AMERICAN ASSOCIATION OF BLOOD BANKS

Accredited Parentage Testing Laboratories October 7, 1999

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Total = 44

1.000 GENERAL POLICIES

ITEM		YES	NO	NA	
1.100	**Personnel**				
1.101	Is the laboratory under the direction of an individual(s) with a doctoral degree who is/are qualified by advanced training and/or experience in parentage testing	____	____	____	D
1.102	Is there evidence that the director(s) is/are spending adequate amounts of time as DIRECTOR	____	____	____	D
1.103	Is there evidence of personal review of the cases by a director	____	____	____	D
1.104	Are there clear-cut assignments of responsibility for:				
1.105	• Day-to-day performance of specific tests	____	____	____	R
1.106	• Scheduling of tests	____	____	____	R
1.107	• Implementation of quality control	____	____	____	D
1.108	• Maintenance of laboratory records	____	____	____	D
1.109	• Review of laboratory performance	____	____	____	D
1.110	• Delegation of responsibility in director's absence	____	____	____	D
1.111	Is there evidence of interaction between the director and staff	____	____	____	R
1.112	If not, comment_____ _____				I

REFERENCE

P1.110 The laboratory shall be under the direction of an individual/individuals with a doctoral degree who is/are qualified by advanced training and/or experience in parentage testing.

P1.130 A qualified individual must be available to act as an expert witness in the event that legal testimony related to the test results is required.

EXPLANATION

The director of a parentage testing laboratory is the most important component of that laboratory. The director provides expertise and ensures that the technical staff are competent to perform their duties. It is the director's responsibility to establish and review policies and procedures that ensure accurate test results. In addition, the laboratory director usually serves as the expert witness and as such must be familiar with all aspects of paternity testing and be able to interpret results for individuals unfamiliar with medical technology and terminology.

The director must have a doctoral degree in an area such as medicine, genetics, biology, or other related fields. The director should be able to demonstrate experience and expertise in those methods the laboratory employs for paternity testing (HLA, red cell antigen tests, enzymes and proteins, DNA). In some larger laboratories, expertise in a given area (such as DNA testing) may be provided by another individual. The laboratory director, however, must still be conversant with all areas of testing and is responsible for the results of testing performed in all areas. It is essential that a laboratory director have adequate experience to detect possible errors in test performance or in the interpretation of test results. Adequate experience is difficult to quantify. It cannot be measured necessarily by years of experience or number of cases reviewed, nor can it be assumed based upon education or coursework. Adequate experience can only be demonstrated in the way that the individual directs his or her laboratory, through the care given to case review, through response to errors or problems, through the procedures and protocols established for the performance of the testing, through interactions with the staff, and through demonstration of adequate understanding of the genetics and statistics that form the foundation of the science of parentage testing. Failure of a director to adequately demonstrate sufficient experience and general competence to the satisfaction of the inspector may result in a deficiency.

Personal review of all cases by a director is required, as this individual is responsible for all results generated by the laboratory. This shall be documented by having the director sign all reports. In addition, the director and/or his/her designee must review and sign or initial important worksheets, autoradiograms, and other pertinent test results. The director shall also review the laboratory's procedures manual and indicate that review by initialing and dating the document. And, there should be evidence that the director reviews results of external (and internal if appropriate) proficiency tests. Corrective action, where appropriate, must be documented.

Some large laboratories may find it necessary or practical to have multiple directors. Thus, there may be several individuals who sign paternity test reports. However, each individual in that laboratory who reviews and signs those reports must meet the qualifications of a paternity laboratory director outlined above. In addition, there must still be one individual who has the overall responsibility for the paternity testing laboratory. Any change in director(s) must be reported to the AABB within 30 days.

Authority for the technical and clerical aspects of the laboratory functions may be delegated. In some institutions the director may arrange for consultative services to augment existing services or for the purpose of dealing with problems requiring special expertise.

The director is also responsible for the development, implementation, and review of the quality assurance (QA) program of the laboratory. The QA program developed and administered by the Director must include procedures for training staff and reviewing their competency periodically. In addition, policies for quality control of reagents and the periodic maintenance of equipment must be a part of the QA plan. The QA plan must also define acceptable limits for all equipment and reagents and must indicate the course of action when these limits are not achieved.

Records must be maintained for at least 5 years unless local law requires a longer retention time. All paternity files are to be considered confidential and stored with security.

EXPLANATION

The laboratory shall have a quality plan in place that describes how the facility plans to develop their quality program, including a time line.

In the future, the laboratory will be required to have a quality program in place that monitors performance to ensure that predetermined quality criteria are met and that laboratory improvement is a management goal. Responsibility for the ongoing implementation of the quality program may be assigned to a designated individual(s), but is ultimately the responsibility of the laboratory director. The quality program must address the items found in the Quality System Essentials (Association Bulletin 97-4).

ESSENTIAL	ACTIVITIES THAT SHOULD BE INCLUDED
Organization	A table of organization or description of organization, is to be included in this section in which lines of responsibility are clearly shown. The individual(s) responsible for the quality program is named here. The goals of the organization and a quality statement should be defined and written.
Personnel	Job descriptions that define educational and experience requirements, duties and responsibilities, and lines of authority are to be included in this section. A description of the training program for new hires and documentation of appropriate training prior to on-line responsibility are also kept here as well as documents of periodic evaluations and competency for each staff member.
Equipment	Each item of equipment must be listed with a unique inventory number. Records of calibration, schedules of periodic maintenance with dates of activity, and repairs are to be kept in this section.
Supplier Issues	A list of suppliers/vendors of all scientific items and services is maintained. The list should document the names of the vendors with addresses, phone and FAX numbers, and what items/services are provided by each vendor.
Process Control	This section contains a description of all the various quality control procedures in place with a calendar schedule of set intervals for checks. A policy should be established to follow when established limits are exceeded. It should also list the various proficiency tests used in the laboratory and what action is taken if a nonconsensus result is reported. Separate notebooks should be used to store the actual quality control data and the proficiency testing records.
Documents and Records	A model format for writing a standard operating procedure (SOP) should display the various sections of the procedure in a set order. There should also be a description of how SOPs are changed and how data entries in records are to be changed when appropriate. The length of time for the retention of records should be established as well as security for any off site storage.
Incidents/Errors/ Accidents	A process must be in place to investigate errors, accidents, and credible complaints. Clients whose challenges about test results appear to have merit must be offered a repeat test at no charge by the laboratory, or, if the client chooses, in another laboratory accredited by the AABB. The director should advise the client to prepare a written appeal to the Parentage Testing Program Unit if the client and director disagree on the merit of the challenge. Errors must be investigated to determine root cause and appropriate action must be taken. Documentation must be kept on errors and accidents regarding discovery, root cause analysis, and corrective action taken.
Assessments	There must be a schedule for internal assessments. The director and the responsible head of the quality program (if not the director) shall establish specific items for periodic review. Appropriate assessments might include test result discrepancies, completeness of records, sigma and delta calculations in RFLP analysis, paternity index and power of exclusion (PE) consistency checks, etc.
Process Improvement	The director and the responsible head of the quality program (if not the director) should set goals with timetables for process improvement activities. Appropriate study areas might include DNA extraction yields, background noise on autorads, number (%) of redraws, etc.
Facilities and Safety	There shall be a description of the safety training program for the staff and records of periodic participation by each staff member must be kept.