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Quality Assurance Standards for Forensic DNA Testing Laboratories

DNA Advisory Board
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(Part 2 of 2)

Read about …

1. Scope

The standards describe the quality assurance requirements that a laboratory, which is defined as a facility in which forensic DNA testing is performed, should follow to ensure the quality and integrity of the data and competency of the laboratory. These standards do not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

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2. Definitions

As used in these standards, the following terms shall have the meanings specified:

Administrative review is an evaluation of the report and supporting documentation for consistency with laboratory policies and for editorial correctness.

Amplification blank control consists of only amplification reagents without the addition of sample DNA. This control is used to detect DNA contamination of the amplification reagents.

Analytical procedure is an orderly step-by-step procedure designed to ensure operational uniformity and to minimize analytical drift.

Audit is an inspection used to evaluate, confirm, or verify activity related to quality.

Calibration is the set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.

Commercial test kit is a preassembled kit that allows the user to conduct a specific forensic DNA test.

Critical reagents are determined by empirical studies or routine practice to require testing on established samples before use on evidentiary samples in order to prevent unnecessary loss of sample.

Examiner/analyst is an individual who conducts and/or directs the analysis of forensic casework samples, interprets data, and reaches conclusions.

Forensic DNA testing is the identification and evaluation of biological evidence in criminal matters using DNA technologies.

Known samples are biological material whose identity or type is established.

Laboratory is a facility in which forensic DNA testing is performed.

Laboratory support personnel are individuals who perform laboratory duties and do not analyze evidence samples.

NIST is the National Institute of Standards and Technology.

Polymerase chain reaction (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles that consist of the following:

- Denaturation of the template;
- Annealing of primers to complementary sequences at an empirically determined temperature; and
- Extension of the bound primers by a DNA polymerase.

Proficiency test sample is biological material whose DNA type has been previously characterized and is used to monitor the quality performance of a laboratory or an individual.

Proficiency testing is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as one of the following:

- *Internal proficiency test* is one prepared and administered by the laboratory.
- *External proficiency test*, which may be open or blind, is one that is obtained from a second agency.

A *qualifying test* measures proficiency in both technical skills and knowledge.

Quality assurance includes the systematic actions necessary to demonstrate that a product or service meets specified requirements for quality.

A *quality manual* is a document stating the quality policy, quality system, and quality practices of an organization.

Quality system is the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Reagent blank control consists of all reagents used in the test process without any sample. This is to be used to detect DNA contamination of the analytical reagents.

Reference material (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by or traceable to a certificate or other documentation that is issued by a certifying body.

Restriction fragment length polymorphism (RFLP) is generated by cleavage by a specific restriction enzyme, and the variation is due to restriction site polymorphism and/or the number of different repeats contained within the fragments.

Review is an evaluation of documentation to check for consistency, accuracy, and completeness.

Second agency is an entity or organization external to and independent of the laboratory and which performs forensic DNA analysis.

Secure area is a locked space (e.g., cabinet, vault, or room) with access restricted to authorized personnel.

Subcontractor is an individual or entity having a transactional relationship with a laboratory.

Technical manager or leader (or equivalent position or title as designated by the laboratory system) is the individual who is accountable for the technical operations of the laboratory.

Technical review is an evaluation of reports, notes, data, and other documents to ensure an appropriate and sufficient basis for the scientific conclusions. This review is conducted by a second qualified individual.

Technician is an individual who performs analytical techniques on evidence samples under the supervision of a qualified examiner/analyst and/or performs DNA analysis on samples for inclusion in a database. Technicians

do not evaluate or reach conclusions on typing results or prepare final reports.

Traceability is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework analysis and includes the following:

- *Developmental validation* is the acquisition of test data and the determination of conditions and limitations of a new or novel DNA methodology for use on forensic samples.
- *Internal validation* is the accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

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3. Quality Assurance Program

Standard 3.1. The laboratory shall establish and maintain a documented quality system that is appropriate to the testing activities.

3.1.1. The quality manual shall address, at a minimum, the following:

- Goals and objectives,
- Organization and management,
- Personnel qualifications and training,
- Facilities,
- Evidence control,
- Validation,
- Analytical procedures,
- Calibration and maintenance,
- Proficiency testing,
- Corrective action,
- Reports,
- Review,
- Safety, and
- Audits.

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4. Organization and Management

Standard 4.1. The laboratory shall do the following:

- Have a managerial staff with the authority and resources needed to discharge their duties and meet the requirements of the standards in this document;
- Have a technical manager or leader who is accountable for the technical operations; and
- Specify and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the validity of the DNA analysis.

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5. Personnel

Standard 5.1. Laboratory personnel shall have the education, training, and experience commensurate with the examination and testimony provided. The laboratory shall do the following:

5.1.1. Have a written job description for personnel to include responsibilities, duties, and skills;

5.1.2. Have a documented training program for qualifying all technical laboratory personnel;

5.1.3. Have a documented program to ensure technical qualifications are maintained through continuing education; and

5.1.3.1. *Continuing Education:* The technical manager or leader and examiner/analyst(s) must stay abreast of developments within the field of DNA typing by reading current scientific literature and by attending seminars, courses, professional meetings, or documented training sessions/classes in relevant subject areas at least once a year.

5.1.4. Maintain records on the relevant qualifications, training, skills, and experience of the technical personnel.

Standard 5.2. The technical manager or leader shall have the following:

5.2.1. *Degree Requirements:* At a minimum, a master's degree in a biology-, chemistry-, or forensic science-related area and successfully complete a minimum of 12 semester or equivalent credit hours of a combination of undergraduate and graduate course work covering the subject areas of biochemistry, genetics, and molecular biology (molecular genetics, recombinant DNA technology), or other subjects that provide a basic understanding of the foundation of forensic DNA analysis, as well as statistics and/or population genetics as it applies to forensic DNA analysis.

5.2.1.1. The degree requirements of section

5.2.1. may be waived by the American Society of Crime Laboratory Directors (ASCLD) or another organization designated by the Director of the FBI in accordance with criteria approved by the Director of the FBI. This waiver shall be available for a period of two years from the effective date of these standards. The waiver shall be permanent and portable.

5.2.2. *Experience Requirements:* A technical manager or leader of a laboratory must have a minimum of three years of forensic DNA laboratory experience.

5.2.3. *Duty Requirements:*

5.2.3.1. *General:* Manages the technical operations of the laboratory.

5.2.3.2. *Specific:*

- Is responsible for evaluating all methods used by the laboratory and for proposing new or modified analytical procedures to be used by examiners.
- Is responsible for technical problem solving of analytical methods and for the oversight of training, quality assurance, safety, and proficiency testing in the laboratory.

5.2.3.3. *Accessibility:* The technical manager or leader shall be accessible to the laboratory to provide onsite, telephonic, or electronic consultation as needed.

Standard 5.3. Examiner/analyst shall have the following:

5.3.1. *Degree Requirements:* At a minimum, a bachelor's degree or its equivalent degree in biology-, chemistry-, or forensic science-related area and must have successfully completed college course work (graduate or undergraduate level) covering the subject areas of biochemistry, genetics, and molecular biology (i.e., molecular genetics, recombinant DNA technology) or other subjects which provide a basic understanding of the foundation of forensic DNA analysis, as well as course work and/or training in statistics and population genetics as it applies to forensic DNA analysis;

5.3.2. *Experience Requirements:* A minimum of six months of forensic DNA laboratory experience, including the successful analysis of a range of samples typically encountered in forensic case work prior to independent case work analysis using DNA technology; and

5.3.3. Successfully completed a qualifying test before beginning independent casework responsibilities.

Standard 5.4. Technicians shall have the following:

5.4.1. On-the-job training specific to their job function(s); and

5.4.2. Successfully completed a qualifying test before participating in forensic DNA typing responsibilities.

Standard 5.5. Laboratory support personnel shall have the following:

5.5.1. Training, education, and experience commensurate with their responsibilities as outlined in their job description.

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6. Facilities

Standard 6.1. The laboratory shall have a facility that is designed to provide adequate security and minimize contamination. The laboratory shall ensure the following:

6.1.1. Access to the laboratory is controlled and limited;

6.1.2. Prior to PCR amplification, evidence examinations, DNA extractions, and PCR setup are conducted at separate times or in separate spaces;

6.1.3. Amplified DNA product is generated, processed, and maintained in a room(s) separate from the evidence examination, DNA extractions, and PCR setup areas; and

6.1.4. The laboratory follows written procedures for monitoring, cleaning, and decontaminating facilities and equipment.

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7. Evidence Control

Standard 7.1. The laboratory shall have and follow a documented evidence control system to ensure the integrity of physical evidence. This system shall ensure the following:

7.1.1. Evidence is marked for identification;

7.1.2. Chain of custody for all evidence is maintained;

7.1.3. The laboratory follows documented procedures that minimize loss, contamination, and/or deleterious change of evidence; and

7.1.4. The laboratory has secure areas for evidence storage.

Standard 7.2. Where possible, the laboratory shall retain or return a portion of the evidence sample or extract.

7.2.1. The laboratory shall have a procedure requiring that evidence sample/extract(s) are stored in a manner that minimizes degradation.

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8. Validation

Standard 8.1. The laboratory shall use validated methods and procedures for forensic casework analyses.

8.1.1. Developmental validation that is conducted shall be appropriately documented.

8.1.2. Novel forensic DNA methodologies shall undergo developmental validation to ensure the accuracy, precision, and reproducibility of the procedure. The developmental validation shall include the following:

8.1.2.1. Documentation exists and is available that defines and characterizes the locus.

8.1.2.2. Species specificity, sensitivity, stability, and mixture studies are conducted.

8.1.2.3. Population distribution data are documented and available.

8.1.2.3.1. The population distribution data would include the allele and genotype distributions for the locus or loci obtained from relevant populations. Where appropriate, databases should be tested for independence expectations.

8.1.3. Internal validation shall be performed and documented by the laboratory.

8.1.3.1. The procedure shall be tested using known and nonprobative evidence samples. The laboratory shall monitor and document the reproducibility and precision of the procedure using human DNA control(s).

8.1.3.2. The laboratory shall establish and document match criteria on the basis of empirical data.

8.1.3.3. Before the introduction of a procedure into forensic casework, the analyst or examination team shall successfully complete a qualifying test.

8.1.3.4. Material modifications made to analytical procedures shall be documented and subject to validation testing.

8.1.4. Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published by reputable technical organizations or in relevant scientific texts or journals or have been appropriately evaluated for a specific or unique application.

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9. Analytical Procedures

Standard 9.1. The laboratory shall have and follow written analytical procedures approved by the laboratory management/technical manager.

9.1.1. The laboratory shall have a standard operating protocol for each analytical technique used.

9.1.2. The procedures shall include reagents, sample preparation, extraction, equipment, and controls that are standard for DNA analysis and data interpretation.

9.1.3. The laboratory shall have a procedure for differential extraction of stains that potentially contain semen.

Standard 9.2. The laboratory shall use reagents that are suitable for the methods employed.

9.2.1. The laboratory shall have written procedures for documenting commercial supplies and for the formulation of reagents.

9.2.2. Reagents shall be labeled with the identity of the reagent, the date of preparation or expiration, and the identity of the individual preparing the reagent.

9.2.3. The laboratory shall identify critical reagents and evaluate them prior to use in casework. These critical reagents include but are not limited to the following:

- Restriction enzyme,
- Commercial kits for performing genetic typing,
- Agarose for analytical RFLP gels,
- Membranes for Southern blotting,
- K562 DNA or other human DNA controls,
- Molecular weight markers used as RFLP sizing standards,
- Primer sets, and
- Thermostable DNA polymerase.

Standard 9.3. The laboratory shall have and follow a procedure for evaluating the quantity of the human DNA in the sample where possible.

9.3.1. For casework RFLP samples, the presence of high-molecular weight DNA should be determined.

Standard 9.4. The laboratory shall monitor the analytical procedures using appropriate controls and standards.

9.4.1. The following controls shall be used in RFLP casework analysis:

9.4.1.1. Quantitation standards for estimating the amount of DNA recovered by extraction.

9.4.1.2. K562 as a human DNA control. (In monitoring sizing data, a statistical quality control method for K562 cell line shall be maintained.)

9.4.1.3. Molecular weight size markers to bracket known and evidence samples.

9.4.1.4. Procedure to monitor the completeness of restriction enzyme digestion.

9.4.2. The following controls shall be used for PCR casework analysis:

9.4.2.1. Quantitation standards that estimate the amount of human nuclear DNA recovered by extraction.

9.4.2.2. Positive and negative amplification controls.

9.4.2.3. Reagent blanks.

9.4.2.4. Allelic ladders and/or internal size markers for variable number tandem repeat sequence PCR-based systems.

Standard 9.5. The laboratory shall check its DNA procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available NIST standard reference material or standard traceable to a NIST standard.

Standard 9.6. The laboratory shall have and follow written general guidelines for the interpretation of data.

9.6.1. The laboratory shall verify that all control results are within established tolerance limits.

9.6.2. Where appropriate, visual matches shall be supported by a numerical match criterion.

9.6.3. For a given population(s) and/or hypothesis of relatedness, the statistical interpretation shall be made following the recommendations 4.1, 4.2, or 4.3 as deemed applicable of the National Research Council report entitled *The Evaluation of Forensic DNA Evidence* (1996) and/or a court-directed method. These calculations shall be derived from a documented population database appropriate for the calculation.

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10. Equipment Calibration and Maintenance

Standard 10.1. The laboratory shall use equipment suitable for the methods employed.

Standard 10.2. The laboratory shall have a documented program for calibration of instruments and equipment.

10.2.1. Where available and appropriate, standards traceable to national or international standards shall be used for the calibration.

10.2.1.1. Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results.

10.2.2. The frequency of the calibration shall be documented for each instrument requiring calibration. Such documentation shall be retained in accordance with applicable federal or state law.

Standard 10.3. The laboratory shall have and follow a documented program to ensure that instruments and equipment are properly maintained.

10.3.1. New instruments and equipment, or instruments and equipment that have undergone repair or maintenance, shall be calibrated before being used in casework analysis.

10.3.2. Written records or logs shall be maintained for maintenance service performed on instruments and equipment. Such documentation shall be retained in accordance with applicable federal or state law.

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11. Reports

Standard 11.1. The laboratory shall have and follow written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory reports.

11.1.1. The laboratory shall maintain, in a case record, all documentation generated by examiners related to case analyses.

11.1.2. Reports according to written guidelines shall include the following:

- Case identifier;
- Description of evidence examined;
- A description of the methodology;
- Locus;
- Results and/or conclusions;
- An interpretative statement (either quantitative or

qualitative);

- Date issued;
- Disposition of evidence; and
- A signature and title, or equivalent identification, of the person(s) accepting responsibility for the content of the report.

11.1.3. The laboratory shall have written procedures for the release of case report information.

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12. Review

Standard 12.1. The laboratory shall conduct administrative and technical reviews of all case files and reports to ensure conclusions and supporting data are reasonable and within the constraints of scientific knowledge.

12.1.1. The laboratory shall have a mechanism in place to address unresolved discrepant conclusions between analysts and reviewer(s).

Standard 12.2. The laboratory shall have and follow a program that documents the annual monitoring of the testimony of each examiner.

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13. Proficiency Testing

Standard 13.1. Examiners and other personnel designated by the technical manager or leader who are actively engaged in DNA analysis shall undergo, at regular intervals of not to exceed 180 days, external proficiency testing in accordance with these standards. Such external proficiency testing shall be an open proficiency testing program.

13.1.1. The laboratory shall maintain the following records for proficiency tests:

- Test set identifier,
- Identity of the examiner,
- Date of analysis and completion,
- Copies of all data and notes supporting the conclusions,
- Proficiency test results,
- Any discrepancies noted, and
- Corrective actions taken.

Such documentation shall be retained in accordance with applicable federal or state law.

13.1.2. The laboratory shall establish at a minimum the following criteria for evaluation of proficiency tests:

- All reported inclusions are correct or incorrect.
- All reported exclusions are correct or incorrect.
- All reported genotypes and/or phenotypes are correct or incorrect according to consensus genotypes/phenotypes or within established empirically determined ranges.
- All results reported as inconclusive or uninterpretable are consistent with written laboratory guidelines. The basis for inconclusive interpretations in proficiency tests must be documented.
- All discrepancies/errors and subsequent corrective actions must be documented.
- All final reports are graded as satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data. Administrative errors shall be documented and corrective actions taken to minimize the error in the future.
- All proficiency test participants shall be informed of the final test results.

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14. Corrective Action

Standard 14.1. The laboratory shall establish and follow procedures for corrective action whenever proficiency-testing discrepancies and/or casework errors are detected.

14.1.1. The laboratory shall maintain documentation for the corrective action. Such documentation shall be retained in accordance with applicable federal or state law.

15. Audits

Standard 15.1. The laboratory shall conduct audits annually in accordance with the standards outlined herein.

15.1.1. Audit procedures shall address, at a minimum, the following:

- Quality assurance program,
- Organization and management,
- Personnel,

- Facilities,
- Evidence control,
- Validation,
- Analytical procedures,
- Calibration and maintenance,
- Proficiency testing,
- Corrective action,
- Reports,
- Review,
- Safety, and
- Previous audits.

15.1.2. The laboratory shall retain all documentation pertaining to audits in accordance with relevant legal and agency requirements.

Standard 15.2. Once every two years, a second agency shall participate in the annual audit.

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16. Safety

Standard 16.1. The laboratory shall have and follow a documented environmental health and safety program.

17. Subcontractor of Analytical Testing for Which Validated Procedures Exist

Standard 17.1. A laboratory operating under the scope of these standards will require certification of compliance with these standards when a subcontractor performs forensic DNA analyses for the laboratory.

17.1.1. The laboratory will establish and use appropriate review procedures to verify the integrity of the data received from the subcontractor.

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