

RFP 23-74828
TECHNICAL PROPOSAL
ATTACHMENT F

Technical Proposal

Instructions: Please supply all requested information in the areas shaded yellow and indicate any attachments that have been included. If a question does not apply to the solution being proposed, please answer the question N/A. Document all attachments and which Section and question they pertain to in Attachment F. DCS is expecting creative cost saving solutions from all of the Respondents in an effort to distinguish the best partner(s) to select. All Service Level Requirements are listed within Attachment K. Pages 8-19.

1. Respondent will provide AABB accreditation for past two years.

Labcorp is accredited for parentage testing by the AABB and adheres to its most current *Standards for Relationship Testing Laboratories*. Labcorp holds all applicable licenses and certifications required to perform parentage testing throughout the United States. A partial list of credentials follows:

- AABB
- Interstate Laboratory License (CLIA)
- College of American Pathologists (CAP)
- State of New York Department of Public Health licensure
- ISO/IEC 15189:2012 by ANSI National Accreditation Board

Labcorp has staff members who belong to AABB committees thus staying abreast of the revisions to standards, which further speaks to Labcorp's experience in providing genetic parentage testing services. In fact, the immediate past chair of AABB's relationship testing committee is our Laboratory Director, Dr. George C. Maha. In addition, the current chairperson of the AABB Relationship Testing Standards Committee is Dr Megan Shaffer, one of our technical directors. Labcorp reviews all standards at the time each new edition of standards is released, as well as part of both internal and external inspections. Labcorp has a quality assurance program and a quality assurance officer to monitor the aspects of care and quality control. Continuing education is also important for all staff and may take the form of attending meetings, on site speakers, webinars and journal review. Based on these criteria Labcorp meets and/or exceeds the latest standards.

A brief description of the accreditation agencies is as follows:

AABB, Association for the Advancement of Blood & Biotherapies, formerly known as the American Association of Blood Banks, is the premier agency accrediting relationship laboratories. It has two committees working on relationship matters. One is a Relationship Testing Standards Committee that updates the standards at regular intervals to update existing standards and to incorporate new scientific and quality principles. The second committee is the Relationship Testing Accreditation Committee, which is involved in accreditations and provides assessors and answers questions that may arise about standards during an inspection. AABB is considered an approved accreditation body pursuant to 42 USC 666(a)(5)(F)(i)(I) for paternity testing by the United States Secretary of Health and Human Services. AABB also accredits laboratories for a number of medical tests. AABB periodically sends on site inspectors to evaluate Labcorp's paternity testing.

Clinical Laboratory Improvement Amendments (CLIA), as a clinical laboratory each of Labcorp's laboratory facilities maintains this certification. The CLIA certification is administered by the Centers for Medicare and Medicaid Services (CMS). CLIA provides the necessary documentation and standards on the expected performance of certified laboratories. This division performs Histocompatibility testing for clinical purposes and thus maintains this certification as well.

The College of American Pathologists (CAP), inspects all of the DNA Identity Division's testing categories. CAP inspectors, like other organizations, review the laboratory for compliance with CAP standards including pre-analytic, analytic and post-analytic phases of the testing process. CAP also provides a widely utilized relationship testing proficiency testing program, in which Labcorp participates.

State of New York Department of Public Health, also specifically inspects Labcorp's parentage testing as well as other testing categories. This is a rigorous process with multiple inspectors evaluating all aspects of the testing process.

ISO/IEC 15189 by ANSI-ASQ National Accreditation Board/FQS, the general requirements for the competence of testing and calibration laboratories. This accreditation is recognized internationally. ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standards. Labcorp is accredited to ISO/IEC 15189 by ANSI-ASQ National Accreditation Board/FQS. Like other accreditation agencies, ANAB sends a team of inspectors to review all aspects of Labcorp's testing, including parentage/relationship testing.

Copies of Labcorp's accreditation certificates/licenses covering the last two years are provided as **Attachment ONE**.

Labcorp will maintain its accreditation as a parentage testing laboratory during the term of the contract.

Labcorp understands that the related liquidated damages for this service level

requirement is (A) Mandatory to maintain the contract.

2. Respondent will affirm agreement to offer equal level of services in every county and briefly describe how large, medium, and small counties' sample collection needs will be met.

Labcorp will provide appropriate genetic testing services to all Indiana counties, regardless of size or location. Labcorp will conduct genetic testing services for the collection of genetic material for all 92 DCS offices, or as requested by a DCS office, at locations and schedules that meet the individual needs of the county. Currently Labcorp provides services to sixty-three (63) DCS offices. Labcorp will promptly provide information outlining our experience and services to any county upon request and will enter into a standard County-Vendor Agreement if a county so chooses Labcorp.

Labcorp maintains, exclusively for the use of its clients, more than 2,000 company-operated Patient Service Centers conveniently located throughout the United States with twenty-four (24) located in Indiana. Through this support system Labcorp provides a variety of specimen collection, client support, and patient services. Our large network of laboratory facilities allows Labcorp to deliver effective and dependable daily service, which is also supported by our extensive courier services. Labcorp also utilizes a large database of over 11,000 alternate sample collection locations worldwide. In total, Labcorp has access to over 13,000 collection sites from which it can satisfactorily service the State accommodating more than the collection needs of this contract, regardless of a county's size. Labcorp's collection site resources include, but are not limited to, our 2,000 company-operated Patient Service Centers, prisons, US Embassies, US Military installations and hospitals. More importantly, Labcorp has extensive experience in scheduling persons for collection in these various sites. Labcorp has a dedicated staff to help with the State's specimen collection needs, including Labcorp's IdentiLinkSM web based computer system.

Labcorp will work with each individual DCS county office to assess and determine their collection needs, whether it is a small, medium or large County. The Regional Account Manager will work with each office to determine location, frequency of Lab collect services. If the DCS office would like training on staff collection on buccal swab collection, the Regional Account Manager will provide training and supplies for each requesting office.

As a current vendor, providing genetic testing services in the State, Labcorp has a clear understanding of the services and requirements as specified in the RFP as these services are currently being performed successfully. Additionally, Labcorp provides genetic testing services to other Agencies, Attorneys and or clients throughout Indiana. As such, Labcorp has established, and maintains, a staff of certified and properly trained individuals to perform sample collections, as well as alternate collection sites throughout the state. Therefore, choosing Labcorp for the upcoming

contract would ensure a seamless transition. Labcorp performs DNA probe analysis on every case received at its testing facility and currently provides a certified report containing the test results in electronic and hard copy formats, including the chain of custody form, as required by the RFP. Labcorp supplies a monthly invoice paper copy format and will work with the State on the implementation of electronic invoicing. Labcorp performs all testing in strict accordance with the most current *Standards for Relationship Testing Laboratories* as published by the AABB, and has been inspected and accredited by the AABB continuously since 1987. Labcorp performs DNA testing using only validated techniques and procedures that are commonly accepted within the scientific and legal communities and are accepted by the agencies accrediting our operations including AABB, and the College of American Pathologists (CAP).

Labcorp understands that the related liquidated damages for this service level requirement is (A) Mandatory to maintain the contract.

3. Describe steps the Respondent will take to ensure the larger counties have weekly scheduled times available for collecting samples, and how much advance notice Respondent requires to cancel collection appearance if no parties are scheduled for testing that week.

Upon award, Labcorp's Account Manager, Ms. Marjorie Loy, will contact each of the 92 County DCS offices to coordinate the collection location and schedule that meets their individual needs. Labcorp shall work with the larger counties to have weekly scheduled times available for sample collection. Labcorp tailors the services around the needs of our clients. The county size will not alter our process for establishing the collection needs of each county DCS office. As a current vendor, Labcorp has established collection locations and schedules for the counties we service. A collection schedule for those counties is provided as **Attachment TWO**.

A list of Labcorp's current Patient Service Centers in the State of Indiana is provided as **Attachment THREE**.

In the counties where there are no parties scheduled for testing in a given week, Labcorp desires a twenty-four (24) hour notice to inform all concerned of the cancellation.

Labcorp understands that the related liquidated damages for this service level requirement is (B) a general standard and will result in CAP/invoice reduction.

4. Describe the factors that are involved in site selection; identify who maintains county list of sites and who obtains a new site if previous site is no longer available; if an existing Vendor, attach current collection sites in counties where services are currently provided.

Labcorp considers a number of things when selecting a site to perform specimen collections; such as: the needs of the client (larger client volume may require a larger site); geographical location; cleanliness; handicap accessibility; public restroom access; rental fees, if applicable, easily accessible, well lighted and safe. Ms. Loy, Account Manager, will coordinate with the County DCS offices to finalize the selected location to ensure their individual needs are met. All collection sites are maintained by Ms. Loy. Should a new site be required she will work with the County DCS office to secure a new approved site and maintain a current list.

Labcorp maintains twenty-four (24) company-operated patient service centers throughout Indiana. Should a new site be needed a Labcorp employee can perform an on-site inspection to determine its feasibility prior to utilization.

As a current vendor, Labcorp has established drawsites throughout in the counties it presently services. A copy of the drawsites for these counties is provided as **Attachment FOUR**.

Labcorp understands that the related liquidated damages for this service level requirement is (B) a general standard and will result in CAP/invoice reduction.

5. Describe steps Respondent takes to ensure the safety of the parties, those waiting for collection, and the collector.

Labcorp routinely schedules the alleged father at a different time from the mother and child. This helps to ensure the safety of everyone, especially in cases where the mother and alleged father are not amicable.

Labcorp understands that the related liquidated damages for this service level requirement is (B) a general standard and will result in CAP/invoice reduction.

6. Describe steps Respondent takes to ensure the confidentiality of the parties during sample collection and release of the test results.

Labcorp is in full compliance with all federal, state and local statutes, regulations and ordinances. Labcorp agrees to protect the confidentiality of any information obtained in the course of providing services under this agreement. Such information shall only be used to the extent necessary to assist in the valid administrative needs of the child support program, and shall not be disclosed without prior written approval of the State or as required by law or regulation.

Labcorp's policy and procedures for maintaining records and genetic testing samples begins with confidentiality. All records and samples are maintained in a card entry secured facility. Once received in the laboratory, the records and samples are stored in rooms that are also secured by card entry reader with limited access. Labcorp's

computer records are also similarly password protected, with various authorization levels. Not all employees have complete access to the records, either paper or computer. As part of Labcorp's quality control program, the access is monitored and a list is maintained of the personnel who have accessed the records and samples. The records include both entry to computer files and entry to the rooms where the paper records and samples are maintained. The location of each paternity case is tracked using a bar coded computer system. This enables authorized Labcorp personnel to quickly locate any file that may be needed and to track the personnel who move a case file through the laboratory during the testing process. Labcorp routinely maintains the paper records as well as any unused samples routinely for seven (7) years and a minimum of five (5) years. Longer storage is negotiable. At the end of the required retention period all records are purged and shredded using a certified shredding agency. The shredding agency provides a certificate of destruction for the records and samples. After the required retention period the computer records are also purged.

Labcorp's Confidentiality Policy is reviewed with each new employee. Additionally, as a condition of continued employment, employees may periodically and/or as appropriate be required to sign all agreements and policies such as, Confidentiality Agreement. Failure to abide by these agreements or policies will result in corrective action, up to and including termination. The DNA Identification Testing Division requires all employees to sign a Confidentiality Agreement on an annual basis. A copy of this Confidentiality Agreement is provided in **Attachment FIVE**. The DNA Identification Testing Division also requires specimen collectors to sign a confidentiality agreement, a copy of the Specimen Collector Confidentiality Agreement is provided in **Attachment SIX**.

Labcorp's Client Authorization/Chain of Custody Form is enhanced with a feature that provides protection of privacy to the persons collected. On Labcorp's collection form the front contains basic information such as addresses, names and date of birth of the parties collected. The back of the form is a chain of custody form that provides for the certified documentation of chain of custody. In order to protect the privacy of the individuals, the form peels apart so, if needed, the demographic information on the front can be separated from the chain of custody information on the back. This is particularly useful for protecting Indiana citizens when there is a need to prevent a party to the case from obtaining demographic information on another person in the case. The use of this feature is at the discretion of the State.

The DNA Identification Testing Division laboratory facility is equipped with surveillance cameras throughout the interior and exterior of the building. The doors are locked at all times with access to the building limited by magnetic card entry. Access to Labcorp's paternity specimens and records require an additional magnetic card entry. This permits only certain authorized paternity department personnel to enter those areas. Employees are trained and required to sign a confidentiality agreement annually. Telephone conversations in the Customer Service Department are periodically monitored by the Customer Service Supervisor to help ensure that the staff is not violating confidentiality rules. Persons other than the account of record asking

detailed questions are asked to provide their questions in writing so the authenticity of the request can be verified and written permission to respond. Labcorp only provides results to persons authorized by the state agency.

Labcorp understands that the related liquidated damages for this service level requirement is (B) a general standard and will result in CAP/invoice reduction.

7. Describe how the Respondent plans to ensure that non-Vendor collectors will have sufficient supplies of postage-prepaid sample- collection kits and how the samples will be sent to the appropriate testing facility.

Labcorp will provide sufficient quantities of all supplies required for specimen collection, party identification, specimen packaging and transportation at no additional charge. An instant camera, film and thumb print supplies will be available to the specimen collector. The specimen packages at each collection site are picked up by an overnight carrier (such as FEDEX) for transport to the Labcorp testing facility in Burlington, North Carolina.

Supply orders can be requested via IdentiLinkSM, Labcorp's web based service.

Upon notification of award, Labcorp will finalize the personnel and collection sites for the specimen collection services. Each County DCS office is contacted to coordinate their desired collection site location and collection schedule. All collection supplies are shipped to the collection site locations, specimen collectors, and/or county staff for those office(s) that will use trained county DCS staff workers to perform collections.

Labcorp understands that the related liquidated damages for this service level requirement is (B) a general standard and will result in CAP/invoice reduction.

8. Respondent will provide: 1) a copy of a training curriculum currently used to teach collectors sampling protocols; and, 2) a copy of a training curriculum used to teach child support workers, attorneys, or judges about genetic testing and the theories behind genetic testing. Affirm Respondent's agreement to provide the required training.

Labcorp has a dual process regarding training. Once the proper individual has been chosen from our vast network of collectors training begins. Two different modules are reviewed with the selected specimen collector; after each module has been presented a test is given to ensure understanding of the specimen collection process. Upon passing the test the collector is then presented with a certificate depicting certification of training. Labcorp has a unique client authorization form which makes it easy for our clients to identify parties that are being tested.

Labcorp will provide certified personnel for specimen collections at mutually

agreeable locations and times, including Agency provided sites, Labcorp provided sites, or at independent facilities. Labcorp recognizes that the specimen collector is one of the most important links between the client and the laboratory. Labcorp employees are expected to project a professional image that will instill confidence for our clients. This is achieved by the specimen collector possessing confidence in his/her own ability, by exercising care and skill in performing his/her job, by presenting a professional appearance to the client, and by showing compassion, understanding and a genuine concern for our clients and their needs. Training for all specimen collectors is essential at Labcorp.

All specimen collectors, receive thorough training and appropriately documents instructions prior to collecting samples. Labcorp's step-by-step buccal swab collection training is offered in person, at a minimum, at the County Prosecutor's office, but also, if needed at local offices, hospitals and clinics.

Labcorp's comprehensive training modules include: scheduling a date/time, sending materials out prior to the training; including a Client Authorization/Chain of Custody Form, buccal swab kit, and invoice form; performing step by step instructional training with the individual(s) and answering any questions.

Prior to completing the training module, all collectors must successfully complete a review to make certain that all key points of the buccal swab collection procedure are understood. A certificate of completion and detailed training manual (used as a resource guide) is provided to each collector who completes the buccal swab collection training session and passes the review.

Labcorp's Buccal Swab Collection PowerPoint Presentation is provided as **Attachment SEVEN**.

Labcorp's Paternity Buccal Swab Specimen Collection Training Manual is provided as **Attachment EIGHT**.

Labcorp understands that the related liquidated damages for this requirement is (B) a general standard and will result in CAP/invoice reduction.

9. Affirm that persons hired to collect samples will be properly trained and certified by the Respondent as qualified collectors, and briefly describe the selection, training, and certification steps.

With the possible exception of specimen collections, Labcorp will not subcontract any portion of this contract. Labcorp understands that it is responsible, in total, for the training and all the work performed by any subcontractor. Labcorp's proposed subcontractors, and required information, are provided as **Attachment NINE**.

Specimens will be collected from all parties in a case using accepted procedures which help to ensure a high level of safety and a minimal level of trauma to the parties, including infants.

Labcorp understands that the related liquidated damages for this requirement is (B) a general standard and will result in CAP/invoice reduction.

10. Describe: 1) how Respondent's collectors will coordinate scheduling with the county offices to ensure timely collection; 2) the Respondent's rescheduling approach; 3) the Respondent's approach to collecting samples in other states and other countries with reciprocal agreements with the United States or Indiana; and, 4) the Respondent's approach to collecting samples from service members who are stationed on a base without civilian access; affirm that the Respondent will work with DCS and the counties to implement and use electronic appointment scheduling if and where available.

Upon award, Labcorp's Account Manager, Ms. Marjorie Loy, will contact each of the 92 County DCS offices to coordinate the collection location and schedule that meets their individual needs to ensure timely collections in every county DCS office. Labcorp will make sure no in-state appointments, even when the parties are in different counties, will be made more than fourteen (14) calendar days after an appointment is requested, unless the party to be tested is not available until after the fourteen (14) day period. As such, intergovernmental appointments will be made within twenty-one (21) calendar days of receipt, and international cases within twenty-eight (28) calendar days of receipt, where possible.

Labcorp's secure on-line web based computer system, IdentiLinkSM allows DCS direct access to request sample collections via the Internet. In an effort to streamline the workflow for its clients, Labcorp developed this automated sample collection scheduling service to enhance efficiency in the scheduling process.

Once DCS submits a scheduling request through IdentiLinkSM they receive a confirmation that specifically identifies their scheduling request. An email notification is sent with the appointment information when the collection is scheduled through IdentiLinkSM. The email notification will include appointment date, time and location. A sample Paternity Specimen Notification Collection Letter is provided as **Attachment TEN**.

Scheduling appointments may be monitored through IdentiLinkSM. Staff can search by schedule number, party name or DCS number for specific scheduling information using the Schedule Search option. Utilizing this option gives detailed appointment information including if the collection is from a deceased person or inmate.

IdentiLinkSM may be accessed via Labcorp's secure website: <https://www.Labcorp.com/paternity>.

IdentiLinkSM is a secure web-based application for online case inquiry with scheduling capabilities. The DCS staff can view in real-time, information detailing each of its cases. Information may be accessed by the party's name, court case number, docket number and/or Labcorp case number. The DCSs' staff can access IdentiLinkSM via an assigned client ID and a password to submit for security verification. As part of Labcorp's awareness concerning the confidentiality of client information, any employee the DCS wishes to have access to Labcorp's database, will be required to sign a security agreement. Labcorp carefully monitors the activity of the IdentiLinkSM system.

Should a party or parties require rescheduling the County DCS offices have multiple options 1) utilize one of twenty-four (24) Labcorp company operated patient service centers located in Indiana; these locations are available and can be utilized for individuals who are unable to make arrangements to appear at the regularly scheduled locations, for emergency situations, to accommodate work schedules, and for military personnel who are being deployed. This option allows for the individual(s) to be collected sooner rather than later which assists the DCS in reaching and maintaining their establishment rates, or 2) reschedule the individual(s) on the next regular appointment schedule.

Labcorp provides an electronic case reporting feature that includes both the final DNA report result and chain of custody documentation, including color pictures of parties in each case. These documents are available via IdentiLinkSM for immediate review and downloading prior to mailing the original hard copies to the Agency. This will allow cases to proceed to court in the most expedient manner for those situations where time is a critical factor.

Labcorp's web enabled IdentiLinkSM User Guide is provided in **Attachment ELEVEN**.

Labcorp's IdentiLinkSM system is designed to assist Child Support Agencies with their need for a timely and complete resolution to their case load. Labcorp is committed to continually providing new features and enhancements to our IdentiLinkSM system.

Labcorp provides comprehensive services nationwide in intergovernmental cases. Labcorp's customer service representative will assist in arranging the collection of samples from the party(s) out-of-county, out-of-state, out-of-country, in prison, and in the military at no additional charge to the County.

Labcorp has huge success in obtaining genetic samples from active military personnel at military installations due to the cooperation of the child support staff and the commanding officers of the military personnel. The process usually consists of obtaining a copy of the court order. A letter, along with a sample collection kit,

instructions, and shipping supplies, is forwarded to the individual's commanding officer requesting cooperation in obtaining a genetic sample from such military personnel. The commanding officer, in turn, arranges for the military medical staff to collect the sample and send it to the laboratory by overnight express carrier. Delays in transit due to a far-away location or delays by customs agents will not cause degradation of the buccal swab samples.

Through the utilization of these resources and tools, Labcorp will be successful in obtaining samples in from active military personnel at military installations and parties that reside in other countries. Labcorp has the ability to coordinate with laboratories and facilities of other states and in other countries to schedule genetic testing.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

11. Affirm that Respondent's staff and subcontractors will be trained to identify and avoid potential conflicts of interest and offer an alternative collector in those cases. The Respondent should describe the process it proposes for identifying, avoiding, and resolving conflict of interest situations and agree that any costs associated with identifying, resolving, or avoiding conflicts of interest will be fully assumed by the vendor.

Labcorp will not knowingly use an employee or a subcontractor to collect samples who has a conflict of interest with any tested party or county or state child support worker.

Labcorp affirms that its employees and subcontractors will be trained to identify and avoid potential conflicts of interest.

At the moment the specimen collector identifies there may be a conflict of interest in a case they will contact Labcorp, to make it known there is/may be a conflict of interest. Labcorp will contact the appropriate County DCS office and inform them of the situation and will arrange for an alternate specimen collector to collect the sample(s) in the case. Labcorp will assume the cost associated with resolving any conflict of interest issues that may arise.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

12. Describe the Respondent's protocols for ensuring that the person from whom the sample is collected is the person who is to provide the sample, and the documentation used. Affirm that the Respondent will obtain a recognizable photograph and thumbprint of each sample donor and provide the necessary tools to document the donor's identity.

Labcorp's specimen collection procedures are consistent with AABB guidelines and *exceed the requirements of the AABB*. Labcorp *exceeds* the requirements in the following areas:

- Chain of Custody forms;
- Labeling specimens and
- Color coded kits

Labcorp has worked with several child support customers to personalize our Chain of Custody form. All supplies required for sample collection, donor identification (including an instant camera, film, and thumbprint supplies), sample packaging and transportation will be provided by Labcorp.

Labcorp shall maintain the chain of custody from specimen collection, throughout the testing process and while they are within the laboratory.

The specimens and all documents associated with the cases are secure and in the sole custody of Labcorp following their receipt into the Laboratory. Labcorp's DNA Identification Testing Division facility is equipped with surveillance cameras throughout the interior and exterior of the building. The doors are locked at all times with access to the building limited by magnetic card entry. Access to Labcorp's paternity specimens and records require an additional magnetic card entry. This permits only certain authorized paternity department personnel to enter those areas. In addition to the use of card entry, both external and internal, and various levels of computer access, all personnel receive training in confidentiality procedures. Labcorp's computer records are password protected, with various levels of authorization. The levels of computer authorization granted (access to information) is based on job responsibility for every employee in the Division. Electronic records are stored in a secure data center separate from the laboratory testing facility. Firewall appliances are in place to protect systems from outside intrusion. Data is stored in a database dedicated to Labcorp's paternity testing and is only accessible by authorized paternity testing division personnel. Again, not all employees have complete access to the records, either paper or computer.

Labcorp's chain-of-custody procedures have been and are routinely accepted in courts throughout the United States, including the State of Indiana and safeguard against the possibility of any mix-up or substitution of specimens, from specimen collection to test completion.

- At least one form of photographic identification (driver's license in most states or other government issued photo ID) is required at the time of specimen collection and any other identification available such as a passport. A photocopy of the identification will also be made, if possible.

- A single form (Client Authorization/Chain of Custody form) contains all the documentation required for specimen submission including chain-of-custody and party identification.
- The front side of this document makes provision for the party information which includes name, alleged relationship(s) of the parties, and date of birth, race/ethnicity designation, blood transfusion and bone marrow/stem cell transplantation history.
- The reverse side provides for signatures of the parties and the specimen collector(s)/packager(s), attachment of photographs and other identification of the parties, fingerprints, date of sample collection and location of sample collection.
- A witness of specimen collection may also sign the Client Authorization Form/Chain of Custody, when applicable.
- Each adult party authorizes the specimen collection by signature, which is witnessed by the specimen collector as required by AABB.
- A photograph of each party is taken at the time of specimen collection and attached to the Client Authorization/Chain of Custody Form as required by AABB. The use of color pictures *exceeds AABB standards*.
- These color-coded swabs are wrapped with a matching color-coded label containing the collected party's name. The label also indicates if the sample is from the mother, child or alleged father. This process *exceeds AABB standards*.
- The accuracy of the specimen collection and labeling process is enhanced by the color-coded swabs and labels in Labcorp's buccal swab kit, which *exceeds AABB standards*.
- Labcorp's chain of custody/client authorization form is color-coded: *pink* for the mother's section, *yellow* for the child's section, and *blue* for the alleged father's section.
- Labcorp's buccal swabs are all color-coded: *pink* for the mother's swab, *yellow* for the child's swab, and *blue* for the alleged father's swab. In fact, Labcorp pioneered the use of color coded swabs in our genetic testing kits in the early 1990s. Since our early use of color coding it has been copied and become an industry standard in helping to insure quality control/quality assurance.



- Following their collection and labeling, each sample is packaged and sealed in a color-coded sample envelope, which *exceeds AABB standards*.
- The sealed color coded envelope has the collected person's name, their signature, date of collection and the collector's initials or signature as required by AABB.
- All collected samples are securely sealed in a separate tamper-proof transportation envelope by the specimen collector for transportation from the collection facility to the laboratory on the same day they are collected.
- Prior to shipping, all samples remain in the specimen collectors' possession in a secure area that is accessible only by authorized individuals.
- Also enclosed in the transportation envelope is the completed Client Authorization/Chain of Custody Form with the first part of the chain of custody signed and dated by the person(s) who collected and packaged the specimens as required by AABB.
- The specimen packages are transported by the specimen collector to a Labcorp facility or overnight carrier (such as FedEx) for transport to the Labcorp testing facility in Burlington, North Carolina.
- Upon receipt at the testing facility, the specimen shipping containers are examined for any signs of tampering as required by AABB.
- The seals are then broken and the contents removed.
- The specimen and all accompanying documents are inspected for integrity and completeness as required by AABB.
- When received at Labcorp, the color-coded envelopes and swabs are verified to make sure the colors all match. If they do not match, an explanation is sought and if no satisfactory response is obtained, then the samples are recollected.
- In the very unlikely event that signs of tampering with the specimens are detected, or if the documentation is defective, the appropriate State staff member will be contacted to discuss the disposition of that particular case.
- Deviations from accepted collection or shipping protocols are immediately investigated and appropriate action taken including, if needed, recollecting the specimens.
- The specimens are assigned unique identifying numbers and are assigned to a case (the group of individuals whose relationship is being investigated).

- The case is also assigned a unique case number.
- In order to track the case, basic demographic information, specimen numbers and case numbers are entered into Labcorp's computer system against a unique account number that will be assigned to each State office.
- The specimen is tracked by the specimen number throughout all procedures and the reporting of results.
- As the sample moves through the laboratory a record is kept of who handled the case and the testing procedures used. All samples are tested immediately upon receipt, regardless of the completeness of the case.
- The specimens and all documents associated with the cases are in the sole possession of Labcorp following their receipt in the Laboratory.
- Within the laboratory specimens are tracked by their specimen number and assigned case number. As a specimen progress through the laboratory the person handling the specimen and the steps performed are tracked in Labcorp's computer system. The location and handling are also tracked for storage of the case and samples after issuance of the report.
- Labcorp doors are locked at all times with access to the building limited by magnetic card entry.
- Access to Labcorp's paternity specimens and records require an additional magnetic card entry permitting only certain authorized paternity department personnel.
- Computer access is also limited to a "job function" with passwords and program limitations to help prevent breaches in security and the chain of custody.

Labcorp provides a copy of the color coded Client Authorization/Chain of Custody Form provided as **Attachment TWELVE**.

All original identification, specimen authorization and chain of custody documentation are returned on the Client Authorization/Chain of Custody Form to the client with the original photographs attached when the certified report is sent.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

13. Describe Respondent's buccal swab protocol and when and how alternative samples are collected. Also describe the training and qualifications of the Respondent's employees or subcontractors who will be collecting samples.

Labcorp's primary specimen collection method is buccal swab collection. This procedure is non-invasive, i.e., an instrument does not pierce the body. Labcorp's buccal swab sample collection kits are all color-coded: *pink* for the mother, *yellow* for the child, and *blue* for the alleged father. These color-coded swabs are wrapped with a matching color-coded label containing the collected parties' name. These labeled swabs are placed in matching color-coded envelopes. This process provides a strong chain of custody.

By using color-coded collection kit, Labcorp exceeds AABB standards which have no requirement for color coding. Labcorp also exceeds AABB Standard for labeling as the wrapping of the swabs with a label is not required, only labeling of the envelope the swabs are placed in is required, which Labcorp also provides.

Labcorp's buccal swab collection kit has many features to help ensure proper specimen collection and integrity, such as: printed instructions, tamper resistant packaging, and a straight forward chain of custody procedure. The collection swabs, specimen labels and specimen envelopes are color coded to minimize any specimen mix-up and enhance the chain of custody. Each individual packaging pouch is equipped with tamper evident seals as well as the pre-addressed shipping envelope.

Labcorp's DNA buccal swab kit is neat, easy to use, and all swab components are securely attached as a complete unit. The labeled swabs are placed in our tamper resistant envelope; an envelope that is NOT transparent thus securing the confidential information enclosed. The envelope allows for a strong seal by a permanent adhesive strip that runs the entire length of the envelope. The envelope is also tamper evident and attempts to open the envelope would be obvious.

Labcorp's alternative method for sample collections will be the blood specimen collection procedure. Labcorp will provide qualified personnel for specimen collection at mutually agreeable locations and times. Specimens will be collected from all parties in a case using accepted procedures which help to ensure a high level of safety and a minimal level of trauma to the parties, including infants. Our patient service center technicians are qualified in the practice of human blood collection and safety procedures associated with this process. The specimen collector(s) for this project will meet any certification(s) required in the location where blood will be collected.

Besides buccal swabs and blood, Labcorp has the ability to perform testing on various sample types, e.g., blood, post mortem blood, hair, bone, amniotic fluid, cord blood. Alternate samples are routinely tested by Labcorp utilizing highly trained laboratory staff.

Labcorp has a dual process regarding training. Once the proper individual has been

chosen from our vast network of collectors, training begins. Two different modules are reviewed with the selected specimen collector; after each module has been presented a test is given to ensure understanding of the specimen collection process. Upon passing the test the collector is then presented with a certificate depicting certification of training.

Labcorp will provide certified personnel for specimen collections at mutually agreeable locations and times, including Agency provided sites, Labcorp provided sites, or at independent facilities. Labcorp recognizes that the specimen collector is one of the most important links between the client and the laboratory. Labcorp employees are expected to project a professional image that will instill confidence for our clients. This is achieved by the specimen collector possessing confidence in his/her own ability, by exercising care and skill in performing his/her job, by presenting a professional appearance to the client, and by showing compassion, understanding and a genuine concern for our clients and their needs. Training for all specimen collectors is essential at Labcorp.

All specimen collectors, receive thorough training and appropriately documents instructions prior to collecting samples. Labcorp's step-by-step buccal swab collection training is offered by telephone or in person, through:

- PowerPoint presentation, via Webex, through group sessions, or one-on-one

Labcorp's comprehensive training modules include: scheduling a date/time, sending materials out prior to the training; including a Client Authorization/Chain of Custody Form, buccal swab kit, and invoice form; performing step by step instructional training with the individual(s) and answering any questions.

Prior to completing the training module, all collectors must successfully complete a review to make certain that all key points of the buccal swab collection procedure are understood. A certificate of completion and detailed training manual (used as a resource guide) is provided to each collector who completes the buccal swab collection training session and passes the review.

Labcorp's Buccal Swab Collection PowerPoint Presentation is provided as **Attachment SEVEN**.

Labcorp's Paternity Buccal Swab Specimen Collection Training Manual is provided as **Attachment EIGHT**.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

14. Describe the circumstances when you would use alternative collection such as collecting at another site (such as a jail) or testing another relative when the party is unavailable, or in the event of other special circumstances (e.g., an abandoned baby).

Labcorp is also very successful in coordinating with appropriate prison officials to enter prisons and collect specimens from incarcerated individuals whether inside or outside of the State. Labcorp's Sample Collector will coordinate with the contact at the correctional facility to arrange a mutually acceptable date or schedule and under conditions directed by the point of contact at each correctional facility. Labcorp's Sample Collectors are familiar with navigating each correctional facilities requirement, such as background checks, pre- and post- entry searches and any other requirements that the correctional facility may have. As with prisons, incarcerated individuals can present a particular challenge for specimen collection. Labcorp's success in obtaining samples from incarcerated individuals located in correctional facilities, local jails, and other facilities has been substantial. In 2022 the DNA Identification Testing Division coordinated 9,695 collections of individuals who were located in a correctional facility, local jail, or other facility. All of these samples are collected with appropriate chain of custody.

Labcorp has experience in testing a variety of samples including, blood, buccal swabs, hair, bone, teeth, amniotic fluid, pathology samples, and other tissues.

Labcorp's testing protocols are designed to readily resolve routine questions of disputed parentage as well as non-routine cases, such as:

- **Deceased Parties** – *With cases involving a deceased alleged father, there are numerous options available. If the alleged father is recently deceased and there is specimen available at the corners/police office, that specimen can usually be obtained for testing. Family study testing may also be performed using the deceased alleged father's relatives.*
- **Absent Mother** – *While it is always best to test the mother to increase the power of the test and reduce fraud risk, it is possible to test just the alleged father and child to obtain valid, conclusive results.*
- **Family Studies** – *Relationship testing can include using grandparents; siblings; aunts, uncles to assist in determining paternity or family relationship.*
- **Related Alleged Fathers** – *With the exception of identical twins, Labcorp is able to test enough loci to determine genetic differences between related alleged fathers.*
- **Multiple Alleged Fathers** - *Labcorp collects four (4) buccal swabs per person and stores specimens for seven (7) years, thereby enabling the use of multiple tests as needed typically without recollection of the mother / child(ren) in cases involving multiple alleged fathers.*

*In cases involving a deceased or missing family member, a family relationship test may be performed in order to reconstruct the decedent's probable DNA profile and/or determine the person's biological relationship to know family members. Labcorp provides an information flyer regarding reconstruction cases as **Attachment THIRTEEN**.*

In response to the request from the State regarding NIPT testing, currently there is only one laboratory who has been accredited by AABB to provide this testing. Labcorp is investigating non-invasive prenatal testing, but it is not currently offered by Labcorp. Labcorp does offer paternity testing prior to birth using Amnio and CVS samples for the child's sample.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

15. Describe Respondent's protocols for partial draw follow-ups.

Labcorp offers multiple approaches for partial draw follow up:

Partial draws can be queried and sorted on IdentiLinkSM Labcorp's web based system. A partial report is offered on IdentiLinkSM which can be reviewed at any time and includes the following information:

- Labcorp case number
- county DCS office case number
- party's name of who has been collected
- party's name who has not been collected
- collection date for parties who are collected

In addition, at the end of each collection day each County DCS office will receive a show/no-show list from the specimen collector indicating the attendance of each person scheduled.

Labcorp will also send notification to each County DCS office if a case is still a partial after thirty (30) days.

A copy of Labcorp's sample partial case letter is provided as **Attachment FOURTEEN**.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

16. Describe Respondent's plans to ensure that sample collections can be properly made in any IV-D jurisdiction at a location reasonably convenient to the person being tested.

Labcorp provides comprehensive services nationwide in intergovernmental cases. Labcorp's customer service representative will assist in arranging the collection of samples from the party(s) out-of-county, out-of-state, out-of-country, in prison, and in the military at no additional charge to the County.

The following services will be provided, at no additional charge:

- Scheduling specimen collection of "absent" parties
- Forwarding of collection kit to appropriate collection site or agency
- Coordinating of all transportation arrangements for the specimens to be forwarded to the laboratory
- Confirming of all arrangements with the County
- "No Show" confirmation of the specimen collections of the parties scheduled

IdentiLinkSM Security: IdentiLinkSM is a web-based application that can be accessed with Microsoft Edge, Firefox, or Google Chrome and concurrent access by agency staff is unlimited.

Confirmation of individuals being collected can also be viewed on IdentiLinkSM. Labcorp's web-enabled IdentiLinkSM User Guide are provided as **Attachment ELEVEN**.

Once the County representative submits a scheduling request through IdentiLinkSM, they receive a confirmation that specifically identifies their scheduling request. An email notification is sent with the appointment information when the collection is scheduled through IdentiLinkSM. An Appointment Letter will be sent back to the respective County representative indicating the appointment date, time and location. Whenever possible, Labcorp schedules sample collection times to assure that the involved donors' samples arrive at the laboratory at approximately the same time. Labcorp will notify the County representative of non-attendance for parties scheduled for specimen collection through written notification by email within forty-eight (48) hours. This notification allows the County representative to request a reschedule or take the next step in their case management. A sample Paternity Specimen Collection Notification Letter is provided as **Attachment TEN**.

In addition, Labcorp has been successful in coordinating with the appropriate prison officials the ability to enter the prisons and collect samples. As with prisons, incarcerated individuals can present a particular challenge for specimen collection. Labcorp's success in obtaining samples from incarcerated individuals located in correctional facilities, local jails, and other facilities has been substantial. In 2022, the DNA Identification Testing Division coordinated 9,695 collections of individuals who were located in a correctional facility, local jail, or other facility. Labcorp is very

successful in coordinating with coroner offices the collection of samples of deceased individuals. All of these samples are collected with appropriate chain of custody.

Labcorp maintains, exclusively for the use of its clients, approximately 2,000 company-operated PSCs conveniently located throughout the United States, including twenty-four (24) located in Indiana, to better facilitate the intergovernmental scheduling process for the County. Through this support system Labcorp provides a variety of specimen collection, client support, and patient services. Our large network of laboratory facilities allows Labcorp to deliver effective and dependable daily service, which is also supported by our extensive courier services. Labcorp also utilizes a large database of over 11,100 alternate sample collection locations worldwide. In total, Labcorp has access to over 13,000 collection sites from which it can satisfactorily service the County, accommodating more than the collection needs of this Contract.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

17. Describe the Respondent's plans to meet these service level requirements.

Labcorp provides comprehensive services in arranging collection of samples from the party(s) in the military and outside the United States.

The following services will be provided:

- scheduling specimen collection of "absent" parties
- forwarding of collection kit to appropriate collection site or agency
- coordinating of all transportation arrangements for the specimens to be forwarded to the laboratory
- confirming of all arrangements with the County DCS office
- "No Show" confirmation of the specimen collections of the parties scheduled.

Labcorp offers the County DCS direct access to request sample collections via our web-based service IdentiLinkSM. In an effort to streamline the workflow for its clients, Labcorp developed this automated sample collection scheduling service to enhance efficiency in the scheduling process. Our system makes scheduling easy. IdentiLinkSM may be accessed via Labcorp's secure website: <https://www.Labcorp.com/paternity>. There are no software requirements and no programming necessary to access IdentiLinkSM. Confirmation of individuals being collected can also be viewed on IdentiLinkSM Labcorp's web-enabled IdentiLinkSM

An email notification is sent with the appointment information when the collection is scheduled through IdentiLinkSM. An Appointment Letter will be sent back to the County DCS office indicating the appointment date, time and location.

Labcorp will notify the appropriate County DCS office representative of non-

attendance for parties scheduled for specimen collection through written notification by fax or email within five (5) business days of the scheduled appointment.

Labcorp has huge success in obtaining genetic samples from active military personnel at military installations due to the cooperation of the child support staff and the commanding officers of the military personnel. The process usually consists of obtaining a copy of the court order. A letter, along with a sample collection kit, instructions, and shipping supplies, is forwarded to the individual's commanding officer requesting cooperation in obtaining a genetic sample from such military personnel. The commanding officer, in turn, arranges for the military medical staff to collect the sample and send it to the laboratory by overnight express carrier. Delays in transit due to a far-away location or delays by customs agents will not cause degradation of the buccal swab samples.

Through the utilization of these resources and tools, Labcorp will be successful in obtaining samples in from active military personnel at military installations and parties that reside in other countries. Labcorp has the ability to coordinate with laboratories and facilities of other states and in other countries to schedule genetic testing.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

18. Describe the Respondent's chain of custody protocol and refer to Respondent's training section in the collector training curriculum.

Labcorp's specimen collection procedures are consistent with AABB guidelines and *exceed the requirements of the AABB*. Labcorp *exceeds* the requirements in the following areas:

- Chain of Custody forms (discussed above)
- Labeling specimens and (discussed above)
- Color coded kits (discussed above)
- Tracking within the laboratory (discussed above)

Labcorp's chain-of-custody procedures have been and are routinely accepted in the courts throughout the United States (including the State of Indiana) and safeguard against the possibility of any mix-up or substitution of specimens, from specimen collection to test completion.

Labcorp's Implementation Training Team will provide comprehensive buccal swab based DNA collection training to the Genetic Testing Liaison and any additional parties the State may request. Labcorp's training process consists of both hands-on and web based training. Labcorp's Implementation Training Team will provide a review of supplies provided, specimen collection procedures using a noninvasive

buccal swab collection process, proper chain of custody documentation, correct specimen packaging, secure sample shipment, and a review of Labcorp's proprietary web based system, IdentiLinkSM. Upon completion of training, a test will be administered to each participant which will assess their understanding of the collection process and required chain of custody protocols. Certificates of Completion will be presented to each participant upon successful completion of testing.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in CAP/invoice reduction.

19. describe the Respondent's handling, shipping, and mailing protocols.

Labcorp will be responsible for the transportation of all samples from the collection site to the testing laboratory. Following sample collection and labeling, each sample is packaged and sealed in a color-coded sample envelope. All collected samples are securely sealed in a tamper-proof envelope by the specimen collector for transportation from the collection site to the laboratory on the same day they are collected. Also enclosed in the shipping container is the completed Client Authorization/Chain of Custody Form with the first part of the chain of custody signed and dated by the person(s) who collected and packaged the specimens.

The specimen packages will be transported by a Labcorp courier or overnight express carrier (FEDEX) for delivery at the Labcorp testing facility in Burlington, North Carolina. Transportation time, from specimen collection to receipt at the testing facility, is usually less than twenty-four (24) hours. Labcorp will provide all the necessary supplies for shipment of the sample by a Labcorp courier or a commercial carrier, such as Federal Express, to the testing facility, at no additional charge.

Labcorp ensures that its staff, subcontractor, and the County DCS staff are trained to appropriately mark, store, handle, record, transport, and mail the sample.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

20. Attach Respondent's PCR genetic testing protocols.

Labcorp's Genetic Testing Protocol is provided as **Attachment FIFTEEN**.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

21. Describe when other testing would be warranted and used. Also, please approximate how often Additional Testing is needed.

Labcorp's routine PCR testing protocol evaluates 27 loci which reduces the need for additional testing. If appropriate, Labcorp has the ability to test additional genetic systems. If an individual is excluded, the results will typically reflect inconsistencies in at least four (4) independent test systems. The laboratory has validated many loci and may test up to 36 or more genetic markers. Additional testing may be required if related alleged fathers are submitted, such as brothers, and one is not clearly excluded in the initial testing then additional testing may be required. Other examples might include the evaluation of potential mutations. If there appears to be a mutation, additional testing may be performed to further evaluate the disputed individual's relationship to the child. Additional testing may also be required in certain family studies / reconstruction cases, where the alleged parent is unavailable for testing, and biological relatives are submitted for testing, such as grandparents. Labcorp has additional tests that can be performed including other autosomal loci, Y Chromosome and HLA testing.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

22. Refer to testing protocol or briefly describe when retesting is necessary and the methodology used to reach exclusion or 99.9% probability of inclusion.

The example of retesting would occur when testing of an alleged father neither excludes the man nor achieves an acceptable probability of paternity. This example would be handled the same as additional testing. Using LabCorp's protocol, the routine test panel already evaluates over twenty-seven (27) loci on every sample which reduces the need for retesting. On the rare occasion that retesting is needed, Labcorp has the ability to perform other testing. If an individual is excluded, the results will typically reflect inconsistencies in at least four (4) independent test systems. The laboratory has validated many loci and may test up to 36 or more genetic markers. Retesting may be needed if related alleged fathers are submitted, such as brothers, and one is not clearly excluded in the initial testing. Labcorp has additional tests that can be performed including Y Chromosome and HLA testing that would help resolve this example. Retesting may occur if an alleged father is utilized in more than one paternity case, such as with multiple mothers and their children. When the father is evaluated with the another mother child pair, retesting of the alleged father's sample may occur. Other reasons for retesting might include the evaluation of mutations observe in the initial testing to confirm the mutation. Confirmation of unusual test results would be another example. Labcorp has protocols in place for the retesting of any individual's samples. The testing utilized may include other autosomal loci, Y Chromosome and HLA.

Labcorp's battery of tests will provide a minimum combined paternity index (CPI) of 100 to 1 and a probability of paternity (POP) of 99.0% with a prior probability

(PP) of 0.5 on all inclusions reported. Labcorp anticipates that almost all (>99%) standard non-exclusion cases will have a POP of 99.99%. Labcorp's PCR test median combined paternity index for non-excluded men is currently greater than one billion to one (1,000,000,000 to 1). Using a prior probability of 0.5, this combined paternity index is converted into a probability of paternity of much greater than 99.0 percent.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

23. Affirm the Respondent will meet the service level requirements and briefly describe the protocols used to meet the turnaround time and to handle exceptional cases.

Labcorp will provide a certified report of the test results no later than fourteen (14) calendar days from receipt of all samples to complete a case to receipt of results by the County DCS office (in format as mutually agreed upon). Labcorp understands that exceptional cases i.e. retesting or alternate collection cases that may exceed the required fourteen (14) calendar day turnaround time is not to exceed 1% of the total number of collected samples and partial cases are measured by the date of the last sample collected to complete the case.

As one of the State's current vendors, Labcorp has maintained an average turnaround time of 9.92 calendar days for Indiana from the date of collection to the date the report is sent.

Labcorp utilizes numerous procedures to minimize turnaround time for cases, briefly these measures are:

- Labcorp operates three (3) work shifts seven (7) days per week; therefore, except for a few key holidays, Labcorp is always open.
- Labcorp maintains a large staff capable of handling current and projected sample volumes.
- Labcorp has five (5) Directors, which helps assure that the final case review is performed in a timely fashion.
- Labcorp has procedures in its record management section to track cases as a function of "age" and to take appropriate action to expedite case release.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

24. Affirm that the report will include the data requested in these service level requirements in an easy-to-read format; attach a redacted copy (to preserve confidentiality) of a genetic test report.

Labcorp will provide professional certified laboratory test results, signed by a Director and notarized, in a scientifically meaningful format and ensure the test results are useful to non-technical readers and maintain all genetic reports based on accreditation standards. This report will include the following:

- DCS Case number, if provided
- other numbers provided by the State,
- identification of parties, including the full name of each individual and relationship to child(ren)
- chain of custody documentation, including the fingerprint and photograph of each individual
- the date the sample was collected and collection location,
- race/ethnic background used for paternity calculation,
- each person's phenotype as determined by the testing,
- individual paternity index for each genetic system reported,
- the cumulative paternity index,
- the prior probability of paternity used in the calculations,
- a statement of conclusion, and
- the name, title, notarized signature and professional title of the expert issuing the report.

Sample reports of the testing and evaluation are provided as **Attachment SIXTEEN**.

All records of testing are strictly confidential and will be released only to the agency that ordered the testing, that agency's designees, or as otherwise required by law. Only the doctoral staff is authorized to discuss results of a specific case with anyone making an inquiry.

Labcorp understands that the related liquidated damages for this requirement is (B) a general standard and will result in CAP/invoice reduction.

25. Affirm that the report data is convertible from paper to electronic form and vice versa, signed electronically or in pen by the appropriate laboratory representative, and that the data will be transmitted electronically if any county or DCS at the state level prefers electronic transmission at some point during the contract's term. Also, identify whether reports are accessible through a secure website if a county Prosecutor selects that option. Respondents should affirm their agreement to mail copies of the results report to the parties tested at the county Prosecutor's request.

Labcorp's reports of testing and evaluation are available in paper or electronic (PDF) formats and are accessible through our secure web-based application **IdentiLinkSM**. **IdentiLinkSM Security:** IdentiLinkSM is a web-based application that can be accessed with Microsoft Edge, Firefox, or Google Chrome and concurrent access by

agency staff is unlimited. At the request of the County DCS office, Labcorp will mail copies of the paper results report to the parties tested. Also at the request of the County DCS office or the State, Labcorp will provide electronic reports to the parties tested.

As part of Labcorp's awareness concerning the confidentiality of client information, any employee the DCS wishes to have access to Labcorp's database, will be required to sign a security agreement.

Client access applications are developed internally following software development lifecycle methodologies and procedures. Information is encrypted using secure socket layer (SSL) encryption technology, which employs 128-bit encryption. Web browsers utilizing 128-bit encryption are also required for use. Data is stored independent of other Labcorp internal applications behind a secure corporate firewall. Both internal access and client access to client case information is logged. Logged data includes user id, user name, IP address, date and time. Logged data will be retained for the duration of the contract.

Access to IdentiLinkSM and customer specific case information is controlled by a unique password protected client ID. Each client ID can be tiered to specific customer access requirements. Each user authorized by DCS will be required to select a password. Passwords are required to be between seven (7) and ten (10) characters in length, this can include alpha, numeric and special characters. The Passwords are required to be changed a minimum of every forty-five (45) days and access is blocked following three (3) failed login attempts. Sessions are automatically terminated following fifteen (15) minutes of inactivity. Labcorp carefully monitors the activity of the IdentiLinkSM system. In the event a DCS staff member no longer requires access to IdentiLinkSM the access will be disabled within one (1) business day after notification by the DCS.

IdentiLinkSM provides the DCS with access to their most current case status information within forty-eight (48) hours of receiving the sample into the laboratory. All data and case information is updated in real time, with no delay. Information may be accessed by the party's name, the DCS case number, and Labcorp case number.

IdentiLinkSM allows the DCS direct access to case status information. IdentiLinkSM has the ability to allow for each DCS office to view/print/download test results in Adobe PDF format and collection activity for all cases in every Indiana County under the Contract.

IdentiLinkSM allows the DCS to view the following information about a case:

- All names in a case
- Date of birth of parties
- Social security number
- DCS case number

- Date specimen(s) received
- Race
- Specimen collection status
- Relationship of parties
- Tests ordered
- Test status
- Chain of Custody/Client Authorization
- Final results
- Management reports
- Sample Collection Scheduling Service

In addition, IdentiLinkSM provides an electronic case reporting feature that includes both the final DNA report result and chain of custody documentation. These documents are available via IdentiLinkSM for immediate review and downloading prior to the mailing of original hard copies to the State office. This electronic feature provides the benefit of allowing cases to proceed to court before hard copies are received which can be especially helpful in those situations where time is a critical factor.

IdentiLinkSM also offers an electronic notification and delivery feature. Individual State offices may choose to receive an email notification of test completion along with a direct link to our website or they may choose to have the final genetic testing report in .pdf format sent directly to the email address of designated agency personnel. All of these options provide real-time access to testing and evaluation reports upon case completion.

Labcorp offers the DCS staff web based access to final test results, photos of customers, chain of custody documents, summation of paternity statistics, court orders and any other documentation associated with the case via Labcorp's secure website, IdentiLinkSM.

A few of the easy-to-use features and functions include:

- unlimited access for DCS staff,
- ability to schedule appointments for collections,
- email notice that certified report is complete and
- email notification of no-show appointments, and more.
- PDF version of results emailed directly to DCS staff

IdentiLinkSM is accessible twenty-four (24) hours a day, seven (7) days a week.

GREEN FEATURES of IdentiLinkSM include:

Electronic Completion and Downloading of Client Authorization/Chain of Custody Form: Offers the DCS staff the ability to view, complete and download to desktop the chain of custody form, complete with photograph(s) and thumbprint(s)

via its IdentiLinkSM system. Once the client authorization/chain of custody is completed, State staff can print the document. The document will contain case information and the State's account information. There will also be two (2) bar-coded numbers that will print on top of the form. These barcodes allow the case information including names, account number and case number to import the information into the laboratory's system, reducing spelling errors. Upon receipt of the sample(s) at the testing facility, the client authorization/chain of custody form is scanned into the computer system and made available by case number, the current status of the sample collection and a photograph of the person(s) being tested.

Electronic Result Reporting and Downloading: Labcorp provides an electronic case reporting feature that includes both the final DNA report result and chain of custody documentation. These documents are available via IdentiLinkSM for immediate review and downloading into a PDF format prior to mailing the original hard copies to the DCS. This will allow cases to proceed to court in the most expedient manner for those situations where time is a critical factor.

Email Notification: Labcorp offers two (2) options for system generated emails to be sent once cases are completed. The individual State offices may choose to receive an email notification of test completion along with a direct link to our website or they may choose to have reports of final genetic testing reports in .pdf format sent directly to the email address of designated agency personnel. Either of these options will provide real-time notification of case completion.

Status reports can be obtained from IdentiLinkSM: Labcorp offers two (2) monthly status reports. One report is a general overview of the account's activity for the month providing: number of full cases reported, number of partial cases reported, number of cases requiring extended testing, percent of exclusions, average probability, average turnaround time, and number of cases reported, per calendar day of the month.

Another status report gives the account's activity for the month down to the individual case level identifying each partial case outstanding, each case reported along with the date sent and whether or not the alleged father was excluded.

Order supplies online: All specimen collection supplies can be ordered on IdentiLinkSM at no additional charge.

Labcorp understands that the related liquidated damages for this requirement is (B) a general standard and will result in CAP/invoice reduction.

26. Describe how an expert witness is chosen and how the expert witness prepares for trial; describe how the Respondent will assist with the preparation of discovery

responses and affirm that the Respondent will pay for all costs associated with the expert witness and assistance in the preparation of discovery responses.

Labcorp will furnish expert witness testimony in legal proceedings involving questions of paternity when requested. Labcorp has a staff of five (5) Scientific Directors holding doctoral degrees with experience in the field of genetic testing.

Labcorp's experts have appeared in hundreds of trials throughout the United States and shall provide expert testimony when necessary and requested by the DCS. Each possesses a bachelor's degree from an accredited four-year institution as well as a doctorate degree in science and combined, represent many years of experience in the specialty of parentage testing and associated expert testimony. Our experts have also been invited to speak at scientific, legal and child support conferences, to consult about the formulation of relevant legislation, and to participate in numerous activities of the National Child Support Enforcement Association and American Bar Association. The doctoral staff serve as the primary technical resources for the DCS, are readily available for consultation, and are available to testify or assist the DCS with preparing written legal documents within thirty (30) days of the DCS's request.

In addition to courtroom testimony, their testimony experience includes in-person testimony, telephonic testimony, discovery requests, written interrogatories, and depositions. The trials in which Labcorp's experts have testified include admissibility hearings (Frye hearings) as well as civil trials and criminal trials.

Expert witness services available to this project, at no additional charge virtually using Webex or other virtual options, are as follows:

- courtroom testimony,
- telephonic deposition,
- response to reasonable interrogatories,
- response to reasonable discovery requests and orders,
- consultation by telephone,
- notarized affidavits,
- telephonic depositions, by special arrangement
- assistance in developing examination of counter-experts who testify in a dispute, and
- other services/sources as negotiated between Labcorp and the DCS

Labcorp's staff of Directors who support our Expert Witnesses include the following:

George C. Maha, JD, PhD, MT(ASCP), D(ABMG) is Laboratory Director and Associate Vice President. He has worked in paternity testing for over thirty-five (35) years and has provided expert testimony in over 100 court cases.

Certification or Boards:

Laboratory Director Certificate of Qualification, New York State Department of Health

Medical Technologist, American Society of Clinical Pathologists,
Diplomate, American Board of Medical Genetics (PhD Medical Geneticist);
Admitted, North Carolina Bar

Professional Associations: AABB, ISFG, ASHI

Gary M. Stuhlmiller, PhD, has worked in Labcorp's DNA Identification Testing Division for over thirty-three (33) years and has provided expert testimony services in over 225 court cases.

Certification or Boards:

Laboratory Director Certificate of Qualification, New York State Department of Health

Professional Associations: ASHI, American Association of Immunologists, NCSEA

Melanie S. Trapani, PhD, F-ABC, completed her PhD degree with Human & Molecular Genetics concentration from the Graduate School of Biomedical Sciences, University of Texas Health Science Center at Houston, 1999 and completed Postdoctoral Fellow at the Human Genetics Center, University of Texas Health Science Center at Houston in 2001. From 2001 to 2005 she was an Assistant Professor and William R. Acquavella Scholar at Columbia University, New York, NY. Dr. Trapani has over sixteen (16) years of experience in human identity testing. She has appeared in over 40 trials. She has been with Labcorp for ten (10) years.

Certification or Boards:

Laboratory Director Certificate of Qualification, New York State Department of Health

Molecular Biology Fellow - American Board of Criminalistics (ABC).

Eric O'Neil, PhD., completed his PhD degree with Biology from Utah State University in 2009. Dr. O'Neill has nineteen (19) years of experience in the collection and analysis of genetic data. Dr. O'Neill joined Labcorp in June 2017 and brings with him expertise in inheritance and population and quantitative genetics.

Certification or Boards:

Laboratory Director Certificate of Qualification, New York State Department of Health.

Dr. Jang Eun Cho, PhD, Associate Technical Director, completed her PhD degree in Molecular Genetics and Microbiology from Duke University in 2015. Dr. Cho performed postdoctoral research at Duke university and at Lineberger Comprehensive Cancer Center at UNC Chapel Hill. Dr. Cho has ten (10) years of research experience in the field of DNA repair and mutagenesis. Dr. Cho joined

Labcorp in November 2019 and brings with her expertise in molecular genetics and DNA analysis. Dr. Cho received the Chancellor's scholarship from Duke University and has been accredited with 13 publications in her field of study. She has appeared in one court case.

Labcorp will notify the DCS immediately upon the receipt of any legal pleading it receives relating to the Contract.

Labcorp witnesses will provide the DCS and/or the attorney representing the DCS with a set of questions to be considered in the direct examination of the expert witness. Our witnesses will also assist the DCS in preparation of cross-examination of any counter-experts scheduled to appear. Labcorp witnesses will appear at a trial with the complete Labcorp record of the case being heard.

Labcorp witnesses thoroughly prepare for trials in which they are scheduled to appear. Each case is considered individually and the expert prepares accordingly. Upon assignment to a case, the expert contacts the attorney handling the case; at that time the case is discussed and a general strategy is formulated. If the County's attorney wishes, the witness will discuss the case with opposing counsel in an effort to enhance the likelihood of case settlement. Our experience is that this can be very effective since most attorneys and their clients may not truly understand the genetic tests.

Curricula Vitae/Resumes for the Labcorp Directors who are available as Expert Witnesses are provided in **Attachment SEVENTEEN**.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

27. Describe Respondent's protocols for rapidly responding to county or DCS inquiries, tracking and escalation of issues, and providing information in writing as appropriate; briefly describe who is responsible for these responses.

Labcorp agrees to be available to discuss the collection approach, chain of custody, test results, and genetic testing theory with a representative of the County DCS offices upon request and will provide certain information in writing, including affidavits, in situations that do not require the presence of an expert witness.

Labcorp's approach to customer service is comprehensive in that it covers all aspects of the needs of our clients; from technical to administrative. Labcorp provides a *multi-tiered* approach to servicing its clients by utilizing customer service representatives to answer routine inquiries. They direct calls to the account managers, supervisory/management staff, or doctoral staff who provide more in-depth investigation, and assures our clients personal and timely answers to questions they may have.

The Customer Service Team consists of courteous and knowledgeable customer service representatives that are available from 8:00 a.m. to 7:00 p.m. Eastern Time, Monday through Friday. They are available for customer support, coordinate specimen collection scheduling, and other program questions. This team of customer service support representatives can be reached by calling **(800) WE-DO-DNA or (800)742-3944**, by fax at (800) 821-9102, or by email at dna@Labcorp.com. Personal attention and interaction are a priority for our clients and every effort is made to address questions within a twenty-four (24) hour timeframe.

The Customer Service Team will coordinate specimen collections. This staff will ensure all requests for obtaining specimens are promptly and satisfactorily completed where one or more persons reside in another state, countries, worldwide, city and county jails, state and federal prisons, work release centers, correctional facilities, and military bases. They will coordinate "courtesy draws" requested while ensuring the specimen collection requirements of the testing laboratory are met. They will work with the DCS or other authorized users to avoid domestic violence issues when scheduling specimen collections.

Labcorp's multi-tier Customer Service Team includes:

- **A Team of customer services representatives** available to answer questions, schedule cases, check on case status, etc.;
- **A dedicated Account Manager** assigned to DCS who is responsible for the overall implementation of the Contract, monitors case status, bills, specimen collections, training, and assists with special needs/requests;
- **A Doctoral (Ph.D.) staff** available for consultation and technical discussion;

The **Account Manager** interacts with clients to ensure training issues are addressed and provide more in-depth research of client questions and issues. The Account Manager, Marjorie Loy is assigned to this Contract and will oversee the implementation of Labcorp's genetic testing services and resolve any issues that may arise regarding these services. Marjorie will also monitor case status, invoices, specimen collections, training, and assists with special needs.

The **Doctoral Staff (Scientists)** will serve as the primary technical resources for the DCS for explaining results and are readily available for consultation on non-routine types of cases.

Labcorp understands that the related liquidated damages for this requirement is (C) an individual case impact and will result in invoice reduction.

28. Attach Respondent's Customer Service Plan that includes the service level requirements and any other provisions concerning customer service. The Respondent should describe the process they will follow when counties have issues with the

services provided, or not provided. The Respondent should describe the method by which customer service issues or disputes are reported by the county and to whom, and the Respondent should agree it will respond to customer service issues or disputes, in writing, within three (3) business days with a proposed resolution.

Labcorp's Customer Service Plan is provided as **Attachment EIGHTEEN**.

Labcorp understands that the related liquidated damages for this requirement is (B) a general standard and will result in CAP/invoice reduction for the plan compliance and (C) an individual case impact and will result in invoice reduction for each Metric.

29. Attach a sample invoice; affirm compliance with service level requirements and cooperation with DCS regarding electronic invoicing.

Labcorp will invoice the State through DCS Accounts Payable on a monthly basis, within ten (10) business days of the last day of the previous month. Labcorp will submit invoices in paper format and in electronic format at which time DCS is able to accept invoices electronically.

Labcorp acknowledges DCS desires a separation of invoices based on the requesting party. The Prosecutor's Offices on one invoice and the DCS Local Offices on another.

Labcorp's invoice will include the information as outlined in the service level requirements and will be mailed to DCS Accounts Payable at the address listed in the service level requirements within the RFS.

During this contract period, Labcorp agrees to participate with the DCS in the planning, designing, building, and testing phases of electronic invoicing. Labcorp will continue to work with DCS Accounts Payable if anything changes in the future to the invoice process.

The invoice will include the following data:

- Cover page that summarizes the number of units billed as county draws and/or vendor draws for each county and summarizes the charge for each county that the vendor did work for and the total for the whole invoice.
- An original copy of the State Form 54716 (Authorization / Request for Genetic Testing Services), that list each individual that the county authorizes for testing.
- An indicator whether the draw was performed by the Vendor, county Prosecutor staff or a third party (i.e., hospital)

- The total price charged per test
- The county requesting the test
- ISETS/INvest case number or DCS Local Office case number
- Date of sample collection scheduling request if on the form sent to Labcorp
- Date of sample collection
- Date sample collection received by lab
- Date test results sent to or accessed by county
- Name/ remit to address of Vendor
- List of genetic tests performed
- Vendor's contact telephone number
- Indicator if the invoice is a duplicate or re-issuance of a prior invoice

Vendor will email the complete invoice to: DCSInvoices@dcs.in.gov

Or mail to:

Maria Cotrina-McInerney
DCS IVD Budget Analyst
402 W. Washington St., Rm W392
Indianapolis, IN 46204

A sample invoice currently being utilized is provided as **Attachment NINETEEN**.

Labcorp will maintain a record of the test results in accordance with federal, state, local, and AABB requirements. Upon request, Labcorp will furnish a copy to the County, at no additional charge, of the Authorization/Request for Genetic Testing Services signed in blue ink.

Labcorp will set up and maintain a separate account number for tests resulting from hospital sample collections.

Labcorp understands that the related liquidated damages for this requirement is (B) a general standard and will result in CAP/invoice reduction.

30. Attach the Respondent's plan or outline of a plan and affirm that the Respondent will follow the service level requirement.

Labcorp maintains a Disaster Recovery Plan that allows for the ability to provide paternity tests and results in the event there is a natural disaster.

Labcorp is a full service high volume clinical Laboratory. As such we have an extensive infrastructure to accommodate virtually any clinical testing situation. We

are staffed twenty-four (24) hours per day, seven (7) days a week, and can receive shipments of samples at almost any time. As a facility that performs critical stat testing we have extensive redundancy and disaster recovery/business continuity plans in place to preclude any interruption of our services. These include multiple means of sample shipment, on site electrical power generation for all critical equipment, and automated off-site archiving of sample related data. In every aspect of these plans Labcorp's quality control procedures are in place to maintain its high quality standard utilized in routine operations.

A copy of Labcorp's Disaster Recovery Plan is provided as **Attachment TWENTY**.

Labcorp understands that the related liquidated damages for this requirement is (B) a general standard and will result in CAP/invoice reduction.

31. Affirm that Respondent will continuously monitor its own performance and take proactive steps to ensure issues are appropriately addressed.
Affirm that Respondent will cooperate with the state in monitoring and tracking its activities, provide reports and records of its performance as requested by the state, and allow access to and inspection of its facilities if requested.
Briefly highlight examples of Respondent's monitoring capabilities.

At Labcorp, quality is our primary concern. Quality control programs developed by Labcorp meet or surpass requirements set by the federal government and other licensing agencies. Using a variety of internal quality control programs, results from every laboratory department are closely monitored. In addition, Labcorp is inspected regularly by state, federal and private accrediting groups.

Labcorp maintains internal monitoring procedures and processes to ensure acceptable performance and compliance with the terms of the contract. Labcorp will monitor its performance and will take proactive steps to ensure issues are appropriately addressed.

A few examples are:

Labcorp offers two (2) monthly status reports. One report is a general overview of the account's activity for the month providing:

- number of full cases reported
- number of partial cases reported
- number of cases requiring extended testing
- percent of exclusions
- average probability
- average turnaround time
- number of cases reported per calendar day of the month

Another status report gives the account's activity for the month down to the individual case level identifying each partial case outstanding, each case reported along with the date sent and whether or not the alleged father was excluded.

These reports may be customized to meet the individual needs of the County DCS office or compile on a statewide level. A sample status report is provided as **Attachment TWENTY-ONE**.

Labcorp's DNA Identification Testing Division holds monthly Quality Control/Quality Assurance (QA/QC) & Safety meetings that include managers, supervisors, and Director's from all areas of the department from technical to administrative. A copy of the Agenda template for this meeting is provided as **Attachment TWENTY-TWO**.

Labcorp's Customer Service Manager, Teresa Clifton, reviews reports of customer service activities. Such activities reported include: hold times on incoming calls, response time for call resolution, number of faxes received, number of scheduling requests received and processed, etc.

Quality of the testing is continuously monitored by the laboratory director, scientists (PhD), laboratory supervisors, and quality assurance officer. The monitoring includes the discussion of test parameters/specifications, proficiency test results, and any testing issues during monthly quality assurance meetings. Each individual case goes through a review process starting with the collection process, receipt, double check of sample labeling, double blind testing, and checks that contract specification are met, for example 99.99% for non-exclusions.

The DNA Identification Testing Division has its own Quality Assurance Manager, Amber Bradsher. Dedicated to the quality control and quality assurance of this department Ms. Bradsher provides leadership in the areas of quality assurance, quality control, quality related training and standardization compliance within the laboratory. She is also responsible for project management activities as they relate to specific areas within the laboratory requiring standardization to improve the quality and/or efficiency of operations. Further responsibilities include attending all safety committee meetings and maintain up to date safety manuals and safety training programs as well as all departmental Standard Operating Procedure Manuals (SOPs).

Labcorp will cooperate with the State in monitoring activity, provide reports and records of performance as requested by the state, and will allow access to and inspection of its facilities at mutually agreed upon times.

Labcorp understands that the related liquidated damages for this requirement is (B) a general standard and will result in CAP/invoice reduction