THE AMERICAN ASSOCIATION OF BLOOD BANKS INSPECTION AND ACCREDITATION PROGRAM FOR PARENTAGE TESTING LABORATORIES

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INTRODUCTION

The Parentage Testing Inspection and Accreditation (PT-I&A) Program of the American Association of Blood Banks (AABB) was conceived and created by the AABB Committee on Parentage Testing in 1984. Although implementation of the program was originally the responsibility of the Parentage Testing Committee, in 1993 the AABB Board of Directors separated the PT-I&A program from the committee and merged it with the AABB National I&A Program for Blood Banks and Transfusion Services which is where it remains today.

The PT-I&A is a voluntary program based upon Standards for Parentage Testing Laboratories (Standards), now in its second edition. The Standards address code of conduct, general policies, identification of the parties, specimen collection, all phases of commonly used methods in laboratory testing for parentage determination, statistical evaluation and the contents of the final report. The Standards are promulgated by the Committee on Parentage Testing after they have been circulated to the parentage testing community for comment.

OBJECTIVES

The primary purpose of the PT-I&A program is to foster the improvement of parentage testing laboratories and their policies and procedures as they relate to services to tested individuals and clients. Adherence to the Standards assists laboratory directors and their staff in providing high quality performance. The AABB PT-I&A Program is designed to assist directors of parentage testing laboratories in determining whether methods, procedures, personnel, equipment and physical plant meet established requirements. It is also a means for detecting problems in practice and provides, when needed, consultation for their correction. The I&A Program provides recognition through accreditation to those facilities functioning in accordance with existing published requirements of the AABB. Accreditation by the AABB is required by many states for contract recipients. The AABB Committee on Parentage Testing has worked closely with the Office of Child Support Enforcement in order to assure that laboratory reports and interpretations have credibility and substance in courts of law. Basic minimum requirements for accreditation of parentage testing laboratories are embodied in the AABB Inspection Report Form (IRF) for Parentage Testing Laboratories. These requirements are based primarily on the text of the Standards.

ORGANIZATION OF PROGRAM

The PT-I&A Program is under the immediate administration of the National Committee on Inspection and Accreditation, members of which are appointed by the Association's President subject to approval by the Board of Directors. The National Committee is composed of a national chair, six vice chairs and three parentage testing area chairs together with liaisons from other related AABB committees, the College of American Pathologists, the FDA, Office of Biologics, the Centers for Disease Control and the US Armed Services Blood Program.

Implementation of the PT-I&A Program is handled by the I&A area chairs with clerical assistance provided through the AABB National Office. Each I&A area chair is responsible for I&A activities in a designated area of the United States (Eastern, Central, and Western).

Serving under the three I&A area chairs are 16 inspectors, all with advanced academic degrees and experience. All of these individuals contribute their time and talents to the program and receive no monetary compensation. Only the inspection-related out-of-pocket expenses incurred by assigned inspections are reimbursed, upon request, by the AABB.

All parentage testing laboratories are urged to seek AABB accreditation. Inspection must be requested by the director responsible for the parentage testing laboratory. Prior to inspection, the director is provided with a copy of the IRF. The IRF indicates most of the questions to be asked and items that will be reviewed by the inspector during the on-site visit. The IRF is partially completed by the director in accordance with the instructions printed on the front page. The IRF is then forwarded to the National Office along with three copies of the laboratory Procedure Manual and all of the records, films and documents relating to four parentage test cases (selected at random by the AABB).

INSPECTION PROCEDURE

The I&A area chair assigns an inspector to complete the inspection within 30 days of receipt of the above materials. The inspector will review all of the submitted documents (IRF, Procedure Manual, and four cases) prior to the on-site inspection.

During the inspector's visit, there will be a detailed review of technical proficiency and quality control procedures; quality assessment program; reports and recording methods; equipment and its functions; and physical plant adequacy. The inspector completes those parts of the IRF applicable to the facility and forwards the report to the I&A area chair.

Any deficiencies found at the time of inspection, or, even subsequently when the I&A area chair reviews the IRF, facility's records and cases, will be reported in writing to the director by the I&A area chair. The report may include recommendations for improvements and means for correcting deficiencies.

The director of the inspected facility sends details of corrective action directly to the I&A area chair. If the stated corrections are satisfactory, the I&A area chair will recommend that accreditation be granted. If the deficiencies noted at the time of the inspection are major and/or numerous, the I&A area chair may inform the director that a reinspection is necessary after the deficiencies have been corrected. In that event, an inspector will return for a second review. Any deficiencies found upon reinspection must be corrected following the above procedure.

ACCREDITATION

AABB accreditation is for a two-year period. The procedures for renewal inspections are the same as for initial inspections except that only new or recently revised procedures are submitted prior to the inspection.

EVALUATION OF THE PROGRAM

The I&A Program is continuously in review. Comments and constructive criticism are sought from all those inspected, through the use of a Post-inspection Questionnaire which provides an opportunity to evaluate all aspects of pre-inspection, on-site inspection and the post-inspection process. Letters of response to criticisms and comments, when appropriate, are initiated by the national chair or by the responsible I&A area chair, or both. Resolution of individual problems is attempted. Criticisms and comments often influence long-range planning, as they are critiqued at the annual meeting of the Inspection and Accreditation Committee-at-Large.

In addition, there are periodic workshops presented by I&A area chairs for the inspectors. The workshops provide an opportunity to discuss and review the I&A Program and result in a more uniform application of AABB requirements during the inspection process.

EDUCATIONAL ASPECTS OF THE PROGRAM

AABB inspections provide an educational experience for all participants. A detailed review of the facility's physical plant, procedures, record forms and techniques and an assessment of compliance with the Standards and I&A accreditation requirements can be an enlightening experience for those who actively participate in the inspection process. Educational benefits are derived from the analysis and feedback provided by the AABB inspectors and I&A area chairs. Additionally, valuable knowledge is gained through letters from I&A area chairs to directors relating deficiencies and recommendations, comments and suggestions on how to correct these deficiencies, thus improving service to the establishment of paternity and to child support. Finally, the process of correcting deficiencies often necessitates a reassessment of the level and quality of practice. This frequently results in greater interaction and cooperation between the facility director and personnel. It often leads to increased communication and awareness within the facility.