

Labcorp's Genetic Testing Protocol

Labcorp will provide State with scientifically reliable genetic methods that will achieve at paternity probability of 99.0% or greater.

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's current test panel utilizes 27 genetic markers. 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. In addition, Labcorp may test Y chromosome or X chromosome genetic markers, in appropriate cases. The testing of X and Y chromosome markers provides Labcorp with the tools needed to strength mother not test cases, mutations, and other potentially difficult cases. This testing in conjunction with our double blind processing of each sample received in our laboratory routinely *exceeds the AABB standard* of a combined paternity index of 100 to 1. The table below represents the loci validated by Labcorp for testing:

D12S391	DXS101	D3S1358	D7S820	VWA
D21S11	TH01	F13B	FGA	D8S1179
D18S51	TPOX	LPL	AMELOGENIN	HLA-DR BETA
D13S317	PENTA D	PENTA E	D19S433	D10S1248
D16S539	F13A	FESFPS	HLA-A	D22S1045
D1S1656	D6S1043	HPRTB	HLA B	D2S441
DYS392	D5S818	CSF1PO	D2S1338	DXS6810
DXS9895		23 markers on Y Chromosome		

Labcorp's commitment to the State is to be a partner in providing dependable and competitively priced genetic testing services. The following quality control procedures are standard protocol at Labcorp and they are an integral part of delivering reliable results you can trust.

Double Blind Testing

As part of Labcorp's exceptionally high level of quality control, two (2) DNA preparations are made for each person tested. One (1) of the color-coded buccal swabs is prepared and tested independently of the second buccal swab. The overlapping independently performed tests must match before we conclude the DNA profiles generated have passed the quality assurance double blind test. This superb quality control check helps prevent the release of potential errors in the testing process. Importantly Labcorp performs this double-blind (duplicate) testing process on all individuals in a case and not just on excluded alleged fathers, which exceeds AABB requirements.

Labcorp also “double checks” the samples; this is not the same as double blind testing. Labcorp has and continues to double check the labeling of the samples received. Labcorp’s double check process includes wrapping an adhesive flag around each person’s buccal swabs at the time of collection, a process that appears unique to Labcorp, labeling the envelope the swabs are placed in and matching these two to the chain of custody form. In the laboratory each of these are checked multiple times against each other to reduce the chance of a sample switch. The combination of the double blind testing confirmation and the color-coded and labeled swabs greatly reduce the opportunity for any sample switches during testing.

Gender Testing

Labcorp, as a quality control step, also tests the gender of each sample. This provides an added check. For example, if the mother tested as male the laboratory would reject the results and perform additional evaluations of the sample to resolve the gender discrepancy, as the mother should test as female.

Controls

A known human control is run for each DNA polymorphism. The genetic markers for this human positive control must match before any interpretation is done. Negative controls are also run. These controls are designed to monitor for possible contamination that may have been introduced during laboratory testing and also to ensure that the laboratory’s amplification reagents and equipment are functioning properly. They may also detect problems with software used in the profile analysis process.

Frequency Tables

Labcorp, to its knowledge, has the largest collection of databases in the parentage business. The frequencies used for the calculations are drawn from Labcorp's extensive collection of databases of adequate size. Upon request, Labcorp can make calculations using published frequency tables. Currently Labcorp has established frequencies tables for over **seventy (70)** distinct populations (racial / ethnic groups). These frequency tables allow Labcorp to generate a more precise combined paternity index and probability of paternity for the citizens of Massachusetts. This provides the best evidence of the relationship for the tested parties and for use in court. This is an example of Labcorp’s continuing dedication to high quality results and scientific leadership. Labcorp also utilizes mutation rates when appropriate.

Testing Standards

Labcorp performs all testing in strict accordance with the most current Standards for Relationship Testing Laboratories, as published by the AABB, and has been regularly 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.

Quality Control/Quality Assurance Program

Labcorp maintains an extensive program of Quality Control implemented at all levels of testing and evaluation. Quality control programs developed by Labcorp meet or surpass the requirements set by the federal government and licensing agencies including, but not limited to the AABB, the College of American Pathologists (CAP), New York State Department of Health and is accredited to ISO/IEC 15189 by ANSI-ASQ National Accreditation Board/FQS. In addition, Labcorp is inspected regularly by government and various accrediting groups. Using a variety of internal quality control programs, results from every area of the laboratory are closely monitored.

The DNA Identification Testing Division has its own Associate Quality Director, Ms. Beth Clifton. Dedicated to the quality control and quality assurance of this department Ms. Clifton 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 maintaining up to date safety manuals and safety training programs as well as all departmental Standard Operating Procedure Manuals (SOPs).

Proficiency Testing

Labcorp participates in numerous proficiency testing programs, both externally sponsored, such as the College of American Pathologists' Parentage/Relationship Testing Program, and internally generated proficiency testing. The purpose of the programs is to assure that the laboratory can reproduce correct testing results. Internal and external proficiency programs evaluate the laboratory anonymously. For paternity, sample cases containing multiple individuals are sent through the laboratory as if they were real cases. This proficiency testing allows Labcorp to evaluate the entire process of generating a paternity case. Lastly the laboratory monitors quality incident reports. Quality incident reports are generated if an aspect of the testing process is not found to be conforming to acceptable standards. This allows the laboratory to quickly respond to any incident with appropriate corrective action. Labcorp's success in these proficiency testing programs is evidenced by its continuous accreditation.

In addition, our staff has served on committees for CAP involved in the development, provision and grading of their proficiency tests. Our staff has also presented multiple presentations on proficiency testing at scientific meetings.

Equipment Validation

Laboratory equipment validation is a critical aspect of our quality control procedures. Each piece of equipment must be reliable and sound to maintain proper throughput. Labcorp maintains an extensive maintenance program and quality control for all of our equipment. Our expansive inventory of state of the art equipment totals over 200 pieces and includes genetic analyzers, thermal cyclers, centrifuges, robotic liquid handlers, computers and many other pieces of equipment. Labcorp has the resources to develop and offer the State of Maryland the latest technological advancements in genetic testing. Labcorp, being on the cutting edge of technology, was the first laboratory to validate and offer to its clients STR testing with a more powerful testing panel of over 20 loci on every sample and since that time Labcorp has further increased the power of the test panel. The utilization of these alleles provides for robust testing up front with no additional testing or kits required in routine cases. Labcorp has validated many additional test kits and can run more loci if needed.

Standard Operating Procedures (SOP)

Labcorp has established and maintains hundreds of SOPs for every testing process we perform. All employees are required to review the SOPs applicable to their area of responsibility and are required to perform procedures following the SOP. Labcorp's SOPs are reviewed annually by various levels of staff and final approval from the Laboratory Director is required.

Labcorp provides reports of high reliability that exceed the industry standard. The laboratory maintains a strong quality control/quality assurance program. These programs are discussed throughout this proposal. Labcorp's quality control/quality assurance programs include:

- Color-coded buccal swabs, with matching color-coded labels and color-coded envelopes
- Double blind testing of all samples
- An initial test battery that will detect on average 99.99999% of falsely accused men
- Extensive additional genetic markers to resolve difficult cases
- An average probability of paternity of 99.999999%
- The majority of cases with a combined paternity index greater than one billion to one (1,000,000,000 to 1)
- Opinions of non-paternity based on three (3) or more inconsistencies
- Computer review of various quality control checks and warning messages when appropriate
- Duplicate review of all cases
- Final review by qualified scientists (PhD)
- Regular participation in continuing education programs
- Full time quality control/quality assurance supervisors
- Internal proficiency testing program

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 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. 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. Using these aspects 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 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.

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

Copies of Labcorp's accreditation certificates/licenses are provided as **Attachment XXX**.