PROPOSED Standards for Relationship Testing Laboratories, 15th edition

Effective, January 1, 2022

A Note to Readers

Individuals not familiar with the standards-setting practices of AABB should be aware of the following:

- Requirements, once stated, are not repeated. For example, standard 5.0 requires that all processes and procedures be validated. Therefore, it is not necessary to require in other areas that a specific process or procedure be validated.

- Words or phrases used in a way different from their usual meaning are defined in the glossary.

- The term "specified requirements" is defined broadly to include accreditation requirements, national, state, or local laws, and any other applicable requirement.

- Please note, that the Summary of Significant Changes to the proposed 15th edition begins on page 2 and runs through page 7. The proposed 15th edition begins on page 8 and runs through page 61.

Significant Changes to the Proposed 15th edition of Standards for Relationship Testing Laboratories

1.6 Assessment of Risk

The facility's executive management shall identify, assess, and address the level of risk associated with activities performed and the data generated in the facility that affect product quality and safety at facility defined intervals. Standards 5.1.1 and 6.1.4 apply.

1.6.1 Mitigation strategies shall identify, assess, and address the level of risk associated with activities performed in the facility.

This standard is new to the proposed edition and new to the quality template. This standard was first introduced in the 10th edition of CT Standards and could eventually be put in all sets of AABB Standards.

3.5.2 The laboratory shall have an alternative system that ensures continuous operation in the event that routine ~~computer~~ **information system**-assisted functions are unavailable. The alternative system shall be tested at least annually.

Throughout this edition of RT Standards, the term "computer" has been replaced with "information system" to ensure that the Standards reflect current language.

3.5.6 The laboratory shall have processes in place to minimize the risk and impact of an internal or external data breach.

This standard is new to the proposed edition and new to the quality template. This standard was first introduced in the 32nd edition of BBTS Standards and will now be put in all sets of applicable AABB Standards.

5.1.5.2 The laboratory shall release an identifiable sample **and/or profile** of an individual only for purposes relevant to the actual testing for which the sample was submitted. Otherwise, a court order or the written permission of the individual(s) who furnished the sample, or the individual(s) with legal authority to provide consent, is required.

The clause "and/or profile" was added to this standard as there are cases when a

sample can be released, or potentially only the profile is provided. This expansion ensures that the standard better reflects current practice.

5.2.3.5 Samples intended for ~~United States of America~~ immigration, visa, passport, and citizenship testing cases **for the United States of America** shall be accepted only if the case is initiated ~~by a facility accredited by~~ **directly between the petitioner and a facility accredited by** AABB for relationship testing activities. **Records of the initiation of this service by the petitioner shall be maintained in the facility's records**. Standard 4.7 applies.

The element in bold is new to this standard was added for clarity. The requirement ensures that the facility maintains records of the direct communication between the accredited facility and the petitioner for the initiation of relationship tests for U. S. immigration purposes This activity is typically occurring but was a blind spot in the Standards.

5.2.4.1 Printed name, alleged relationship, and date of birth of each individual tested and **untested person(s) signing consent for a minor child or legally incompetent adult**.

This element was added at the request of AABB's lead assessor as something that needed to be included in the identification records for completeness.

5.2.4.8 Original or legible photocopies of **at least** one ~~or both~~ of the following items **for each individual tested and untested person(s) signing consent for a minor child or legally incompetent adult:**

1. **Valid** government-issued photo identification (ID).
2. Photograph that is suitable for positive identification.

To ensure parallel requirements and construction, the committee added the phrase in bold above for the same reasons as stated in standard 5.2.4.1.

5.2.4.8.1 For cases intended for immigration, visa, passport, and citizenship **for the United States of America**, both a photo suitable for positive ID and a legible

copy of the government-issued photo ID shall be submitted for each tested individual **and untested person(s) signing consent for a minor child or legally incompetent adult**. If these documents are not available, the collector shall document the explanation.

To ensure parallel requirements and construction, the committee added the phrase in bold above for the same reasons as stated in standards 5.2.4.1 and 5.2.4.8.

5.3.8 Two-Party Comparisons of Full Siblings, Half Siblings, Avuncular, and Single Grandparentage Combined Likelihood Ratios

The laboratory shall have policies, processes, and procedures for two-party comparisons of full siblings, half siblings, avuncular, and single grandparentage **combined** likelihood ratios. **Reference Standard 6.3A, #3(e) applies**.

The term "combined" was included in the standard for accuracy. The crossreference to 6.3A was added for completeness.

5.3.11.2 For nonparentage **cases** where the genetic evidence does not support the **alleged** ~~tested~~ relationship, **either by exclusions or a low likelihood ratio, phenotypes for parties in question** shall be ~~exclusionary, any relationships that are alleged shall be~~ confirmed with an independent isolation. For closed systems, Standard 5.4.2 applies.

This standard was re-written for clarity. The standard is now written in a way that focuses on confirming the phenotypes of each tested party which is the intent.

5.3.14.3 For **new multiplex kits** or loci (or locus) added to existing test methods, the validation process shall require the analysis of at least 20 biological test samples, with accuracy and reproducibility of test results within the laboratory. If the laboratory establishes its own frequency database for the loci (or locus), the power of exclusion shall be determined and

compared with published values, if available, as part of the validation process.

The elements in bold were added for clarity based on a suggestion from AABB's lead assessor.

5.5 Calculations

~~Calculation methods shall be validated.~~ **The laboratory shall have policies, processes and procedures for the use of validated calculation methods used in relationship testing.**

The committee rewrote this standard to match the typical method by which a standard is written. The intent and content has not changed.

5.5.2 When linked loci are used, the laboratory shall have policies, processes and procedures for estimating and minimizing the effects of linkage on non-parentage cases.

This standard is new to the proposed edition and was added for completeness. These elements were introduced in a previous edition of Guidance and should be familiar to our member laboratories.

6.3.2 Nonautosomal Findings

Nonautosomal results, when tested for parentage, avuncular, full sibling, half sibling, and grandparent, shall be incorporated with autosomal results into the combined relationship index. **In addition to the combined relationship index, the laboratory shall have the opportunity to discuss autosomal and nonautosomal findings separately.**

The addition in bold was added to this standard for clarity. This will ensure the standard reflects current practice.

6.3.2.2 A single haplotype frequency for loci in **linkage** disequilibrium shall be incorporated into calculations for X chromosome transmission results.

The element in bold was added for consistency with other edits made to the Standards.

Reference Standard 6.3A. Requirements for Test Reports	
Chain of Custody Reports	
A. Identifiers	
5	Racial/ethnic background(s) used by the laboratory for calculations **as designated by the participants or closest available frequency database**. **Standard 5.2.5.2 applies.**

The committee added this clause to ensure that member laboratories do not use an allelic frequency database compiled from multiple populations or racial groups *as standard practice. Wherever possible, an allelic frequency database closest to the self-identified racial designation of the tested parties should be used to provide the most accurate determination of relatedness. In guidance, the committee intends to provide examples.*

Reference Standard 6.3A. Requirements for Test Reports		
Chain of Custody Reports		
B. Findings		
3	IF:	THEN:
	There is a failure to exclude and the combined relationship index meets the established reporting policies for the indices obtained for the tested relationship (Standard 5.3.9 applies).	The report shall include the following information: a. The individual relationship index for each genetic system used in the conclusion. b. The combined relationship index. c. The probability of relationship expressed as a percentage. The prior probabilities used to calculate the probability of relationship shall be stated. d. When autosomal loci are not tested, the conclusion shall not overstate the relationship. **An explanation on non-recombining haplotypes inheritance and limitations to these markers shall be provided.** **e. When autosomal likelihood ratios are not in agreement with non-recombining haplotypes (leading to a different conclusion) an explanation on non-autosomal inheritance and limitations to these markers shall be provided.**

The committee expanded subletter "d" was added for clarity to ensure that any report articulates the limitations inherent with non-recombining haplotypes in terms of identifying a familial link, ie determining a specific relationship of two individuals who are distantly related vs identifying lineage from a common relative.

Subletter "e" is new to this edition and was added based on the expansion of subletter "d." ie A very high likelihood ratio obtained from non-recombining haplotype markers used in combination with autosomal markers CRI of < 1.0

Glossary

Linkage Disequilibrium: When alleles at two or more loci are found together more or less often than expected as calculated by the product of their individual frequencies.

This definition is not new but was merely relabeled as "linkage disequilibrium" for clarity. The content of the definition has not changed.

Non-Recombining Haplotypes: A set of genetic markers that are inherited as a group from one parent in its entirety, e.g., commonly used Y chromosome markers.

This definition is new to this edition and was included in concert with the update to reference standard 6.3A, #3, d and e.

1. ORGANIZATION

1.0 Organization

The relationship testing laboratory (hereinafter referred to as the laboratory) shall have an organizational structure that clearly defines and documents the parties responsible for key functions, including quality, but not limited to the provision of relationship test reports and relationship testing services.

1.1 Executive Management

The laboratory shall have a defined executive management. Executive management shall have responsibility and authority for:

1.1.1 Compliance with these *RT Standards* and applicable laws and regulations.

1.1.2 Defining, documenting, implementing, maintaining, and improving the quality system.

1.1.3 Ensuring that a quality representative is appointed to oversee the quality system and to report to executive management.

1.1.3.1 The quality representative shall have relevant training and experience.

1.1.4 Conducting scheduled management reviews to assess the effectiveness of the quality system. Standard 8.0 applies.

1.1.5 Ensuring that operational policies, processes, and procedures are defined, recorded, implemented, maintained, and improved.

1.1.6 Ensuring adherence to quality and operational policies, processes, and procedures.

1.1.7 Obtaining official transcripts for laboratory directors, laboratory director designees, and laboratory supervisors.

1.2 Laboratory Director Qualifications and Responsibilities

1.2.1 The laboratory shall have a laboratory director who has a doctoral degree in medicine, biology, chemistry, genetics, or clinical

laboratory science.

1.2.1.1 The laboratory director shall have at least 2 years of training or experience in relationship testing in an AABB-accredited laboratory (or equivalent) or under the guidance of the laboratory director currently or previously employed in an accredited laboratory. Participation in proficiency testing shall be part of the training/experience. Where indicated, the laboratory director may delegate responsibilities to another qualified individual; however, the laboratory director shall retain ultimate responsibility for laboratory director duties.

1.2.2 The laboratory director shall be a part of executive management.

1.2.2.1 The laboratory director shall have responsibility and authority for all policies, processes, and procedures.

1.2.3 Laboratory Director Designee
Any laboratory director designee shall have a doctoral degree in medicine, biology, chemistry, genetics, or clinical laboratory science and shall be qualified by training or experience. Standard 1.2.4 applies.

1.2.4 Technical Leader Serving as Laboratory Director
For forensic laboratories accredited to the current Federal Bureau of Investigation (FBI) quality assurance standards for forensic DNA testing laboratories, the technical leader serving as a laboratory director shall be qualified by education, training, or experience to serve in the role of laboratory director for the purposes of these *RT Standards*. The technical leader shall have 3 years of training, or experience in relationship testing in an AABB-accredited relationship testing laboratory (or equivalent) or under the guidance of a laboratory director currently or previously employed in an accredited laboratory. Participation in proficiency testing shall be part of the training/experience.

1.3 Laboratory Supervisor Qualifications and Responsibilities
The laboratory shall have one or more supervisor(s) with responsibility for the day-to-day supervision of laboratory processes and procedures. The laboratory supervisor(s) shall have, at a minimum, a bachelor's degree in

biology, chemistry, genetics, clinical laboratory science or a related field, and at least 2 years of training or experience in relationship testing.

1.4 Staffing Changes

The laboratory shall communicate to AABB all initial appointments or staffing changes for the laboratory director, laboratory director designee(s), laboratory supervisor(s), and/ or quality representative within 30 days of appointment.

1.5 Laboratory Status Changes

The laboratory shall communicate, in writing, status changes to AABB within 30 days from when the laboratory ceases or resumes onsite testing.

1.6 Assessment of Risk

The facility's executive management shall identify, assess, and address the level of risk associated with activities performed and the data generated in the facility that affect product quality and safety at facility defined intervals. Standards 5.1.1 and 6.1.4 apply.

1.6.1 Mitigation strategies shall identify, assess, and address the level of risk associated with activities performed in the facility.

1.7 Communication of Concerns

The laboratory shall have a process for personnel to directly or anonymously communicate concerns about quality, safety, or conflict(s) of interest. Personnel shall be given the option to communicate such concerns either to their facility's executive management, the AABB, or both. AABB's contact information shall be readily available to all personnel. Standards 6.1.5 and 9.1 apply.

1.8 Customer Focus

Executive management shall identify the laboratory's customers and their needs and expectations for products and services.

2. RESOURCES

2.0 Resources

The laboratory shall have policies, processes, and procedures to ensure the provision of adequate resources to perform, verify, and manage all activities in the laboratory.

2.1 Human Resources

The laboratory shall have a process to ensure the employment of an adequate number of qualified (by education, training, and/or experience) individuals. Current job descriptions shall be maintained and shall define appropriate qualifications and responsibilities for each job position.

2.1.1 Qualification

Personnel shall be qualified to perform assigned activities on the basis of appropriate education, training, and/or experience.

2.1.2 Training

The laboratory shall have a process for identifying training needs and shall provide training for personnel performing critical tasks. All personnel shall be trained in the application of the quality system.

2.1.3 Competence

Evaluations of competence shall be performed before independent performance of assigned activities and at least annually for personnel performing specific critical tasks. Assessment of a specific task shall include the following when applicable:

1. Task outcomes using blinded testing materials.
2. Task execution for all applicable methods using direct observation.
3. Performance of calculations, or reviews of specific testing outcomes.

2.1.3.1 Action shall be taken when competence has not been demonstrated. Standard 7.3 applies.

2.1.4 Continuing Education

Employees performing and/or reviewing specific testing methods or calculations as defined by Standards 5.3, 5.4, and 5.5 shall participate in a minimum of 12 hours of relevant continuing education on an annual basis. The laboratory director shall define the continuing education needs of these personnel.

2.1.5 Personnel Records

Personnel records for each employee shall be maintained. For those authorized to perform or review critical processing steps, records of names, signatures, initials or identification codes, and inclusive dates of employment shall be maintained.

2.2 Laboratory Director Oversight

The laboratory director shall oversee a maximum of 10 accredited facilities. No more than five of those shall be testing laboratories and the remaining may be collection/verification facilities.

2.2.1 The DNA technical leader acting as the laboratory director under these *RT Standards* shall oversee only those facilities that are a part of the forensic laboratory's system.

3. EQUIPMENT

✎3.0 Equipment

The laboratory shall identify the equipment that is critical to the provision of relationship test reports and relationship testing services. The laboratory shall have policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of critical equipment conform to these *RT Standards* and other specified requirements.

3.1 Selection of Equipment

The laboratory shall have a process to define the selection criteria for equipment.

✎3.2 Qualification of Equipment

Equipment shall be qualified for its intended use. Equipment repairs and upgrades shall be evaluated and equipment requalified based on the facility's policies and manufacturer recommendations.

3.2.1 Installation Qualification

Equipment shall be installed per the manufacturer's specifications.

3.2.2 Operational Qualification

The functionality of each piece of equipment and each component of a computer system shall be verified before actual use, and shall meet the manufacturer's operational specifications.

3.2.3 Performance Qualification

The laboratory shall demonstrate that equipment performs as expected for its intended use.

3.2.3.1 Performance specifications established by the manufacturer shall be met.

✎3.3 Unique Identification of Equipment

Equipment shall have unique identification.

✎3.4 Control of Equipment

The laboratory shall have a process for scheduled maintenance, monitoring, and calibration of equipment that shall include the following elements:

1. Calibration and adjustment for accuracy and precision before initial use, after activities that may affect the calibration, and at prescribed intervals.
2. A calibration process that includes details of equipment type, manufacturer's instructions, unique identification, location, frequency of checks, check method, acceptance criteria, action to be taken for unsatisfactory results, a mechanism to determine calibration status, and,

where applicable, safeguards to prevent equipment from adjustments that would invalidate the calibration setting.

3. Assessment of the validity of relationship test results when equipment is found to be out of calibration.

3.4.1 Calibration procedures shall follow the manufacturer's written instructions, and shall include the following:

1. Instructions for performing calibrations.
2. Acceptance criteria.
3. Actions to be taken when unsatisfactory results are obtained.

3.4.2 If the manufacturer's written instructions are not followed, the equipment shall be calibrated using the laboratory's validated procedures for the intended use.

3.4.3 Investigation and Follow-up

Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include:

1. Assessment of reports and services provided when equipment is found to be out of calibration.
2. Steps to ensure that the equipment is removed from service.
3. Investigation of the malfunction, failure, or adverse event.
4. Steps for requalification of the equipment.
5. Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.

Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.

3.5 Information Systems

The laboratory shall have processes to support the implementation and modification of software, hardware, and databases relating to the requirements of these *RT Standards*. Standard 5.1.1 applies. These processes shall include:

1. Risk analysis, training, validation, implementation, and evaluation of postimplementation performance.
2. Description of system maintenance and operation.
3. Documentation written in language that is understandable to the user.
4. A system for display and verification of added or amended data before final acceptance.
5. Description of how modifications to the system are authorized and recorded.
6. Validation of calculation software including all formulae used by the laboratory to generate test reports.

3.5.1 Information System Records

Records of the following shall be maintained:

1. Validation of system software, hardware, databases, user-

defined tables, electronic data transfer, and/or electronic data receipt.

2. Fulfillment of life-cycle requirements for internally developed software.
3. Numerical designation of system versions, if applicable, with inclusive dates of use.
4. Monitoring of data integrity for critical data elements.

3.5.2 The laboratory shall have an alternative system that ensures continuous operation in the event that routine information system-assisted functions are unavailable. The alternative system shall be tested at least annually.

3.5.3 Personnel responsible for management of information systems shall be responsible for compliance with the specified requirements that affect their use.

3.5.4 There shall be policies, processes, and procedures to support the management of information systems.

3.5.5 A system designed to prevent unauthorized access to information systems and electronic records shall be established and followed.

3.5.6 The laboratory shall have processes in place to minimize the risk and impact of an internal or external data breach.

4. SUPPLIER AND CUSTOMER ISSUES

4.0 Supplier and Customer Issues
The laboratory shall have policies, processes, and procedures to verify that critical services and supplies (including equipment, reagents, and materials) and samples obtained from outside sources consistently meet specified requirements.

✎ **4.1 Supply Identification**
Requirements and specifications for critical supplies and services shall be identified.

✎ **4.2 Supplier Qualification**
The laboratory director or a designated representative shall evaluate and participate in the selection of suppliers before acceptance of an agreement.

4.2.1 The laboratory director or a designated representative shall qualify suppliers based on their ability to meet specified supply or service requirements before acceptance of an agreement.

4.2.2 The laboratory director or a designated representative shall participate in the ongoing evaluation of suppliers.

4.2.3 Laboratory testing and other services required by these *RT Standards* shall be performed in a laboratory accredited by either the AABB or other, equivalent, accrediting body.

4.2.3.1 When another laboratory provides genetic test results, that laboratory shall be accredited by the AABB or other, equivalent, accrediting body for that activity. Reference Standard 6.3A, Requirements for Test Reports, #A7 applies.

4.3 Agreements
Agreements, or changes to those agreements, to obtain or provide materials, relationship test reports, and relationship testing services shall define supplier and customer expectations and shall reflect agreement.

✎ **4.3.1 Agreement Review**
The laboratory director or designated representative shall verify that the identified requirements are reflected in agreements.

4.3.2 Agreements shall be reviewed at defined intervals, and revised as needed.

4.3.3 There shall be written agreements between laboratories and third-party administrators that define the following:

1. Collection requirements.
2. Responsibility for the testing process.
3. Reporting of test results.
4. Appropriate marketing materials and claims.
5. Use of the laboratory's name and accreditation status.
6. Unless accredited for collection or verification activities by AABB, third-party administrators are prohibited from initiating cases for United States of America immigration, visa, passport, and citizenship testing.

Standards 5.2.3.5, 6.4.4, and 6.4.5 apply.

4.4 Supplier Evaluation

The laboratory director or a designated representative shall evaluate at defined intervals whether suppliers have met agreed-upon requirements and take appropriate follow-up action.

4.4.1 When a supplier fails to meet specified requirements, the laboratory director or a designated representative shall take appropriate action and report it to the facility's purchasing authority. Standard 7.0 applies.

✎4.5 Receipt, Inspection, and Testing of Incoming Critical Supplies and Samples

Incoming reagents, samples, materials, equipment, and products shall be inspected and tested before reporting of results. The laboratory shall ensure that:

1. Each lot shall be tested.
2. Each shipment, regardless of lot, shall be tested.
3. Each lot within a shipment shall be tested.

4.5.1 Criteria for acceptance and rejection of the inspection and testing shall be established.

✎4.6 Management of Supplies and Materials

The laboratory director or a designated representative shall ensure that the laboratory has processes that address the availability, control, storage, handling, and transportation of critical supplies and reagents.

4.7 Traceability

Critical supplies and samples shall be traceable to the finished product and/or service.

4.7.1 The facility shall have policies, processes, and procedures to evaluate and respond to possible altered or fabricated documents.

5. PROCESS CONTROL

5.0 Process Control

The laboratory shall have policies and validated processes and procedures that ensure the quality of the relationship test reports and relationship testing services. The laboratory shall ensure that these policies, processes, and procedures are carried out under controlled conditions.

5.1 General Elements

5.1.1 Change Control

The laboratory shall have a process to develop new processes and procedures or change existing ones. This process shall include identification of specifications and verification that specifications have been met. Before implementation, the new or changed processes and procedures shall be validated. Standard 5.3.14.1 applies.

5.1.1.1 The laboratory shall ensure that the implementation of new or changed processes is controlled. Laboratory employees shall be trained in the new or changed process(es) or procedure(s). Standard 2.1.2 applies.

5.1.2 Proficiency Testing Program

The laboratory shall participate in a proficiency testing program for each genetic system used for reporting test results. Standard 7.2 applies.

5.1.2.1 A laboratory seeking initial accreditation shall participate in either one of the following:

1. A proficiency testing program for 2 years with successful results.
2. An exchange of at least 12 blinded cases representative of the casework the laboratory proposes to perform with an accredited relationship testing laboratory and demonstrate concordant results.

5.1.2.2 The laboratory shall participate in graded proficiency testing for the assignment of phenotypes and the assessment of relationships.

5.1.2.3 When a formal graded external proficiency testing program is available for one or more of the genetic systems used to report test results, the laboratory shall participate three times a year for each genetic system analyzed in the laboratory.

5.1.2.4 When no formal graded external proficiency testing program is available for any of the genetic systems used to report test results, the laboratory shall use one of the following methods:

1. Test on a monthly basis known samples from when graded proficiency testing was available.
2. Test on a monthly basis a standard trio of samples developed from persons of an undisputed relationship.
3. Participate three times a year in a sample exchange program.

Standard 5.1.4.1 applies.

5.1.2.5 When formal graded proficiency testing programs are available for some but not all genetic systems, the laboratory shall test the genetic systems not evaluated by a formal proficiency testing program using one of the following methods:

1. Test on a monthly basis known samples from when graded proficiency testing was available.
2. Test on a monthly basis a standard trio of samples developed from persons of an undisputed relationship.
3. Participate three times a year in a sample exchange program.

5.1.2.6 Proficiency testing, whether graded or not graded, shall be representative of the cases the laboratory performs, including standard trios, single parent, and family studies (reconstruction cases).

5.1.3 Quality Control

A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods function as expected. Results shall be reviewed and corrective and preventive action taken, where appropriate.

5.1.3.1 The validity of test results and methods and the acceptability of products or services provided shall be evaluated when quality control failures occur.

5.1.3.2 Quality control results shall be reviewed and evaluated against acceptance criteria. Quality control failures shall be investigated. Chapter 9, Process Improvement Through Corrective and Preventive Action, applies.

5.1.4 Sample Retention

If available, an adequate sample of remaining biological materials obtained from a tested individual shall be stored for a minimum of 6 months after the completion of testing for the purpose of additional testing, if required.

5.1.4.1 If proficiency testing is not available for all of the genetic systems relied upon to report test results, the samples tested, if available, shall be stored for as long as records are maintained. Standards 5.1.2.4 and 6.2 apply.

5.1.5 Privacy and Confidentiality

The laboratory shall have a policy to ensure that the relationship testing process is private and confidential.

5.1.5.1 The laboratory shall release test results only for purposes relevant to the relationship testing for a specific case. Otherwise, a court order or the written permission of the individual(s) tested or the individual(s) with legal authority to provide consent is required. Standard 6.2.2 applies.

5.1.5.2 The laboratory shall release an identifiable sample and/or profile of an individual only for purposes relevant to the actual testing for which the sample was submitted. Otherwise, a court order or the written permission of the individual(s) who furnished the sample, or the individual(s) with legal authority to provide consent, is required.

5.2 Sample Collection for Chain-of-Custody Cases

The laboratory shall have policies, processes, and procedures for consent, collection, verification, and acquisition and maintenance of identification records.

5.2.1 Consent

Before sample collection, consent shall be obtained according to applicable law from each tested person, or, in the case of a minor child or legally incompetent adult, from either an individual with legal authority to provide consent or a tribunal with legal authority to order testing.

5.2.2 Collection

All collections of samples shall be performed or witnessed by a

competent person with no interest in the test outcome. Collection materials shall be sent directly only to collectors and/or witnesses. Collection materials shall not be in the possession of any of the tested parties either before or after collection.

5.2.2.1 Collection methods shall protect the safety of the person from whom the sample is taken, preclude contamination, and maintain integrity of the sample.

5.2.2.2 The laboratory shall have policies, processes, and procedures to ensure that collectors are trained. Standard 2.1.2 applies.

5.2.3 Verification of Sample Collection and Documentation

The person collecting the sample and/or verifying the process shall confirm that the following conditions exist:

1. The identification of the tested person is accurate and the stated relationship is recorded.
2. Consent was obtained as stated in Standard 5.2.1.
3. The sample was collected from the intended person.
4. The label is accurate.
5. The sample is packaged in a tamper-evident manner.

5.2.3.1 Each sample shall bear an affixed label containing the following information:

1. A unique identification for each sample collected.
2. Date of collection.
3. Initials or signature of the person collecting the sample.
4. The label shall not be obscured or removed.

5.2.3.2 The accuracy of the affixed label shall be verified in writing by the person whose sample is collected or by the individual with legal authority accompanying a minor or legally incompetent adult.

5.2.3.3 Test participants shall not package or transfer samples. Standard 5.2.2 applies.

5.2.3.4 Upon receipt of a sample, the laboratory shall verify package integrity.

5.2.3.5 Samples intended for immigration, visa, passport, and citizenship testing cases for the United States of America shall be

accepted only if the case is initiated directly between the petitioner and a facility accredited by AABB for relationship testing activities. Records of the initiation of this service by the petitioner shall be maintained in the facility's records. Standard 4.7 applies.

5.2.3.6 The laboratory shall have policies, processes, and procedures to identify and clearly indicate on the final report whether it is a chain-of-custody or non-chain-of-custody case. Standard 4.7 applies.

5.2.4 Identification Records

The following records relating to each sample collected shall be acquired and maintained:

5.2.4.1 Printed name, alleged relationship, and date of birth of each individual tested and untested person(s) signing consent for a minor child or legally incompetent adult.

5.2.4.2 Race/ethnic background of each parent/alleged parent or other participant(s) being tested, with the exception of the child.

5.2.4.3 For non-parent-child relationship, the race/ ethnic background of the participants.

5.2.4.4 Place, date, and type of sample collected.

5.2.4.5 Printed name, signature, and contact information of the person collecting the sample and/or witnessing the sample collection.

5.2.4.6 Printed name, signature, and contact information of the person verifying the collection process, if different from the person collecting the sample.

5.2.4.7 A history of transfusion in the preceding 3 months, or any history of allogeneic hematopoietic progenitor cell transplantation.

5.2.4.8 Original or legible photocopies of at least one of the following items for each individual tested and untested person(s) signing consent for a minor child or legally incompetent

adult:

3. Valid government-issued photo identification (ID).
4. Photograph that is suitable for positive identification.

5.2.4.8.1 For cases intended for immigration, visa, passport, and citizenship for the United States of America, both a photo suitable for positive ID and a legible copy of the government- issued photo ID shall be submitted for each tested individual and untested person(s) signing consent for a minor child or legally incompetent adult. If these documents are not available, the collector shall document the explanation.

5.2.4.9 Name of the person receiving the sample in the laboratory, date of receipt, and documentation of shipment receipt.

5.2.5 Special Circumstances

In circumstances (eg, prenatal sample, coroner's sample, or samples provided by law enforcement agencies) where the sample cannot be obtained according to Standards 5.2 through 5.2.4.8, documentation of chain of custody shall be obtained.

5.3 Testing and Results

5.3.1 When autosomal markers are used, multiple loci shall be the basis for the laboratory's findings.

5.3.2 Testing Requirements for the Null Hypothesis and Alternate Hypothesis

5.3.2.1 When the null hypothesis is that a child inherited its parental obligate allele (POA) from a person with the genotype of the alleged parent and the alternate hypothesis is that the child inherited its POA from a random person in the alleged parent's population, the laboratory shall test three or more independent autosomal loci.

5.3.2.2 When the null hypothesis is that a child inherited its POA from a person with the genotype of the alleged parent and the alternate hypothesis is that the child inherited its POA from a person who is related to the tested alleged parent, and there

is a failure to exclude, the laboratory shall test eight or more independent autosomal loci.

5.3.3 Autosomal loci shall be used to evaluate a relationship unless one of the following conditions exists:

1. Results for autosomal loci are not obtained.
2. Results for autosomal loci are inconclusive.
3. Results for nonautosomal markers exclude the relationship.
4. Autosomal markers are not informative because the hypothesized relationship is beyond second order.

5.3.4 When the genetic profile of the untested party can be reconstructed, the laboratory shall use autosomal markers. Nonautosomal markers may additionally be used. Standard 6.3.2 applies.

5.3.5 The laboratory shall use validated loci.

5.3.6 The laboratory shall use loci with chromosomal locations that are recorded in the scientific literature.

5.3.7 This group of tests shall, with rare exceptions, provide a nonexcluded alleged parent with a relationship index of at least 100.

5.3.8 Two-Party Comparisons of Full Siblings, Half Siblings, Avuncular, and Single Grandparentage Combined Likelihood Ratios

The laboratory shall have policies, processes, and procedures for two-party comparisons of full siblings, half siblings, avuncular, and single grandparentage combined likelihood ratios. Reference Standard 6.3A, #3(e) applies.

5.3.8.1 Before reporting an inconclusive result, the laboratory shall use a minimum test battery of at least 20 autosomal short tandem repeat (STR) loci when testing.

5.3.8.2 Likelihood ratios greater than 10 shall be considered genetic evidence supporting the tested relationship.

5.3.8.3 Likelihood ratios of 0.1 through 10 shall be considered inconclusive for the tested relationship.

5.3.8.4 Likelihood ratios less than 0.1 shall be considered genetic evidence not supporting the tested relationship.

5.3.8.5 The laboratory shall report an estimate of the percentage of individuals of known relationship that may have a combined likelihood ratio that is inconclusive, or supportive, or not supportive of the tested relationship for the laboratory's test protocol at the combined likelihood ratio reported for the case work.

5.3.9 With relationship testing other than parentage and relationships described in Standard 5.3.8, the laboratory shall establish reporting policies for the indices obtained.

5.3.10 When using a computer algorithm(s) to evaluate a large number of loci (see Standard 5.3.12.3) that does not produce a standard combined relationship index, the laboratory shall provide an explanation of the evaluation, the equivalency to the combined relationship index of 100, and the version of the algorithm used.

5.3.11 Before releasing any report excluding a biological relationship:

5.3.11.1 The phenotype of an excluded alleged parent(s) shall be confirmed with an independent isolation (DNA extraction), and in cases without a known parent, the child's phenotype shall also be confirmed with an independent isolation. For closed systems, Standard 5.4.2 applies.

5.3.11.2 For nonparentage cases where the genetic evidence does not support the alleged relationship, either by exclusions or a low likelihood ratio, phenotypes for parties in question shall be confirmed with an independent isolation. For closed systems, Standard 5.4.2 applies.

5.3.12 A standard method of nomenclature for describing phenotypes in each genetic system shall be used.

5.3.12.1 For any apparent homozygote, only the observed phenotype shall be listed.

5.3.12.2 For mitochondrial DNA, the laboratory shall report the position of all nucleotide differences in comparison to the Revised Cambridge Reference Sequence and the portion of the mitochondrial genome evaluated (eg, HVI, HVII, or HVIII).

5.13.2.3 When single nucleotide polymorphism (SNP) assays use more than 100 loci, the laboratory shall report the number of SNPs used in each specific report. The laboratory shall keep records of all SNP loci and data utilized in the calculation of the relationship probability and provide them to the client upon request.

5.3.13 Minimum performance thresholds shall be defined and monitored for reliability, acceptability, and accuracy on a scheduled basis.

5.3.14 The laboratory director shall ensure that:

5.3.14.1 Before the laboratory changes a process or procedure for an existing test method or adds a new process or procedure, it shall be validated.

5.3.14.2 For new or novel test methods, part of the validation process shall require the analysis of at least 20 biological test samples, with accuracy and reproducibility of test results within the laboratory and between the laboratory and other laboratories. The complete validation process shall identify thresholds and acceptability criteria (eg, measurements, metrics) and include the evaluations of persons whose phenotypes are unknown, but whose relationships are well established. Standard 5.3.14.3 applies. Validation studies shall be reviewed and accepted by the Relationship Testing Standards Committee (RT SC) of the AABB before implementation.

5.3.14.3 For new multiplex kits or loci (or locus) added to existing test methods, the validation process shall require the analysis of at least 20 biological test samples, with accuracy and reproducibility of test results within the laboratory. If the laboratory establishes its own frequency database for the loci (or locus), the power of exclusion shall be determined and compared with published values, if available, as part of the validation process.

5.3.15 All test results shall be reviewed by two people, one of whom shall be the laboratory director or director designee. At a minimum, this review shall include critical test results, critical calculations, and worksheets that record interpretations and conclusions.

5.3.16 If the test battery in a case employs only methods or loci that are not used by other laboratories, the laboratory shall store samples for a minimum of 5 years in such a manner as to allow for confirmatory testing.

5.4 Specific Testing Methods

Specific testing methods shall ensure that accurate results are produced. Appropriate test controls shall be incorporated into the testing processes to ensure accurate results.

5.4.1 DNA Polymorphism Testing

The laboratory shall use validated processes and procedures for DNA testing. The laboratory shall have a process that demonstrates reproducibility of test results.

1. For systems dependent on accurate measurement of allele sizes, a human DNA control of known phenotype shall be tested with each analysis.
2. Appropriate stringency conditions shall be used to ensure accurate allele determination.
3. For closed systems, reproducibility studies shall be a part of the acceptance process. Standard 4.5 applies.

5.4.1.1 Nucleic Acid Testing (NAT) for Short Tandem Repeat (STR) Analysis

When NAT is used for STR analysis, the process shall include the following requirements:

1. Unless an expert system is used, all electropherogram or gel results shall be interpreted twice, independently. Phenotypes that are manually determined shall be read twice independently. Standard 5.3.15 applies.
2. When an expert system is used to interpret allele determinations, results that contain no artifacts that require human review may be interpreted solely by the expert system. Results containing artifacts that are flagged by the system should be interpreted by at least one human reviewer. If the reviewer makes a change to an allele determination, that change shall be confirmed by a second human reviewer.
3. The conditions for amplification, hybridization, and detection shall be defined and controlled to ensure accurate allele determination.
4. When electrophoresis is used, ladders composed of discrete fragments of known size or tandem repeat

number shall encompass the range of allele sizes routinely detected at the locus in question. Flanking size markers shall be used with sufficient frequency to accurately determine allele size.

5. STR alleles shall be identified by repeat number as adopted by the International Society of Forensic Genetics.
6. Negative control(s) shall be processed with samples from extraction through analysis to monitor for sample contamination and NAT product contamination. For closed systems, this shall be part of the acceptance process. Standard 4.5 applies.
7. The laboratory shall have policies and procedures to evaluate contamination, artifacts, and preferential amplification for each sample.
8. Postamplification products shall be prevented from contaminating preamplification materials.

5.4.1.2 NAT for Nucleotide Sequence Determination or SNP Analysis

When NAT is performed for sequencing or SNP analysis, the process shall include the following requirements:

1. All results shall be interpreted twice, independently.
2. When an expert system is used to interpret SNP allele determination, all phenotypes that pass the established and validated criteria may be interpreted solely by the expert system. Allele determinations that do not pass criteria shall not be used in the final relationship calculations.
3. When using a computer algorithm(s) to evaluate a large number of loci (see Standard 5.3.12.3) a single interpretation is acceptable.
4. The conditions for amplification, hybridization, and detection shall be defined and controlled to ensure accurate allele or sequence determination.
5. When a sequence-specific oligonucleotide probe (SSOP) method is used for allele determination, a control probe shall be used to ensure adequate target nucleic acid is available for analysis.
6. When a sequence-specific primer (SSP) method is used for allele determination, a positive internal control primer shall be included to verify that amplification has occurred for each reaction.
7. DNA sequence data shall be confirmed by sequence

analysis of both strands of nucleic acid.

8. Negative control(s) shall be processed with samples from extraction through analysis and used to monitor for sample contamination and NAT product contamination.
9. The laboratory shall have policies and procedures to evaluate contamination, artifacts, and preferential amplification for each sample.
10. Postamplification products shall be prevented from contaminating preamplification materials.

✎ **5.4.2 Closed Systems**

The laboratory shall have policies, processes, and procedures for performing DNA testing using a closed system, including profile anomalies that may affect the result.

5.4.2.1 Laboratories using closed systems shall confirm the placement of the sample in the specified location on the instrument through a visual check with a witness or electronic equivalent.

5.4.2.2 In cases where there is a finding of no relationship, the laboratory shall test a confirmatory sample:

1. If the sample is flagged for review by the closed system, or
2. If the closed system fails and the sample is manually manipulated.
3. Unless a human review is conducted and the flagged loci are found not to affect the results of the relationship findings.

5.5 Calculations

The laboratory shall have policies, processes and procedures for the use of validated calculation methods used in relationship testing.

5.5.1 The results from loci exhibiting significant linkage disequilibrium shall not be used independently in calculations.

5.5.2 When linked loci are used, the laboratory shall have policies, processes, and procedures for estimating and minimizing the effects of linkage on non-parentage cases.

✎ **5.5.3** Manual calculations and computer-assisted calculations shall be reviewed by the laboratory director or a director designee before serving as the basis for a final report.

5.5.4 If only manual calculations are performed, they shall be performed by two individuals, one of whom shall be the laboratory director or a director designee.

5.5.5 Validation of Tables and Calculations

5.5.5.1 Formulae used for statistical calculations shall be specified and shall be validated. The weight of the genetic evidence for the hypothesized relationship shall be calculated, and based on likelihood ratios (paternity index or other indices) or upon probabilities in the case of algorithms utilized to evaluate data from extensive SNP arrays. Standard 3.5 #6 applies.

5.5.5.2 Tables including, but not limited to, allele or haplotype frequencies and mutation rates shall be validated. Tables shall be developed in-house, published, or imported with a sample exchange.

5.5.5.2.1 Tables developed in-house shall be compared with other published data (when available) from similar populations.

5.5.5.2.2 The size of the population from which tables are developed shall be scientifically adequate.

5.5.5.2.3 Published tables shall be used only for systems/methods with discrete alleles.

5.5.5.2.4 The laboratory validating an imported table by sample exchange shall share a minimum of 20 samples from unrelated individuals with the laboratory that originally validated the table. The table shall be validated to ensure accuracy in identifying alleles by size, repeat number, or sequence.

5.5.5.2.5 The laboratory using a serology-based frequency table for HLA molecular typing results shall validate the conversion of nucleic acid allele designations to equivalent serologic types.

5.5.6 Validation of Expert Systems

A laboratory using an expert system to make allele determinations from electropherogram data of STR loci, instead of a laboratory director or laboratory director designee review, shall validate the expert system.

5.5.6.1 Validation shall include:

1. Evidence that the system correctly determines alleles and identifies artifacts that require human review by comparing at least 200 determinations made by the expert system with allele determinations made by a laboratory director or laboratory director designee.
2. Evidence that the system makes accurate allele determinations and identifies artifacts that require human review by comparing results from at least 200 electropherograms.
3. Demonstration that the expert system produces complete concordant results for at least 100 electropherograms that contain artifactual peaks or other anomalies requiring human review (eg, spikes, off- ladder alleles, contamination, size standard shifting).

5.5.6.1.1 For closed systems, the laboratory shall establish thresholds for allelic drop-in and drop-out and establish procedures to ensure those thresholds are consistent with the validation studies. Standard 5.5.5.1 applies.

5.5.6.1.2 Validation studies shall be reviewed and accepted by the RT SC of the AABB before implementation.

6. DOCUMENTS AND RECORDS

6.0 Documents and Records

The laboratory shall have policies, processes, and procedures to ensure that documents are identified, reviewed, approved, and retained and that records are created, stored, and archived in accordance with record retention policies.

6.1 Documents

The laboratory shall have a process for document control that includes the following elements:

6.1.1 A master list of documents, including policies, processes, procedures, labels, and forms that relate to the requirements of these *RT Standards*.

6.1.2 Use of standardized formats for all policies, processes, and procedures. Additional procedures (such as those in a manufacturer's instructions or package insert) may be incorporated by reference and shall be incorporated into the master list of documents.

6.1.3 Review and approval by the laboratory director of new and revised technical documents before use.

6.1.4 Review of all policies, processes, and procedures shall be performed by the laboratory director at a minimum of once every 2 years.

6.1.5 Use of current and valid documents. Applicable documents shall be available at all locations where activities essential to meeting the requirements of these *RT Standards* are performed. Out-of-date documents shall be removed from work stations when updated ones are placed in service.

6.1.6 Identification and appropriate archival of obsolete documents.

6.1.7 Storage in a manner that preserves legibility and protects from accidental or unauthorized access, destruction, or modification.

6.2 Records

The laboratory shall ensure identification, collection, indexing, access, filing, storage, and final disposition of records.

6.2.1 Facility Records

Records shall be complete; retrievable in a period of time appropriate to the circumstances; protected from accidental or unauthorized disclosure, destruction, or modification; and retained for a minimum of 5 years, except as noted in Reference Standard 6.2.1A.

6.2.1.1 Records shall be legible and indelible.

6.2.1.2 Copies
Before the destruction of the original records, the laboratory shall have a process to ensure that copies of records are identified as such. Copies of records shall be verified as containing the original content and shall be legible, complete, and accessible.

6.2.2 A system designed to prevent unauthorized access and ensure confidentiality of all records shall be established and followed.

6.2.2.1 Reports shall be released only to authorized individuals. Standard 5.1.5.1 applies.

6.2.3 The record system shall make it possible to trace any relationship test report or relationship testing service from its source to final disposition and to review the records applying to the specific relationship test report or relationship testing service.

6.2.4 The records system shall ensure the traceability of all of the following:

1. Critical activities performed.
2. The individual who performed each activity.
3. When each activity was performed.
4. Results obtained.
5. Method(s) used.
6. Equipment used.
7. Critical materials used.
8. The facility where each activity was performed.

6.2.5 Changes to Records
Changes to records shall be controlled.

6.2.5.1 The date of changes and the identity of the individual who changed the record shall be recorded and this information shall be maintained for the retention period of the original record.

6.2.5.2 Record changes shall not obscure previously recorded information.

6.2.5.3 Changes to records (including electronic records) shall be verified for accuracy and completeness.

6.2.5.4 If an amended report is issued, the original report shall be maintained. Standard 6.2.1 applies.

6.2.6 Electronic Records

There shall be processes and procedures to support the management of computer systems.

6.2.6.1 There shall be a process in place for routine backup of all critical data.

6.2.6.1.1 Procedures shall be in place to ensure that data are retrievable within a timeframe appropriate to the circumstances, and in a usable format.

6.2.6.1.2 Backup data shall be stored in an offsite location.

6.2.6.1.3 The laboratory shall verify and document the effectiveness of its data retrieval through periodic testing.

6.2.7 Storage of Records

Records shall be stored to:

1. Preserve record legibility and integrity for the entire retention period.
2. Protect from accidental or unauthorized access, destruction, or modification.
3. Allow retrieval.

6.2.8 Destruction of Records

Destruction of records shall be conducted in a manner that protects the confidential content of the records.

6.3 Relationship Test Reports

When the relationship tests have been completed, a relationship test report shall be generated that includes the information required by Reference Standard 6.3A, Requirements for Test Reports.

6.3.1 Findings of No Relationship

The facility shall have policies, processes, and procedures indicating the basis on which findings of no relationship are determined. These policies, processes, and procedures shall identify genetic inconsistencies that may lead to a false opinion of no relationship.

6.3.1.1 A finding of no relationship shall not be rendered on the basis of a single inconsistency without supporting evidence.

6.3.1.2 Genetic inconsistencies shall be reported and incorporated appropriately into the calculations as applicable.

6.3.1.3 If the laboratory renders an opinion of no relationship in family study cases solely on the basis of a low likelihood ratio, that likelihood ratio and a statement indicating that the finding of no relationship is based on the low likelihood ratio shall be included on the report.

6.3.2 Nonautosomal Findings

Nonautosomal results, when tested for parentage, avuncular, full sibling, half sibling, and grandparent, shall be incorporated with autosomal results into the combined relationship index. In addition to the combined relationship index, the laboratory shall have the opportunity to discuss autosomal and nonautosomal findings separately.

6.3.2.1 A single haplotype frequency for all loci shall be incorporated into calculations for paternal Y chromosomal transmissions, and mitochondrial DNA results.

6.3.2.2 A single haplotype frequency for loci in linkage disequilibrium shall be incorporated into calculations for X chromosome transmission results.

6.3.3 The laboratory shall have a process to ensure that relationship testing services and test reports meet these *RT Standards* before distribution or delivery. Reference Standard 6.3A, Requirements for Test Reports, applies.

6.3.3.1 The AABB-accredited facility shall manage all processes in the generation and delivery of a relationship report including but not limited to collection, testing, data analysis, and

report creation.

6.3.3.1.1 If a process is outsourced to another accredited facility, the accredited facility outsourcing the process shall perform its own review of the case and confirm that it meets both AABB and customer requirements before release to the client.

6.3.4 When the facility determines the final conclusion, the individual relationship index shall be reported for each genetic system tested.

6.3.4.1 If the laboratory evaluates more than one possible relationship (eg, full sibling vs unrelated and half sibling vs unrelated) and presents one of the relationships as the final conclusion, the other relationships considered may also be reported without presenting the alternative individual likelihood ratios. A record of the alternative likelihood ratios shall be maintained.

6.4 Promotional Materials

The laboratory shall have a process to ensure that promotional materials conform to all AABB requirements.

6.4.1 An AABB-accredited laboratory shall use AABB trademarks, including logos, or make claims about AABB accreditation only in reference to activities for which it is accredited by AABB.

6.4.2 The facility shall distinguish between AABB-accredited and nonaccredited activities with respect to all claims in promotional, marketing, and educational materials in which the AABB trademarks are used.

6.4.3 The facility shall be truthful in advertising its accreditation status and its implications.

6.4.4 The facility shall ensure that "AABB" or AABB.org (or any derivation thereof, eg, AABB.edu, AABB.fr) will not be used in any domain name or email address that is owned or used in any way by an accredited facility or through cooperative agreement with a third party.

6.4.5 The facility shall ensure that "AABB" or AABB.org (or any

derivation thereof, eg, AABB.edu, AABB.fr, etc) will not be used in search engine advertisements or the web page title tags displayed on search engine results pages that are owned or used in any way by an accredited facility or through cooperative agreement with a third party. Usage shall be restricted to the accredited facility's official website.

6.4.6 The laboratory shall participate in data collection and submission for the AABB Relationship Testing Annual Report through the provision of requested data.

Reference Standard 6.2.1A. Retention of Records		
Item No.	**Standard No.**	**Record to Be Maintained**
1	1.0	Organizational structure defines parties responsible for quality functions of relationship testing.
2	1.1	Description of executive management and participation in review of the quality system.
3	1.1.3.1	Quality representative training and experience.
4	1.1.4	Management review of effectiveness of the quality system.
5	1.1.7	Official transcripts for laboratory director, laboratory director designee, and laboratory supervisor.
6	1.2, 1.2.1, 1.2.1.1	Laboratory director and director designee(s) qualifications and experience.
7	1.2.2.1	Laboratory director responsibility for policies, processes, and procedures.
8	1.2.4	Technical leader qualifications and experience.
9	1.3	Supervisor qualifications and experience.
10	1.4	Laboratory director, laboratory director designee(s), laboratory supervisor(s), and/or quality representative change notification within 30 days.
11	1.5	Interruption of onsite testing notification within 30 days.
12	1.6	Level of risk associated with laboratory activities
13	2.1	Current job descriptions.
14	2.1.1	Qualification of personnel performing activities affecting quality.
15	2.1.2	Training for personnel performing critical tasks affecting quality.
16	2.1.3	Annual competency evaluation of employees.
17	2.1.4	Continuing education for employees performing critical steps.
18	2.1.5	Personnel records of employees. For those authorized to perform or review critical significant processing steps, maintain records of signatures, initials, or identification codes for 10 years.
19	3.0	List of critical equipment.
20	3.2	Equipment qualification.
21	3.3	Unique identification of equipment.

22	3.4	Monitoring, calibration, and maintenance of critical equipment.
23	3.5	Implementation of new or modified software, hardware, or databases and modifications of existing software, hardware, or databases.
24	3.5.1	Validation of computer system software, hardware, databases, and user-defined tables; fulfillment of life-cycle requirements for internally developed software; numeric designation of system versions, if applicable with inclusive dates of use; monitoring of data integrity for critical data elements.
25	3.5.4	Policies, processes, and procedures to support management of computer systems.
26	4.1	Requirements and specifications for critical supplies.
27	4.2	Evaluation and participation in selection of suppliers.
28	4.3.1	Review of agreements.
29	4.5	Inspection of incoming materials and samples.
30	4.6	Quality control of critical supplies and reagents.
31	5.1.1	Validation of new or changed processes and procedures.
32	5.1.2	Participation in proficiency testing program.
33	5.1.2.1	For laboratories seeking initial accreditation, either results of successful participation in proficiency testing program for previous two years or concordant results with a relationship testing laboratory accredited by the AABB or other, equivalent accrediting body for sample exchange of at least 12 blinded cases.
34	5.1.2.4	Monthly testing of samples.
35	5.1.2.5	Monthly testing of samples.
36	5.1.2.6	Proficiency testing, whether graded or not graded, shall be representative of the cases the laboratory performs, including standard trios, single parent, and family studies (reconstruction cases).
37	5.1.3	Review of quality control results for reagents, equipment, and methods.
38	5.2.1	Chain of custody consent from each tested person, legal guardian, or conservator; include record in case file.
39	5.2.2	Individual performing collection; include record in case file.
40	5.2.2.2	Training of collectors.
41	5.2.3	Individual verifying sample collection; include record in

		case file.
42	5.2.3.2	Verification by person providing legal consent of accuracy of label.
43	5.2.3.4	Verification of package integrity upon receipt.
44	5.2.3.5	Verification that chain of custody samples received are from an AABB-accredited relationship testing facility that initiated the case.
45	5.2.4	Identification records, including: 1. Name, relationship, date of birth, and the race/ethnic background of each parent/alleged parent. 2. Name, relationship, and date of birth of the child. 3. Place, date, and type of sample collected. 4. Printed name, signature, and contact information of the person collecting the sample, if applicable. 5. Printed name, signature, and contact information of the person verifying collection process, if different from the person collecting the sample. 6. A history of transfusion in the preceding 3 months or any history of allogeneic hematopoietic progenitor cell transplantation. 7. Original or legible photocopies of one or both of the following items: a. Government photo identification. b. Photograph that is suitable for positive identification. 8. Name of person receiving sample, date of receipt, and documentation of the shipment.
46	5.2.4.8.1	Explanation for a lack of government issued photo identification for immigration, visa, passport and citizenship.
47	5.2.5	Chain of custody where sample cannot be obtained according to these *RT Standards*
48	5.3.5	Use of validated loci
49	5.3.14.1	Validation of test methods (10 years after retirement of the system).
50	5.3.14.2	Validation studies for new test methods.
51	5.3.15	Review of case by two people, including the laboratory director or designee; review of critical test results, worksheets that record interpretations, conclusions, critical calculations, and case reports.
52	5.4.1	Validated processes and procedures for DNA polymorphism

		testing.
53	5.4.1.1, #1	Unless an expert system is used all electropherogram or gel results shall be interpreted twice, independently. Phenotypes that are manually determined shall be read twice.
54	5.4.1.1, #3	Defined conditions of amplification, hybridization, and detection of NAT for STR.
55	5.4.1.2, #4	Control probe to ensure adequate target nucleic acid is available for analysis.
56	5.4.1.2, #5	Control primer pairs to confirm that amplification has occurred.
57	5.4.1.2, #6	Defined conditions of amplification, hybridization, and detection for SNP.
58	5.4.2	DNA testing using a closed system
59	5.5.2	Laboratory supervisor and/or laboratory director-designated representative review of calculations before issue of report.
60	5.5.3	Duplicate manual calculations.
61	5.5.4.2.1	Validation of in-house-developed tables compared with published data.
62	5.5.4.2.3	Use of published databases.
63	5.5.5	Validation of expert systems.
64	6.1.3	Review and approval of new and revised technical documents before use.
65	6.1.4	Biennial review of policies, processes, and procedures.
66	6.1.6	Archival or appropriate disposal of obsolete documents.
67	6.2.6.1.3	Data retrieval system testing.
68	6.3.4.1	Alternative likelihood ratios.
69	6.4	Review of promotional materials.
70	6.4.6	Data collection and submission for the AABB Relationship Testing Annual Report.
71	7.1	Evaluation and resolution of nonconforming relationship test reports, materials, samples, and relationship testing services.
72	7.1.3	Description and resolution of nonconformances that have been identified after release.
73	7.2	Evaluation of and corrective action taken in response to nonconforming proficiency testing results.
74	7.2.2	Investigation and resolution of discrepant test results, among laboratories participating in a sample exchange program.
75	7.3	Retraining and reevaluation of laboratory personnel who

		failto meet expected performance criteria for competency testing for performance of those procedures before they are permitted to test client samples.
76	8.1	Management of assessment results.
77	9.1	Results of follow-up action to corrective action.
78	9.2.4	Results of follow-up action to preventive action.
79	10.1.2.1	Environmental condition monitoring.
80	10.2.1.1	Monitoring of adherence to biological, chemical, and radiation safety standards and regulations.
81	10.3	Environmental conditions.
82	10.4	Emergency preparedness.
83	10.5	Operational continuity.

Reference Standard 6.3A. Requirements for Test Reports		
Chain of Custody Reports		
A. Identifiers		
1	Date of collection for each sample.	
2	Name, address, and contact information of the laboratory or, if the laboratory is a subcontractor, the agreed-upon contact information.	
3	The laboratory's accession or case number, if assigned.	
4	Name or other unique identifier of each person tested and his/her relationship or alleged relationship to the other individual(s) in the case.	
5	Racial/ethnic background(s) used by the laboratory for calculations as designated by the participants or closest available frequency database. Standard 5.2.5.2 applies.	
6	The original signature of the laboratory director or director designee.	
7	The identity of any other laboratory that provided genetic test results used in the report and any portion(s) of the report for which that laboratory was responsible.	
B. Findings		
1	Report the phenotypes of tested individuals for all genetic systems that meet the laboratory's minimum performance thresholds, as applicable with the exception of amelogenin, other markers used for gender determination, and linked loci, as defined in standard 5.5 (Standards 5.3.12 and 5.3.13 apply).	
2	A statement as to whether the alleged relationship can be excluded.	
3	IF:	THEN:
	A statement of nonrelationship is rendered.	The loci providing the basis for the finding shall be indicated in the statement of non-relationship. For large-array SNP assays, the number of loci tested, the number of informative loci, and the number of loci that successfully yielded a result.
	There is a failure to exclude and the combined relationship index meets the established reporting policies for the indices obtained for the tested relationship (Standard 5.3.9 applies).	The report shall include the following information: a. The individual relationship index for each genetic system used in the conclusion. b. The combined relationship index. c. The probability of relationship expressed as a percentage. The prior probabilities used to calculate the probability of relationship shall be stated. d. When autosomal loci are not tested, the conclusion shall not overstate the relationship. An explanation on non-recombining haplotypes inheritance and limitations to these markers shall be provided. e. When autosomal likelihood ratios are not in agreement with non-recombining haplotypes (leading to a different conclusion) an explanation on non-autosomal inheritance and limitations to these markers shall be provided.

		f. For large-array SNP assays, the probability value. g. A statement that the calculations compare the tested individual(s) to a defined population. h. As appropriate, a statement that the calculations compare the tested individual to either an unrelated or related individual. i. A statement of the equivalency to the combined relationship index. j. For large-array SNP assays, only d, e, f, g and h apply.
	There is a failure to exclude and results are unusual, inconclusive, or involve relationship testing other than parentage and do not meet Standard 5.3.9.	Report according to the laboratory's policies, which shall include an explanation of the reported results. The explanation shall include one of the following: a. A statement supporting the alleged relationship. b. A statement supporting no relationship. c. An inconclusive finding.
4	For DNA polymorphisms the names of the DNA loci tested.	
5	Identification of any test methods not covered by these *RT Standards*.	

7.0 Deviations and Nonconforming Products and Services

The laboratory shall have policies, processes, and procedures to ensure the capture, assessment, investigation, and monitoring of deviations from, or failures to meet, specified requirements. The responsibility for review and authority for the disposition of nonconforming materials, samples, and services shall be defined. Deviations shall be reported in accordance with specified requirements.

7.1 Nonconforming Materials, Samples, and Services

Upon discovery, the root causes of nonconforming materials, samples, and services shall be investigated and the disposition of these nonconforming materials, samples, and services shall be determined.

7.1.1 Discrepant test reports that do not conform to specified requirements shall be prevented from unintended distribution or use.

7.1.2 The laboratory shall have a process for the quarantine, retrieval, and recall of nonconforming materials, samples, and services.

7.1.3 Materials, samples, and services that are determined after release or issue to be nonconforming shall be reported to the customer.

7.1.4 The laboratory shall have policies, processes, and procedures for circumstances that warrant the issuing of an amended report.

7.1.4.1 The laboratory shall identify an amended report. The new report shall indicate that it is an amended report and that it supersedes the previous report. Changes shall be identified in the amended report.

7.1.4.2 If a laboratory issues an amended report, the laboratory shall distribute amended reports to all recipients of the original report.

7.2 Nonconforming Proficiency Test Results

When nonconforming proficiency test results are obtained, the laboratory shall evaluate and take appropriate action in response to results with unacceptable grades or deviation from nongraded challenges with known answers or that have reached 80% consensus.

7.2.1 Nonconforming results in a graded proficiency testing program shall be investigated in accordance with Standard 9.1 and a corrective action plan shall be developed and implemented.

7.2.2.1 If the laboratory fails an overall conclusion regarding alleged genetic relationship, the corrective action plan shall include communicating to AABB's Accreditation and Quality Department within 30 days the following items:

1. The nonconformance(s).
2. The corrective actions taken.
3. The plan to monitor the effectiveness of the corrective actions.

7.2.2 Discordant test results among laboratories participating in a sample exchange program shall be investigated in accordance with Standard 9.1. A corrective action plan shall be developed and implemented.

7.3 Nonconforming Competency Assessments

Laboratory personnel who fail to meet expected performance criteria for competency testing shall be retrained and reevaluated for performance of those procedures before they are permitted to test client samples.

8.0 Assessments: Internal and External

The laboratory shall have a process to ensure that external assessments are obtained and that internal assessments of operations and the quality system are scheduled and conducted annually using these *RT Standards*.

✎8.1 Management of Assessment Results

8.1.1 The results of internal and external assessments shall be reviewed by personnel having responsibility for the area being assessed.

8.1.2 Corrective and/or preventive action shall be implemented to address deviations and nonconformances discovered through internal and external assessments. Standard 9.1.5 applies.

8.1.3 Follow-up action shall verify the implementation and effectiveness of corrective and preventive action. Standard 9.1.5 applies.

8.1.4 The results of internal and external assessments and associated corrective and preventive action shall be reviewed by relevant testing personnel and executive management.

8.2 Quality Monitoring

The laboratory shall have a process to collect and evaluate quality indicator data on a scheduled basis that includes preanalytic, analytic, and postanalytic data.

9.0 Process Improvement Through Corrective and Preventive Action

The laboratory shall have policies, processes, and procedures for data collection, analysis, and follow-up of issues requiring corrective and preventive action.

9.1 Corrective Action

The laboratory shall have a process for corrective action that includes the following elements:

9.1.1 Documentation of deviation reports, reports of nonconformances, and complaints.

9.1.2 Investigation of the root cause of nonconformances relating to samples and services, or customer complaints.

9.1.3 Determination of the corrective action needed to eliminate the cause of nonconformances and deviations.

9.1.4 Policies, processes, and procedures for completion of the corrective action within a timeframe appropriate to the nature of the nonconformance.

9.1.5 Initiation of corrective action and review of the effectiveness after implementation.

9.1.6 An assessment of risk.

9.2 Preventive Action

The laboratory shall have a process for preventive action that includes the following elements:

9.2.1 An assessment of risk.

9.2.2 The review of information, including assessment results, proficiency testing results, quality control records, and complaints, to detect and analyze potential causes of nonconformances.

9.2.3 Determination of steps needed to respond to potential problems requiring preventive action.

9.2.4 Initiation of preventive action and application of controls to monitor effectiveness.

10.0 Facilities and Safety

The laboratory shall establish and maintain policies, processes, and procedures to provide a work environment that minimizes health and safety risks. Programs shall meet local, state, and federal regulations, where applicable.

10.1 Facilities and Work Environment

Space allocation and work flow shall be adequate to support the activities carried out by the facility.

10.1.1 The work environment shall be clean and well- maintained.

10.1.2 The laboratory shall define the environmental conditions that have the potential to affect the quality of critical materials, tests, products, or services provided by the facility. Standard 5.2 applies.

✎ **10.1.2.1** Conditions shall be monitored and controlled.

10.1.3 Storage space for critical materials, products, samples, and records shall be adequate to meet specified requirements and to prevent mix-ups.

10.1.4 The infrastructure for communication and information management shall be adequate to support the needs of the facility and its customers.

10.2 Health and Safety

There shall be safety programs that address fire, biological, chemical, and, where applicable, radiation safety. These programs shall include appropriate interventions to prevent and mitigate exposure.

10.2.1 The laboratory shall define the environmental conditions that have the potential to cause harm to staff, clients, and visitors to the facility.

✎ **10.2.1.1** The laboratory shall have a process for monitoring adherence to biological, chemical, and radiation safety standards and regulations, where applicable. Standard 2.1.1 applies.

✎ **10.3 Environmental Monitoring**

The laboratory shall monitor, control, and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results.

✎10.4 Emergency Management

The emergency management plan shall address preparation for, response to, and recovery from the effects of internal and external disasters and other emergency situations.

10.4.1 The emergency management plan, including emergency communication systems, shall be tested at defined intervals.

✎10.5 Operational Continuity

Executive management shall ensure that the laboratory has policies, processes, and procedures that address continuity in the event that operations are at risk.

GLOSSARY

Agreement: A contract, order, or understanding between two or more parties, such as between a facility and one of its customers.

Agreement Review: Systematic activities carried out before finalizing the agreement to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable by the parties involved.

Allele: An alternative form of a gene or an alternate sequence of DNA at a specific locus.

Allelic Drop-in: Detection of additional alleles whose source cannot be identified.

Allelic Drop-out: Missing information in STR analyses in which one or both allelic copies at a locus fall below the detection threshold.

Amended Report: A subsequent report that corrects and/or supersedes a previous report.

Anonymous Testing: Cases where the identity of the persons tested is not known to the laboratory. The identity is maintained by another responsible person, such as an attorney or physician. For this type of testing, exceptions to the requirements for identification of the tested parties are acceptable, although requirements not relating to the identification of the tested parties will still apply.

Assessment: A systematic, independent examination to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments usually include a comparison of actual results to expected results. Types of assessments include external assessments, internal assessments, peer review, and self-assessments.

Backup: Digital data storage media (USB drive, CD, cloud-based, etc) containing copies of information system data.

Blinded Testing: The analysis of samples for which the results are unknown to the analyst.

Calibrate: To set measurement equipment parameters with the use of a known standard.

Change Control: A structured method of revising a policy, process, or procedure, including hardware or software design, transition planning, and revisions to all related documents.

Claims: With respect to these *RT Standards*, the direct or indirect implication that a facility or a service offered by that facility is accredited. Claims may appear in any information made available by the facility to potential clients or others, such as websites, educational or promotional materials, final reports, or other communication vehicles, including information given verbally to prospective clients.

Closed System: An instrument and pre-assembled set of reagents that consist of cartridges, chips, or biochips whose purpose is to perform DNA extraction, or purification, amplification, and separation in a single unit without human intervention.

Collection: The controlled process for obtaining a sample for relation- ship testing, including but not limited to: client scheduling and instruction, consent, identification, sampling, chain-of-custody documentation, and secure transport to the testing laboratory.

Collection/Verification Facility: An organization or location that is assessed and accredited by the AABB for the specific activities of collection and verification.

Competence: The ability to perform a specific task according to procedures.

Competency Testing: Evaluation of the ability to perform a specific task according to procedures and to obtain expected results.

Compliance: Conformance.

Confirmatory Testing: Repeat testing to confirm an initial test result. Confirming a test result includes an answer to an exclusion/nonexclusion question and/or the phenotype of the tested individual in a particular genetic system or systems.

Conformance: Fulfillment of requirements. Requirements may be defined by customers, practice standards, standard operating procedures, regulatory agencies, or law.

Contract: See Agreement.

Corrective Action: An activity performed to investigate and eliminate the cause of an existing nonconformance or other undesirable situation in order to prevent reoccurrence.

Critical Equipment/Materials/Services/Tasks: Equipment, materials, services, or tasks that can affect the quality of the facility's products or services.

Customer: The receiver of a product or service. A customer may be internal (eg,

another department within the same organization) or external (eg, another organization or individual person).

Database: In the context of Standard 5.5.3 of these *RT Standards*, database means the frequency table that is the source of the frequencies used to calculate a likelihood ratio.

Deviation: An activity or event that is not in conformance with established policies, processes, or procedures.

Document (noun): Written or electronically generated information and work instructions. Examples of documents include reports, quality manuals, procedures, or forms.

Equipment: A durable item, instrument, or device used in a process or procedure. Establish: To define, document, and implement.

Expert System: Software that has been validated as an alternative to the decision-making process of a human expert.

Facility: A location or operational area within an organization that is assessed and accredited by the AABB for a specific activity or activities.

Final Inspection: To measure, examine, or test one or more characteristics of a product or service, and compare results with specified requirements in order to establish whether conformance is achieved for each characteristic.

Genetic Inconsistencies: Findings that appear to exclude a relationship. These could include true exclusions, apparent mutations, or silent (null) alleles.

Genetic System: Each locus or DNA site analyzed and reported by a lab-oratory.

Graded Proficiency Testing Program: A proficiency testing program in which results submitted by a participant are evaluated by an organization independent of the laboratory and declared as conforming or nonconforming.

Hematopoietic Progenitor Cell: Primitive pluripotent hematopoietic cells capable of self-renewal and/or differentiation as well as maturation into any of the hematopoietic lineages (granulocytes, lymphocytes, monocytes, erythrocytes, and platelets) including committed and lineage-restricted progenitor cells, unless otherwise specified, regardless of tissue source (eg, marrow, mobilized peripheral blood, or umbilical cord blood).

Hypothesis: For the purpose of these *RT Standards*, a hypothesis is a mutually

exclusive, limited statement regarding the biological relationship that exists among tested individuals.

Inconclusive Result: When determining relationship a result that does not provide evidence for or against the hypothesized result.

Independent Genetic Systems: When the inheritance of the alleles of a genetic system used for testing is demonstrated, by the laboratory or by published literature, to be statistically independent from the inheritance of the alleles of any other loci used for testing.

Inspect: To measure, examine, or test one or more characteristics of a product or service and compare results with specific requirements.

Key Quality Functions: Essential job functions that affect the services provided by the organization.

Label: An inscription affixed for identification.

Laboratory: A location where testing is performed. Unless a standard specifically indicates otherwise, the terms facility and laboratory are used interchangeably in these *RT Standards*. See facility.

Likelihood Ratio: A ratio of two probabilities of the same event under different hypotheses. The relationship index is an example of a likelihood ratio, as well as related vs unrelated, full siblings vs half siblings, or a possible alleged father vs an uncle. See Appendix 3 in Guidance for Standards for relationship Testing Laboratories.

Linkage Disequilibrium: When alleles at two or more loci are found together more or less often than expected as calculated by the product of their individual frequencies.

Linked Loci: Two or more loci that are on the same chromosome with a recombination rate between them of less than 50%.

Locus (loci): A specific region or address on a chromosome or on mitochondrial DNA.

Maintain: To keep in the current state.

Marker: See Genetic System.

Material: A good or supply item used in the manufacturing or testing process. Specimens and reagents are types of materials.

Multiple Genetic Systems: For the purposes of these *RT Standards*, three or more independent genetic systems.

Mutation: Alteration or change at a locus or site resulting in an apparent inconsistency in a putative biological relationship. See Genetic Inconsistencies.

New Test Method: As opposed to a novel method, a new test method is a change to or addition of a peer-reviewed existing technology already applied in relationship testing. For example, changing from RFLP-based testing to STR-based testing or STR-based testing to SNP-based testing is a new test method. Changing from gel-based PCR testing to capillary- based PCR testing is not an example of a new test method, but an example of a new procedure.

Non-Chain-of-Custody Testing: Sample collections that do not have a record showing where a sample was collected, who collected the sample, date of collection, and other information found in Standard 5.2.

Non-Recombining Haplotypes: A set of genetic markers that are inherited as a group from one parent in its entirety, e.g., commonly used Y chromosome markers.

Nonconformance: Failure to meet requirements.

Novel Method: A procedure that has not been peer-reviewed for the purposes of relationship testing. It may include a procedure that has been peer-reviewed for other purposes or a method that has not been peer-reviewed for other purposes.

Organization: An institution, or part thereof, that has its own functions and executive management.

Phenotype: The observed testing result.

Policy: A documented general principle that guides present and future decisions.

Power of Exclusion: The ability of a genetic test or test battery to detect an inconsistency between a nonparent and child. The average (mean) power of exclusion measures this ability over all relationship tests and is used by laboratories to assess the potential usefulness of genetic tests and test batteries. The individual power of exclusion expresses the ability of a genetic test or test battery to exclude a nonparent of a defined ethnic background as a parent of a particular child.

Preferential Amplification: The formation of more PCR products of one allele in comparison with another allele at the same locus, usually due to less efficient amplification of larger alleles.

Prior Probability: The strength of the nongenetic evidence that the hypothesized relationship is correct.
Probability of Paternity: Requires the use of Bayes' Theorem. This incorporates the combined likelihood ratio and a prior probability.

Procedure: A series of tasks performed according to instructions.

Process: A set of related tasks and activities that accomplish a goal.

Process Control: Standardized efforts to manage a set of associated procedures in order to produce predictable output.

Product: A tangible result of a process or procedure.

Proficiency Testing: The structured evaluation of laboratory methods of testing that encompass the suitability of processes, procedures, equipment, materials, and personnel to produce expected results.

Qualification (qualified): For individuals, the education, training, and experience necessary to successfully meet the requirements of a position. For equipment, verification that specified attributes required to accomplish the desired task are met.

Quality: Characteristics of a product or service that ensure its ability to meet requirements, including those defined during agreement review.

Quality Control: Testing routinely performed on materials and equipment to ensure their proper function.

Quality Function: Activities of persons designated by the organization to administer the approved quality system.

Quality System: The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve the quality policy.

Quarantine (verb): To isolate nonconforming materials, results, or unissued reports in a clearly designated manner or marked area so that they cannot accidentally be used in a downstream process.

Reagent: A substance used to perform an analytical procedure. A substance used (as in detecting or measuring a component or preparing a product) because of its biological or chemical activity.

Record (noun): Information captured in writing or through an electronically generated medium that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.

Regulations: Rules promulgated by federal, state, or local authorities to implement laws enacted by legislative bodies.

Relationship Index: A likelihood ratio that compares the probability of the observed types given the hypothesized biological relationship between individuals and the probability of the observed types given the alternative hypothesized relationship.

Release: Removal of product from quarantine or in-process status for distribution.

Risk: The threat of quantifiable damage or any other negative occurrence that is caused by external or internal vulnerabilities and that may be avoided through preemptive action. An analysis of risk includes predictable kinds of negative occurrences, severity and the probability of their happening.

Root Cause: Factor(s) resulting in a nonconformance that should be eliminated through process improvement.

Sample Exchange Program: A process among two or more independent organizations to exchange samples to monitor proficiency.

Sensitivity: The percent of persons of a known relationship that have a likelihood ratio (LR) greater than a set threshold. For example, if a population of known half siblings are tested and a threshold is set at a LR of 10, and 60 out of 100 half siblings exceed 10, the sensitivity is 60%.

Service: The intangible result of a process or procedure.

Shall: A term used to indicate a requirement.

Specified Requirements: Any requirements in these *RT Standards* that may be defined by customers, manufacturer's instructions, regulatory agencies (such as the Food and Drug Administration), standards of practice, or accrediting organizations (such as AABB). These may be the expectations for products or services.

Specificity: The percent of random pairs with likelihood ratios less than a set threshold. For example, if a population of known random individuals are tested as half siblings and a threshold is set at a LR of 10, and 98 out of 100 comparisons are less than 10, the specificity is 98%.

Standard: A set of specified requirements upon which a facility may base its criteria for the products and/or services provided.

Standard Test Battery: A group of tests, each of which is covered by these *RT Standards*, that is performed routinely on each case evaluated by the laboratory.

Supplier: An organization that provides an input product or service.

Supplier Qualification: An evaluation method designed to ensure that input materials and services (eg, materials, reagents, patient blood samples) obtained from a supplier meet specified requirements.

Task: See procedure.

Technical Leader: An individual identified in a forensic laboratory that is responsible for the technical operations of the laboratory may be qualified to serve as a laboratory director under these *RT Standards*. This individual must meet and have been audited to all FBI quality assurance standards for forensic DNA testing laboratory technical leaders in addition to being the technical leader in a DNA testing laboratory audited to FBI quality assurance standards. See Standard 1.2.4.

Third-Party Administrators: Businesses that are not laboratories them- selves, but market relationship tests and then send the client or client's samples to a laboratory for the relationship testing. Also referred to as brokers, vendors, or resellers. Traceability: The ability to follow the history, application, or location of a material, product, or service by means of recorded identification.

Validation: Establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.

Verification: Confirmation by examination and provision of objective evidence that specified requirements are met.