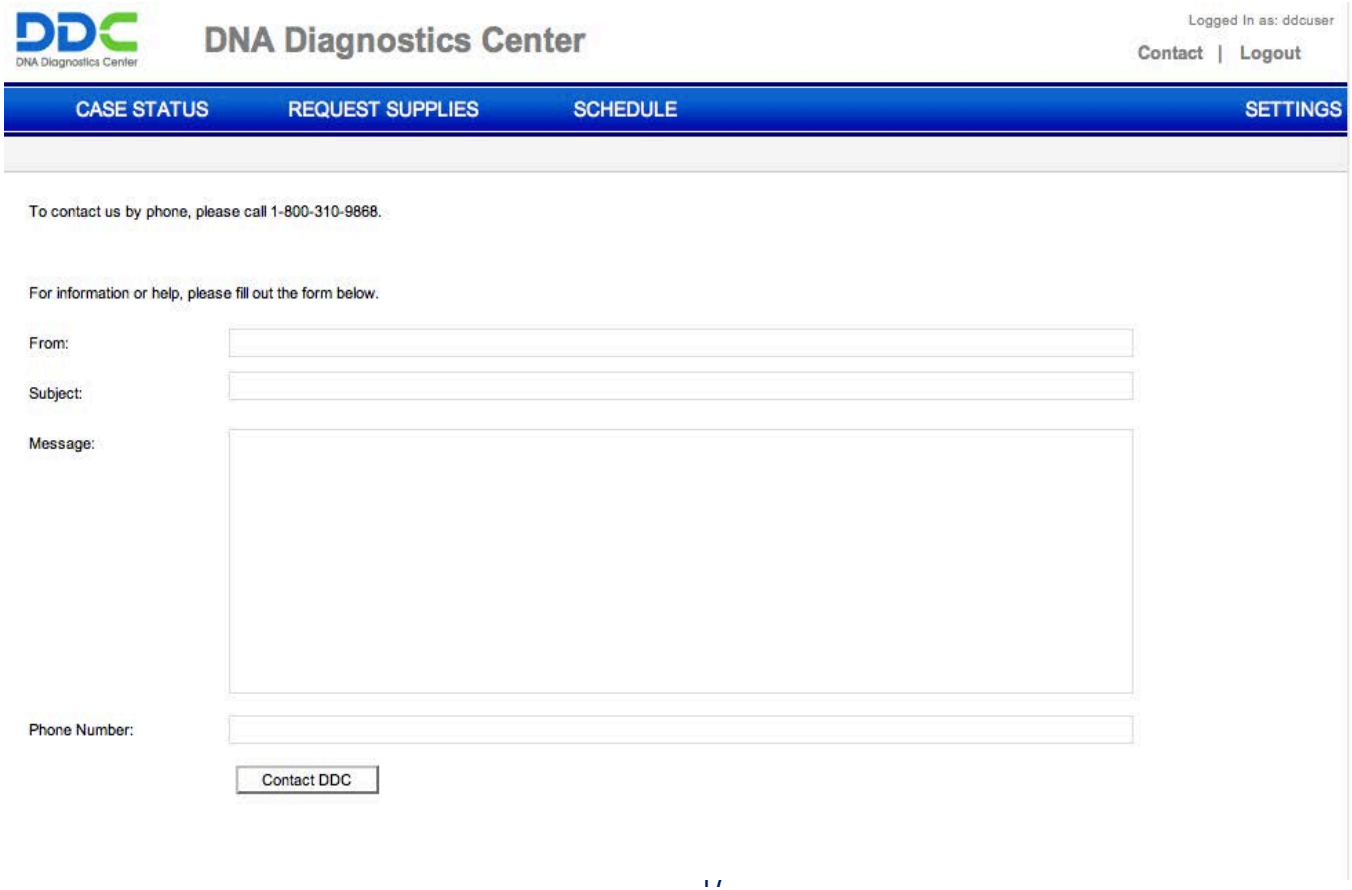
Forgot Password: This option will prompt you to enter your Email/User Name and the system will send an email with a link to reset your password.



Contact: Email

Enter the following information:

1. FROM field: Enter your Email address
2. SUBJECT field: Enter Subject
3. MESSAGE field: Enter your questions or concerns into the body of the email.
4. Click the CONTACT DDC button.



Summary

For questions about the new website, please contact us at **1-800-310-9868**.

We are available **Monday-Friday, 8:00am – 8:00pm Eastern Time.**