

AABB ACCREDITATION OF PARENTAGE TESTING LABORATORIES

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The 4th Edition of Standards for Parentage Testing Laboratories from the American Association of Blood Banks (AABB) became effective on July 1, 1999. This new edition of Standards was written in a Quality System Essentials format. In addition, the AABB has implemented a new accreditation program for parentage testing coinciding with the implementation of the 4th Edition of Standards.

The 4th Edition of Standards for Parentage Testing Laboratories differs significantly from previous Editions. The 4th Edition is quality based and requires documentation of how standards are met. The 4th Edition of Standards is divided into 10 areas.

The first section in the 4th Edition of Standards is Organization. The laboratory should have a defined structure that clearly identifies the parties responsible for the provision of parentage testing services and the relationship of individuals responsible for key quality functions. This is done to assign responsibilities for the overall operation and the implementation and support of a quality management system. The laboratory should have a description of the executive management of the laboratory and the duties of the laboratory director. A diagram of how the laboratory fits in with the larger organization is often helpful. Also the quality system of the laboratory should be documented as well as the policies, processes, and procedures utilized by the laboratory to ensure that the requirements of the Standards and the quality system are satisfied. Lastly, there should be a schedule for periodic management review to assess the continuing suitability and effectiveness of the quality system.

The second section in the 4th Edition of Standards is Resources. Here the laboratory should have documentation of a process to ensure competency testing of the technical staff, at least 4 hours per year of continuing education for the technical staff, and a qualified person available as an expert witness in the event that legal testimony is required.

The third section in the 4th Edition of Standards is Equipment. The laboratory should have a process to ensure that instruments, equipment, and measuring devices critical to providing services are identified, validated, calibrated, and maintained according to applicable regulations and requirements to ensure ongoing performance at expected levels. The laboratory should identify the critical instruments, equipment, and measuring devices. Documentation of maintenance and calibration is required for all equipment and software.

The fourth section in the 4th Edition of Standards is Supplier and Customer Issues. This section is new to this edition of standards and requires that there is a process to ensure that providers of critical goods meet agreed upon requirements to assure that each party's expectations are defined. This section covers such areas as supplier qualification, agreement review, as well as receipt, inspection, and evaluation of incoming supplies.

The fifth section in the 4th Edition of Standards is Process Control which deals with the processes the laboratory has to ensure that the testing is performed correctly. This included the records from at least three external graded proficiency tests per year as well as the general quality control utilized to ensure that reagents, equipment, and methods function as required. Appropriate records need to be maintained for each sample collected to ensure proper identification, verification, and traceability. SOPs for each of the test methods also need to be available to the laboratory personnel and there must be documentation of the training and competency. Lastly, new or changed services need to have a process to ensure validation.

The sixth section of 4th Edition of Standards is Documents and Records which ensures that documents are identified, approved, implemented, and retained. The laboratory should have procedures which address the

periodic review of laboratory records and their approval by the laboratory director. Likewise, procedures which address confidentiality and record retention should also be present in the laboratory.

The seventh section of the 4th Edition of Standards deals with Incidents, Errors, and Accidents. The laboratory should have a process to ensure the capture, assessment, investigation, and monitoring of events that deviate from accepted policies, processes or procedures or fail to meet requirements of the laboratory. This is done in order to prevent recurrence of similar types of deviations.

The eighth section of the 4th Edition of Standards deals with Assessments: Internal and External. The laboratory should have a process to manage external assessments and schedule, perform, and document internal assessments of operations and the quality system. The results should be reported to management.

The ninth section of the 4th Edition of Standards deals with Process Improvement. The laboratory should have a process to ensure that the defined methods for identification, data collection, and analysis are followed. Preventative and corrective actions should be followed up. This is to ensure active resolution of potentially costly or high-risk issues.

The last section of the Standards deals with Facilities and Safety. The laboratory should have a process to ensure the provision of safe and adequate environmental conditions in the workplace.

The accreditation process has also changed. The laboratory is now assessed every other year by an assessor instead of inspections by an inspector. To facilitate the assessment a number of forms have been developed by the AABB National Office. First the assessor is contacted by a member of the Parentage Testing Accreditation Program Unit with an assessment assignment. Once an assessor agrees, the laboratory to be assessed is contacted with the name of the potential assessor. The laboratory can either accept the assessor assigned or request a different assessor. Once an assessor and laboratory are matched, the assessor will contact the laboratory director and arrange for a mutually convenient time for the on site assessment. The assessor may also request additional documents from the laboratory prior to his/her visit to facilitate the assessment. Prior to the assignment of an assessor, the laboratory has submitted a Facility Data Verification Record (FDVR) which indicates what type of testing and how much is conducted. The laboratory is also asked to provide a number of documents prior to the assessment including: new or changed procedures since the last assessment, and 4 random cases to be selected by the National Office. A Parentage Testing Assessment Tool has been developed to help both the laboratory and the assessor determine whether the laboratory meets the standards and how it is documented. The PT Assessment Tool addresses each of the standards and asks how each of the areas is ensured to be met. There is also a Parentage Testing Guidance Document which gives examples of how each of the standards can be met. Finally there is an Accreditation Information Manual (AIM) which contains examples of all of the forms and information about the assessment program from the AABB National Office. Those needing additional information about the AABB assessment program can contact the AABB National Office at 8101 Glenbrook Road, Bethesda, MD 20814-2749, telephone number (301) 907-6977.