THE GUIDANCE DOCUMENT FOR

THE FBI QUALITY ASSURANCE STANDARDS

FOR FORENSIC DNA TESTING

AND DNA DATABASING LABORATORIES

EFFECTIVE JULY 1, 2025

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INTRODUCTION

The DNA Identification Act of 1994 required the formation of a panel of distinguished professionals, from the public and private sectors, to address issues relevant to forensic DNA applications. This panel, known as the Federal DNA Advisory Board (DAB), first convened in 1995. The mission of the DAB was to develop and implement quality assurance standards for use by forensic DNA testing laboratories. The scope was quickly expanded to include forensic DNA databasing laboratories as well. The DAB fulfilled its statutory responsibilities, recommending separate documents detailing quality assurance standards for both forensic and databasing applications. The "Quality Assurance Standards for Forensic DNA Testing Laboratories" and the "Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories" were issued by the Director of the Federal Bureau of Investigation in October 1998 and April 1999, respectively.

The “Quality Assurance Standards for Forensic DNA Testing Laboratories" and the retitled "Quality Assurance Standards for DNA Databasing Laboratories" have become benchmarks for assessing the quality practices and performances of DNA laboratories throughout the country. When the Federal DNA Advisory Board’s statutory term expired, it transferred responsibility for recommending revisions of these quality assurance standards to the Scientific Working Group on DNA Analysis Methods (SWGDAM).

The DNA Identification Act of 1994 also required that the FBI Laboratory ensure that all DNA laboratories that receive federal grant funds or participate in the National DNA Index System (NDIS) demonstrate compliance with the FBI’s Quality Assurance Standards (QAS). A laboratory's documentation of compliance with the QAS is measured through an accreditation/audit process. Such accreditation inspections or audits are performed by forensic scientists, either internal or external to the laboratory, and are intended to evaluate and document compliance with established standards.

Since the issuance of the original QAS, the FBI Laboratory recognized that a uniform interpretation guide would minimize interpretation variability among auditors. For the initial QAS, the FBI Laboratory developed, in collaboration with inspection and accreditation agencies and other interested stakeholders, audit documents for assessing compliance with the required Forensic and Databasing standards. Previous Audit Documents contained a checklist for assessing compliance with each standard and additional discussion sections with interpretation guidance for laboratories and auditors.

With the 2020 QAS revisions, the QAS discussion sections for the Forensic and Databasing Standards, formerly part of the Audit Documents, have been transitioned into this QAS Guidance Document. This Guidance Document clarifies standards, as needed, and provides additional guidance to assist the laboratory and auditors in determining compliance. The Forensic and Databasing Audit Documents now contain only the checklists for assessing compliance with each standard.

Discussions in this QAS Guidance Document were applicable to the Forensic and Databasing QAS which took effect July 1, 2020 and are not to be applied retroactively. The most recent revisions to this QAS Guidance Document will take effect with the July 1, 2025 versions of the Forensic and Databasing QAS as noted in the Latest Revision date following the discussion. Editorial revisions (e.g., updated reference to a renumbered Standard, typographical edits) or non-substantive edits are not reflected in the "Latest Revision" date.

The current Forensic and Databasing QAS are the primary resources for the definitions and quality assurance standards and take precedence over this Guidance Document which should be consulted only for additional clarification as a secondary resource.

Standard 1. Scope and Applicability

Forensic Standard 1	Database Standard 1
No additional guidance	
	Latest Revision: 07/01/2020

Standard 2. Definitions

Forensic Standard 2	Database Standard 2
Refer to the definitions in the QUALITY ASSURANCE STANDARDS FOR FORENSIC DNA TESTING LABORATORIES or QUALITY ASSURANCE STANDARDS FOR DNA DATABASING LABORATORIES effective July 1, 2025. Throughout this document “CODIS Administrator” is used to refer to the Casework CODIS Administrator or CODIS Administrator, as applicable to the particular standard. When appropriate, a casework reference sample can also be collected from an unknown/unnamed individual (e.g., unidentified human reference sample) and processed as a casework reference sample when obtained directly from the unidentified person.	
	Latest Revision: 07/01/2025

Standard 3. Quality Assurance Program

Forensic Standard 3.1	Database Standard 3.1
To successfully satisfy **Standard 3.1**, compliance must be demonstrated with all of the substandards of **Standard 3.1.1 and Standard 3.1.2**. The quality system must be appropriate to the testing activities performed by the laboratory. Various approaches may be used to accomplish the quality system, as long as the requirements are clearly defined in a quality assurance program. A laboratory may choose the format in which it maintains its quality system, as long as it is on-site and readily available to DNA personnel. A laboratory’s quality system must be equivalent to or more stringent than the “Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories” or “Quality Assurance Standards (QAS) for DNA Databasing Laboratories”, as applicable. If a laboratory has requirements more stringent than the QAS, it must be audited to the more stringent requirements. For example, if the laboratory is in compliance with these standards, but is not adhering to its own more stringent requirements, the finding shall be documented in the Audit Document.	
	Latest Revision: 07/01/2020

Forensic Standard 3.1.1	Database Standard 3.1.1

Standards 3.1.1.1 through 3.1.1.15 are elements of the quality system that a laboratory must ensure are documented or referenced in a quality system manual(s). The laboratory may rely on laboratory or agency-wide policies, procedures, and guidelines that address such elements, but must ensure that the laboratory references them. The following are the elements as defined by **Standards 3.1.1.1 through 3.1.1.15** and what should be addressed within each of those elements. Further requirements for each element will be found within the corresponding standard.

- **Goals and objectives** must define, establish, or reference the goals and objectives for the laboratory.

- **Organization and management** must define, establish, or reference the organization and management structure of the laboratory, the interrelationship of the various DNA positions, as well as the responsibilities of personnel. (Refer to **Standard 4**)

- **Personnel** must define, establish, or reference the educational and experience requirements for technical personnel. (Refer to **Standard 5**)

- **Training** must define, establish, or reference the training requirements for qualifying technical personnel. (Refer to **Standard 6**)

- **Facilities and evidence control** must define, establish, or reference the laboratory's procedures for laboratory security and its approach for maintaining the integrity of DNA analyses and evidence examination as well as the procedures for handling and preserving evidence, and the laboratory's definitions for what constitutes work product and evidence. (Refer to **Forensic Standard 7**)

- **Facilities and sample control** must define, establish, or reference the laboratory's procedures for laboratory security and its approach for maintaining the integrity of DNA analyses as well as the procedures for handling and preserving database, known, and/or casework reference samples, and the laboratory's definitions for what constitutes work product and evidence. (Refer to **Database Standard 7**)

- **Validation** must define, establish, or reference the practices and procedures for evaluating and implementing new methods, modified methods, expert systems, and software used by the laboratory. (Refer to **Standard 8**)

- **Analytical procedures** must define, establish, or reference the use of current and approved analytical procedures, including quality assurance parameters, interpretation guidelines, mixture interpretation guidelines, and the application of appropriate statistical calculations. These procedures must be based on and supported by validation studies. (Refer to **Standard 9**)

- **Equipment** must define, establish, or reference the laboratory's program for maintaining equipment and conducting performance checks of equipment and instruments. (Refer to **Standard 10**)

- **Reports** must define, establish, or reference the laboratory's procedures for maintaining case files, generating laboratory reports, and maintaining confidentiality and privacy of reports, case files, DNA records, and databases. (Refer to **Forensic Standard 11**)

- **Documentation** must define, establish, or reference the laboratory's procedures for maintaining documentation for database, known, or casework reference samples, generating analytical documentation, and maintaining confidentiality and privacy of analytical documentation, DNA records, and databases. (Refer to **Database Standard 11**)

- **Review** must define, establish, or reference the laboratory's procedures for performing technical and administrative reviews of all case files or databasing DNA records, the qualifications of personnel who perform reviews, and the verifications associated with the upload of DNA data. (Refer to **Standard 12**)

- **Proficiency testing** must define, establish, or reference the laboratory's program for administering external proficiency tests to technical personnel and evaluating the results of those proficiency tests. (Refer to **Standard 13**)

- **Corrective action** must define, establish, or reference the laboratory's process for addressing nonconformities in casework or database analysis, proficiency testing, testimony, and audits. (Refer to **Standard 14**)

- **Audits** must define, establish, or reference the laboratory's program for participation in internal and external audits to the Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories or DNA Databasing Laboratories. (Refer to **Standard 15**)

- **Professional Development** must define, establish, or reference the laboratory's program for continuing education, annual review of scientific literature, and annual review of analyst testimony. (Refer to **Standard 16**)

- **Outsourcing ownership** must define, establish, or reference the laboratory's procedures for outsourcing samples and accepting ownership of the products of DNA analyses. Laboratories shall address this element, regardless of whether or not the laboratory outsources. For example, outsourcing may be referenced in the quality manual as "Not Applicable" or "NA" if the laboratory does not outsource any analyses. (Refer to **Standard 17**)

For a laboratory that uses Rapid DNA and/or has Rapid DNA Partner Agencies, the elements of the quality system must also address the Rapid DNA applications as required in Standards 18 and 19.
Latest Revision: 07/01/2025

Forensic Standard 3.1.2	**Database Standard 3.1.2**
Any document referenced within the quality manual(s) must be available on-site or readily accessible (e.g., available online).	
Latest Revision: 07/01/2020	

Forensic Standard 3.2	**Database Standard 3.2**
To successfully satisfy **Standard 3.2**, compliance must be demonstrated with all of the components of **Standard 3.2**. The laboratory may address document retention through a single policy or a combination of several policies. However, retention of each of the listed documents must be addressed.	
Latest Revision: 07/01/2020	

Forensic Standard 3.3	**Database Standard 3.3**
An annual review (calendar year) of the quality system is important for ensuring that measures are being taken by the laboratory to continually provide the highest quality of service. The annual review may identify areas in need of attention and provide the basis for changes to the quality system. Quality system documents that are updated or revised in the calendar year may be exempt from an additional annual review, provided that the Technical Leader's approval of the quality system review addresses these revisions. The annual review of the quality system must be independent of the audit requirement as stated in **Standard 15**. The laboratory must demonstrate that the annual review of its quality system is performed under the direction of the Technical Leader and the completion of the review must be documented and approved by the Technical Leader.	
Latest Revision: 07/01/2020	

Forensic Standard 3.4	
An annual review of case files is a useful quality assurance mechanism to evaluate the products of forensic DNA analysis. A case file review must be conducted each calendar year. The scope of the review must be defined and approved by the Technical Leader and address both the representative sample and the time period of the case files under review. For example, the time period may include case files from the previous calendar year or for a specified period of time. The Technical Leader will determine what will be used as the representative sample for the annual review, and the representative sample may vary from year to year. The	

Technical Leader may select the sampling based on corrective actions, perceived analytical gaps, and/or at random. The sampling may be based on a percentage or a specified number of cases. Additionally, the representative sample may be selected based on the forensic samples tested, technology, conclusions reported, complexity of the typing results, or cases where testimony has occurred and transcripts were available for review. As examples, a representative sample may be a percentage of all sexual assault cases, a percentage of all YSTR cases, a specific number of random cases from each analyst, or a specific number of complex mixture cases.

This annual review may not be replaced by technical reviews as a part of **Standard 12**.

The annual audit to these standards required by **Standard 15** cannot be used to replace the annual review of case files; however, the annual case file review may be conducted concurrently with an internal audit.

Latest Revision: 07/01/2020

	Database Standard 3.4

An annual review of sample processing records is a useful quality assurance mechanism to evaluate the products of DNA databasing analysis.

A review of sample processing records must be conducted each calendar year. The scope of the review must be defined and approved by the Technical Leader and address both the representative sample and the time period of the processing records under review. For example, the time period may include processing records from the previous calendar year or for a specified period of time.

The Technical Leader will determine what will be used as the representative sample for the annual review, and the representative sample may vary from year to year. The Technical Leader may select the sampling based on corrective actions, perceived analytical gaps, and/or at random. The sampling may be based on a percentage or a specified number of database analyses. Additionally, the representative sample may be selected based on the database samples tested or technology.

This annual review may not be replaced by technical reviews as a part of **Standard 12**.

The annual audit to these standards required by **Standard 15** cannot be used to replace the annual review of sample processing records; however, the annual sample processing records review may be conducted concurrently with an internal audit.

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Standard 4. Organization and Management

Forensic Standard 4.1	Database Standard 4.1

To successfully satisfy **Standard 4.1**, compliance must be demonstrated with all of the substandards of **Standard 4.1**.

For **Standard 4.1.2**, **Standard 5.2.5** and its substandards must be satisfied in order to demonstrate that the Technical Leader is accountable for the technical operations. **Standard 4.1.2** does not preclude, for example, the existence of additional program or Technical Leaders, each of whom may be assigned a subset of clearly defined duties (e.g., training program manager, quality assurance program manager, assistant Technical Leader); however, a single DNA Technical Leader, as defined in the laboratory's organizational chart, will retain the ultimate DNA-related authority and oversight responsibility for the laboratory's technical operations. However, a laboratory may have more than one Technical Leader if there is no overlap between them and the role of each is clearly defined. For example, a laboratory may designate a Technical Leader over a specific technology (e.g., a mitochondrial DNA Technical Leader and an STR Technical Leader), over an operational group (e.g., a casework Technical Leader and a databasing Technical Leader), or for a multi-laboratory system, Technical Leaders may be assigned to each location with each having the ultimate authority over the designated technology, operation group or laboratory location, as applicable.

For **Standard 4.1.3**, **Standards 5.3.5** and its substandards, and **Standard 5.3.6** must be satisfied in order to demonstrate that the CODIS Administrator is accountable for CODIS operations on-site at each individual laboratory facility using CODIS.

For **Standard 4.1.4**, **Standard 5.4** and its substandards must be satisfied in order to demonstrate that the DNA analysts are full-time employees and are qualified. Contract employees cannot be counted when determining if a laboratory satisfies the two full-time employee requirement of **Standard 4.1.4**.

For **Standard 4.1.5**, an organizational chart, job descriptions, and/or other laboratory documentation must specify the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the validity of the DNA analysis. A current organizational chart can be used to demonstrate the interrelation of personnel. The organizational chart may reference specific personnel by name with their specific position assignments (e.g., Technical Leader, Casework CODIS Administrator), or the organizational chart may reference the specific position assignments. If the organizational chart references the specific position assignments, those assignments need to be augmented with the job description for the member of the laboratory assigned to the specific position.

For **Standard 4.1.6**, the laboratory must have a documented contingency plan in place, approved by laboratory management, for a vacancy in the Technical Leader position and in the event the number of qualified analysts falls below two full-time employees who are qualified analysts. This plan may be a single policy or a

combination of several policies. A contingency plan should include or address the appropriate notifications naming an individual who may serve in the Technical Leader position, the time period that individual may serve, and how the laboratory will proceed if no one is qualified. The contingency plan must also address the laboratory's course of action in the event the number of qualified analysts falls below two full-time employees who are qualified analysts. The contingency plan for a multi-laboratory system in the event the number of qualified analysts falls below two full-time employees who are qualified analysts may include or address the availability of similarly trained analysts that can temporarily be reassigned to fill an analyst vacancy.

For an NDIS participating laboratory, the contingency plan for how the laboratory will proceed if no one is qualified to fill the Technical Leader vacancy or in the event the number of qualified analysts falls below two full-time employees who are qualified analysts requires the notification of the NDIS Custodian and State CODIS Administrator as required by the *NDIS Operational Procedures Manual*. Refer to Appendix B for the Contingency Plan Notification Form. If a contingency plan was submitted to the FBI, then documentation must be reviewed to ensure that DNA analytical procedures on new casework or new database analyses were not initiated until FBI approval was granted. Casework or database analyses in which DNA analytical procedures have been initiated prior to the Technical Leader's vacancy may be completed. Casework or database analyses in which DNA analytical procedures have been initiated may not be able to be completed if the number of qualified analysts falls below two full-time employees who are qualified analysts.

Latest Revision: 07/01/2020

Forensic Standard 4.2	**Database Standard 4.2**
The laboratory policy must specify the date of hire/appointment/promotion or the date of qualification as the defined date to be used by the laboratory for determining the applicable version of the *Quality Assurance Standards for Forensic DNA Testing Laboratories* or *Quality Assurance Standards for DNA Databasing Laboratories* for requirements to assess education, experience and training. If an individual does not change her/his role with a promotion or appointment (e.g., Analyst I to Analyst II, Alternate CODIS Administrator to CODIS Administrator), then reevaluation of her/his education, experience and training is not required. If an individual does change her/his role with a promotion or appointment (e.g., Analyst to Technical Leader, Technician to Analyst, Analyst to CODIS Administrator), then evaluation of her/his education, experience, and training for the new role is required.	
Latest Revision: 07/01/2020	

Standard 5. Personnel

Forensic Standard 5.1	**Database Standard 5.1**
To successfully satisfy **Standard 5.1**, compliance must be demonstrated with all of the substandards of **Standard 5**.	

Technical personnel are individuals (however titled) involved in testing and support of testing of forensic, casework reference, or database samples. Individuals not involved in the stream of testing (e.g., evidence management, sample control, administrative, clerical) are not considered technical personnel for the purposes of Standard 5.

Appendix D shall be completed by auditors conducting external QAS audits. Individuals in the positions of Technical Leader, CODIS Administrator, and analyst or technical reviewer will be listed in Appendix D if compliance with **Standard 5.1** and the applicable standards for education, experience, and training are demonstrated. The minimum education, experience and training qualifications of those individuals reviewed and documented in Appendix D in an external audit of the laboratory system are considered compliant with **Standard 5.1** and do not require additional review in subsequent audits, provided that the individuals are in the same role and the Appendix D from the past audit document is available. If an individual previously memorialized as an analyst or technical reviewer in Appendix D becomes a Technical Leader or CODIS Administrator, the applicable standards for education, experience, and training must be reviewed for that individual and must be memorialized during an external audit with respect to the new position.

Latest Revision: 07/01/2025

Forensic Standard 5.1.1	**Database Standard 5.1.1**
Documentation must define the general responsibilities, duties, and skills associated with each technical position. Documentation may include position descriptions in a laboratory quality manual (e.g., a “Y-screen analyst” is an individual authorized to interpret quantitation results in the analysis of sexual assault evidence) or human resources documentation (e.g., hiring criteria).	
Latest Revision: 07/01/2025	

Forensic Standard 5.1.2	**Database Standard 5.1.2**
Documentation describing the qualifications, training, skills, and experience of each individual involved in testing and support of testing must be maintained. This documentation should demonstrate that the individual meets the requirements of their technical responsibilities (e.g., academic transcripts where applicable, curriculum vitae, training authorizations [see **Forensic Standard 6.10/Database Standard 6.8**]).	
Latest Revision: 07/01/2025	

Forensic Standard 5.2	**Database Standard 5.2**
Full-time shall be considered the standard work week as defined by the laboratory or its organizational umbrella. The Technical Leader must be a full-time employee of the laboratory or laboratory system although not required to occupy physical (on-site) facility space. If the Technical Leader oversees multiple laboratories of a multi-laboratory system or primarily works remotely, refer to **Standard 5.2.6**. In accordance with **Standard 15.2.1**, the approval of the minimum educational requirements along with the Technical Leader’s experience and any required training shall be reviewed and documented in the Appendix D during an external audit.	

If the minimum education, experience and training qualifications of the laboratory's Technical Leader have been reviewed during an external audit of the laboratory and documented in the Appendix D, then **Standards 5.2.1 through 5.2.4** do not require review provided that the Appendix D from the past audit is available.

Latest Revision: 07/01/2025

Forensic Standard 5.2.1 through 5.2.1.3	**Database Standard 5.2.1 through 5.2.1.3**

A biology-, chemistry-, or forensic science-related degree must include science coursework. Criminal justice degrees that do not include science coursework are not considered to be forensic science-related degrees.

For **Standard 5.2.1.1**, coursework that provides an understanding of the foundation of DNA analysis can include courses titled with terms such as molecular biology, genetics, biochemistry, biological chemistry, population genetics, molecular genetics, cell and molecular biology, genomics, and bioinformatics. This list is not exhaustive of all relevant courses that can be used to satisfy this standard. Courses with titles not listed here can be used to satisfy the coursework requirements; however, general education science courses (e.g., Biology 101) cannot be used to satisfy the educational course requirements.

A population genetics course used to satisfy **Standard 5.2.1.2** cannot also be used toward the credit hours for **Standard 5.2.1.1**.

The credit hours must be completed successfully (college- or university-determined passing grade or credits earned).

For the purposes of these standards, a credit hour is based on the semester credit hour system where a typical course receives 3 credit hours. A quarter credit hour is considered equivalent to a semester credit hour for these standards, but other conversions may be necessary dependent upon the transcript (e.g., universities that assign 1 graduation unit for a traditional semester course).

For **Standard 5.2.1.3**, at least one course used to satisfy **Standard 5.2.1.1** or **5.2.1.2** must have been completed at the graduate level.

The DNA training program previously offered by the FBI Laboratory, with graduate credit hours from the University of Virginia, may be applied toward the coursework requirements. Unless specifically stated by the FBI, other FBI courses do not fulfill this requirement.

Latest Revision: 07/01/2025

Forensic Standards 5.2.1.4	**Database Standards 5.2.1.4**

The ASCLD waiver is permanent and portable. Documentation of the waiver must be available. The application for the ASCLD waiver was available until October 1, 2000 and is no longer available. If the Technical Leader possesses a waiver from ASCLD

as per **Standard 5.2.1.4, Standards 5.2.1, 5.2.1.1, 5.2.1.2, and 5.2.1.3** are not applicable.

Latest Revision: 07/01/2025

Forensic Standards 5.2.1.5	**Database Standards 5.2.1.5**

The review and documentation of the Technical Leader's minimum education requirements while employed as a Technical Leader at a different laboratory may be accepted at the discretion of the hiring laboratory.

If a prior external audit review of the educational requirements for the Technical Leader were accepted by the hiring laboratory in accordance with **Standard 15.2.1**, the laboratory must retain the documentation from the prior external audit memorializing the Technical Leader. This audit documentation, along with the Technical Leader's experience and required training, if applicable, shall be reviewed and documented in the Appendix D during an external audit at the new laboratory.

If prior audit documentation is not available or accepted, **Standard 5.2.1.5** is not applicable and the minimum educational requirements must be reviewed in accordance with **Standards 5.2.1 and 5.2.1.1 through 5.2.1.4**.

Latest Revision: 07/01/2025

Forensic Standard 5.2.2	

Technical Leaders appointed or hired prior to July 1, 2009, are considered compliant with the minimum experience requirement.

Technical Leaders appointed or hired on or after July 1, 2009 must demonstrate compliance with **Forensic Standard 5.2.2** through documented employment as a qualified analyst on forensic samples. Training records, authorization records, or previous Appendix D with the Technical Leader memorialized as an analyst may be used to demonstrate the Technical Leader was a qualified analyst.

It should be noted that the experience time frame is measured not by the number of years with any particular employer but rather by the number of years in a position specific for gaining the experience necessary to satisfy this standard.

Latest Revision: 07/01/2025

	Database Standard 5.2.2

Technical Leaders appointed or hired prior to July 1, 2009, are considered compliant with the minimum experience requirement.

Technical Leaders appointed or hired on or after July 1, 2009 must demonstrate compliance with **Database Standard 5.2.2** through documented employment as a qualified analyst on database or forensic samples. Training records, authorization records, or previous Appendix D with the Technical Leader memorialized as an analyst may be used to demonstrate the Technical Leader was a qualified analyst.

It should be noted that the experience time frame is measured not by the number of years with any particular employer but rather by the number of years in a position specific for gaining the experience necessary to satisfy this standard.
Latest Revision: 07/01/2025

Forensic Standard 5.2.3	**Database Standard 5.2.3**
If a Technical Leader appointed on or after July 1, 2020 was not a qualified analyst, currently or previously, in each technology for which they will be responsible, the laboratory will ensure that the Technical Leader has documented training within one year of appointment. Training should be sufficient to understand the scientific theory, evaluate the analysis and interpretation, and conduct troubleshooting as required by the Technical Leader responsibilities. A recently appointed Technical Leader who has not completed the minimum training requirements will not be recorded in Appendix D, and the education, experience and training must be reviewed in a subsequent external audit.	
Latest Revision: 07/01/2025	

Forensic Standard 5.2.4	**Database Standard 5.2.4**
Evidence of successful completion of the current FBI DNA Auditor training will be assessed through an FBI-issued certificate. The Technical Leader shall have successfully completed the FBI's QAS auditor training within one year of assuming the Technical Leader role or position. If the recently appointed Technical Leader has already successfully completed the current FBI's QAS auditor training on the FBI Audit document, no additional QAS auditor training shall be required. A recently appointed Technical Leader who has not completed the minimum training requirements will not be recorded in Appendix D, and the education, experience and training must be reviewed in a subsequent external audit.	
Latest Revision: 07/01/2025	

Forensic Standard 5.2.5	**Database Standard 5.2.5**
To successfully satisfy **Standard 5.2.5**, the laboratory must clearly define and document the Technical Leader's duties and authority. Compliance must be demonstrated with all of the substandards of **Standard 5.2.5** For **Standard 5.2.5.1**, overseeing the technical operations of the laboratory may include ensuring that technical assistance in matters of analysis, interpretation, instrumentation, and troubleshooting is available to laboratory staff. For **Standard 5.2.5.2**, while other laboratory personnel (such as Laboratory Director or Quality Manager) may also have the authority to suspend technical operations for the laboratory or an individual, the authorization of the Technical Leader is required to initiate or resume the technical operations for the laboratory, an individual, and when applicable, a Rapid DNA partner agency. A forensic DNA testing laboratory that does	

not have a Rapid DNA partner agency must still demonstrate that the Technical Leader has this authority.

For **Standard 5.2.5.4**, the Technical Leader is responsible for ensuring the education, experience, and training are sufficient for the authorized responsibilities of technical personnel and in compliance with the applicable standards in **Standards 5 and 6**. For the educational requirements, this may be achieved via a review of academic transcripts or a review of the external audit documentation for personnel transferring from another laboratory as described in **Standard 15.2.1**.

For **Standard 5.2.5.5**, a laboratory that does not currently outsource must still demonstrate that the Technical Leader has this responsibility.

For **Standard 5.2.5.9**, it is the responsibility of the contract employee to disclose employment by multiple NDIS participating laboratories and/or vendor laboratories to all employing laboratories for which the contract employee is performing DNA typing and/or analytical services. The Technical Leader must review the employment of contract employees by multiple NDIS participating laboratories and/or vendor laboratories for any potential conflicts of interest. If there are no potential conflicts of interest, the Technical Leader may approve the employment by multiple NDIS participating and/or vendor laboratories. For example, Vendor Laboratory A performs the forensic analysis of DNA samples for State Laboratory Z. An employee of Vendor Laboratory A shall not perform ownership review services for State Laboratory Z on cases that were analyzed by Vendor Laboratory A as this would constitute a conflict of interest. A laboratory that does not use contract employees must still demonstrate that the Technical Leader has this responsibility.

Latest Revision: 07/01/2025

Forensic Standard 5.2.6	**Database Standard 5.2.6**

For the Technical Leader to be considered accessible, the Technical Leader must be on-site at the laboratory at least semi-annually.

In a multi-laboratory system, the semi-annual on-site visits are intended to maintain consistency between facilities in the performance of analytical procedures, to ensure proper handling of evidence, and to promote discussion among analysts. The Technical Leader must demonstrate knowledge and oversight of the DNA program sufficient to ensure that each laboratory is following standards and written protocols.

Standard 5.2.6 does not require the Technical Leader to visit facilities with Rapid DNA as the only capability since those locations are not defined as a laboratory.

Latest Revision: 07/01/2025

Forensic Standard 5.2.7	**Database Standard 5.2.7**

Newly appointed Technical Leaders should strive to review validation studies and analytical procedures currently used by the laboratory at the earliest available time. The review of training records of currently qualified analysts and technical reviewers

is required for those who have not yet been memorialized by an external audit. These reviews must be completed and documented within one year of appointment.

If one year has not passed between the appointment of the Technical Leader and the next audit and the Technical Leader has not completed the reviews of the validation studies, analytical procedures, and training records, then **Standard 5.2.7** is not applicable. In this situation, this standard must be evaluated during the following external audit to ensure that the necessary reviews were completed within one year of appointment.

An acting Technical Leader that serves in the role for less than one year is not required to complete and document these reviews. The acting Technical Leader should have sufficient familiarity with the validation studies and analytical procedures to perform the responsibilities of the Technical Leader for an interim period.

If the Technical Leader position has not been assumed by a newly appointed Technical Leader since the last audit, then **Standards 5.2.7, 5.2.7.1** and **5.2.7.2** are not applicable.

Latest Revision: 07/01/2025

Forensic Standard 5.3	**Database Standard 5.3**

For a vendor laboratory or a laboratory that is not an NDIS participating lab, **Standard 5.3** and all of its substandards are not applicable.

For a laboratory applying for NDIS participation, **Standard 5.3** and all of its substandards will be assessed but may be not applicable.

All references to CODIS Administrator in Standard 5.3 and its substandards are intended to include Casework CODIS Administrator as applicable.

Latest Revision: 07/01/2020

Forensic Standards 5.3.1 - 5.3.2	**Database Standards 5.3.1 - 5.3.2**

If the minimum education, experience and training qualifications of the laboratory's CODIS Administrator have been reviewed during an external audit of the laboratory and documented in the Appendix D, then **Standards 5.3.1 through 5.3.3** do not require review provided that the Appendix D from the past audit is available. CODIS Administrators appointed prior to July 1, 2009, who have never been qualified as an analyst will be considered compliant with the minimum education and experience requirements.

An individual appointed as the Alternate CODIS Administrator as required by the *NDIS Operational Procedures Manual* after June 1, 2018, will be reviewed in accordance with **Standards 5.3.1 through 5.3.3** and be documented in Appendix D of the Audit Document. The Alternate CODIS Administrator designation and responsibilities are described in the *NDIS Operational Procedures Manual*.

The CODIS Administrator's education requirement is satisfied with the required degree. Coursework does not need to be rereviewed for CODIS Administrator(s) since the minimum educational requirements would have been reviewed during the approval as a qualified analyst.

For **Database Standard 5.3.2**, the CODIS Administrator shall be a currently or previously qualified forensic or database analyst; while in **Forensic Standard 5.3.2** the Casework CODIS Administrator shall be a currently or previously qualified forensic analyst. Database analyst experience is not accepted for the Casework CODIS Administrator. Status as a currently or previously qualified analyst can be established through authorization documentation and/or prior external audit documentation.

The laboratory will ensure that the CODIS Administrator has documented training in mixture interpretation. Training should be sufficient to understand the results of searching mixture profiles in the database. The CODIS Administrator does not need to be authorized in mixture interpretation.

Latest Revision: 07/01/2025

Forensic Standards 5.3.3	**Database Standards 5.3.3**

If the recently appointed CODIS Administrator has not completed the current FBI's DNA auditor training and it has been less than one year since the appointment of the CODIS Administrator, **Standard 5.3.3** is not applicable and must be evaluated during a subsequent external audit to ensure that the necessary training was completed within one year of appointment.

If the recently appointed CODIS Administrator has not completed the current FBI sponsored CODIS training and it has been fewer than six months since the appointment of the CODIS Administrator, then **Standard 5.3.3** is not applicable and must be evaluated during a subsequent external audit to ensure that the necessary training was completed within six months of appointment.

A recently appointed CODIS Administrator who has not completed the minimum auditor and CODIS training requirements will not be listed in Appendix D until these training requirements are complete.

Latest Revision: 07/01/2025

Forensic Standards 5.3.4	**Database Standards 5.3.4**

The review and documentation of the CODIS Administrator's minimum education requirements while employed as a CODIS Administrator at a different laboratory may be accepted at the discretion of the hiring laboratory's Technical Leader.

If the educational requirements of the CODIS Administrator were accepted by the Technical Leader in accordance with **Standard 15.2.1**, the laboratory must retain the documentation from a prior external audit memorializing the CODIS Administrator. This audit documentation, along with the CODIS Administrator's experience and

training, shall be reviewed and documented in the Appendix D during an external audit at the new laboratory.

If prior audit documentation is not available or accepted, **Standard 5.3.4** is not applicable and the minimum educational requirements must be reviewed in accordance with **Standard 5.3.1**.

Latest Revision: 07/01/2025

Forensic Standards 5.3.5 – 5.3.6	**Database Standards 5.3.5 – 5.3.6**

To successfully satisfy **Standards 5.3.5 and 5.3.6**, the laboratory must document the CODIS Administrator's duties, responsibilities and authority.

For **Standard 5.3.6**, other laboratory personnel (such as Laboratory Director, Quality Manager, or Technical Leader) may also have the authority to terminate an analyst's, laboratory's, or, when applicable, a Rapid DNA partner agency's participation in CODIS. The authorization of the CODIS Administrator is required for an analyst, laboratory, or, when applicable, Rapid DNA partner agency to resume CODIS participation. A forensic DNA testing laboratory that does not have a Rapid DNA partner agency must still demonstrate that the Casework CODIS Administrator has this authority.

Latest Revision: 07/01/2025

Forensic Standard 5.3.7	**Database Standard 5.3.7**

If the CODIS Administrator position has not been vacant since the last external audit, then **Standard 5.3.7** is not applicable.

If the CODIS Administrator position was vacated but the alternate CODIS Administrator (whose designation is described in the *NDIS Operational Procedures Manual*) assumed the CODIS Administrator responsibilities, the laboratory may continue to upload DNA profiles to NDIS and **Standard 5.3.7** is not applicable.

If the CODIS Administrator position was vacated and the designated alternate CODIS Administrator is unable to assume the casework CODIS Administrator responsibilities, then the laboratory shall not upload any new profiles to NDIS until a CODIS Administrator is appointed.

Latest Revision: 07/01/2020

Forensic Standard 5.4	**Database Standard 5.4**

Standards 5.4.1 through 5.4.2 will be completed for analysts undergoing a review during an external audit and documented in Appendix D. If the minimum education and experience qualifications of an analyst have been reviewed during an external audit of the laboratory where the analyst is employed and documented in the Appendix D, then **Standards 5.4.1 through 5.4.2** do not require review for that analyst provided that the Appendix D from the past audit is available.

The laboratory shall have defined either the date of hire/appointment/promotion or the date of qualification to be used in the evaluation of analyst education, experience and training requirements in accordance with **Standard 4.2**. Regardless of the date used by the laboratory, the evaluation of an analyst's education, experience and training requirements will not be completed until the analyst is authorized to independently perform assigned job responsibilities.

Latest Revision: 07/01/2025

Forensic Standard 5.4.1	**Database Standard 5.4.1**

A biology-, chemistry-, or forensic science-related degree must include science coursework. Criminal justice degrees that do not include science coursework are not considered to be forensic science-related degrees.

A variety of college course work may apply toward satisfying this standard and is not limited exclusively to the course titles listed in prior versions of these standards.

For **Standard 5.4.1**, coursework that provides an understanding of the foundation of DNA analysis can include courses titled with terms such as molecular biology, genetics, biochemistry, biological chemistry, population genetics, molecular genetics, cell and molecular biology, genomics, and bioinformatics. This list is not exhaustive of all relevant courses that can be used to satisfy this standard. Courses with titles not listed here can be used to satisfy the coursework requirements; however, general education science courses (e.g., Biology 101) cannot be used to satisfy the educational course requirements.

A population genetics course used to satisfy **Standard 5.4.1.2** may not also be used toward the credit hours for **Standard 5.4.1.1**.

The credit hours must be completed successfully (college- or university-determined passing grade or credits earned).

For the purposes of these standards, a credit hour is based on the semester credit hour system where a typical course receives 3 credit hours. A quarter credit hour is considered equivalent to a semester credit hour for these standards, but other conversions may be necessary dependent upon the transcript (e.g., universities that assign 1 graduation unit for a traditional semester course).

The DNA training program previously offered by the FBI Laboratory, with graduate credit hours from the University of Virginia, may be applied toward the coursework requirements associated with this standard. Unless specifically stated by the FBI, other FBI courses do not fulfill this requirement.

In accordance with **Standard 15.2.1**, the approval of the minimum educational requirements along with the analyst's experience and any required training shall be reviewed and documented in the Appendix D during an external audit.

Prior to July 1, 2020, the statistics and/or population genetics requirement could be satisfied through internal or external training. For external statistics and/or population genetics training, a variety of methods may have been used, including academic coursework; workshops at local, national, or international meetings or symposia; or other external, Technical Leader-approved, training courses. The laboratory must maintain documentation of such attendance. Internal statistics and/or population genetics training must be documented.

In circumstances where an analyst qualified before July 1, 2020 in one laboratory is hired by another laboratory, the Technical Leader in the hiring laboratory can opt to accept audit documentation (i.e., Appendix D) from the prior laboratory demonstrating the review of the analyst's education qualifications, including training in statistics and/or population genetics in lieu of having formal coursework as required on/after July 1, 2020.

Latest Revision: 07/01/2025

Forensic Standard 5.4.1.3	**Database Standard 5.4.1.3**

The review and documentation of an analyst's minimum education requirements while employed as an analyst at a different laboratory may be accepted at the discretion of the hiring laboratory's Technical Leader.

If the educational requirements of the analyst were accepted by the Technical Leader in accordance with **Standard 15.2.1**, the laboratory must retain the external audit documentation of a prior external audit memorializing the analyst. This audit documentation shall be reviewed, along with the analyst's experience and training per **Standard 5.4.2**, and documented in the Appendix D during an external audit at the new laboratory.

Accepting prior external audit documentation for an analyst's education does not fulfil the requirements for training or competency testing in the new lab. The analyst's training, even if modified in accordance with **Standard 6.2**, and competency testing, in accordance with **Standard 6.3**, must be reviewed during an external audit prior to memorializing the analyst in the Appendix D at the new laboratory. (Refer to **Standard 15.2.1.4**)

If prior audit documentation is not available or accepted, **Standard 5.4.1.3** is not applicable and the minimum educational requirements must be reviewed in accordance with **Standards 5.4.1, 5.4.1.1 and 5.4.1.2.**

Latest Revision: 07/01/2025

Forensic Standard 5.4.2	

An analyst must have forensic human DNA laboratory experience gained at a facility where forensic DNA testing was performed for the identification and evaluation of biological evidence in criminal matters. The experience is not measured by the length of time spent with any particular employer but rather by the time in a position specific for gaining the experience necessary to perform the authorized responsibilities. The experience gained by an individual must include the successful analysis of a range of

samples typically associated with forensic casework. An individual's participation after appointment or hiring in a formal forensic DNA training program is acceptable for fulfilling or being applied toward fulfilling the experience requirement of this standard.

The laboratory must ensure that an analyst has the experience necessary to independently perform the authorized responsibilities as required by **Standard 6.10**. This allows laboratories to have modular training of tasks such that, for example, an analyst limited to reporting Y-screening results might be authorized with less experience than an analyst performing complex mixture interpretation. Per **Standard 5.2.5.4,** the Technical Leader is responsible for ensuring the experience and training are adequate to perform the authorized tasks.

Refer to **Standard 6** for guidance on the requirements for analyst training.

Latest Revision: 07/01/2025

	Database Standard 5.4.2

An analyst must have human DNA laboratory experience in a forensic or database DNA laboratory. The experience is not measured by the length of time spent with any particular employer but rather by the time in a position specific for gaining the experience necessary to perform the authorized responsibilities. The experience gained by an individual must include the successful analysis of a range of samples typically associated with database analysis. An individual's participation after appointment or hiring in a formal database DNA training program is acceptable for fulfilling or being applied toward fulfilling the experience requirement of this standard.

The laboratory shall ensure that an analyst has the experience necessary to independently perform the authorized responsibilities as required by **Standard 6.8**. This allows laboratories to have modular training of tasks. Per **Standard 5.2.5.4**, the Technical Leader is responsible for ensuring the experience and training are adequate to perform authorized tasks.

Refer to **Standard 6** for guidance on the requirements for analyst training.

Latest Revision: 07/01/2025

Forensic Standard 5.5	**Database Standard 5.5**

Standard 5.5 will be completed for technical reviewers undergoing a review during an external audit, including individuals whose sole responsibility is technical review, and documented in Appendix D. For a technical reviewer not previously memorialized in Appendix D as an analyst and/or technical reviewer in the laboratory system being audited**,** the review and approval of the education, experience, and training requirements for the technical reviewer will be documented in Appendix D during an external audit. A technical reviewer who is a currently or previously qualified analyst in the laboratory does not need to be separately listed in Appendix D as a technical reviewer.

As defined in **Standard 2**, a technical reviewer is an employee or contract employee who is a currently or previously qualified analyst that performs a technical review. As

such, all analysts that perform technical review must also fulfill the requirements of a technical reviewer.
Latest Revision: 07/01/2025

Forensic Standard 5.5.1	**Database Standard 5.5.1**
Currently qualified analysts that are authorized to conduct technical reviews will be considered compliant with **Standard 5.5.1** if the requirements of **Standard 5.4** are satisfied. If the technical reviewer is/was not a qualified analyst in the laboratory system being audited, the technical reviewer must demonstrate that they were previously qualified as an analyst in another laboratory system. Status as a currently or previously qualified analyst can be established through prior external audit documentation. If the prior external audit documentation is not available, , then authorization documentation and the education to meet the requirements of analyst must be reviewed and memorialized as required in **Standard 15.2.1.3**.	
Latest Revision: 07/01/2025	

Forensic Standard 5.5.2	**Database Standard 5.5.2**
If a laboratory authorizes an analyst to perform technical reviews upon completion of the analyst training program, documented training must be included as part of the analyst training records in accordance with **Standard 6.1.3.1**. If a laboratory requires additional training and authorization to perform technical reviews, training records for analysts/technical reviewers authorized to perform technical review shall be required for **Standard 5.5.2.** An analyst qualified prior to July 1, 2020 that is authorized to perform technical reviews will be considered compliant with **Standard 5.5.2**. Refer to **Standard 6** for guidance on the requirements for technical reviewer training.	
Latest Revision: 07/01/2025	

Forensic Standard 5.6	**Database Standard 5.6**
Refer to **Standard 6** for guidance on the requirements for technician training.	
Latest Revision: 07/01/2020	

Forensic Standard 5.7	**Database Standard 5.7**
The Technical Leader must verify the degree obtained and coursework completed for each analyst and technical reviewer. Transcripts and other appropriate documentation must be available to the Technical Leader for approving an individual's education. This can include prior external audit documentation from the analyst's or technical reviewer's previous employer, if the Technical Leader is accepting that prior review and approval of qualifications.	
Latest Revision: 07/01/2025	

Standard 6. Training

Forensic Standards 6.1 – 6.1.5	Database Standards 6.1 – 6.1.5

To successfully satisfy **Standard 6.1**, compliance must be demonstrated with all of the substandards of **Standard 6.1**.

The training program applies to individuals who serve as analysts or technicians in any capacity. The training manual can be designed so that an analyst or technician can be authorized in specific methods, methodologies, or responsibilities independent of the whole manual. Refer to **Forensic Standard 6.10/Database Standard 6.8** for authorizations.

For **Standard 6.1.1**, the training program must address all procedures; however, the laboratory will determine which procedure(s) the analyst or technician will be qualified to perform on casework or on database, known, or casework reference samples. Any newly validated analytical, interpretation, and/or statistical procedure implemented by the laboratory should be incorporated into the laboratory's training program as soon as practicable.

For **Standard 6.1.2**, practical exercises are not limited to lab work but can also be in the form of data analysis and review. The practical exercises should reflect the extent to which the individual will be trained in an analytical, interpretation, and/or statistical procedure. Examples of a range of samples routinely encountered may include degraded, partial, mixed contributor, low template, off-ladder alleles and microvariant samples.

For **Standard 6.1.3.1**, the training program for an analyst will cover the elements of technical review even if the laboratory requires additional experience or training for an analyst to be authorized to perform technical review. The laboratory can determine when and how analysts are authorized to perform technical reviews and if the analyst will be required to have additional experience or training.

For **Standard 6.1.4**, individuals who process forensic, database or casework reference samples may be required to testify in court even if they do not generate a report; therefore, the requirement for an assessment of oral communication skills and/or a mock court exercise applies to analysts and technicians.

For **Standard 6.1.5**, refer to **Standard 6.3** for the required elements of competency testing of trainees. The competency testing must be sufficient for the trainee to demonstrate that they have achieved the technical skills and met minimum standards of knowledge necessary to perform the forensic DNA analysis or databasing for which the trainee will be authorized to perform on casework or on database, known, or casework reference samples.

Latest Revision: 07/01/2020

Forensic Standard 6.2	Database Standard 6.2
It is the technical leader's responsibility to evaluate the adequacy of previous training for any individual who has not otherwise completed the laboratory's training program. Modifications to the individual's training based on this evaluation will be documented and approved by the Technical Leader. Examples may include: the hiring of a fully trained analyst from another laboratory, a technician that is entering the analyst training program, or laboratory support personnel that enter the technician or analyst training program.	
Latest Revision: 07/01/2025	

Forensic Standard 6.3	Database Standard 6.3
This standard applies to analysts or technicians completing the laboratory's training program who will be authorized to perform independent casework analysis or independent database analysis/processing for the first time as an analyst or technician in the laboratory (e.g., a new hire or a technician promoted to analyst). For **Standard 6.3.1**, the practical component of competency testing should be relevant to the task(s) that the analyst will be authorized to perform on casework or on database, known, or casework reference samples. The laboratory will determine if the competency testing of a new analyst will also include a written component, an oral component, or both. The competency testing must be sufficient to demonstrate that the trainee has achieved the technical skills and knowledge necessary to perform and explain forensic DNA analysis or DNA databasing. For **Standard 6.3.2**, the practical component of competency testing should be relevant to the task(s) that the technician will be authorized to perform on casework or on database, known, or casework reference samples. The competency testing must be sufficient to demonstrate that the trainee has achieved the technical skills and knowledge necessary to perform the forensic DNA or DNA databasing methods.	
Latest Revision: 07/01/2020	

Forensic Standard 6.4	Database Standard 6.4
This standard will be applicable when an analyst or technician who has completed the laboratory training program is undergoing training in an additional method for which they are not currently qualified or when an analyst or technician is trained in a newly validated and implemented method. For an analyst who also performs technical review, elements of both roles need to be addressed in the training. For example, if the analyst is trained on a new extraction procedure, the analyst should also be familiar with the notes generated during the process that would need to be evaluated during technical review. An additional competency test in technical review is not required. The practical component of competency testing should be relevant to the task(s) that the analyst or technician will be authorized to perform on casework or database samples. Examples of a practical component may include performing the method on a	

test sample, interpreting data generated by the method, and/or reviewing the notes and/or data generated when performing the method.

For personnel intimately involved in a validation, the Technical Leader may allow the validation to serve as the demonstration of competency. Documentation must be available to indicate that the involvement in the validation was representative of the extent to which the individual will use the method in casework or databasing.

Latest Revision: 07/01/2020

Forensic Standard 6.5	**Database Standard 6.5**

This standard will be applicable when a qualified analyst is trained in the interpretation of data using an additional technology, typing test kit, platform, or interpretation software for which they are not currently qualified or when the laboratory analysts are trained in a newly validated and implemented technology, typing test kit, platform, or interpretation software. Refer to **Standard 15.2.1.5** for audit documentation of this training.

For an analyst that also performs technical review, elements of both roles need to be addressed in the training. For example, if the analyst is trained on a new typing test kit, the analyst should also be familiar with the notes generated during the data interpretation that would be evaluated during technical review. An additional competency test in technical review is not required.

The training for interpretation software pertains to the implementation of new or additional software. The requirements for new or additional interpretation software may not expand to new versions of interpretation software in use in the laboratory. For example, updates or modifications to interpretation software that would not require the analysts to learn new skills and knowledge to interpret data, reach conclusions, or generate reports using that software would not require training under **Standard 6.5**. However, an updated or modified interpretation software with fundamental changes that requires the analysts to learn new skills and knowledge to interpret data, reach conclusions, or generate reports would require training under **Standard 6.5**.

The practical component should be relevant to the task(s) that the analyst will be authorized to perform on casework or on database, known, or casework reference samples. Examples of a practical component may include interpreting data, performing a statistical calculation, generating a report and/or reviewing the notes and/or data generated with the additional technology, typing test kit, platform, or interpretation software.

In instances where the technology, typing test kit, platform, or interpretation software also involve training in a new method(s), both **Standards 6.4 and 6.5** will apply to the analyst(s). In these instances, the competency testing may be combined. For example, the analyst may complete a practical competency test by performing the method in the laboratory and interpreting the data and/or generating a report.

For personnel intimately involved in a validation, the Technical Leader may allow the validation to serve as the demonstration of competency. Documentation must be available to indicate that the involvement in the validation was representative of the extent to which the individual will use the method in casework or databasing.

Latest Revision: 07/01/2020

Forensic Standard 6.6	**Database Standard 6.6**

This standard applies to individuals who will be trained and authorized to conduct technical reviews but are not or will not be authorized as an analyst in the method, technology, typing test kit, platform, or interpretation software (or legacy version). The training is intended to ensure the individual can conduct a technical review of the case notes, data analysis, interpretation, and reports or database processing records, data analysis, and interpretation generated by the laboratory.

This standard does not apply to a laboratory that does not have individuals that solely conduct technical reviews. If the technical reviews in the laboratory are conducted by analysts qualified in the method, technology, typing test kit, platform, or interpretation software (or legacy version) in the laboratory, then **Standard 6.6** will be marked not applicable and these individuals will be evaluated under **Standard 6.5**.

Competency testing for a technical reviewer must establish that the technical reviewer has demonstrated achievement of technical skills and met minimum standards of knowledge necessary to perform a technical review.

For personnel intimately involved in a validation, the Technical Leader may allow the validation to serve as the demonstration of competency. Documentation must be available to indicate that the involvement in the validation was representative of the extent to which the individual will use the method in casework or databasing.

Standard 6.6.1.1 is only applicable for an NDIS participating laboratory with contract employee technical reviewers conducting reviews for the NDIS participating laboratory.

Latest Revision: 07/01/2020

Forensic Standard 6.7	

This standard applies to analysts who were not previously qualified in the laboratory to interpret data from a legacy technology, typing test kit, and/or platform and will be authorized to reinterpret legacy data.

At a minimum, the training should include a review of the relevant portions of the validation of the legacy procedures and the standard operating procedure(s) relevant to the original interpretation of the legacy data.

The training should address the laboratory's procedures for the reinterpretation of legacy data. (Refer to **Forensic Standard 9.9**)

The practical component of competency testing needs to include interpretation of legacy data but does not require the analyst to generate new data using the legacy technology, typing test kit, and/or platform.
Latest Revision: 07/01/2020

Forensic Standard 6.8	
The laboratory procedures must address how analysts and technical reviewers, whose external proficiency testing does not include a legacy technology, typing test kit or platform for which they are qualified or previously qualified, will demonstrate that they maintain or have reestablished the technical skills and knowledge in the reinterpretation of legacy data. For laboratories that do not reinterpret legacy data (refer to **Forensic Standard 9.9**), this standard is not applicable. Mechanisms for maintaining or reestablishing technical skills and knowledge on a legacy technology, typing test kit and/or platform may include reviewing the validation and standard operating procedures, undergoing training or reviewing previous training, or completing an interpretation competency test. For **Forensic Standard 6.8.1**, the Technical Leader must review the documentation that the analyst or technical reviewer completed the elements of the laboratory's procedures and authorize the analyst or technical reviewer to reinterpret legacy data for no more than a two year period.	
Latest Revision: 07/01/2020	

Forensic Standard 6.9	**Database Standard 6.7**
No additional guidance	
Latest Revision: 07/01/2020	

Forensic Standard 6.10	**Database Standard 6.8**
The laboratory must have documentation that provides a formal means for recognizing an individual's successful completion of the training program (e.g., certificate, letter, memorandum). Authorization documentation will clearly state the approval to conduct independent forensic DNA analysis or databasing using the applicable methods, technologies, typing test kits, and platforms. The authorization for technical review may be concurrent with authorization as an analyst or a separate authorization but needs to be clearly addressed. Authorization documentation may provide a specific list of responsibilities (e.g., NAME is authorized to perform DNA extraction and quantitation of casework reference samples) or may reference a specific job title as defined in a laboratory quality manual (e.g., NAME is authorized to perform the duties of a Y-screen analyst.)	

The date of authorization of an individual must be documented. The authorization date has particular relevance to proficiency testing requirements discussed in **Standard 13** (Proficiency Testing), which requires that newly qualified individuals participate in an external proficiency test within eight months of the authorization date.
Latest Revision: 07/01/2025

Forensic Standard 6.11	**Database Standard 6.9**
Laboratory support personnel must have documented training in the laboratory duties they perform. Training should include, at a minimum, those tasks that are necessary for performance of or may impact the results of an analytical procedure (e.g., making reagents or preparing an instrument for operation).	
Latest Revision: 07/01/2020	

Forensic Standard 6.12	**Database Standard 6.10**
Retraining of an analyst, technician, or technical reviewer may be necessary as a result of an extended absence from casework or databasing duties, as part of corrective action, or when determined necessary by the Technical Leader. The **Forensic Standard 6.12.1/Database Standard 6.10.1** requirement to successfully complete competency testing prior to return to participation in casework or databasing analyses will also apply to individuals who have been on extended leave for a period that takes them out of the proficiency test cycle. The Technical Leader will determine if the individual requires training or retraining prior to competency testing. The competency testing should be relevant to the task(s) that the analyst, technician, or technical reviewer will return to performing on casework samples or on databasing, known, or casework reference samples.	
Latest Revision: 07/01/2020	

Forensic Standard 6.13	**Database Standard 6.11**
The laboratory must have available for review the training and authorization records for each analyst, technician, and technical reviewer. The laboratory must have available for review the documented training completed by each laboratory support personnel.	
Latest Revision: 07/01/2020	

Standard 7. Facilities and Evidence/Sample Control

Forensic Standard 7.1	**Database Standard 7.1**
To successfully satisfy **Standard 7.1**, the laboratory must demonstrate compliance with all of the substandards of **Standard 7.1**.	

Secure, controlled access areas for evidence/sample storage must exist within the laboratory.

The laboratory must be arranged in a way to ensure the integrity of the analyses as described in **Standards 7.1.2** and **7.1.3**.

Through a combination of clearly written analytical procedures, notes, and/or personal observation, the laboratory's approach to evidence/sample processing for PCR-based procedures must demonstrate a separation in time or physical space for each activity. The laboratory's design must ensure that evidence/sample flow through the various steps of DNA processing does not compromise the integrity of the evidence/sample. The amplification room must be enclosed with walls from the floor to the ceiling and door(s) for passage. The amplification room(s) must physically separate amplified DNA from all other areas of the laboratory by keeping doors in the closed position.

See **Standard 18** for facility requirements for Rapid DNA instrument/Systems.

Latest Revision: 07/01/2025

Forensic Standard 7.2	**Database Standard 7.2**
A laboratory's security system must control access and limit entry to the operational areas. Internal controlled areas shall limit access to only authorized personnel. The distribution system of all keys, combinations, etc. must be current, accurate, clearly documented, and available for review. Many other control systems which include card keys, surveillance cameras, and intrusion alarms, are acceptable when they complement the laboratory's security system by controlling unauthorized access and/or limiting authorized access to the operational laboratory and evidence storage areas.	
Latest Revision: 07/01/2020	

Forensic Standard 7.3	
An evidence control program may be addressed through a single policy/procedure or combination of several policies/procedures. Key components of an evidence control system include proper labeling and sealing of evidence, a documented chain-of-custody record, and a secure area designated for evidence storage.	
Latest Revision: 07/01/2020	

	Database Standard 7.3
A sample inventory control program may be addressed though a single policy/procedure or a combination of several policies/procedures. Key components of a sample inventory control system include labeling, storage, security of samples, documentation of identity, collection and receipt. A database laboratory that performs known or casework reference sample analysis must have clearly written well-understood procedures that address handling and preserving the integrity of these evidence samples. Key components of such an evidence-control procedure include proper labeling and sealing of evidence, a	

documented chain-of-custody record, and a secure area designated for evidence storage.
Latest Revision: 07/01/2020

Forensic Standard 7.3.1	**Database Standard 7.3.1**
Each item of evidence or each database, known, or casework reference sample must be marked with a unique identifier on at least the evidence packaging or sample container. The laboratory must clearly define what constitutes evidence and what constitutes work product because the laboratory may establish different criteria for the handling and control of evidence versus work product. For example, a forensic laboratory may define extracts as evidence and require the extracts be tracked on the chain of custody or a laboratory may define extracts as work product and may not require the extracts be tracked on the chain of custody. If the laboratory retains or returns extract to meet **Forensic Standard 7.4.1**, the extract shall be treated as evidence. While a databasing laboratory may not receive or process evidence, what constitutes evidence and what constitutes work product must be defined by the laboratory. A database laboratory that processes casework reference samples must define these samples as evidence and ensure the laboratory procedures address proper labeling and sealing of evidence, a documented chain-of-custody record, and a secure area designated for evidence storage as required throughout **Standard 7**. The laboratory must have a method to distinguish each sample throughout processing; the use of plate or rack mapping may not require the assignment of unique identifiers or individual evidence seals for each sample.	
Latest Revision: 07/01/2020	

	Database Standard 7.3.2
The laboratory shall document the identity, collection, receipt, storage, and disposition of database samples. Documentation may be in hard copy or electronic format.	
Latest Revision: 07/01/2020	

Forensic Standard 7.3.2	**Database Standard 7.3.2.1**
The chain of custody record must provide a comprehensive, documented history for each evidence transfer over which the laboratory has control. Electronic tracking of evidence is an acceptable alternative to a written record as long as the computerized data are sufficiently secure, detailed, and accessible for review and can be converted to a hard copy when necessary. An electronic equivalent may be used when it can only be applied by the individual for whom the electronic equivalent represents. If the database laboratory is processing known or casework reference samples it shall address how it handles the chain of custody for evidence samples and must document all that is listed under **Database Standard 7.3.2.1**. If the database	

laboratory does not process known or casework reference samples, **Database Standard 7.3.2.1** is not applicable.
Latest Revision: 07/01/2020

Forensic Standard 7.3.3	**Database Standard 7.3.3**
The laboratory must have written procedures that address handling and preserving the integrity of evidence/sample and work product, including known and casework reference samples processed by databasing laboratories. The laboratory may demonstrate compliance with **Standard 7.3.3** by specifying short-term and long-term storage that demonstrate proper security. Short-term storage areas may vary from a locked file cabinet to an entire examination room temporarily housing large or bulky items of evidence. The laboratory may not require a container be sealed when testing on the item is in progress. For **Forensic Standard 7.3.3.2**, the laboratory procedures must define when evidence must be properly sealed. An evidence container is sealed properly if its contents cannot escape readily and if opening the container results in a detectable alteration to the container or seal. The seal must be labeled in a manner that identifies the individual responsible for sealing the evidence. The immediate container need not be sealed (but securely closed) if it is enclosed in a larger container that meets the requirements of a proper seal. In such instances, the container must be closed securely such that its contents are protected from loss, contamination, and/or deleterious change. For **Database Standard 7.3.3.1,** if the database laboratory processes known or casework reference samples, the laboratory must ensure that samples stored under its custody are properly sealed as described above.	
Latest Revision: 07/01/2020	

Forensic Standard 7.4	**Database Standard 7.4**
The laboratory must have a policy on sample consumption. The policy is expected to provide instruction for if and/or when the laboratory may or may not consume a sample and any documentation that the laboratory requires. If a portion of evidence sample is not available and the laboratory retains or returns extract to meet **Forensic Standard 7.4.1**, the extract shall be treated as evidence.	
Latest Revision: 07/01/2020	

Forensic Standard 7.5	
The laboratory policy for the disposition of evidence should address how the disposition will be communicated in the report. (Refer to **Forensic Standard 11.2.8**)	
Latest Revision: 07/01/2020	

Standard 8. Validation

Forensic Standard 8.1	**Database Standard 8.1**
Methods used for forensic DNA analysis or DNA databasing must be validated for the intended use. Validation studies must establish the conditions under which a method is effective and reliable. To successfully satisfy **Standard 8.1**, the laboratory must demonstrate compliance with all of the substandards of **Standard 8**. The validation studies found to be in compliance with **Standard 8.1** and documented in accordance with **Standard 15.2.2** after one external audit do not need to be reviewed during subsequent audits. If there are no validation studies during the scope of the audit to be evaluated, **Standards 8.1.1 through 8.1.5** are not applicable. A validation to be memorialized should be evaluated to the standards that were in place at the time the studies were approved by the Technical Leader. All validations reviewed and approved during the audit will be documented in Appendix E. Only completed and summarized validation studies will be reviewed by the audit team. However, validations can be reviewed and memorialized prior to the completion of training and implementation of the new method. A comment should be made in the Audit Document to prompt the review of training and applicable procedures for the new method during the next external audit (i.e., as applicable, **Standards 6.4 and 6.5** and **Standards 8.1.3 through 8.1.5**). A validation found to not meet all of the relevant requirements of these standards should not be memorialized in Appendix E. The comments in the Audit Document should describe the reason the validation is not memorialized. The validation should be provided to a subsequent external audit team for review and memorialization in Appendix E.	
Latest Revision: 07/01/2025	

Forensic Standard 8.1.1	**Database Standard 8.1.1**
Developmental validation studies are required for all validations of a new technology, typing test kit, or platform regardless of whether they were performed by the laboratory or performed by an external agency (either commercial vendor or another laboratory). If a laboratory is relying on externally performed developmental validation studies, the source material of those studies (e.g., peer reviewed publications, scientific meeting presentations, summaries prepared by other forensic labs) shall be available and accessible. Peer reviewed publications are encouraged, but other materials can be relied upon. If a laboratory has performed its own developmental validation, it must show evidence of how the elements of **Standard 8.1.1** were addressed.	

Characterization of the genetic marker: The basic characteristics of a genetic marker must be determined and documented. The basic characteristics may be determined by examining inheritance, mapping, detection and polymorphism(s) of the genetic marker.
Inheritance: The mode of inheritance of DNA markers may be demonstrated through family studies
Mapping: Determining the genomic location
Detection: The method for identifying the genetic marker (e.g., capillary electrophoresis, DNA sequencing, hybridization assays)
Polymorphism: Determining the type of variation (e.g., sequence and/or length variants)

Species specificity: The ability to detect genetic information from non-targeted species (e.g., detection of microbial DNA in a human assay) must be determined. The detection of genetic information from non-targeted species does not necessarily invalidate the use of the assay, but may help define the limits of the assay. Species cross-reactivity may be demonstrated using a number of commercially available non-human DNA.

Sensitivity studies: A range of DNA quantities, to include the upper and lower limits of the assay must be evaluated. Sensitivity may be demonstrated utilizing a dilution series of extracted DNA.

Stability studies: Measuring the ability to obtain the results from DNA recovered from biological samples deposited on various substrates and subjected to various environmental and chemical insults should be evaluated. Stability may be demonstrated by titrating commercially available environmental and purification related PCR inhibitors (e.g., hematin, humic acid, tannic acid, EDTA) into extracted DNA or a PCR reaction. For database samples, stability studies may include samples on various substrates and subjected to potential PCR inhibitors (e.g., tobacco) or various storage conditions.

Case-type samples: Case-type samples may be those samples that are from adjudicated cases or mock samples that mimic casework samples. Samples should be representative of items and/or stains typically encountered by the testing laboratory (e.g., blood, semen, saliva, transferred epithelial cells, bones). Samples that mimic casework samples may include samples that are created in the laboratory such as artificially degraded or inhibited samples or mixed DNA samples made from normalized extracted DNA.

Database-type samples: Database-type samples may encompass the types of samples (e.g., blood, saliva) and/or sample substrates that are routinely submitted to the database laboratory.

Population studies: The distribution of genetic markers in relevant populations groups must be determined. Population databases must be tested for independence expectations (e.g., Hardy Weinberg Equilibrium and Linkage Equilibrium).

Mixture studies: Mixed DNA samples that are representative of those typically encountered by the testing laboratory must be evaluated. Mixture studies should use known samples that represent the number of contributors and the range of general mixture types for which the procedure will be used in casework (e.g., mixture proportions, template quantities).

Precision and accuracy studies: Precision and accuracy should address repeatability (i.e., evaluate results of the same instrument and/or operator) and/or reproducibility (i.e., evaluate results among different instruments and/or operators), when practicable. Precision and accuracy may be accomplished by examining the migration and sizing of allelic ladders.

PCR-based studies: Publication of the sequence of individual primers is not required in order to appropriately demonstrate the reliability and limitations of PCR-based technologies. PCR-based studies must include:

- Reaction conditions needed to provide the required degree of specificity and robustness must be determined. These include, but are not limited to, thermal cycling parameters, the concentration of primers, buffers, DNA polymerase, and other critical reagents. Evaluation of the reaction conditions may be demonstrated by amplification of extracted DNA at various thermal cycling parameters, evaluating DNA extracts with primer, buffer, and DNA polymerase concentrations above and below the recommended concentration to assess the impact on peak height balance and PCR artifacts.

- Assessment of differential and preferential amplification measures the specificity and robustness of the PCR reaction. Assessing differential and preferential amplification of the PCR reaction may be demonstrated by amplifying a range of DNA quantities, to include the upper and lower limits of the reaction, to determine the impact on peak height balance between and within a genetic marker. A dilution series of extracted DNA may be used.

- Effects of multiplexing measures the specificity and robustness of the PCR reaction. The effects of multiplexing may be demonstrated by amplification of a range of DNA quantities, to include the upper and lower limits of the reaction, to assess the impact on peak height balance and the presence of PCR artifacts. A dilution series of extracted DNA may be used.

- Assessment of appropriate controls ensures that the method works correctly and ensures the data are valid.

- Product detection studies allow the criteria for the detection of amplified product to be determined based on the platform and/or method used.

A laboratory's internal validation can be used to supplement any elements in which the developmental validation is deficient.

Latest Revision: 07/01/2025

Forensic Standard 8.1.2	**Database Standard 8.1.2**

To successfully satisfy **Standard 8.1.2**, the laboratory must demonstrate compliance with all of the applicable substandards of this standard. When an internal validation includes new or modified software used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations, the laboratory must also demonstrate compliance with the applicable substandards of **Standard 8.5**. The studies performed under **Standard 8.1.2** or evaluations performed under **Standard 8.3** may be concurrently used as the software testing.

Prior to implementing a DNA method, the laboratory must perform internal validation studies. The appropriate sample number and the type of samples used in the internal validation studies should be sufficient to support and document the reliability and potential limitations of the method.

Latest Revision: 07/01/2025

Forensic Standard 8.1.2.1	**Database Standard 8.1.2.1**

The laboratory shall perform the applicable internal validation studies. This must precede implementation of any DNA analysis methods. Studies determined to be not applicable shall be addressed in the internal validation summaries. (Refer to **Standard 8.1.5**) A laboratory's internal validation can be used to supplement any studies in which the developmental validation is deficient. If conducted within the same laboratory, developmental validation studies may satisfy some of the elements of the internal validation.

Known and non-probative evidence samples or mock evidence samples: Methods shall be evaluated and tested using known samples and non-probative evidence samples or mock case samples. Mock evidence samples should be reflective of the type and quality expected to be encountered in casework (e.g., various substrates, various stain concentrations). Results from these studies should be compared to the previous results where possible to ensure concordance (i.e., demonstrate agreement between the results obtained compared to those using previous methods or published data). Observed discordance should be documented and, where possible, a reason given for the discordance.

Known database-type samples: Methods shall be evaluated and tested using known samples, available database samples, or mock samples. Mock samples should be reflective of the type and quality expected to be encountered in databasing (e.g., various substrates, various stain concentrations). Results from these studies should be compared to the previous results where possible to ensure concordance (i.e., demonstrate agreement between the results obtained compared to those using previous methods or published data). Observed discordance should be documented and, where possible, a reason given for the discordance.

Precision and accuracy studies: Precision and accuracy studies should address repeatability (i.e., evaluate results of the same instrument and/or operator) and/or reproducibility (i.e., evaluate results among different instruments and/or operators), when practicable. Precision and accuracy may be accomplished by examining the migration and sizing of allelic ladders.

Sensitivity and stochastic studies: Sensitivity studies are used to determine the dynamic range, ideal target range, limit of detection, limit of quantification, heterozygote balance (e.g., peak height ratio) and the signal to noise ratio associated with the assay. Sensitivity studies should include a range of template DNA/cellular material that brackets and, where possible, extends beyond the optimal quantity.

Stochastic studies are used to evaluate excessive random effects (e.g., allele drop-out, peak height imbalance) generally resulting from low quantity and/or low quality samples. Where appropriate to the interpretation model utilized, these studies are used to determine the laboratory's stochastic threshold.

Mixture studies: Mixed DNA samples that are representative of those typically encountered by the testing laboratory shall be evaluated. Forensic mixture studies should use known samples that represent the number of contributors and the range of general mixture types for which the procedure will be used in casework (e.g., mixture proportions, template quantities) and must be used to develop interpretation guidelines.

Contamination assessment studies: The laboratory shall evaluate the detection of exogenous DNA (e.g., allele drop-in) originating from reagents, consumables, operator and/or laboratory environment using both controls and known samples. The contamination assessment should be used when developing quality control procedures and interpretation guidelines.

Latest Revision: 07/01/2025

Forensic Standard 8.1.2.2	**Database Standard 8.1.2.2**

For laboratory systems that consist of more than one laboratory, each of the laboratories must complete and maintain site specific precision, sensitivity, and contamination assessment studies. Remaining validation studies may be shared among all locations in a multi-laboratory system. Summaries of a system's internal validation studies must be available at all sites. Multi-laboratory studies are considered internal validation studies and must be reviewed and approved by the Technical Leader prior to implementing a procedure in accordance with **Standard 8.1.5**.

A laboratory that relocates to a new facility shall be considered a multi-laboratory system for an audit that spans the relocation period of the two laboratory facilities. As such, the laboratory must complete at a minimum, precision, sensitivity, and contamination assessment studies in the new facility. A summary of the pertinent

studies must be written and approval by the Technical Leader must be documented prior to the initiation of casework or databasing at the new facility.
Latest Revision: 07/01/2020

Forensic Standard 8.1.3	**Database Standard 8.1.3**
Validation data used for generating quality assurance parameters may include criteria for acceptable analytical controls (e.g., reagent blank, positive amplification control, internal size standard), sample data (e.g., contamination detection, signal saturation), and limitations associated with a method (e.g., accuracy of quantification estimate, performance with inhibited or degraded DNA). Refer to **Standard 9** for analytical procedure requirements.	
Latest Revision: 07/01/2025	

Forensic Standards 8.1.4 and 8.1.4.1	
Validation data used for generating interpretation guidelines may include evaluating thresholds (e.g., quantification, analytical, stochastic), DNA typing results (e.g., detecting degradation, drop-out, drop-in, heteroplasmy), whether DNA typing results are interpretable or uninterpretable, and conclusions from comparisons (e.g., inclusionary, exclusionary, inconclusive). Mixture interpretation procedures must be based on validation data covering a range of inputs expected to be observed in casework and may include assessing the number of contributors and mixture ratio proportions, discerning major and minor contributor(s), and/or probabilistic genotyping software models and validation. Guidelines for the appropriate statistical calculations developed through validation data may include application to single source and mixed DNA samples, binary and/or probabilistic approaches, use of allele frequency databases, and other modeling parameters (e.g., drop-out, rare allele frequencies). Where statistical thresholds are used to make conclusions for direct comparisons (e.g., inclusion, exclusion), these thresholds must be determined based on validation data. Statistical thresholds may not be applicable to relationship testing. Refer to **Standard 9** for analytical procedure requirements.	
Latest Revision: 07/01/2025	

	Database Standard 8.1.4
Validation data used for generating interpretation guidelines may include evaluating thresholds (e.g., quantification, analytical, stochastic, stutter, as applicable), DNA typing results (e.g., detecting artifacts), and whether DNA typing results are interpretable or uninterpretable. Refer to **Standard 9** for analytical procedure requirements.	
Latest Revision: 07/01/2025	

Forensic Standard 8.1.5	Database Standard 8.1.5
Summaries must be written for all internal validation studies and include all relevant information to demonstrate that they meet the standards and support the laboratory's interpretation guidelines. Documentation of the validation review and date of approval by the Technical Leader, prior to implementation in forensic or databasing applications, must be maintained.	
Latest Revision: 07/01/2025	

Forensic Standard 8.2	Database Standard 8.2
Certified reference materials are accompanied by a Certificate of Analysis (COA) that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. Examples of certified reference materials include the National Institute of Standards and Technologies (NIST) standard reference material (SRM) for PCR-based DNA profiling (e.g., SRM 2391d and subsequent successors to the 2391 series). Laboratories have the option of using a certified reference material or creating a sample traceable to a certified reference material. For a sample to be considered traceable to an appropriate certified reference material, the laboratory must demonstrate the proof of homogeneity, stability, and verification of the new lot of the traceable material. The laboratory documentation must detail the preparation, storage, and characterization of the new lot of traceable material. SRM expiration dates may be extended by NIST (or other manufacturer) throughout the life of a material. It is important to ensure the most recently issued certificate accompanies any SRM or in-house traceable material. In creating a sample traceable to a certified reference material, when the reference material (SRM) expires or is replaced by a successor, the traceability of any in-house materials also expires. If used beyond the original expiration date, the laboratory should obtain the updated certificate or supporting documentation. Certified values are values NIST has the highest confidence in and were confirmed with sequencing and sizing with available commercial PCR kits. These values may be used to create a material traceable to a certified reference material. Non-certified values (or values of interest) are values that have not been sequenced and only confirmed with commercial PCR kits or in-house primer sets. These non-certified values are a best estimate of the "true" value without the determination of all possibilities of uncertainty. They may be used for confirmation but may not be made traceable in an in-house material. **Standard 8.2** is not required for validation of a method that does not generate a DNA type. Laboratories have the option of using additional NIST SRMs that may be available (e.g., NIST SRM 2372a Human Quantification Standard), but their use is not required by **Standard 8.2** unless specifically referenced by the laboratory.	

The check against an appropriate and available certified reference material prior to implementation is not required for an NDIS approved Rapid DNA System that has been performance checked in accordance with **Forensic Standard 18.7/Database Standard 18.6** or for a Rapid DNA instrument used for modified Rapid DNA analysis that has been internally validated in accordance with **Standard 8 and Forensic Standard 18.6/Database Standard 18.5**.

Latest Revision: 07/01/2025

Forensic Standard 8.3	**Database Standard 8.3**

If a laboratory modifies a method in such a way as to alter the validated steps, reagents, or critical instruments, the modified method must be evaluated by comparing the original method to the modified method using similar DNA samples. The evaluation performed under **Standard 8.3** may be used to fulfill the requirement of a performance check for new critical equipment or instruments under **Standard 10.3.1**. Modification evaluations must be documented and approved by the Technical Leader before being implemented in casework or databasing applications.

If the modification has an impact on the efficacy or reliability of the forensic casework or databasing analysis (such as modifications that impact the efficacy of the PCR process or the detection of DNA types), internal validation studies (such as sensitivity and stochastic studies) may be necessary to demonstrate the continued reliability and potential limitations of the method. The laboratory should evaluate the appropriate sample number, sample type, and the studies necessary to ensure concordance.

If the modification includes new or modified software, then the new or modified software would need to be validated or tested as required under **Standard 8.5**.

Example scenarios:
If a laboratory changes a thermal cycler model in use for their amplification method, then this modification for the new thermal cycler would require evaluation under **Standard 8.3** and a performance check under **Standard 10.3.1**. However, if the evaluation does not demonstrate that the new thermal cycler is performing similarly to the previously used thermal cycler, the laboratory may need to do validation studies to ensure the modification has not impacted the reliability and potential limitations of the method. For the new thermal cycler, altering the time or temperature of the cycling parameters would require internal validation studies to ensure these changes do not impact the previously validated sensitivity or the interpretation guidelines.

If a laboratory modifies an extraction procedure for a new robotic system that also requires new reagents and alters the steps of the procedure, then this would be considered a new method and would require internal validation to demonstrate the reliability and potential limitations of the method.

If a laboratory modifies a quantification procedure to incorporate a new real-time PCR instrument model but does not alter the reagents or steps used for the quantification reaction, then the new instrument would require evaluation under **Standard 8.3** and a performance check under **Standard 10.3.1**. However, if the new instrument impacts

the reliability and potential limitations of the method, internal validation studies under **Standard 8.1.2** may be necessary.

If a laboratory modifies a method to allow for performing an automated method manually, then the manual procedure must be evaluated by comparing to the automated procedure using similar DNA samples. If a laboratory modifies a procedure to allow for performing a manual method using a robotic system, then the automated procedure including the new robotic system must be appropriately validated.

Latest Revision: 07/01/2025

Forensic Standard 8.4	**Database Standard 8.4**

If the NDIS participating laboratory uses an Expert System to conduct the analysis and/or technical review of database, known, casework reference, or single source forensic samples, and/or to enter data directly into CODIS, it shall use an NDIS approved Expert System. Depending on the rule order and set up of Expert System parameters, the laboratory may need to perform developmental validation of that Expert System. Developmental validations of Expert Systems used by NDIS participating laboratories shall be approved by NDIS.

For **Standard 8.4.1**, as required by the *NDIS Operational Procedures Manual*, NDIS participating laboratories must recertify their NDIS approved Expert Systems quarterly.

These standards are not applicable for non-NDIS participating laboratories and laboratories that are not using an Expert System.

Latest Revision: 07/01/2025

Forensic Standard 8.5	**Database Standard 8.5**

These standards are applicable to software used as a component of instrumentation, used for the analysis and/or interpretation of DNA data, or used for statistical calculations.

For commercial off the shelf (COTS) software products (e.g., word processing, electronic spreadsheets, database management) that the laboratory uses to create software tools (e.g., macros, workbooks, databases), the COTS software does not require a validation but, if used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations, the laboratory developed tool must be validated as appropriate for its intended use in the laboratory.

Any new software, new modules of existing software, or a major modification to software that is used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations shall be subjected to the relevant validation studies, as described in **Standard 8.5.2**.

Functional testing: Functional testing may include using the software to perform the intended task and ensuring it functions as expected. For example, ensuring that a software tool used to perform a calculation generates the same value as if hand

calculated. For a software tool that transcribes or aggregates information from various locations, a functional test may ensure that the expected information is being transcribed or referenced correctly.

Reliability testing: Reliability testing should establish that the software can run in the laboratory's environment. For example, if the laboratory is multi-site, multi-user, or uses a network, the laboratory should ensure that the software functions reliably at each site, for multiple and/or concurrent users, or on the network. Reliability studies should also test the usability limits of the software's functions.

Accuracy and precision studies: Accuracy and precision studies are relevant when measurements and numerical values or calculations are reported. For example, evaluating the accuracy and precision of sizing algorithms when assigning DNA types or the accuracy and precision of a software calculating a random match probability.

Sensitivity studies: Sensitivity studies should evaluate the upper and lower limits of the software. For example, the maximum number of contributors a probabilistic genotyping software can interpret or the dynamic range (i.e., minimum and/or maximum detection) of a typing software.

Specificity studies: Specificity studies are used to evaluate the ability of the system to provide reliable results over a broad variety of typing results (e.g., mixtures, low level profiles). For example, evaluating that a probabilistic genotyping software provides reliable results for contributors and non-contributors.

Regression testing: Regression testing is used to confirm that modifications or new functionality do not impact the performance of the functionality of the software that was previously evaluated and working as intended prior to implementation of the change(s). Regression testing is similar to a functional test but tests functionality that was not directly impacted by the software modifications. Testing may not be able to check every prior functionality but should focus on those components that are critical.

To assist with software testing, laboratories may consider creating test scenarios or cases that interact with the critical operations of the software or module. Test scenarios or cases can provide a metric for concordance with other methods and/or modified software. These test scenarios or cases may also assist with regression testing. Testing may be conducted by personnel outside of the DNA section (e.g., contracted validation studies); in these instances, the Technical Leader must review and approve the testing documentation prior to implementation for DNA use.

Latest Revision: 07/01/2025

Forensic Standard 8.5.1	**Database Standard 8.5.1**
The laboratory must consider the suitability of the software for its intended use in the laboratory. For example, analytical/interpretation software applications should be supported by underlying scientific principle(s) (e.g., local southern sizing, Markov Chain Monte Carlo) and statistical software should use scientifically supported formulae.	

The impact of the software on the DNA analysis and/or interpretation process should be considered when designing the appropriate validation studies and may include a risk-based approach to determining the extent of the testing to be conducted. The validation studies should also establish what, if any, limitations must be applied for the use of the software. For example, a maximum number of contributors that will be input into a deconvolution software or a maximum quantity of DNA that can be extrapolated with a quantification software. Limitations established by the software developer should be used to inform the boundaries tested during internal validation.

Latest Revision: 07/01/2025

Forensic Standard 8.5.2	**Database Standard 8.5.2**

If a laboratory determines a particular module within the software will not be used, validation of that particular module is not required; however, if at a later date, a laboratory decides to use that particular module, an internal validation of the new module of the existing software is required, as applicable.

Refer to **Standard 2** and the guidance in **Standard 8.5** for the definitions of and examples for, functional testing, reliability testing, regression testing, accuracy, precision, sensitivity and specificity studies.

Documentation of software testing (e.g., functional testing, reliability testing, regression testing) may include tools as simple as a checklist or a summary of the features that were tested.

Not all validation studies are relevant to every type of software. For example, internal validation of data collection software may not require precision studies. The scope of the intended use of the software should dictate the nature of the validation.

Studies performed under **Standard 8.1.2** or evaluations performed under **Standard 8.3** may be concurrently used as the software testing.

Release notes from software developers can be used to assist in determining if a software modification results in a major or minor revision and if any applicable changes may need to be tested.

Examples of a major revision can include, but are not limited to, modifications of any algorithm, any statistical and/or calculation equation, sequence alignment strategy, data reports, and/or export of results. Refer to the guidance in **Standard 8.5.3** for examples of a minor revision.

The purpose of regression testing is to ensure that modifications to software have not detrimentally affected any functions of the previously validated software. A laboratory may accomplish regression testing using a set of relevant scenarios run with the original version and the modified software. For example, a laboratory may re-run samples on an instrument with the modified software and compare the new DNA types to the previously generated DNA types. Similarly, a laboratory may opt to re-

analyze, re-interpret, and/or re-calculate data using the modified software and compare the output for concordance with previously generated results.

A laboratory should test modifications to software on computer systems that are not part of the laboratory's workflow (e.g., test servers) or can temporarily be removed as a part of the laboratory's workflow. If this is not feasible, the laboratory should limit access to the modified software to prevent its use when conducting casework or database analysis and be cautious not to report any data from a system that is currently being internally validated.

Latest Revision: 07/01/2025

Forensic Standard 8.5.3	**Database Standard 8.5.3**

Minor revisions are generally those that do not impact the DNA analysis, interpretation processes and/or statistical calculations. Examples of a minor revision can include, but are not limited to, cosmetic modifications, improved printing or viewing features, fixing invalid error messages or a modification that only impacts a module within the software that will not be used.

Operating system or security patches that are compatible with the system requirements of the software do not fall into the scope of these standards.

A functional test is intended to verify that the software is functioning as expected for its use but does not require exhaustive testing of every feature the software can perform. The testing may focus on the pertinent functions of the software.

Latest Revision: 07/01/2025

Forensic Standard 8.5.4	**Database Standard 8.5.4**

Reliability testing should establish that the software can run in the laboratory's environment. For example, if the laboratory is multi-site, multi-user, or uses a network, establishing that the software functions reliably at each site, for multiple and/or concurrent users, or on the network. Reliability studies should also test the usability limits of the software's functions. If each laboratory of a multi-laboratory system is accessing the software on a centralized laboratory system network then it may not be necessary to perform site-specific studies from every laboratory location.

Latest Revision: 07/01/2025

Forensic Standard 8.5.5	**Database Standard 8.5.5**

Internal validation of software, as described in **Standard 8.5.2**, must be reviewed and approved by the Technical Leader. Software testing without additional internal validation studies (e.g., functional testing for a minor revision) does not require review and approval by the Technical Leader unless required by the laboratory.

Latest Revision: 07/01/2025

Forensic Standard 8.6	**Database Standard 8.6**

Developmental validation studies, internal validation studies, modified procedure evaluations, and software validation and testing, including the approval of the

Technical Leader where applicable, shall be retained and available for review for at least as long as the method or software is in use by the laboratory.
Latest Revision: 07/01/2020

Standard 9. Analytical Procedures

Forensic Standard 9.1	**Database Standard 9.1**
No additional guidance	
Latest Revision: 07/01/2020	

Forensic Standard 9.1.1	**Database Standard 9.1.1**
Each analytical procedure must specify the reagents, sample preparation, equipment, and controls used in the analytical process. The laboratory procedures must be current and readily available.	
Latest Revision: 07/01/2020	

Forensic Standard 9.2	**Database Standard 9.2**
To successfully satisfy **Standard 9.2**, the laboratory must demonstrate compliance with all of the substandards of **Standard 9.2**.	
Latest Revision: 07/01/2020	

Forensic Standard 9.2.1	**Database Standard 9.2.1**
The procedures for documenting commercial reagents should address what information will be recorded upon receipt of a commercial reagent for quality control and tracking purposes. The procedures for the formulation of in-house reagents should address the recipe to prepare the reagent and the records that will be retained for quality control and tracking purposes.	
Latest Revision: 07/01/2020	

Forensic Standards 9.2.2 and 9.2.3	**Database Standards 9.2.2 and 9.2.3**
If the laboratory has determined an expiration date beyond that provided by the manufacturer, supporting documentation for that date must be available at the laboratory. For those reagents having no expiration date provided by the manufacturer, the laboratory must have a policy or procedure for setting the expiration date. The laboratory may use an electronic barcoding system to capture the required labeling information. If the laboratory has an electronic barcoding system for the management of its reagents, the name of the reagent must be on the container in addition to the barcoded information.	
Latest Revision: 07/01/2020	

Forensic Standard 9.3	**Database Standard 9.3**
The intent of identifying a reagent as a critical reagent is to ensure that the reagent functions correctly prior to its use on samples (e.g., evidence) that may be limited in such a way that the test could not be repeated if the reagent were to fail. For those reagents identified as critical reagents, laboratory procedures must include the quality control measures used for evaluation, the acceptable range of results, procedures for addressing unacceptable data, and mechanisms used for documentation and subsequent approval/rejection of data. At minimum, the laboratory must identify the reagents listed in **Standards 9.3.1** and **9.3.2** as critical reagents, if used by the laboratory. For laboratories performing Next-Generation Sequencing (NGS), **Standard 9.3.1** will include each new lot of sequencing library preparation reagents and sequencing reagents. A minimum of one positive control or previously characterized DNA sample and one negative control should be sequenced with each new lot of sequencing library preparation reagents and/or sequencing reagents. This can be done separately or in parallel with database, known, or casework reference samples. If a laboratory processes the control samples in parallel with reference samples, the data shall only be interpreted, searched and/or uploaded to CODIS after the controls are interpreted and meet the laboratory's criteria for successful approval of the quality control data. Laboratories must have written procedures for handling data processed in parallel with sample controls, if the quality control data fails.	
Latest Revision: 07/01/2025	

Forensic Standard 9.4	
Except as allowed by **Forensic Standards 9.4.1 and 9.4.2,** quantification of forensic and casework reference samples must be assessed prior to nuclear DNA amplification. "Otherwise calculate" refers to methods, such as cell counting, that are based on empirical data from the sample being typed. "Otherwise calculate" does not include approaches that provide an estimate of DNA quantity based on what is expected for a similar sample type or cutting size. For items that are subjected solely to mitochondrial DNA analysis, **Forensic Standard 9.4** is not applicable.	
Latest Revision: 07/01/2025	

Forensic Standard 9.4.1	
Direct amplification and Rapid DNA instruments/Systems are examples of methods that the laboratory could validate that would not require quantification prior to amplification of casework reference samples. If the laboratory quantifies all DNA samples, **Forensic Standard 9.4.1** is not applicable.	
Latest Revision: 07/01/2020	

Forensic Standard 9.4.2	
The laboratory shall define the specific sample types that may be included in this exception (e.g., samples collected from cartridge casings). An NDIS approved amplification kit that includes internal quality controls must be used. Internal quality controls can confirm successful PCR amplification and if a sample contains potential PCR inhibitors. These internal controls can also assist the analyst in determining if the sample may be degraded. **Forensic Standard 9.4.2** allows for the calculation of the amount of human DNA to occur after amplification with data generated simultaneous with the amplification reaction. This standard does not allow for simultaneously performing separate quantitation and amplification reactions. If the laboratory quantifies all DNA samples prior to nuclear DNA amplification, **Forensic Standard 9.4.2** is not applicable.	
	Latest Revision: 07/01/2025

Forensic Standard 9.5	**Database Standard 9.4**
Forensic Standard 9.5/Database Standard 9.4 and all the substandards do not apply for Rapid DNA instruments/Systems used for Rapid DNA analysis and modified Rapid DNA analysis. Refer to **Standard 18 and Forensic Standard 19** for monitoring the analytical procedures through the use of analytical controls and standards for Rapid DNA instruments/Systems. Laboratory procedures must define criteria to evaluate quantification standards, internal size standards, allelic ladders, and analytical controls as required by **Forensic Standard 9.6.1/Database Standard 9.5.1.** The criteria for evaluation must include the acceptable results and procedures for addressing sample data processed in parallel if the standards, ladders, or controls fail.	
	Latest Revision: 07/01/2025

Forensic Standard 9.5.1	**Database Standard 9.4.1**
A laboratory must associate at least one reagent blank control with each extraction set or batch of samples, as defined by the laboratory. The requirements for reagent blank controls specified in **Forensic Standards 9.5.1.1** through **9.5.1.3/Database Standards 9.4.1.1** through **9.4.1.3** are applicable to samples extracted on or after July 1, 2009.	
	Latest Revision: 07/01/2020

Forensic Standard 9.5.1.1	**Database Standard 9.4.1.1**
The reagent blank(s) are extracted concurrently with the set or batch of samples, as defined by the laboratory. The extractions must be occurring at the same time to be considered concurrent. For example, initiating a run on a robot that processes the set or batch of samples simultaneously or sequentially would be considered concurrent; whereas initiating multiple runs consecutively on an extraction robot are not	

considered concurrent. If using more than one extraction robot, each must be of the same model and using the same program (e.g., protocol card) for the run to be considered a concurrent set.

To achieve the most sensitive conditions, the reagent blanks should be treated in such a way to maximize the detection of potential contamination. For example, if a laboratory has validated eluting its extracted casework evidence samples in various elution volumes, the reagent blank should be eluted in the smallest volume as the samples in the batch or set. For a laboratory that concentrates its extracts, the reagent blank should be eluted in the largest volume prior to concentration.

For direct amplification, if a reagent blank is concurrently used as a negative amplification control and multiple volumes of reagent are concurrently amplified, the laboratory needs to determine the volume(s) of reagent blank(s)/negative amplification control(s) that are needed to be concurrently amplified to meet the sensitivity requirements of **Forensic Standards 9.5.1.1** and **9.5.1.2/Database Standards 9.4.1.1** and **9.4.1.2.** If a database laboratory is only performing direct amplification without pre-processing steps, **Database Standard 9.4.1.1** is not applicable.

Latest Revision: 01/01/2023

Forensic Standard 9.5.1.2	**Database Standard 9.4.1.2**

Amplification using the same sensitivity conditions requires amplifying at least the maximum volume of reagent blank as any associated sample from the extraction batch.

The laboratory analytical procedures (**Standard 9.1.1**) should include the approach to amplification of reagent blanks. If the laboratory extracts multiple reagent blanks, the procedures should include selecting which blanks to amplify. The laboratory needs to determine the volume(s) of reagent blank(s) that are needed to be amplified to meet the sensitivity requirements of **Forensic Standards 9.5.1.1** and **9.5.1.2/Database Standards 9.4.1.1** and **9.4.1.2.**

The reagent blank is not required to be amplified concurrently with the samples in the associated extraction batch as long as it is amplified using the same typing test kit, instrument model, and sensitivity conditions as the samples within the extraction batch. As required by **Forensic Standard 9.5.3/Database Standard 9.4.3**, a positive and negative amplification control must be included concurrently on each instrument used for amplification.

If a laboratory uses multiple amplification test kits and the laboratory has depleted its reagent blank(s) associated with the extraction set or sample being amplified, a laboratory shall not continue on to a different amplification test kit without a reagent blank.

For a laboratory that extracts multiple reagent blanks within its extraction set, at least one of the reagent blanks must be amplified utilizing the same typing test kit,

instrument model, and sensitivity conditions as required by the sample(s). If all reagent blanks are quantified, the laboratory must amplify and characterize at least the reagent blank that demonstrates the greatest signal, if any, in accordance with the laboratory procedures. If a laboratory does not quantify its reagent blanks, at least one reagent blank needs to be amplified in accordance with the laboratory procedure.

For differential extractions that result in a reagent blank control(s) for each fraction, the reagent blank(s) from each fraction will be independently evaluated with the corresponding fraction.

If samples are manipulated after extraction, at least one reagent blank must undergo the same manipulation. For example, if a sample is reconstituted or concentrated, at least one of the reagent blanks associated with that extraction set or batch must also follow through that process. Alternatively, an additional reagent blank(s) may be introduced to control for any subsequent manipulation of sample(s) within the extraction batch as long as an original reagent blank associated with the extraction set and an additional reagent blank are both amplified and typed in accordance with **Forensic Standards 9.5.1.2** and **9.5.1.3/Database Standards 9.4.1.2** and **9.4.1.3**.

If a laboratory determines at the quantification stage to terminate all evidentiary sample processing for a given extraction set, in order to monitor analytical quality, the reagent blank control must be either quantified or typed in order for the evidentiary sample processing to be terminated. In order for a laboratory to determine that evidentiary sample processing is to be terminated after DNA quantification, the laboratory shall have validation data to support that determination.

If the reagent blank is concurrently used as the negative amplification control (e.g., direct amplification) the reagent blank must be amplified concurrently on the same instrument using the same typing test kit as the samples. The laboratory needs to determine the volume(s) of reagent blank(s)/negative amplification control(s) that are needed to be concurrently amplified to meet the sensitivity requirements of **Forensic Standards 9.5.1.1** and **9.5.1.2/Database Standards 9.4.1.1** and **9.4.1.2**.

If a laboratory re-amplifies a sample with the same typing test kit and does not increase the template volume over that of the original reagent blank nor alter the amplification parameters to increase sensitivity, then the laboratory does not need to re-amplify the reagent blank associated with the extraction set being re-amplified, provided, however, that the laboratory included amplification positive and negative controls with the extraction set or batch being re-amplified. If a laboratory re-amplifies a sample with the same typing test kit and increases the template volume over that of the original reagent blank, the laboratory needs to re-amplify a reagent blank associated with the extraction set being re-amplified with the increased volume.

Latest Revision: 07/01/2020

Forensic Standard 9.5.1.3	**Database Standard 9.4.1.3**
If a laboratory injects samples at varying injection times, amplicon volumes, and/or injection voltages, the reagent blank must satisfy the most sensitive injection	

conditions. For example, if a laboratory uses a five-second injection and a 10-second injection on a sample set, the laboratory must inject its reagent blank with at least the 10-second injection.

If the laboratory increases injection conditions for the samples (including re-amplified samples) the laboratory needs to re-inject a reagent blank associated with the extraction set being re-injected with the increased injection conditions.

Latest Revision: 07/01/2020

Forensic Standard 9.5.2	**Database Standard 9.4.2**

If the laboratory's validated quantification method allows for the use of a virtual or external standard curve, the calibrator sample(s) does not need to be a certified reference material but must be run concurrently with the samples to demonstrate that the data on the plate is performing within expectations. The laboratory procedures should address when reevaluation of the virtual or external standard curve is necessary (e.g., with each new lot of quantification kit).

Latest Revision: 01/01/2023

Forensic Standard 9.5.3	**Database Standard 9.4.3**

If a batch of samples being typed will be amplified on multiple instruments, each instrument must contain a positive and negative amplification control amplified concurrently using the same typing test kit as the samples on the instrument. If a batch of samples being typed will be amplified with subsequent amplifications on the same instrument, each amplification on that instrument must contain a positive and negative amplification control amplified concurrently using the same typing test kit as the samples on the instrument.

Latest Revision: 07/01/2020

Forensic Standard 9.5.3.1	**Database Standard 9.4.3.1**

Except as provided in **Forensic Standard 9.5.4.1/Database Standard 9.4.4.1**, if a batch of samples being typed was amplified on multiple instruments or multiple amplifications on the same instrument, each positive and negative amplification control shall be typed.

Latest Revision: 07/01/2020

Forensic Standard 9.5.4	**Database Standard 9.4.4**

The positive amplification control may also be used as the positive sequencing control. A reagent blank and/or negative amplification control may be used as the negative sequencing control.

The reagent blank and negative amplification controls should be sequenced with at least an equivalent sensitivity compared to the most sensitive sequencing conditions of any corresponding samples. Considerations may include the number of libraries in the pool, the flow cell/chip type, the concentration of libraries pooled, and the lot number(s) of the sequencing reagents.

To monitor carryover from one run to another and detect index contamination, the negative control could include an index/index combination from a previous run. Laboratories may assess unused indexes/index combinations as an alternate negative control. This computational negative control monitors crosstalk between sequencing runs and sample-to-sample contamination post-indexing (if the contaminating sample was not intentionally included in the sequencing pool).
Latest Revision: 07/01/2025

Forensic Standard 9.5.4.1	**Database Standard 9.4.4.1**
Next-Generation Sequencing (NGS) of extremely low-quality DNA (e.g., capture or whole genome sequencing of severely degraded/damaged/ancient DNA samples) with a positive amplification control may interfere with the sample data. In the event that a positive amplification control has a detrimental impact on sample and/or control data, a different positive control may be used to monitor the sequencing process. In this case, the laboratory must have and follow validated procedures to monitor the success of the positive amplification control (e.g., observing a quantification result in the expected range of quantification values based on validation).	
Latest Revision: 07/01/2025	

Forensic Standard 9.5.5	**Database Standard 9.4.5**
Allelic ladders and internal size standards must be used to appropriately assign DNA types to the fragments produced in PCR-based systems. Where allelic ladders and internal size standards are not required to assign DNA types, this standard is not applicable.	
Latest Revision: 07/01/2020	

Forensic Standard 9.6	**Database Standard 9.5**
To successfully satisfy **Forensic Standard 9.6/Database Standard 9.5**, the laboratory must demonstrate compliance with all of the substandards of **Forensic Standard 9.6/Database Standard 9.5**. A laboratory is required to have and follow interpretation guidelines, even if using an NDIS approved and internally validated Expert System. The Expert System may replace human review for single-source forensic samples and database, known, and casework reference samples only. The laboratory must have procedures that define interpretation guidelines for samples that are marked for review or do not pass the Expert System and address the requirements for human review or reanalysis. It is recommended that the laboratory guidelines ensure that, to the extent possible, DNA typing results from forensic samples are interpreted before comparison to any casework reference samples, other than those of assumed contributors.	
Latest Revision: 07/01/2025	

Forensic Standard 9.6.1	**Database Standard 9.5.1**
A laboratory shall verify that all quantification standards, internal size standards, allelic ladders and analytical control results meet the laboratory's interpretation	

guidelines for all reported results. A documented method must exist to demonstrate that control values are verified when used (e.g., check-off, technical review, validated Expert System).

The laboratory may use an NDIS approved Expert System to verify that internal size standards, allelic ladders and analytical controls produce the expected results. Analysis software tools that are not validated as an Expert System may only be used to verify that internal size standards, allelic ladders, and analytical controls produce expected results. Expert Systems or analysis software tool(s) used for the verification must be appropriately validated and implemented in accordance with laboratory defined quality assurance rules. The laboratory procedures must define interpretation guidelines for internal size standards, allelic ladders, and analytical controls that are marked for review or do not pass the Expert System or analysis software tool(s) and address the requirements for human review or reanalysis.

Latest Revision: 07/01/2025

Forensic Standard 9.6.2	**Database Standard 9.5.2**
The laboratory shall define criteria for the interpretation of non-allelic peaks/signal (e.g., stutter, non-templated nucleotide addition, non-specific amplification product, spikes, raised baseline, pull-up or bleed through) specific to the typing test kit, platform used, and where appropriate, Expert Systems or analysis software tool.	
Latest Revision: 07/01/2025	

Forensic Standard 9.6.3	**Database Standard 9.5.3**
The laboratory shall define criteria for the interpretation of allelic peaks/signal which addresses interpretation of alleles that fall above the largest or below the smallest allele or virtual bin of the allelic ladder. Where allelic ladders and internal size standards are not required to assign DNA types (e.g., using sequencing platforms), the laboratory shall define the criteria for the interpretation of allelic calls. The laboratory shall define criteria for the designation of alleles containing an incomplete repeat motif (e.g., an off-ladder allele falling within the range spanned by the ladder alleles or virtual bins). For mitochondrial DNA analysis via Sanger sequencing, the laboratory shall define criteria to assign nucleotide base calls to appropriate peaks and to determine whether the results are of sufficient quality for interpretation purposes.	
Latest Revision: 07/01/2020	

Forensic Standard 9.6.4	**Database Standard 9.5.4**
The laboratory must define the thresholds used for interpretation based on the interpretation model utilized (e.g., binary, probabilistic genotyping). If thresholds are not required by the model utilized, the laboratory must address that thresholds are not used.	

A laboratory that uses a threshold-based approach where alleles and genotype combinations for a contributor are either present or absent (i.e., binary) must comply with **Forensic Standards 9.6.4.1** and **9.6.4.2/Database Standards 9.5.4.1** and **9.5.4.2**.

For **Forensic Standard 9.6.4.1/Database Standard 9.5.4.1**, the laboratory shall have and define an analytical threshold to determine the minimum height/magnitude requirement for distinguishing peaks/signal from background noise. The analytical threshold shall be supported by validation studies.

For **Forensic Standard 9.6.4.2/Database Standard 9.5.4.2**, the laboratory shall have and define a stochastic threshold to define the peak height/signal magnitude value below which it is reasonable to assume that, at a given locus, allelic dropout of a sister allele in a heterozygous pair may have occurred. The stochastic threshold shall be supported by validation studies.

If a laboratory uses measures to enhance the detection sensitivity (e.g., allele height, signal magnitude), additional studies to establish independent criteria for the application of a separate stochastic threshold(s) shall be performed. Such measures may include increased amplification cycle number, increased injection time, and post-amplification purification/concentration of amplified products relative to the laboratory's standard method.

Latest Revision: 07/01/2020

Forensic Standard 9.6.5	**Database Standard 9.5.5**

A laboratory shall have criteria for determining when DNA typing results are uninterpretable. Uninterpretable DNA typing results may consist of data of limited or poor quality as well as DNA typing results that do not meet the laboratory's quality assurance parameters (e.g., drop-in in an analytical control, data potentially affected by contamination). The laboratory's quality assurance parameters shall be determined based on validation studies.

The laboratory procedures should address conclusions that can be made for uninterpretable data (e.g., data unsuitable for comparisons).

Latest Revision: 07/01/2020

Forensic Standard 9.6.6	

The laboratory procedures for mixture interpretation, to include procedures for assigning the number of contributors, discerning major and minor contributors (when applicable), and the criteria for the deduction of a contributor, must be supported by validation studies. Criteria for deducing potential contributors may rely on the assumptions that can be made when formulating conclusions as addressed in the laboratory's procedures for **Forensic Standard 9.8.1**.

Latest Revision: 07/01/2020

Forensic Standard 9.7	
The laboratory procedures must address the criteria used for the formulation of conclusions (e.g., inclusionary, exclusionary, inconclusive) when comparing a casework reference sample to the data interpreted from a forensic sample. The procedures could include how to perform a comparison based on the presence or absence of alleles, based on the use of possible genotype combinations, considering the overall quality of the profile (e.g., degradation, preferential amplification, inhibition, drop-out), appropriate use of assumptions, or other guidance for interpretation. The criteria for these conclusions do not require the use of categorical terms such as inclusion or exclusion. The laboratory procedures for reporting of results and conclusions (**Forensic Standard 9.8**) should address the conclusions that can be reported (under **Forensic Standard 11.2.5**) and the application of appropriate statistical calculations (see **Forensic Standards 9.8.2** and **11.2.6**). If the laboratory uses interpretation software (e.g., probabilistic genotyping) to aid in the formulation of conclusions, the procedures must address the use of the software and the interpretation of the statistical results. For mitochondrial DNA analysis, the laboratory shall define criteria for conclusions based on the evaluation of regions of interpretable sequence and the number of nucleotide base differences. These criteria should address heteroplasmy and homopolymeric cytosine tracts.	
Latest Revision: 07/01/2025	

Forensic Standard 9.8	
All substandards of **Forensic Standard 9.8** must be addressed in laboratory procedures for statistical calculations and/or procedures for reporting of results and conclusions. The laboratory's procedures shall describe the statistical calculation(s) to be used on single source and mixed DNA samples. The formulae used shall be documented and where applicable, the procedures shall address how to apply statistical calculations for loci that are within the laboratory's stochastic region or for profiles that display stochastic effects. Refer to **Forensic Standard 11** for the requirements for reporting of results and/or conclusions. To successfully satisfy **Forensic Standard 9.8**, compliance must be demonstrated with all substandards of **Forensic Standard 9.8**.	
Latest Revision: 01/01/2023	

Forensic Standard 9.8.1	
Laboratory procedure must address what assumptions can be made, or if no assumptions can be made, when formulating conclusions. Any assumptions used	

when formulating a conclusion (e.g., number of contributors, the presence of a known contributor) shall be documented and supported by the data and case information.
Latest Revision: 07/01/2020

Forensic Standard 9.8.2	
The laboratory may determine that inclusions to an expected contributor (e.g., intimate samples, consensual partner) are not relevant in the context of the case.	
Latest Revision: 07/01/2020	

Forensic Standard 9.8.3	
The documentation should be sufficient such that in the absence of the analyst who reports the results and conclusions, another qualified analyst could determine the genetic loci and the assumptions, if applicable, used for the statistical calculation(s). For mitochondrial DNA testing, the genetic loci refers to the mitochondrial DNA regions (e.g., HVI, HVII) used for the statistical calculation(s).	
Latest Revision: 07/01/2020	

Forensic Standard 9.8.4	
The laboratory procedures must address when data determined to be uninterpretable, as required by **Forensic Standard 9.6.5**, will not be used in a statistical calculation. For example, the procedure could address when individual loci are uninterpretable, when a portion of a profile is uninterpretable, or when an entire profile is uninterpretable.	
Latest Revision: 07/01/2020	

Forensic Standard 9.8.5	
The approach used to perform a statistical calculation may include listing the formula(e) used on single source and mixed DNA samples. It also may be accomplished through the description of the statistical software (e.g., PopStats, probabilistic genotyping software) used by the laboratory. When applicable, the laboratory procedures must address approaches to performing statistical calculations using data determined to be within the laboratory's stochastic region, as required by **Forensic Standard 9.6.4**, or for profiles that display stochastic effects. For **Forensic Standard 9.8.5.1**, the procedures must address all components of **Forensic Standard 9.8.5.1**. If a laboratory does not perform statistical calculations for biological relationships, the laboratory's procedure is not required to address biological relationships. For **Forensic Standard 9.8.5.2**, (e.g., YSTR, mtDNA), the procedures must address the parameters used for the specific calculations (e.g., upper bounds, confidence interval, counting method, likelihood ratio).	

For **Forensic Standard 9.8.5.3**, the laboratory may reference the publication for the population database used for statistical calculations to demonstrate that loci are in Hardy-Weinberg equilibrium and statistically unlinked. For laboratories that use a population database that has not been published (i.e., created internally), the requirements for Hardy-Weinberg and linkage equilibrium may be met by documented independence testing on the population database.

For statistical calculations that do not use the product rule (e.g., lineage marker calculations), **Forensic Standard 9.8.5.3** is not applicable.

The laboratory may apply the product rule when combining autosomal STR, YSTR, XSTR, SNP, or mitochondrial DNA statistical calculations, if shown to be in Hardy-Weinberg equilibrium and statistically unlinked. If independence cannot be demonstrated between the autosomal STR, YSTR, XSTR, SNP, and/or mtDNA results, combining these systems is not recommended unless the approach for combining is supported through peer-reviewed publications.

Latest Revision: 01/01/2023

Forensic Standard 9.8.6	
The source of the population database(s) used may be addressed by identifying the name of the database in the procedure. For laboratories that use published population databases, this may also be accomplished by referencing the publication for the population database used for statistical calculations in the procedure.	
Latest Revision: 07/01/2020	

Forensic Standard 9.8.7	
The source attribution declaration (i.e., identifying the individual as the source of the DNA produced from an evidentiary profile) shall be based on a statistical estimate that meets or exceeds a laboratory defined threshold.	
Latest Revision: 07/01/2020	

Forensic Standard 9.9	
The laboratory procedures must address if the laboratory does or does not conduct reinterpretation of legacy data. Reevaluating allele calls, genotype calls (to include potential allelic drop-out), a change in the assumptions used, or removing alleles (or entire loci) from statistical estimates from legacy amplification test kit data, are all considered reinterpretation. The generation of a report for the comparison of two samples as a result of a CODIS high stringency match is not considered reinterpretation of legacy data.	

If the interpretation of the DNA profile from a forensic sample has previously been documented regarding the genotypes that would be allowed for possible contributors, that interpretation is not considered reinterpretation.

The laboratory's reinterpretation procedure may direct the analyst to archived procedures used for the interpretation of data at the time of data generation, or the laboratory may create procedures to directly address reinterpretation of legacy data. For example, a laboratory's reinterpretation procedures may include a compilation of previous interpretation procedures and any additional interpretational considerations that had been incorporated by the laboratory (e.g., subsequent revisions to a legacy interpretation procedure) or were developed by reviewing legacy validations (e.g., developing a stochastic threshold when none previously existed).

Refer to **Forensic Standards 6.7** and **6.8** for guidance on applicable training and authorization to perform reinterpretation.

Latest Revision: 07/01/2020

Forensic Standard 9.10 and 9.10.1	**Database Standard 9.6**

The control of contamination includes reducing the possibility of contamination (e.g., by cleaning and decontaminating facilities) and investigating or monitoring potential sources of a detected contaminant. The procedure may also address subsequent action steps or the limitations to the interpretation of data in which contamination was detected.

The procedures used by a laboratory for cleaning and decontaminating facilities and equipment should also address, when appropriate, minimizing surface contamination from samples (e.g., unidentified human remains) prior to sampling.

Latest Revision: 07/01/2020

Standard 10. Equipment

Forensic Standard 10.1	**Database Standard 10.1**

To be in compliance with **Standard 10.1**, the laboratory must use equipment suitable for the methods employed and be in compliance with all standards and substandards of **Standard 10**.

Latest Revision: 07/01/2020

Forensic Standard 10.2	**Database Standard 10.2**

The laboratory must have and follow a program to ensure all critical equipment and instruments are maintained. The laboratory must document the equipment and instruments the laboratory has determined to be critical. If used by the laboratory, the laboratory must include those instruments listed in **Standard 10.2.1** and any additional equipment or instrumentation whose accurate functionality directly affects the results of the DNA typing. If the laboratory maintenance program is more stringent than the requirements in **Standard 10.3**, it must be audited to the more stringent requirements. If the laboratory is in compliance with **Standard 10.3** but is not

following its own more stringent maintenance program, the finding shall be documented under **Standard 10.2** and the applicable substandard(s) of **Standard 10.3** (i.e., **Standard 10.3.2.7** and/or **10.3.3.5**).

For **Standard 10.2.1.2**, the laboratory must have at least one thermometer that has a certificate that indicates the traceability to national or international standard(s). This thermometer may be used for the performance check of critical equipment (e.g., heat blocks) and/or to ensure the accurate measurements of non-certified thermometers used to monitor temperatures that are critical to the analytical procedures. A certified traceable thermometer may be used to meet this standard for the duration of its certification.

For **Standard 10.2.1.6**, the thermal cycler temperature verification systems may be used to meet this standard for the duration of its certification.

For **Standard 10.2.1.8**, an example of additional instruments or equipment that produce DNA typing results would include the instruments or equipment used for Next Generation Sequencing.

Latest Revision: 07/01/2025

Forensic Standard 10.3	**Database Standard 10.3**

The laboratory must have procedures for conducting a performance check, for evaluating results (to include the acceptable ranges), for addressing unacceptable data, and for documenting the completion and subsequent approval/rejection of the performance check. These criteria should be based on validation data (Refer to **Standard 8.1.3**).

Calibration may be utilized as a laboratory defined method to performance check equipment.

Procedures for conducting a performance check may be tailored to the purpose of the performance check. For example, a performance check of a new instrument may be different than the performance check for a minor repair to an instrument.

Latest Revision: 07/01/2025

Forensic Standard 10.3.1	**Database Standard 10.3.1**

New critical equipment not requiring validation requires a performance check prior to use on casework or for database analysis. If the laboratory defines calibration as the method to performance check equipment, and the new equipment is accompanied by a certificate of calibration, that certification may be used as the initial performance check prior to use. For example, a new pipette received with a valid certificate of calibration may be used without undergoing an additional calibration prior to use. When it is not clear that validation is required, a modified procedure evaluation (**Standard 8.3**) may be used to determine if internal validation of a new model of equipment or instrument is required.

If the new critical equipment includes new or modified software, the new or modified software would need to be validated or tested as required under **Standard 8.5**.

Example scenarios:
If a new thermal cycler model uses the same times and temperatures for the cycling parameters and the evaluation under **Standard 8.3** demonstrates that the new thermal cycler is performing similarly to the previously used thermal cycler, then it would not require validation.

If a new robotic system for extraction uses new reagents and alters the steps of a previously validated procedure, then it would be considered a new method and would require validation to demonstrate the reliability and potential limitations of the new method.

A new real-time PCR instrument model using the same quantification reaction would require evaluation under **Standard 8.3** and a performance check under **Standard 10.3.1**. However, if the new instrument impacts the reliability and potential limitations of the method, internal validation studies under **Standard 8.1.2** may be necessary.

If a new robotic system will be used to perform a validated manual method, the automated method must be validated to demonstrate the reliability and potential limitations of the method on that new robotic system.

The initial performance check may be used to meet compliance with **Standard 10.3.2** for the current calendar year.

An evaluation performed under **Standard 8.3** may be used to fulfill the requirement of a performance check for new critical equipment or instruments under **Standard 10.3.1**.

Latest Revision: 07/01/2025

Forensic Standard 10.3.2	**Database Standard 10.3.2**

The equipment listed under **Standard 10.3.2** requires at least an annual performance check.

For **Standard 10.3.2.1**, the performance check of a handheld pipette may be accomplished by certification by an outside vendor or accomplished in-house through the comparison of a series of predefined measurements. For example, measurements are evaluated at a high and low setting of the pipette's range.

For **Standard 10.3.2.2**, the performance check of an incubator or heat block may be accomplished through: (1) certification by an outside vendor; (2) in-house by the comparison of one or more temperature readings at various time intervals against a certified NIST-traceable thermometer; or (3) utilizing a traceable thermometer to monitor the temperature of the incubator or heat block. Incubator/heat blocks used in an analytical procedure includes similarly functioning equipment where the correct temperature reading is pertinent to the analytical procedure (e.g., lysis temperature).

Incubator/heat blocks used by the laboratory for analytical purposes shall be distinguishable from those used by the laboratory for only non-analytical purposes. For example, an incubator used to thaw reagents or other non-analytical purposes does not require an annual performance check.

For **Standard 10.3.2.3,** the performance check of a robotic system shall be defined by the laboratory based on its application. For example, the performance check of a robotic system used for pipetting should include a check of the pipetting mechanism, while the performance check of a robotic system used for extraction may necessitate the extraction of a known sample to assess the functionality. The performance check of a robotic system may be accomplished by an outside vendor or in-house by the laboratory.

For **Standard 10.3.2.4**, the performance check of a thermal cycler, including quantitative-PCR, may be accomplished by the system's diagnostic programs and the use of an appropriate certified temperature verification system or process.

For **Standard 10.3.2.5,** the performance check of an electrophoresis detection system may be accomplished by analyzing positive controls, internal standards, or using previously characterized DNA samples for comparison. For example, a laboratory may choose to complete the performance check of a Genetic Analyzer by analyzing a set containing an amplification positive control, an amplification negative control and a ladder.

For **Standard 10.3.2.6**, the performance check on any additional instruments or equipment that produce DNA typing results may be accomplished by analyzing positive controls, internal standards, or using previously characterized DNA samples for comparison.

For laboratories performing Next-Generation Sequencing (NGS), **Standard 10.3.2.6** will include the performance check of the NGS system. This may be accomplished by sequencing positive controls or previously characterized DNA samples separately or in parallel with database, known, or casework reference samples. If a laboratory processes the control samples in parallel with reference samples, the data shall only be interpreted, searched and/or uploaded to CODIS after the controls are interpreted and meet the laboratory's criteria for successful approval of the quality control data. Laboratories must have written procedures for handling data processed in parallel with sample controls, if the quality control data fails.

For **Standard 10.3.2.7**, the annual performance check of any additional critical instrument or equipment shall be defined by the laboratory based on its application. If the laboratory does not define any instrument or equipment beyond those listed in **Standards 10.3.2.1** through **10.3.2.6** as requiring an annual performance check, this standard is not applicable.

Laboratories have the option of using an available NIST SRM for a performance check, but their use is not required unless specifically referenced by the laboratory.
Latest Revision: 07/01/2020

Forensic Standard 10.3.3	**Database Standard 10.3.3**
The critical instruments and equipment identified in **Standard 10.3.3** require additional (beyond annual) performance checks after repair or service. When the repair or service does not directly affect the results of the analysis, a performance check other than that used for the annual performance check may be used. The performance check after repair or service must ensure the repair or service was successful. For example, if a repair to the door on a robotic workstation is made, ensuring the door is properly functioning may be used as the performance check for that repair. This may be accomplished by an outside vendor or in-house by the laboratory. For laboratories performing Next Generation Sequencing (NGS), **Standard 10.3.3.4** will include the performance check of the NGS system. (Refer to the guidance for **Standard 10.3.2.6**) For **Standard 10.3.3.5**, the performance check after repair or service of any additional critical instrument or equipment shall be determined by the laboratory based on its application. If the laboratory does not define any instrument or equipment beyond those listed in **Standard 10.3.3.1** through **Standard 10.3.3.4** as requiring a performance check after repair or service, **Standard 10.3.3.5** is not applicable.	
Latest Revision: 07/01/2020	

Forensic Standard 10.4	**Database Standard 10.4**
No additional guidance	
Latest Revision: 07/01/2020	

Forensic Standard 11. Reports

Forensic Standard 11.1	
Laboratory case records to demonstrate compliance with this standard may be in hard copy, electronic files, or a combination of both formats. The laboratory should have a written procedure detailing documentation maintained under this standard. The laboratory must generate sufficient documentation for each technical analysis to support the reported conclusions such that in the absence of the analyst who reported the analysis, another qualified analyst could evaluate and interpret the resulting data. Documentation must also be sufficient for the completion of a technical review under **Standard 12**.	
Latest Revision: 07/01/2020	

Forensic Standard 11.2	

For **Forensic Standard 11.2.2**, sufficient description of the evidence examined and identification of samples collected from an item of evidence, when applicable, must be included in the report to allow for the unambiguous identification of the samples tested. Evidence includes both forensic samples and casework reference samples. Any stain, sample, or item on which an attempt is made to isolate DNA, regardless of the outcome or result, must be addressed in the final report.

For **Forensic Standard 11.2.4**, the loci, sequence region, or amplification system can be limited to those that generate a DNA type.

For **Forensic Standard 11.2.5**, the data generated by the analysis may be considered the results and may include the analyst's evaluation of the results. Conclusions, such as inclusions, exclusions, and other conclusions defined by the laboratory, must be reported for each forensic sample that generated results when applicable casework reference samples are available but do not require the use of these specific terms (Refer to **Standard 9.7**). Final reports of forensic casework shall address each tested item or its probative fraction. In the case of a differential extraction, the results and/or conclusions for at least the probative fraction must be included in the final report.

For **Forensic Standard 11.2.6**, the quantitative or qualitative interpretation statement provides a weight or additional information to support the conclusion. A quantitative, or, where appropriate, qualitative statement must be reported for at least all inclusions determined to be relevant in the context of the case (See **Standard 9.8.2**) but may also be reported for other conclusions. The use of statistics and/or attribution statements will be defined by the laboratory. Attribution statements may include a statistically supported source attribution statement, an assumed contributor (for instances where the presence of an individual's DNA on an item is expected), or another qualitative statement as defined by the laboratory.

For **Forensic Standard 11.2.7**, the date of the report must be defined by the laboratory and consistently applied. For example, the date of the report may represent the date the report was drafted, the date the final draft was completed, or the date the report was issued.

For **Forensic Standard 11.2.8**, the disposition of evidence should be specific to the evidence in the report. Examples of the disposition of evidence include whether the evidence is returned to the submitting agency, retained by the laboratory, consumed, and/or other wording to convey the status of the evidence at the time of reporting the DNA results. The disposition may be a general statement for all items with the same disposition but must convey the status of each of the items of evidence. The disposition of evidence may be omitted when no evidence is received (e.g., supplemental comparison reports, CODIS Hit reports).

For **Forensic Standard 11.2.9**, one person shall accept responsibility for the content of the report. A secure electronic signature is considered equivalent identification

when the laboratory can demonstrate the electronic equivalent can only be applied by the individual for whom it represents. A physical or electronic signature need not be displayed on the report when a secure electronic equivalent is utilized.
Latest Revision: 07/01/2025

Forensic Standard 11.3	
The release of database information in **Forensic Standard 11.3** is specifically limited to database applications and does not apply to forensic (anonymous) population databases that are used by casework laboratories to estimate allele frequency information. Laboratories participating in the National DNA Index System (NDIS) must comply with the provisions limiting access and disclosure to the DNA analyses and DNA samples maintained by federal, state and local criminal justice agencies (and the Secretary of Defense under 10 U.S.C. §1565) in accordance with the Federal DNA Identification Act ('Federal DNA Act'; 34 U.S.C. §12592). The Federal DNA Act provides for limited access to the DNA analyses and DNA samples to the following: "(A) to criminal justice agencies for law enforcement identification purposes; (B) in judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules; (C) for criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged; or (D) if personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes." 34 U.S.C. §12592(b) (3). Generally, the state laws on confidentiality will be found in the respective state DNA database laws. Many of the state laws have provisions similar to those in the Federal DNA Act but for states with more expansive access and disclosure laws (such as, humanitarian purposes), the state has agreed, as a condition for its participation in NDIS, to comply with the more restrictive provisions of the Federal DNA Act. For those states having DNA database laws with more restrictive access and disclosure provisions than the Federal DNA Act, laboratories in those states are required to comply with their state laws. A state or local laboratory should have the applicable state laws readily available.	
Latest Revision: 07/01/2020	

Database Standard 11. Documentation

	Database Standard 11.1
Laboratory database sample records may be in hard copy, electronic files, or a combination of both formats.	

The laboratory should have a written procedure detailing documentation maintained under this standard. Materials contained in sample records must demonstrate compliance with this standard.

The laboratory must generate sufficient documentation for each technical analysis to support the interpretation such that in the absence of the analyst who reported the analysis, another qualified analyst could evaluate and interpret the resulting data. Documentation must also be sufficient for the completion of a technical review under **Standard 12**.

Latest Revision: 07/01/2020

	Database Standard 11.2
No additional guidance	
	Latest Revision: 07/01/2020

	Database Standard 11.3

Laboratories participating in the National DNA Index System (NDIS) must comply with the provisions limiting access and disclosure to the DNA analyses and DNA samples maintained by federal, state and local criminal justice agencies (and the Secretary of Defense under 10 U.S.C. §1565) in accordance with the Federal DNA Identification Act ('Federal DNA Act'; 34 U.S.C. §12592). The Federal DNA Act provides for limited access to the DNA analyses and DNA samples to the following:

> "(A) to criminal justice agencies for law enforcement identification purposes;
> (B) in judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules;
> (C) for criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged; or
> (D) if personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes." 34 U.S.C. §12592(b) (3).

Generally, the state laws on confidentiality will be found in the respective state DNA database laws. Many of the state laws have provisions similar to those in the Federal DNA Act but for states with more expansive access and disclosure laws (such as, humanitarian purposes), the state has agreed, as a condition for its participation in NDIS, to comply with the more restrictive provisions of the Federal DNA Act. For those states having DNA database laws with more restrictive access and disclosure provisions than the Federal DNA Act, laboratories in those states are required to comply with their state laws. A state or local laboratory should have the applicable state laws readily available.

The laboratory procedure for the release of personally identifiable information in connection with a database hit shall be compliant with the *NDIS Operational Procedures Manual*.

Latest Revision: 07/01/2020

Standard 12. Review

Forensic Standard 12.1	
This standard is intended for data generated within the DNA laboratory. The review of data generated external to the laboratory is governed by Standard 17. The laboratory shall have a written procedure detailing the elements of its technical and administrative review including how the completion of the technical and administrative review will be documented. The laboratory may address the elements of technical and administrative review through a single procedure or a combination of several procedures. The laboratory's technical and administrative review of forensic casework must include the elements in **Forensic Standards 12.2** and **12.3**. For the review of the case file, the elements in **Forensic Standards 12.2.2 and 12.2.3** may be technically reviewed, sometimes referred to as a batch review, prior to the generation of the report as described in a laboratory's procedure. For laboratories that use multiple technical reviewers, each review shall be documented. In laboratories that use a team approach, the procedure must preclude an individual from technically reviewing their own work. The laboratory must ensure the work is assessed by 2 individuals (i.e., one analyst and one technical reviewer). The laboratory must conduct and document both administrative and technical reviews of all case files and reports prior to issuing the report.	
Latest Revision: 01/01/2023	

	Database Standard 12.1
This standard is intended for data generated within the DNA laboratory. **The review of data generated external to the laboratory is governed by Standard 17.** The laboratory must have written procedures defining the elements associated with both technical and administrative reviews. NDIS participating laboratories must have and follow procedures for reviewing database matches including the verification and resolution of the matches. If a database laboratory issues reports, both technical and administrative reviews are required. Notification letters issued in the course of a database hit which do not contain technical data require, at a minimum, an administrative review.	
Latest Revision: 07/01/2020	

Forensic Standard 12.1.1	**Database Standard 12.1.1**
The individual conducting technical reviews must be qualified as an analyst or a technical reviewer in the method, technology, typing test kit, platform, and interpretation software that the review encompasses and undergo semi-annual proficiency testing. The technical reviewer of a report shall not be the analyst that authored the report.	

A technical reviewer not currently or previously qualified in a method, technology, typing test kit, platform, or interpretation software must be trained in accordance with **Standards 5.5.2 and 6.6** to perform a technical review.

When a laboratory implements a new or additional method, technology, typing test kit, platform, or interpretation software, a technical reviewer who is not qualified as an analyst in the laboratory (in accordance with **Standard 6.4 or 6.5**), must receive training in accordance with **Standard 6.6** as necessary to be qualified to perform technical reviews.

For modifications to procedures (in accordance with **Standard 8.3**) that do not entail additional qualification/authorization, the analyst or technical reviewer will also retain the ability to conduct technical reviews of case files and reports using the modified procedure without additional qualification/authorization.

An analyst proficiency tested in accordance with **Standard 13** can serve as a technical reviewer without needing to take an additional proficiency test as a technical reviewer.

The administrative reviewer is not required to be a current or previously qualified DNA analyst or a technical reviewer.

For the review of the case file, the elements in **Standards 12.2.2 and 12.2.3** may be technically reviewed prior to the generation of the report as described in a laboratory's procedure, sometimes referred to as a "batch review" or "spot-review." For laboratories that use multiple technical reviewers, each review shall be documented. In laboratories that use a team approach, the procedure must preclude an individual from technically reviewing their own work.

Latest Revision: 07/01/2025

Forensic Standard 12.2	

Laboratory procedures must describe the method used for documenting the completion of the technical review(s).

For **Forensic Standard 12.2.2**, the laboratory may use an NDIS approved and internally validated Expert System or analysis software tool(s) to review analytical controls, internal lane standards and allelic ladders to verify that the expected results were obtained as long as the laboratory's validation of the Expert System or software tool(s) demonstrates that laboratory defined quality assurance rules and interpretation guidelines are appropriately applied. The laboratory must have procedures that address the technical review of analytical controls, internal lane standards and allelic ladders that are marked for review, do not pass the Expert System or software tool and require human intervention. The technical reviewer would then ensure that the expected results had been verified.

Forensic Standard 12.2.3 The laboratory may use an NDIS approved and internally validated Expert System or analysis software tool(s) to review the DNA types from

single-source forensic samples as long as the laboratory's validation of the Expert System or software tool(s) demonstrates that laboratory defined quality assurance rules and interpretation guidelines are appropriately applied. The laboratory must have procedures that address the technical review of single-source forensic samples that are marked for review, do not pass the Expert System or software tool and require human intervention. The technical reviewer would then verify that the DNA types are supported by the raw or analyzed data.

Forensic Standard 12.2.7 and its substandards are not applicable for non-NDIS participating laboratories.

Forensic Standard 12.2.7.2, prior to the upload or search of a profile at SDIS, the two concordant assessments of the DNA types can be verified by the reporting analyst followed by another qualified analyst or technical reviewer. For single-source forensic samples, an NDIS approved and internally validated Expert System may be used in lieu of the two concordant assessments by a qualified analyst or technical reviewer. Use of an Expert System cannot replace the evaluation or review of CODIS eligibility and specimen category by a qualified analyst or technical reviewer as required in **Forensic Standard 12.2.7.1.**

Forensic Standard 12.2 and its substandards do not apply for laboratories using an NDIS approved Rapid DNA System on casework reference samples but do apply to laboratories using Rapid DNA instruments to perform modified Rapid DNA analysis as required by **Forensic Standard 18.11**.

Latest Revision: 07/01/2025

	Database Standard 12.2

Laboratory procedures must describe the method used for documenting the completion of the technical review(s). The laboratory's technical review procedures for database samples must include each of the elements in **Database Standards 12.2.1** through **12.2.3**. The review of the DNA types may be accomplished by an NDIS approved and internally validated Expert System.

A documented technical review of the data must be completed by the NDIS participating laboratory prior to uploading or searching the data at SDIS. **Database Standard 12.2** and its substandards do not apply for laboratories using an NDIS approved Rapid DNA System but do apply to laboratories using Rapid DNA instruments to perform modified Rapid DNA analysis as required by **Database Standard 18.9**.

Latest Revision: 07/01/2025

Forensic Standard 12.3	

Laboratories must describe the method used for documenting the completion of the administrative review. The laboratory's administrative review procedures of forensic casework must include the elements in **Forensic Standards 12.3.1** and **12.3.2**.

Laboratories that include some or all of the administrative review elements listed in **Forensic Standard 12.3** in their technical review procedure also must document the completion of the administrative review. The technical and administrative review may be accomplished by a single qualified individual.

The review of the chain of custody and disposition of evidence may be limited to the items received by the laboratory. At a minimum, the review should ensure the chain of custody supports the reported disposition of the evidence.

Latest Revision: 07/01/2020

	Database Standard 12.3
The laboratory's administrative review procedures of database hit correspondence must include the elements in **Database Standards 12.3.1** through **12.3.3**. Laboratories must describe the method used for documenting the completion of the administrative review. Laboratories that include some or all of the administrative review elements listed in **Database Standard 12.3** in their technical review procedure also must document the completion of the administrative review. The technical and administrative review may be accomplished by a single qualified individual. The review of the chain of custody and disposition of evidence may be limited to the known or casework reference samples received by the DNA database laboratory.	
Latest Revision: 07/01/2020	

Forensic Standard 12.4	**Database Standard 12.4**
The laboratory must have and follow a documented policy and/or procedure that defines the course of action necessary in the event of an unresolved discrepant conclusion or interpretation.	
Latest Revision: 07/01/2020	

Forensic Standard 12.5	
Forensic Standard 12.5 is not applicable for non-NDIS participating laboratories.	
Latest Revision: 07/01/2020	

	Database Standard 12.5
Database Standard 12.5 is not applicable for non-NDIS participating laboratories.	
Latest Revision: 07/01/2020	

Standard 13. Proficiency Testing

Forensic Standard 13.1	**Database Standard 13.1**
Each analyst, technical reviewer, technician, and other personnel designated by the Technical Leader shall undergo semi-annual proficiency testing in accordance with **Standards 13.1.1** through **13.1.6**. Semi-annual requires testing to take place two times during one calendar year, with the first event taking place in the first six months	

of that year and the second event taking place in the second six months of that year, and where the interval between events is at least four months and not more than eight months. The interval between two events applies to events within and between calendar years. The date used for tracking compliance with this standard is as defined by **Standard 13.3**.

Individuals who have been on leave for a period that takes them out of the proficiency test cycle, must comply with **Forensic Standard 6.12.1/Database Standard 6.10.1** prior to resuming casework or databasing and then return to the proficiency testing cycle within eight months.

Proficiency testing requirements do not apply to the use of a Rapid DNA System; however, analysts qualified to perform modified Rapid DNA analysis must be proficiency tested in accordance with **Forensic Standard 18.12/Database Standard 18.10**.

Where an external proficiency test is not available or not appropriate for a technology (e.g., SNPs), performance of personnel shall be monitored in accordance with the laboratory's accreditation requirements.

Latest Revision: 07/01/2025

Forensic Standard 13.1.1	**Database Standard 13.1.1**
If the analyst is qualified in only one technology, then the analyst will take both semi-annual tests in that technology. All applicable samples in a single proficiency test shall be worked for each technology. It is permissible for multiple technologies to be reported on a single proficiency test. Alternatively, an analyst qualified in multiple technologies may be separately tested in each technology. For example, a laboratory may administer one test in the first half of the year with their YSTR technology and one test in the second half of the year with their autosomal STR technology.	
Latest Revision: 01/01/2023	

Forensic Standard 13.1.1.1	**Database Standard 13.1.1.1**
The applicable CODIS core loci or CODIS core sequence ranges shall be attempted for the applicable technology at least once per year. For example, if the laboratory is testing the STR technology, the 20 CODIS core loci must be attempted at least once per year. If the laboratory is testing the mitochondrial DNA technology, at minimum the NDIS accepted sequence ranges of 73-340 and 16024-16365 must be attempted at least once per year. For the YSTR, XSTR, and SNP technologies, there currently is not an NDIS defined set of CODIS core loci.	
Latest Revision: 07/01/2020	

Forensic Standard 13.1.2	**Database Standard 13.1.2**
If the analyst is qualified in only one typing test kit, then the analyst will take both semi-annual tests with that typing test kit. An analyst qualified to use multiple typing test kits for casework or database examinations may be separately tested using each typing test kit. For example, a laboratory that uses 2 different kits for the STR	

technology may administer one test with their STR Kit #1 and one test with their STR Kit #2 provided that STR Kit #1 and/or STR Kit #2 include the 20 CODIS core loci as required by **Standard 13.1.1.1**.

Latest Revision: 01/01/2023

Forensic Standard 13.1.3	**Database Standard 13.1.3**

Standard 13.1.3 applies to analysts, technicians, and other personnel designated by the Technical Leader who perform analytical procedures on forensic, database, known, or casework reference samples. The laboratory documentation shall demonstrate that each individual has performed at least one method in each methodology for which they are qualified to perform casework or database examinations at least once per year. For example, if an analyst is qualified to perform 3 different extraction methods (e.g., two robotic methods and a manual method), the analyst must extract on a proficiency test at least once per year but the laboratory may determine which of the extraction methods will be used.

If the individual is authorized in extraction and/or quantitation for Y-screening and DNA typing, then the extraction and/or quantitation methods associated with the DNA typing may be used to satisfy **Standard 13.1.3** without requiring the Y-screening to be separately performed on a proficiency test. If Y-screening is categorized as a separate methodology, or an individual is only qualified in Y-screening methods, then a Y-screening method must be performed in accordance with **Standard 13.1.3**.

Latest Revision: 01/01/2023

Forensic Standards 13.1.4 and 13.1.4.1	**Database Standards 13.1.4 and 13.1.4.1**

The individual need not perform every methodology on a single test when performed in accordance with **Standard 13.1.4.1**. For laboratories that employ technicians and/or use a team approach (i.e., multiple analysts/technicians are involved in the laboratory processing of a sample or case) in accordance with **Standard 13.1.4.1**, a methodology may be performed by a technician or another analyst. For example, for a laboratory whose analysts perform all methodologies and utilize technicians, the analysts may perform extraction on one test and utilize a technician to perform the extraction on the second test in a year.

If a laboratory has separate Y-screening analysts and typing analysts that are qualified to report results, separate proficiency tests must be used for these analysts and reported results cannot be combined on one test for both analysts. Results interpreted by a Y-screening technician [as defined in **Standard 2**, technicians “do not interpret data to reach conclusions on typing results or prepare final reports”] can be reported by an analyst, provided that all requirements of **Standard 13** are met for each individual.

The individual(s) that participate on each test must be tracked to demonstrate compliance with **Standard 13.4.2**; however, only one analyst will be assigned to and responsible for completing the interpretation of test sample data and reporting the results for submission to the proficiency test provider. Each participant will be

informed of the results of the evaluation of their test(s) in accordance with **Standard 13.6.1**.
Latest Revision: 01/01/2023

Forensic Standard 13.1.5	**Database Standard 13.1.5**
Individuals whose sole responsibility is technical review shall be proficiency tested in accordance with **Standard 13.1.5** and the applicable substandards. Technical reviewers that are qualified to review data from multiple technologies or typing test kits shall be proficiency tested in technical review of each technology and typing test kit at least once a year. Technical reviewers that are qualified to review data from a single technology or typing test kit shall be proficiency tested semi-annually in technical review of data from that technology and typing test kit. An analyst proficiency tested in the specific technology may serve as a technical reviewer without needing to take an additional proficiency test as a technical reviewer.	
Latest Revision: 07/01/2020	

Forensic Standard 13.1.5.1	**Database Standard 13.1.5.1**
Refer to the guidance for **Standard 13.1.1.1**	
Latest Revision: 07/01/2020	

Forensic Standard 13.1.5.2	**Database Standard 13.1.5.2**
The contract employee performing technical reviews must be administered a proficiency test by an NDIS participating laboratory. The contract employee performing technical review may be administered a proficiency test by the NDIS laboratory or by another NDIS participating laboratory. If the contract employee performing technical review completes a proficiency test for another NDIS participating laboratory, the Technical Leader of the NDIS participating laboratory for which the technical reviewer is under contract to conduct reviews shall review and approve the proficiency testing administered by the other NDIS participating laboratory. For example, if a technical reviewer is a contract employee of NDIS Lab A and NDIS Lab B, the contract employee performing technical review may take a proficiency test for NDIS Lab A and NDIS Lab B or may take a proficiency test for NDIS Lab A and provide that proficiency test to the Technical Leader of NDIS Lab B. The Technical Leader of NDIS Lab B must review and approve that proficiency test.	
Latest Revision: 07/01/2020	

Forensic Standard 13.1.6	**Database Standard 13.1.6**
A newly qualified individual shall undergo external proficiency testing within eight months of their qualification date. The date used for tracking compliance with this standard is as defined for **Standard 13.3**. An individual will be considered in compliance with the semi-annual proficiency testing requirement (**Standard 13.1**) if the initial proficiency test is taken within 8 months of qualification. For example, an analyst qualified in December is permitted to wait until July to enter the proficiency	

testing cycle. The individual is required to be in compliance with the applicable requirements of **Standards 13.1.1** through **13.1.5** in the next full calendar year.
Latest Revision: 07/01/2020

Forensic Standard 13.2	**Database Standard 13.2**
The laboratory must not have access to the proficiency test results until all participants have completed the test. A laboratory that is participating in a proficiency test provider's pre-distribution program may count the pre-distribution tests as one of the two external proficiency tests for the calendar year. To comply with **Standard 13.2**, the laboratory must resubmit the pre-distribution test results during the general distribution testing phase for that specific test in order to be included in the provider's published external summary report. The pre-distribution test will be considered received, assigned, submitted, or due with the general distribution testing phase of the proficiency test in accordance with **Standard 13.3**. For example, if the laboratory uses the assigned date for tracking purposes, the pre-distribution test will be given an assigned date when the general distribution testing phase commences.	
Latest Revision: 07/01/2020	

Forensic Standard 13.3	**Database Standard 13.3**
No additional guidance	
Latest Revision: 07/01/2020	

Forensic Standards 13.4 – 13.4.7	**Database Standards 13.4 – 13.4.7**
No additional guidance	
Latest Revision: 07/01/2020	

Forensic Standard 13.5	**Database Standard 13.5**
To satisfy **Standard 13.5**, the laboratory must evaluate external proficiency test results to demonstrate compliance with each of the substandards of **Standard 13.5**. The laboratory's evaluation criteria must include each of the substandards under **Standard 13.5** such that the evaluation criteria may be assessed even if a criteria was not applicable during the evaluation of proficiency test results during the scope of the audit.	
Latest Revision: 07/01/2020	

Forensic Standards 13.5.1 – 13.5.3	**Database Standards 13.5.1 – 13.5.2**
No additional guidance	
Latest Revision: 07/01/2020	

Forensic Standard 13.5.3.1	
The Technical Leader review of any inconclusive conclusion for compliance with laboratory guidelines may be part of the evaluation of proficiency test results or have occurred prior to submission of the proficiency test and the documentation will be reviewed during the evaluation of proficiency test results.	

Latest Revision: 07/01/2020

Forensic Standard 13.5.4	**Database Standard 13.5.3**
A satisfactory grade is attained for a proficiency test when there are no analytical errors for the DNA typing data or reported conclusions.	
Latest Revision: 07/01/2020	

Forensic Standard 13.5.4.1	**Database Standard 13.5.3.1**
All discrepancies or errors, to include the occurrence of administrative errors, and subsequent corrective actions, as applicable, shall be documented. Non-administrative discrepancies and errors will be handled in accordance with **Standard 14**. The laboratory should not wait for correspondence from an accrediting body's proficiency review committee when evaluating proficiency tests or investigating potential discrepancies or errors. Proactive investigation and subsequent communication with an accrediting body's proficiency review committee could eliminate or expedite the closure of inquiries that result from an accrediting body's observation of a possible discrepancy or error. Correspondence with an accrediting body's proficiency review committee should be retained as documentation under **Forensic Standard 13.5.4.1/Database Standard 13.5.3.1**.	
Latest Revision: 07/01/2020	

Forensic Standards 13.6 – 13.6.3	**Database Standards 13.6 – 13.6.3**
No additional guidance	
Latest Revision: 07/01/2020	

Standard 14. Corrective Action

Forensic Standards 14.1 and 14.1.1	**Database Standards 14.1 and 14.1.1**
The laboratory policy and/or procedure must address, at a minimum, nonconformities resulting from casework or database analysis, proficiency tests, testimony and audits. Nonconformities not requiring a corrective action plan may be remediated with documented correction or other documentation. A corrective action plan that is developed to evaluate and remediate the nonconformity, must be documented and include the elements listed in **Standard 14.2**. The laboratory policy and/or procedure should include an assessment of the impact of the nonconformity and the acceptability of any resulting data. When necessary, the assessment should consider the risk to the quality of the sample(s) and justification for the use of data that may not conform with the all aspects of these standards or the laboratory's quality system. Where applicable, the documentation and/or the corrective action plan should document the path forward for work impacted by the nonconformity.	
Latest Revision: 07/01/2025	

Forensic Standard 14.2	Database Standard 14.2
The goal of the corrective action plan is to identify, correct, and/or prevent reoccurrence of the nonconformity, when possible. The identification of the cause(s) of the nonconformity may include a root cause analysis. Corrective actions are intended to remediate the nonconformity with time frames to ensure appropriate response to the nonconformity. Preventive measures are intended to minimize the potential reoccurrence of the nonconformity in the future. For **Standard 14.2.1**, the corrective action plan requires the approval of the Technical Leader before implementation. If necessary, the Technical Leader has the authority to initiate, suspend, and resume technical operations for the laboratory or an individual. (Refer to **Standard 5.2.5.2**) For **Standard 14.2.2**, **Standard 5.3.5.4** requires the CODIS Administrator to ensure that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures; the CODIS Administrator must be notified when the nonconformity impacts DNA records entered into CODIS. If necessary, the CODIS Administrator may terminate an analyst's or laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified in accordance with **Standard 5.3.6**.	
Latest Revision: 07/01/2020	

Standard 15. Audits

Forensic Standard 15.1	Database Standard 15.1
The required annual audit shall, at a minimum, occur once every calendar year and shall be at least 6 months but no more than 18 months apart. Annual audits may be conducted in an internal and/or external manner and, at the discretion of the laboratory, may consist exclusively of external audits or be performed on more than an annual basis. The audit must entail the review of documentation since at least the last annual audit to assess compliance to the standards. The scope will be expanded to at least the last external audit, for the assessment of compliance to the standards for personnel, training, and validation. (Refer to **Standards 15.2.1** and its substandards and **15.2.2**) In accordance with **Standard 15.4**, only audits that were performed using the current (as of the time of the respective audit) FBI Quality Assurance Standards Audit Document shall be eligible for compliance with **Standards 15.1** and **15.2**. For laboratories undergoing their first external QAS audit, the audit being conducted should be used to assess **Standards 15.2** and **15.4**; however, the remaining substandards of **Standard 15** may not be applicable.	
Latest Revision: 07/01/2020	

Forensic Standard 15.2	Database Standard 15.2
For **Standards 15.2** and **15.3**, Appendix C will be used to document the self-verification by the auditor(s). This verification is documented and provided to the laboratory prior to the beginning of the audit to ensure that the audit team consists of appropriately qualified individuals. For example, the audit team includes at least one individual with casework experience for an audit of a casework laboratory and at least one individual with databasing experience for an audit of a databasing laboratory. These appendices will be retained with the audit documentation. The auditor(s) from the second agency(ies) must have successfully completed the FBI's DNA auditor training course. For the external audit, it is the laboratory's responsibility to ensure that there is at least one person who is, or has previously been, a qualified analyst for each specific DNA technology performed and platform used. This may be accomplished by having a single auditor who meets all of the specified qualifications or through a combination of the various members of a multi-person audit team. NGS is considered a platform. **Standard 15.2** requires that an external audit be performed at least once every two years and shall meet the timing requirements of **Standard 15.1** (i.e., occurs at last 6 months but no more than 18 months from the laboratory's previous annual audit). Laboratories that conduct an internal QAS audit in addition to an external QAS audit during the same calendar year cannot use the internal QAS audit for purposes of satisfying the timing requirements of **Standard 15.1**. **Standard 15.5.2** requires that all external audits performed on an NDIS laboratory, regardless of frequency, shall be submitted to the NDIS Custodian. If an external audit to fulfill **Standard 15.2** does not meet the timing requirements of **Standard 15.1** (i.e., occurs less than 6 months or more than 18 months from the laboratory's previous annual audit), the NDIS Custodian should be contacted for additional guidance. In accordance with **Standards 15.2.1** and **15.2.2**, when documentation of the required reviews has been memorialized in previous external audit documents of the laboratory, the audit team is not required to perform additional review with respect to the personnel or validations that were previously reviewed and documented; however, this in no way prohibits the audit team from performing such additional reviews as they may deem appropriate or necessary. The laboratory should alert their external audit team of records to be reviewed and approved in accordance with **Standards 15.2.1 and 15.2.2**. The external audit team should also review past audit documentation to ensure any outstanding reviews (e.g., memorialization of previously unapproved validation or completion of training) are performed.	
Latest Revision: 07/01/2025	

Forensic Standard 15.2.1	Database Standard 15.2.1
For **Standard 15.2.1**, the date defined by the laboratory according to **Standard 4.2** will be used for determining the applicable version of the standards for evaluating the	

education, experience and training requirements. Approval of the education, experience and training qualifications will be documented in Appendix D during an external audit. Personnel documented in an Appendix D prior to July 1, 2025 do not require a second review of education after the effective date of these standards.

A Technical Leader or analyst that was previously memorialized in the database audit document of a laboratory system that becomes a casework TL or analyst must be reviewed in accordance with the forensic QAS to ensure the minimum experience requirements are met.

The independent external auditor approval of personnel referenced in **Standard 15.2.1** may be transferrable to another laboratory or laboratory system. Education approvals memorialized in an audit document to the standards in effect at the time of that external audit may be accepted by a new lab at the discretion of that laboratory's Technical Leader or the relocating individual may be required to meet the requirements of the current standards. This also may be applied to individuals with a break in service or returning to employment in the same laboratory.

To aid the external audit team in determining who requires these independent external reviews, the laboratory should generate a list of analysts/technical reviewers who have completed the initial training and require external review and a list of analysts/technical reviewers who have completed additional training in a technology, typing test kit or platform whose additional training requires review. This list should include individuals who have been authorized to independently perform assigned job responsibilities since the last external audit, even if no longer employed by the laboratory.

If the laboratory has accepted the prior review of a Technical Leader, CODIS Administrator, or analyst/technical reviewer's education, at a minimum, the external audit documentation memorializing the educational review of the individual shall be retained by the laboratory accepting the review. The review of the accepted audit documentation shall be documented in the Appendix D of the new laboratory during an external audit. If the prior review and documentation of the individual's educational requirements was not accepted, the audit team shall review and approve the individual's educational requirements, to include a review of transcripts.

For **Standard 15.2.1.1**, the Technical Leader's education and experience will be reviewed as required by **Standards 5.2.1** and **5.2.2**. A Technical Leader is required to have completed technology training, if required per **Standard 5.2.3**, and DNA Auditor Training, as required by **Standard 5.2.4**. A recently appointed Technical Leader who has not completed the minimum training requirements, as in **Standard 5.2.3**, if applicable, and **Standard 5.2.4**, will not be listed in Appendix D until the training requirements are complete.

For **Standard 15.2.1.2**, the CODIS Administrator and alternate CODIS Administrator (as required by the *NDIS Operational Procedures Manual*) need to be reviewed to ensure compliance with the education, experience and training requirements listed in

Standards 5.3.1, 5.3.2, and **5.3.3**. A CODIS Administrator who is also an analyst or technical reviewer undergoing external review will be listed independently in the Analyst/Technical Reviewer sections and the CODIS Administrator sections. A recently appointed CODIS Administrator who has not completed the minimum CODIS training requirements, as in **Standard 5.3.3**, will not be listed in Appendix D until the CODIS training requirements are complete.

For **Standards 15.2.1.3 and 15.2.1.4,** the external reviews of each analyst's education and experience requirements listed in **Standards 5.4.1** and **5.4.2**, and completion of the analyst's initial training as required by **Standard 6.1** will be documented. Analysts whose education has been approved during an external audit at a prior lab and accepted by the Technical Leader at the new lab per **Standard 5.4.1.3** must have their training (even if abbreviated/modified) and authorization reviewed during one external audit at the new lab.

A technical reviewer, who is a currently or previously qualified analyst in the laboratory, does not need to be separately listed in Appendix D as a technical reviewer. A technical reviewer who is not currently or previously qualified as an analyst in the laboratory for which they are performing technical reviews must have their education, experience, and training in the laboratory, as described in **Standard 6.6**, reviewed and be memorialized in Appendix D.

For **Standard 15.2.1.5,** analysts that receive additional training in a technology (e.g., STR, YSTR, mitochondrial DNA), typing test kit, platform or interpretation software as required by **Standard 6.5** will be documented. Additional training in a new method other than a technology, typing test kit or platform (e.g., extraction method A, quant method B) as described in **Standard 6.4**, does not require documentation in Appendix D. For analysts that are under review for additional training, the auditor does not need to review education, experience, and initial training that was previously memorialized in the Appendix D of a past external audit document.

For **Standard 15.2.1.5**, training qualifications for the laboratory's analysts/technical reviewers in an additional technology(ies), typing test kit(s), or platform(s) will be evaluated in accordance with **Standards 6.5, 6.6** and/or **6.7**. A CODIS Administrator or Technical Leader who performs the role of analyst or technical reviewer will also have training qualifications in an additional technology(ies), typing test kit(s), or platform(s) evaluated in accordance with **Standards 6.5, 6.6,** and/or **6.7**. Approval of the additional training qualifications will be documented in Appendix D for one external audit.

Latest Revision: 07/01/2025

Forensic Standard 15.2.2	**Database Standard 15.2.2**
Standard 15.2.2 is only applicable to those methods that are currently used by the laboratory. Validation studies under this standard includes modified procedure evaluations and software validation. Approval of the validations will be documented in Appendix E for one external audit. The training associated with the implementation of	

a newly validated technology(ies), typing test kit(s), or platform(s) will be documented in accordance with **Standard 15.2.1.5**, as applicable.

If the entirety of a validation is not approved (e.g., due to a finding under a specific section of **Standard 8**), the approval will not be documented in Appendix E. A subsequent external audit team will need to review and document the approval of the validation.

Latest Revision: 07/01/2025

Forensic Standard 15.3	**Database Standard 15.3**

Appendix C will be used to document the self-verification to ensure that the audit team consists of appropriately qualified individuals. This verification should be maintained by the laboratory.

The audit team must include at least one auditor who has successfully completed the FBI's DNA auditor training course. It is the laboratory's responsibility to ensure that there is at least one person on the audit team who is, or has previously been, a qualified analyst for each specific DNA technology performed and platform used. This may be accomplished by having a single auditor who meets all of the specified qualifications or through a combination of the various members of a multi-person audit team.

Latest Revision: 07/01/2020

Forensic Standard 15.4	**Database Standard 15.4**

The Audit Documents for Forensic DNA Testing Laboratories and DNA Databasing Laboratories correspond to the standards in effect at the time of the audit. Additionally, this QAS Guidance Document interprets each standard with added discussion points clarifying the criteria necessary for compliance. The most recent version of this Guidance Document should also be used during the audit and documented on the cover of the Audit Document(s).

Latest Revision: 07/01/2020

Forensic Standard 15.5	**Database Standard 15.5**

The completed Audit Document(s) should be prepared by the auditor(s) and sent to the laboratory within 30 days of the audit. The Audit Document includes the completed checklist and associated appendices with any areas of noncompliance listed under the Findings section of Appendix A. All findings must be clearly identified and referenced to the appropriate Standard. **Recommendations must not be included in the Audit Document.**

The laboratory must ensure that an adequate response detailing any incorporated corrective action, if appropriate, has been generated with regard to all findings and documented. A laboratory's written course of action or response to the findings should be maintained as part of the audit documentation.

Prior audit documentation must be available to the auditor(s) as a measure of the laboratory's response to previous findings. It is critical that findings identified in a previous audit document be thoroughly addressed and resolved (if possible) within the DNA laboratory's capabilities. To fulfill the requirements associated with **Standard 15.5**, the laboratory must show evidence of a response and/or corrective action to all findings detailed during the previous audit.

Standard 5.3.5.4 requires the CODIS Administrator to ensure that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures; therefore, internal and external audit documentation and, if applicable, corrective action must be provided to the CODIS Administrator as required by **Standard 15.5.1**.

In accordance with the *NDIS Operational Procedures Manual*, the external Audit Document must be submitted to the FBI within 30 days of receipt of the final report, but a laboratory may request an extension from the NDIS Custodian for the laboratory responses (e.g., corrective action plan/documents, contested findings). Audit documentation must be electronically submitted to the FBI via QAS@fbi.gov. To comply with **Standard 15.5.2**, it is incumbent on the NDIS participating laboratory to document for each external audit, the date that the Audit Document was received from the auditor(s) and the date that the laboratory sent the external audit documentation and laboratory responses to the FBI.

For NDIS participating laboratories, the submission of an external audit document with findings must include the applicable corrective action plan(s) and supporting documentation (e.g., revised procedure) and/or justification for any contested findings. If an extension is needed for completion of corrective action plan(s) or supporting documentation, extensions must be requested via email to NDIS@fbi.gov and QAS@fbi.gov.

For non-NDIS participating laboratories, **Standards 15.5.1** and **15.5.2** are not applicable.

Latest Revision: 07/01/2025

Forensic Standard 15.6	**Database Standard 15.6**
Prior audit documentation must be available to the auditor(s). Appendices may be requested to ensure education, experience and training of personnel and validations have been previously memorialized.	
Latest Revision: 07/01/2020	

Standard 16. Professional Development

Forensic Standard 16.1	Database Standard 16.1
Continuing education is intended to maintain technical qualifications through participation in activities that expand an individual's knowledge and awareness of topics relevant to the field of DNA analysis. Activities in the laboratory's training program that are required for establishing an individual's competency are not considered continuing education with respect to this standard.	
Latest Revision: 07/01/2020	

Forensic Standard 16.1.1	Database Standard 16.1.1
Laboratory management must provide the Technical Leader, CODIS Administrator(s), analyst(s), and technical reviewer(s) with the opportunity to stay abreast of developments and issues in the field of forensic or databasing DNA analysis annually. Continuing education in topics relevant to the field of forensic or databasing DNA analysis may include seminars on new methods and techniques for obtaining DNA profiles, lectures on troubleshooting current methods or techniques, courses on providing testimony on DNA results and conclusions, as well as the QAS auditor training or relevant CODIS training. A Technical Leader or CODIS Administrator who is newly hired/appointed or an analyst or technical reviewer who completes the laboratory's initial training program within the calendar year is not expected to complete the 8 hours of continuing education until the next calendar year. Although continuing education should be formalized (e.g., lectures, seminars, professional meetings), this does not necessarily require earned credit hours or grade evaluations; however, this would be acceptable. Reading of scientific literature and subsequent lab-sponsored discussions (e.g., journal club, article presentation) do not count toward the continuing education hours. Activities required as part of the laboratory's training program and/or that are required for establishing an individual's competency do not count toward the continuing education hours. Regional, national, or international conferences related to forensic or biological sciences that include presentations relevant to forensic or databasing DNA typically provide sufficient content to satisfy the continuing education requirement. The program agenda, record of presentations, or curriculum vitae of presenters is not required for regional, national, or international conferences. The Technical Leader must approve the use of multimedia or internet delivered programs to satisfy continuing education hours. The approval of multimedia or internet delivered continuing education, to include the QAS auditor training or relevant CODIS training, may be documented for the specific course or may be documented	

for each individual completing a course. Completion must be documented and documentation must include the time required to complete the program. For multimedia training that is internally generated (e.g., video recording of an internal lecture), Technical Leader approval and the time needed to complete the training may be documented prior to or with the dissemination of such training.
Latest Revision: 07/01/2020

Forensic Standard 16.1.2	**Database Standard 16.1.2**
The laboratory program must include how completion of ongoing reading of the literature will be documented.	
Latest Revision: 07/01/2020	

Forensic Standard 16.2	**Database Standard 16.2**
Individuals who provide testimony as part of their current positions must be monitored at least once annually. The laboratory's program must include how to document analysts who do not testify during the calendar year (e.g., list of analyst(s) that did not testify). The elements that may be evaluated by the laboratory should include the analyst's ability to communicate clearly and accurately within the bounds of the scientific expertise. The mechanisms for testimony review should include how a review may be conducted. If necessary, corrective actions related to testimony monitoring shall be handled in accordance with **Standard 14**.	
Latest Revision: 07/01/2020	

Standard 17. Outsourcing Ownership

Forensic Standard 17	**Database Standard 17**
As defined in **Standard 2**, ownership applies if any of the following will occur: 1. The NDIS participating laboratory will use any samples, extracts, or materials from the vendor laboratory for the purposes of forensic testing (e.g., a vendor laboratory prepares an extract that will be analyzed by the NDIS laboratory); 2. The NDIS participating laboratory will interpret the data generated by the vendor laboratory; 3. The NDIS participating laboratory will issue a report drawing conclusions on the results of a forensic sample analyzed by the vendor laboratory; or 4. The NDIS participating laboratory will enter or search a DNA profile in CODIS from data generated by the vendor laboratory. **Laboratories shall demonstrate compliance with Standard 17 if any of the criteria of ownership are or may become applicable, including situations where a vendor laboratory subcontracts. Except as provided in Standard 17.2.2, failure**	

to comply with Standard 17 by an NDIS participating laboratory or non-NDIS participating laboratory will preclude the entry, searching or uploading of the outsourced DNA data into CODIS.

A vendor laboratory cannot be considered a Rapid DNA partner agency. NDIS laboratories must comply with the requirements of both **Standards 17 and 18** to accept ownership of modified Rapid DNA data for CODIS entry and/or searching.

Compliance with **Standard 17** is not applicable when a profile generated by another laboratory will only be used by the NDIS participating laboratory for comparison purposes and will not be re-interpreted. Generally, this involves the sharing of casework reference profiles or profiles from alternative reference samples (e.g., unidentified human reference sample, secondary reference, surveillance sample) between laboratories. The comparison done by the NDIS participating laboratory is not considered taking ownership provided the NDIS participating laboratory does not re-interpret the profile being compared to their forensic sample profile. The NDIS participating laboratory should ensure it is clear in the report that the results from the casework reference sample or alternate reference sample used for comparison was generated by another laboratory.

Compliance with **Standard 17** is not applicable if the NDIS participating laboratory has not outsourced any DNA-related services for the purposes of taking ownership in the scope of the audit. However, if a contract for outsourcing is in place or outsourcing is occurring without a contractual agreement, the laboratory must demonstrate compliance with the applicable portions of **Standard 17** (e.g., vendor laboratory accreditation, technical specification approvals, site visits, and ownership review procedures) even if no samples were outsourced in the scope of the audit. Compliance with **Standard 17** is not applicable and ownership does not apply to the reporting of missing person associations between NDIS participating laboratories within CODIS. Generally, the NDIS participating laboratory that processed the Unidentified Human Remain (UHR) issues a report of association, including applicable statistics, that clearly references all laboratories involved in the association. Datalinking that occurs between two NDIS participating laboratories does not constitute ownership. DNA data is not included in this report of association.

When a laboratory transfers ownership of an extract(s) to another laboratory for a specific DNA analysis using a technology that the laboratory is not qualified to perform, or when the laboratory will not take or retain ownership of the data, **Standard 17** does not apply to the laboratory transferring those samples.

When a laboratory will take or retain ownership of an extract(s), the receiving laboratory must ensure the extraction was conducted in a laboratory that complies with these standards and is accredited. The Technical Leader of the receiving lab must approve the technical specifications for the creation of the extract prior to initiating analysis and the receiving lab must verify the integrity of the extract (i.e., evaluate the applicable reagent blank). For purposes of transferring ownership of extracts, DNA data in **Standard 17.3** includes the documentation to support the

creation of the extract and its associated reagent blank(s) to ensure these extracts can demonstrate compliance with **Standard 9.5.1** for the testing conducted in the receiving laboratory. This requires compliance with **Standards 17.1, 17.1.1, 17.2, and 17.3** to ensure the quality of the extracts exchanged. When this transfer of ownership occurs between two NDIS participating laboratories, the substandards of **Standard 17.2**, the substandards of **Standard 17.3**, and **Standard 17.4** and its substandards are not applicable.

For example, if Lab A sends extracts to Lab B for YSTR testing that Lab A is not qualified to perform, or Lab A will not take or retain ownership of the YSTR data, then Lab A is not outsourcing with respect to these standards for the YSTR testing. The Technical Leader of Lab B must approve the technical specifications for the creation of the extract and Lab B must ensure the integrity of the extracts received prior to performing the additional testing on the extracts.

For vendor laboratories, the following standards are not applicable: Standards 17.1.1, 17.2, and 17.2.3 and Standards 17.2.2, 17.3 and 17.4 and their substandards.

Latest Revision: 07/01/2025

Forensic Standards 17.1	**Database Standards 17.1**

For **Standard 17.1**, a vendor laboratory must comply with the current FBI *Quality Assurance Standards for Forensic DNA Testing Laboratories* or *DNA Databasing Laboratories* in their entirety, as applicable, and the accreditation requirements of federal law.

For **Standard 17.1.1**, an NDIS participating laboratory that has entered into an outsourcing agreement, or if criteria of ownership applies, shall maintain the vendor laboratory's external audit documentation to include the audit document and the vendor laboratory's responses and/or corrective actions for any findings. Such documentation or copies must be reviewed by the NDIS participating laboratory's Technical Leader and be retained by the NDIS participating laboratory. Laboratories that use FBI coordinated visits do not have to retain a vendor laboratory's accreditation and external audit documentation separately.

Latest Revision: 07/01/2020

	Database Standard 17.1.2

No additional guidance

Latest Revision: 07/01/2020

Forensic Standards 17.2 and 17.2.1	**Database Standards 17.2 and 17.2.1**

Standard 17.2 applies to those laboratories that have entered into an outsourcing agreement or have had a multi-year agreement in effect with a vendor laboratory since their last external audit.

For **Standard 17.2**, the NDIS participating laboratory must maintain the date of the Technical Leader's documented approval of the technical specifications of the outsourcing agreement as required in **Standard 17.2** and/or the documented prior approval of the acceptance of ownership of the DNA data as specified in **Standard 17.2.1**.

For **Standard 17.2.1**, when a vendor laboratory is performing forensic DNA analysis for a law enforcement agency or entity other than the NDIS participating laboratory, it is incumbent on the vendor laboratory to obtain approval from the Technical Leader of the NDIS participating laboratory that has agreed to accept ownership of the DNA data, as well as the date that the vendor laboratory first initiated analysis for a specific case or set of cases. The approval provided by the NDIS participating laboratory's Technical Leader to the vendor laboratory must precede the vendor laboratory initiating analysis. Approval could be in the form of an e-mail but must be provided in writing. If the vendor laboratory has not performed work on any samples intended for the purposes of ownership by an NDIS participating laboratory that would require the prior approval by the NDIS participating laboratory, this standard is not applicable.

For the NDIS participating laboratory, **Standard 17.2.1** is not applicable; however, if compliance with **Standard 17.2** and/or **17.2.1** have not been demonstrated and ownership applies, the NDIS participating laboratory must demonstrate compliance with **Standard 17.2.2**.

Latest Revision: 07/01/2020

Forensic Standard 17.2.2	

If, in rare instances, the vendor laboratory fails to obtain prior approval from the Technical Leader of the NDIS participating laboratory which will take ownership, the NDIS participating laboratory can accept the results of analysis if the conditions described in **Forensic Standard 17.2.2** are met.

For **Forensic Standard 17.2.2.2**, the NDIS participating laboratory's Technical Leader must approve the technical specifications of the testing conducted.

For **Forensic Standard 17.2.2.3**, the NDIS participating laboratory's Technical Leader must perform an on-site visit or review and document acceptance of an on-site visit of the vendor laboratory that was performed within 18 months, prior to or following, initiation of the conducted analysis. The on-site visit must be documented in accordance with **Forensic Standard 17.4**.

Latest Revision: 07/01/2020

	Database Standard 17.2.2

For **Database Standard 17.2.2**, documentation will need to be retained by the NDIS participating laboratory demonstrating compliance with **Database Standard 17.2 and/or 17.2.1** as well as the date that the NDIS participating laboratory first uploaded DNA data or first accepted DNA data for upload to CODIS. Approval could be in the form of an e-mail but must be provided in writing. This standard also applies to data generated by a vendor laboratory when there is no existing outsourcing agreement,

which includes contractual agreements, between the vendor and the laboratory accepting the data. If the NDIS participating laboratory has not uploaded or accepted DNA data for upload into CODIS from a vendor laboratory, this standard is not applicable.

Latest Revision: 07/01/2020

Forensic Standard 17.2.3	**Database Standard 17.2.3**

Standard 17.2.3 recognizes the importance of maintaining DNA records that have been databased in the event an NDIS participating laboratory ceases DNA analysis operations and closes. If another NDIS laboratory agrees to accept ownership of the closing laboratory's DNA records, written approval of that change in ownership shall be obtained from the NDIS Custodian to ensure the smooth transition of those DNA records in the CODIS software and at NDIS. Additional information on the transfer of ownership of DNA records is described in the *NDIS Operational Procedures Manual*.

Latest Revision: 07/01/2025

Forensic Standard 17.3	**Database Standard 17.3**

To satisfy the requirements of **Standard 17.3**, the laboratory must have procedures for verifying the integrity of data received from a vendor laboratory of which the NDIS participating laboratory will take ownership of and must demonstrate compliance (as applicable) with each of the substandards of **Standard 17.3**.

Latest Revision: 07/01/2020

	Database Standard 17.3.1

No additional guidance

Latest Revision: 07/01/2020

Forensic Standards 17.3.1 – 17.3.2	**Database Standards 17.3.2 – 17.3.3**

The reviews required by **Forensic Standards 17.3.1** and **17.3.2/Database Standards 17.3.2** and **17.3.3** may be performed by an employee or contract employee of the NDIS participating laboratory.

In the event that an NDIS participating laboratory chooses to conduct a search of outsourced DNA data in SDIS prior to the completion of the ownership review, the NDIS participating laboratory must, at a minimum, verify the CODIS eligibility and the correct specimen category for entry into CODIS. Since the outsourced DNA data will have been technically reviewed by the vendor laboratory in accordance with **Standard 12**, the search of outsourced DNA data at SDIS may be done prior to the completion of the ownership review.

Forensic Standard 17.3.1/Database Standard 17.3.2 is not applicable to requests for the searching of DNA data for investigative purposes between NDIS laboratories that do not involve outsourcing agreements.

For **Forensic Standard 17.3.2/Database Standard 17.3.3**, the ownership review of a vendor laboratory's data shall be performed by an analyst or technical reviewer who is

qualified by the NDIS participating laboratory in the technology, platform, and typing test kit used to generate the data. A portion of this review may be accomplished through the use of an NDIS approved and internally validated Expert System. This ownership reviewer must participate in an NDIS participating laboratory's external proficiency testing program (or be authorized to review a legacy technology, typing test kit, and/or platform according to **Forensic Standard 6.8**) to the extent necessary to be proficient in the technology, platform, and typing test kit under review in the outsourced data. For example, an analyst or technical reviewer participates and is proficiency tested on casework using one typing test kit, technology, or platform and performs the ownership review of outsourced casework which was analyzed using a different technology, platform and/or typing test kit. Such analyst or technical reviewer must also be proficiency tested on at least the ownership review of the technology, platform and/or typing test kit used by the outsourcing laboratory. The NDIS laboratory must also maintain the proficiency test records and qualifications of any contract employee that performs ownership reviews. If proficiency testing for a contract technical reviewer is administered by another NDIS participating laboratory refer to the guidance under **Standard 13.1.5.2**.

Latest Revision: 07/01/2025

Forensic Standards 17.3.3	**Database Standards 17.3.4**

The ownership reviews must include the elements listed under **Forensic Standards 17.3.3/Database Standards 17.3.4**, as applicable.

Forensic Standard 17.3.3.3 is not applicable if the NDIS participating laboratory does not receive a final report from the vendor laboratory in accordance with their outsourcing agreement.

As provided in **Forensic Standard 17.3.2/Database Standard 17.3.3**, a portion of the ownership review may be accomplished through the use of an NDIS approved and internally validated Expert System.

Latest Revision: 07/01/2025

Forensic Standard 17.4	**Database Standard 17.4**

To satisfy the requirements of **Standard 17.4**, the laboratory must have and follow procedures and demonstrate compliance (as applicable) with each of the substandards of **Standard 17.4**.

For **Standard 17.4**, except as provided in **Forensic Standard 17.2.2.3**, an on-site visit must be performed prior to the vendor laboratory's initiating work on a forensic or on a database, known, or casework reference sample, whether performed as a part of a contractual agreement or as a part of an agreement of the NDIS participating laboratory to accept ownership of data outside of an existing contractual agreement, regardless of the number of samples or cases being accepted.

The laboratory shall retain documentation demonstrating the date the on-site visit was performed, a summary of the visit, and the documentation of the personnel who performed the on-site visit. While an on-site visit is not required if an individual is only

providing technical review services for the NDIS participating laboratory, the NDIS participating laboratory's Technical Leader shall evaluate how and where such services are being performed and document their approval to ensure compliance with **Standard 11.3**. For example, if the technical reviewer will not be performing the technical review services at the NDIS participating laboratory, the Technical Leader will want to know where the services will be performed and the security precautions in place to safeguard the confidentiality of the information being reviewed. The Technical Leader will want to ensure that only authorized persons have access to the information being reviewed if such information is taken outside the controlled NDIS participating laboratory environment.

Standard 17.4.2 is applicable when an outsourcing agreement has been extended (e.g., extensions, renewals or re-award) and the technical specifications (e.g., technology, platform and typing amplification test kit) used to generate the DNA data have not changed. If an outsourcing agreement was in force with the specific vendor laboratory in an essentially consistent, continuous manner (with a delay not to exceed six months), it is not required that an additional, initial on-site visit be performed, as required for new outsourcing agreements in **Standard 17.4.1**.

It is noted that an on-site visit is different from an external audit and does not necessarily require that an external audit be performed during an on-site visit.

The Technical Leader of the NDIS participating laboratory may elect to accept documentation generated from an on-site visit of the vendor laboratory conducted by an NDIS participating laboratory using the same technology, platform, and typing test kit. Alternatively, the Technical Leader of the NDIS participating laboratory may accept an on-site visit coordinated by a designated FBI employee. For **Standard 17.4.1.1** and/or **17.4.2.1**, an NDIS participating laboratory accepting an on-site visit from another NDIS participating laboratory or the FBI shall have documentation demonstrating the review and approval of the on-site visit by the NDIS participating laboratory's Technical Leader. The on-site visit documentation should include the date the on-site visit was performed, a summary of the visit, and the personnel who performed the on-site visit.

Latest Revision: 07/01/2020

Standard 18. Laboratory/Database Laboratory Use of Rapid DNA

Forensic Standard 18	**Database Standard 18**

Forensic Standard 18 applies to laboratories using Rapid DNA on casework reference samples and/or forensic samples obtained from a crime scene either through operation of Rapid DNA in the laboratory or laboratory operation of a Rapid DNA instrument/System in a temporary/mobile facility that is recognized under the scope of accreditation of the laboratory.

Database Standard 18 applies to databasing laboratories using Rapid DNA on database, known, or casework reference samples in the laboratory. There is no

Standard 19 in the QAS for DNA Databasing Laboratories. Booking Station implementation of Rapid DNA is not under the scope of **Standard 19** as booking station implementation has their own separate national Standards and Procedures (see *Standards for the Operation of Rapid DNA Booking Systems by Law Enforcement Agencies* and *National Rapid DNA Booking Operational Procedures Manual* at https://le.fbi.gov/science-and-lab/biometrics-and-fingerprints/codis/rapid-dna).

If the laboratory designates the database section to oversee the operation of a Forensic Rapid DNA Program, the database section shall be audited to the more stringent **Forensic Standard 18** and, if applicable, **Forensic Standard 19**.

Latest Revision: 07/01/2025

Forensic Standard 18.1	

To successfully satisfy **Forensic Standard 18.1**, compliance must be demonstrated with all the substandards of **Forensic Standard 18.1**.

Rapid DNA applications include the use of Rapid DNA on casework reference samples and/or forensic samples in the laboratory (**Forensic Standard 18**) or in conjunction with Rapid DNA partner agencies (**Forensic Standard 19**). All Rapid DNA applications shall be recorded in Appendix F of the QAS audit document. See summary of possible applications below:

Forensic Standard 18:

- Laboratory operation of Rapid DNA instruments/Systems in the laboratory
- Laboratory operation of Rapid DNA instruments/Systems in mobile/temporary capacity
- Laboratory operation of Rapid DNA instruments/Systems in locations outside of the DNA laboratory space but under physical control of the laboratory (e.g., in a secure room in the DNA laboratory's building, secure room outside the laboratory building, or a regional laboratory location).
    - Example: Due to physical security requirements of the NDIS laboratory, a Rapid DNA instrument located within the laboratory could not be accessed 24/7 by all personnel trained to operate the Rapid DNA instrument/System. A laboratory could establish a nearby physical location for Rapid DNA processing that meets all laboratory requirements and allowing 24/7 access to designated personnel. The laboratory operates and controls the remote location, and the location is covered under the laboratory's scope of accreditation. Personnel operating the Rapid DNA instruments/Systems are considered laboratory technicians under **Forensic Standard 18**. A laboratory may train law enforcement personnel to use a Rapid DNA instrument/System at these remote locations; these personnel are considered contract employees of the laboratory according to these Standards and must be included in the laboratory's technician training program.

- Example: A state police NDIS participating laboratory establishes remote Rapid DNA processing locations outside the laboratory at state police locations throughout the state. The laboratory operates and controls these remote locations, and these locations are covered under the laboratory's scope of accreditation. Personnel operating the Rapid DNA instruments/Systems are considered laboratory technicians under **Forensic Standard 18**. A laboratory may train law enforcement personnel to use a Rapid DNA instrument/System at these remote locations; these personnel are considered contract employees of the laboratory according to these Standards and must be included in the laboratory's technician training program.

Forensic Standard 19:

- Operation of a Forensic Rapid DNA Program in conjunction with a Rapid DNA partner agency at a partner agency location
  - The Rapid DNA partner agency location can be with a single partner agency or a joint partnership of several LE agencies that have a Rapid DNA instrument/System at a single location. The location must be covered under the laboratory's scope of accreditation.
  - The Rapid DNA partner agency may be the primary/parent agency of the laboratory. For example, if the laboratory is a division under the local/state police department, the Forensic Rapid DNA Program operated by the local/state police department in a partnership with the laboratory falls under **Forensic Standard 19**. The location must be covered under the laboratory's scope of accreditation.
- Operation of a Forensic Rapid DNA Program with a Rapid DNA partner agency operating a mobile/temporary location. The mobile/temporary capacity must be covered under the laboratory's scope of accreditation.

Latest Revision: 07/01/2025

Forensic Standard 18.1.1	**Database Standard 18.1**

For **Forensic Standard 18.1.1**, Rapid DNA must be on the laboratory's scope of accreditation for each application and location defined in **Forensic Standard 18.1**. The Laboratory should contact their accrediting body for more information about adding Rapid DNA to the laboratory scope of accreditation, adding a mobile/temporary capacity to their scope of accreditation, or adding an additional location or partner agency to their scope of accreditation. For laboratories attempting ISO 17025 DNA accreditation for the first time, a full QAS audit including Standards 18 and 19 (if applicable) will be part of the accreditation process and some Standards and substandards will be assessed, but not applicable until the next QAS audit. For laboratories already ISO 17025 accredited in DNA, Standard 18 and if applicable Standard 19 will be evaluated during the next regularly scheduled annual QAS audit.

For **Database Standard 18.1**, Rapid DNA must be listed on the laboratory's scope of accreditation.

Latest Revision: 07/01/2025

Forensic Standard 18.1.2	
A Forensic Rapid DNA Program falls under the laboratory's quality system and must comply with the applicable requirements to include the annual review of the quality system in **Forensic Standard 3.3** to include the Rapid DNA laboratory and if applicable partner agency procedures for each Rapid DNA application.	

Latest Revision: 07/01/2025

Forensic Standard 18.2	**Database Standard 18.2**
An organizational chart, job descriptions, and/or other laboratory documentation must specify the responsibility, authority, and interrelationship of all personnel who manage, perform, or review work affecting the validity of the laboratory's Forensic Rapid DNA Program defined in **Forensic Standard 18.1**. Laboratory documentation must include any Rapid DNA partner agency personnel involved in the laboratory's Forensic Rapid DNA Program (if applicable). For **Forensic Standard 18.2.1**, the Technical Leader duties are outlined in **Forensic Standard 5.2.5** and its substandards. For Forensic Rapid DNA Programs that have a Laboratory Rapid DNA Administrator (duties outlined in **Forensic Standard 19.2.2**, **19.4.2** and any substandards), the interrelationship between the Technical Leader and the Laboratory Rapid DNA Administrator must be defined by the laboratory. The Laboratory Rapid DNA Administrator can act as a delegate of the Technical Leader for the Rapid DNA partner agency. The Technical Leader can designate the Laboratory Rapid DNA Administrator to review and approve the training records for each Forensic Rapid DNA Operator/Lead Operator (see **Forensic Standard 19.4.2**). The Technical Leader and the Laboratory Rapid DNA Administrator share some duties such as suspending Rapid DNA operations, reviewing Forensic Rapid DNA Program procedures, review of training records and approval of Rapid DNA Operator qualifications, when appropriately documented under this Standard. The Technical Leader retains the ultimate authority over technical operations of a Forensic Rapid DNA Program. For **Forensic Standard 18.2.2**, the CODIS Administrator duties are outlined in **Forensic Standard 5.3.5, 5.3.6** and any substandards. For Forensic Rapid DNA Programs that have a Laboratory Rapid DNA Administrator (duties outlined in **Forensic Standard 19.2.2, 19.4.2** and any substandards), the interrelationship between the CODIS Administrator and the Laboratory Rapid DNA Administrator must be defined by the laboratory. The CODIS Administrator and the Laboratory Rapid DNA Administrator share some duties such as terminating a Rapid DNA partner agency's Rapid DNA participation in CODIS, when appropriately documented under this Standard. The CODIS Administrator has the ultimate authority over CODIS operations and CODIS eligibility.	

Latest Revision: 07/01/2025

Forensic Standard 18.3	Database Standard 18.3
To successfully satisfy **Standard 18.3**, compliance must be demonstrated with all of the substandards of **Standard 18.3**. A finding in **Standard 18.3** or its substandards does not initiate a corresponding finding in **Standard 6**. A training program for modified Rapid DNA analysis is required for all Forensic Rapid DNA Programs that include testing of forensic samples. If a Forensic Rapid DNA Program only tests casework reference samples, only uses an NDIS approved Rapid DNA System, and does not attempt modified Rapid DNA analysis on any casework reference sample that does not pass the system, **Forensic Standard 18.3.1.1** can be marked N/A. For **Standard 18.3.1**, for analysts whose sole responsibility will be operating a NDIS approved Rapid DNA System on database, known, or casework reference samples, training in interpretation and/or technical review is not required because Rapid DNA analysis does not require human intervention. NDIS has not approved a fully automated Rapid DNA System for use on single source forensic samples to date; once approved for use on single source forensic samples, the above will also apply to single source forensic samples identified by the Rapid DNA System. Training in interpretation for modified Rapid DNA analysis is currently required on all forensic samples. For **Database 18.3**, a training program for modified Rapid DNA analysis is only needed if the laboratory uses modified Rapid DNA analysis for database, known, or casework reference samples. For **Standard 18.3.2**, certain specialized forensic sample types such as bone and sexual assault kit evidence require additional laboratory equipment, reagents, and sample preprocessing before being placed in a Rapid DNA instrument/System. Additional training for these sample types is required. Additional training is also required if a laboratory implements a mobile/temporary capacity. Law enforcement personnel or non-DNA laboratory personnel that operate a Rapid DNA instrument/System in laboratory space and under laboratory control are considered contract employees and must be included in the laboratory's technician training program in accordance with **Standard 5.6**, which may or may not include the processing of the specialized samples above.	
Latest Revision: 07/01/2025	

Forensic Standard 18.4	Database Standard 18.4
To successfully satisfy **Standard 18.4**, compliance must be demonstrated with all of the substandards of **Standard 18.4**. A Rapid DNA instrument/System maintained in a room that contains amplified DNA shall comply with **Standard 18.4.1**. The amplified DNA generated by the Rapid DNA instrument/System is fully encapsulated in the Rapid DNA cartridge/chip and therefore does not contribute to a room being identified as containing amplified DNA.	

For **Standard 18.4.1**, if the Rapid DNA instrument/System is located inside an area that contains amplified DNA, samples must be loaded into the Rapid DNA Cartridge/chip in areas that do not contain amplified DNA.

For **Forensic Standard 18.4.2**, an uninterruptable power supply (UPS) capable of powering a run from start to finish is required in temporary/mobile applications to prevent loss of sample and Rapid DNA data. It is recommended that a UPS is also used for laboratory applications when an instrument needs to maintain the temperature conditions of onboard reagents to prevent reagent degradation.

For **Forensic Standard 18.4.3**, operation of a Rapid DNA instrument/System outside of normal indoor facilities may require shelter, heat, air-conditioning and/or humidity mitigation. Refer to manufacturer recommendations or specifications for instrument requirements.

Latest Revision: 07/01/2025

Forensic Standard 18.5	

Since the Rapid DNA instruments can consume the entirety of the sample placed in the instrument, the use of Rapid DNA must be addressed in the evidence consumption policy.

The policy for sample selection should identify which samples will be collected and subjected to Rapid DNA analysis. Quantity, quality, potential mixtures, and sample consumption should be considered when developing the policy. Criteria should be based on validation data, the training level of the user, and quality assurance concerns.

Laboratories should determine the best evidence collection method to ensure the ability to process the evidence using non-Rapid DNA laboratory forensic DNA analysis when needed. Some possible methods include swabbing the original evidence with a specialized Rapid DNA swab, leaving the original evidence for non-Rapid DNA laboratory forensic DNA analysis, cutting a portion of the swab for potential non-Rapid DNA laboratory forensic DNA analysis, or employing an “A-Swab/ B-Swab” strategy. “A-Swab/ B-Swab” approaches include collecting an A-Swab (swab/sample for non-Rapid DNA laboratory forensic DNA analysis if needed) and then a B-Swab (“additional swab” for Rapid DNA analysis) or a side-by-side collection where biological material is collected “together” during the swabbing motion (bouquet method) versus the sequential collection. Laurin *et al* (FSI:Genetics 67 (2023) 102928) suggests that due to the large difference in sensitivity between non-Rapid DNA laboratory techniques and Rapid DNA analysis, the success of Rapid DNA analysis may be limited when using swab “B” from a consecutive swabbing approach. It may therefore be preferable to use the dual/simultaneous swabbing technique to ensure sufficient and consistent amounts of DNA for both analyses.

Latest Revision: 07/01/2025

Forensic Standard 18.6	Database Standard 18.5

Laboratories are required to validate modified Rapid DNA Analysis if they use Rapid DNA on forensic samples or if they have a Forensic Rapid DNA Program with partner agencies (**Forensic Standard 19**).

Forensic Standard 18.6 can be marked N/A if a laboratory only uses an NDIS approved Rapid DNA System on casework reference samples and does not attempt to interpret the data if flagged by the Rapid DNA System. **Database Standard 18.5** can be marked N/A if a laboratory only uses an NDIS approved Rapid DNA System on database, known, or casework reference samples and does not attempt to interpret the data if flagged by the Rapid DNA System.

Any attempt to interpret the data or quality flags triggers modified Rapid DNA analysis. Modified Rapid DNA analysis includes the evaluation of all loci in the DNA profile and not only the loci flagged by the Rapid DNA System. A forensic or database laboratory is not required to validate modified Rapid DNA analysis on database, known, or casework reference samples if the laboratory only uses Rapid DNA as a fully automated Rapid DNA System and reworks the sample when the sample is not passed by the Rapid DNA System.

Validation of modified Rapid DNA is required for all forensic sample uses, whether single source, partial and/or mixtures. For forensic samples and if a Rapid DNA instrument is used on database, known, or casework reference samples and the data will be interpreted using modified Rapid DNA analysis, the modified Rapid DNA analysis requires validation in accordance with **Standard 8.** This validation is to ensure the instrument and the interpretation parameters are established for the laboratory in which the instrument will be used.

Each cartridge/chip type used for modified Rapid DNA analysis by the laboratory must be included in the validation. Different cartridge/chip types can have different amplification and thus interpretation parameters, for example a cartridge/chip designed for reference samples vs a cartridge/chip designed for forensic samples. Validation of each cartridge/chip type is applicable even if the STR kit used in the Rapid DNA cartridge/chip is the same PCR typing kit validated by the laboratory for conventional use. It is possible for a laboratory to validate modified Rapid DNA analysis for reference samples on a cartridge/chip designed for forensic samples. This can be accomplished using a “swab the swab” technique where a portion of the reference sample is transferred to the Rapid DNA swab and processed in a forensic sample cartridge/chip. Validations shall cover all applications of the laboratory’s Forensic Rapid DNA Program defined in **Forensic Standard 18.1** or covered by **Database Standard 18.1** to include relocation of the instrument or operation of the instrument outside the laboratory facility, if applicable. For forensic samples, the validation shall include representative sample types that will be routinely used in casework using cartridges/chips approved by NDIS for forensic sample use.

For Forensic Rapid DNA Programs that include a mobile/temporary component, relocation of the Rapid DNA instrument/System must be incorporated into the

laboratory validation. When relocating to a mobile/temporary location, a performance check after relocation is the best mechanism to ensure the instrument operates appropriately and within the environmental conditions outlined in **Forensic Standard 18.4.3**. If supported by validation, a performance check may not be required. Validation data must demonstrate that a relocation of the instrument and the resultant changes to the environmental conditions are mediated by operational accommodations. A subset of representative sample types must be processed in a mobile/temporary location as part of the validation.

Once a Rapid DNA instrument/System is validated, it is possible for a laboratory to deploy all Rapid DNA instrument(s)/System(s) and no longer have one onsite in the laboratory. Laboratory procedures must address how all aspects of **Standard 18** will be met if a Rapid DNA instrument/System is not onsite at the laboratory, including but not limited to quality assurance measures, performance checks, and proficiency testing. Laboratory procedures must also address bringing the Rapid DNA instrument/System back online at the laboratory after deployment.

For **Forensic Standard 18.6.1**, Rapid DNA is not as sensitive as other non-Rapid DNA laboratory techniques and can require several nanograms of total cellular DNA. Rapid DNA is ideal for forensic samples from potentially a single donor, such as blood, neat semen, drinking containers, chewing gum and some high contact areas of clothing. Samples that may be unsuitable for Rapid DNA are swabbings from public areas, firearms, drug bags, car door handles, and other swabbings that may only contain trace amounts of DNA. The validation shall reflect the appropriate types of forensic samples for use in a Forensic Rapid DNA Program with partner agencies (**Forensic Standard 19**).

Some sample types, such as bone and sexual assault kits, require additional laboratory equipment, reagents, and preprocessing before placing the sample swab into the Rapid DNA instrument. Preprocessing that requires additional laboratory equipment and reagents must be completed by qualified laboratory technical personnel. In addition, Unidentified Human Remains may require additional validation due to multiple sample types encountered, low amounts of DNA present in the samples, and potential artifacts encountered with environmentally challenged samples. Due to the additional quality assurance parameters associated with specialized forensic samples, pre-processing of these samples must be conducted in laboratory space and under laboratory control.

For **Forensic Standard 18.6.2**, due to the decreased sensitivity and increased potential for allelic dropout of Rapid DNA instruments/Systems, mixture interpretation can be challenging. A laboratory must determine if mixture interpretation will be conducted on Rapid DNA data. If a laboratory determines not to interpret mixtures, mixture samples are still required during the validation in order be able to identify when a mixture is present. If a laboratory decides to conduct mixture interpretation on Rapid DNA data, mixture interpretation must be approached with extreme caution and requires a full validation by the laboratory.

If an NDIS approved Rapid DNA System (fully automated with no manual interpretation of the data required) for forensic samples is available, the Rapid DNA expert system for forensic samples will not require validation for full profile single source forensic samples. Analyst interpretation and technical review is not required for single source forensic samples processed without any quality flags on an NDIS approved Rapid DNA System; however, **Forensic Standard 18.6** requires the laboratory to validate modified Rapid DNA analysis to interpret forensic sample Rapid DNA data that is flagged by the NDIS approved Forensic Rapid DNA System.

For **Forensic Standard 18.6.3,** evaluation of the raw Rapid DNA data (e.g., fsa files) must be part of the laboratory's validation of modified Rapid DNA analysis for forensic samples. Evaluation of only an electropherogram image during validation of modified Rapid DNA analysis does not meet this Standard. Interpretation procedures for modified Rapid DNA analysis must be supported by validation data.

If a Rapid DNA instrument is used for testing other than that defined as Rapid DNA analysis or modified Rapid DNA analysis, it must be validated in accordance with **Standard 8** for its intended use in the laboratory. If the intended use will include uploading and/or searching profiles in CODIS, the use must comply with the *NDIS Operational Procedures Manual*.

Latest Revision: 07/01/2025

Forensic Standard 18.7	**Database Standard 18.6**

An NDIS approved Rapid DNA System does not require a validation for database, known, or casework reference samples because the Rapid DNA System has been extensively validated as part of the NDIS approval process. No changes or modifications are permitted to the (1) Rapid DNA instrument; (2) the chemistries and/or concentrations of the PCR STR typing kit/Rapid DNA cartridge/chip; (3) amplification parameters; (4) the settings of the Expert System; or (5) any other software parameters affecting the analysis and/or interpretation of DNA data, without NDIS approval as detailed in the *NDIS Operational Procedures Manual*. The performance check is required to ensure the Rapid DNA System is functioning appropriately prior to use. *NDIS Operational Procedures* define which reference sample types are included in the NDIS approval.

The minimum requirements for a performance check of an NDIS approved Rapid DNA System upon installation requires running a positive sample control in each sample position of the Rapid DNA cartridge/chip (when the cartridge/chip allows for multiple samples to be run at one time in the Rapid DNA instrument) prior to the initial use of the Rapid DNA instrument/System for the analysis of database, known, or casework reference or forensic samples. A negative control is also required upon installation (see also **Forensic Standard 18.9.1/Database Standard 18.8.1** guidance).

Latest Revision: 07/01/2025

Forensic Standard 18.8	Database Standard 18.7

To successfully satisfy **Forensic Standard 18.8/Database Standard 18.7**, compliance must be demonstrated with all of the substandards of **Forensic Standard 18.8/ Database Standard 18.7**.

For **Forensic Standard 18.8.1**, the laboratory shall have and follow a procedure for determining when non-Rapid DNA laboratory forensic DNA analysis is necessary as required by **Forensic Standard 18.5** and, if applicable, **Forensic Standard 19.5.1**. Examples include but are not limited to a failed instrument run, a potential mixed source sample, or presence of excessive quality flags for the sample.

For **Forensic Standard 18.8.2/Database Standard 18.7.1**, for data to be eligible for CODIS entry, an NDIS approved Rapid DNA cartridge/chip must be used.

For **Forensic Standard 18.8.3/Database Standard 18.7.2**, Rapid DNA chips, Rapid DNA cartridges, and Rapid DNA primary cartridges are critical reagents. The laboratory must evaluate each new lot of Rapid DNA critical reagents prior to use. A positive and negative sample control shall be processed and analyzed for each new Rapid DNA chip, Rapid DNA cartridge, or primary cartridge lot number, before or in parallel with database, known, casework reference or forensic samples analyzed on the Rapid DNA instrument. Positive and negative sample controls should only be run in parallel with forensic samples in instances where an abundance (enough sample to run multiple analyses) of forensic sample is available for processing using non-Rapid DNA laboratory methods, if needed. If a laboratory processes the positive and negative sample control in parallel with samples, the data shall only be searched and/or uploaded to CODIS after the controls are interpreted and meet the laboratory's criteria for successful approval of the quality control data. Laboratories must have written procedures for handling sample data processed in parallel with sample controls if the control quality data fails.

For **Forensic Standard 18.8.4.1**, Rapid DNA cartridges/chips for forensic sample use must contain internal quality controls that confirm successful PCR amplification and if a sample contains potential PCR inhibitors. These internal controls can also assist the analyst in determining if the sample may be degraded. Quantitation for forensic samples can be based on the nuclear DNA amplification on Rapid DNA instruments/Systems. Quantitation is not required for database, known, or casework reference samples using Rapid DNA instruments/Systems.

Forensic Standard 18.8.4.2 is not applicable until a Rapid DNA System for forensic samples is approved by NDIS. Once approved by NDIS, forensic samples containing any quality flags must be evaluated using modified Rapid DNA analysis. It is important for the analyst to evaluate the entire DNA profile and not only the loci flagged by the Rapid DNA System. Until NDIS approves Rapid DNA Systems for forensic samples, all forensic samples must undergo modified Rapid DNA analysis.

For **Forensic Standard 18.8.5/Database Standard 18.7.3**, Forensic Rapid DNA Programs that only process database, known, or casework reference samples using

an NDIS approved Rapid DNA System are not required to validate modified Rapid DNA analysis unless modified Rapid DNA analysis is used by the laboratory for the database, known, or casework reference samples.

For **Forensic Standard 18.8.5.2**, the laboratory shall have and follow a procedure to address if mixture interpretation will be conducted on Rapid DNA data. If Rapid DNA mixtures will be interpreted, the laboratory shall have validation data to support the procedures under **Forensic Standard 9.6** for Rapid DNA mixtures. Due to the decreased sensitivity and increased potential for allelic dropout of Rapid DNA instruments/Systems, the laboratory shall define the limitations of modified Rapid DNA analysis mixture interpretation.

For **Forensic Standard 18.8.5.3/Database Standard 18.7.3.2**, for modified Rapid DNA analysis, the laboratory shall have and follow procedures for the use of internal size standards and allelic ladders to monitor the Rapid DNA process. These procedures shall identify the acceptable results for internal size standards and allelic ladders and how to the document the verification of their use. The laboratory shall verify that all internal size standards and allelic ladder results meet the laboratory's interpretation guidelines for all reported results. A procedure must exist to demonstrate that the standard values are verified when used (e.g., checklist, technical review).

For **Forensic Standard 18.8.5.4**, the laboratory shall have and follow procedures to verify the internal controls and quantification results for forensic samples that satisfy the laboratory's interpretation guidelines. These procedures shall identify the acceptable results for internal controls and quantification results and how to document the verification of their use. The laboratory shall verify that all internal controls and quantification results meet the laboratory's interpretation guidelines for all reported results. A procedure must exist to demonstrate that the standard values are verified when used (e.g., checklist, technical review).

For **Forensic Standard 18.8.5.5/Database Standard 18.7.3.3**, the laboratory shall have and follow procedures that address what sample controls, if any, will be used. These include controls that are incorporated by the manufacturer into the Rapid DNA cartridge/chip and if additional controls are processed by the laboratory. Certain specialized forensic sample types such as bone and sexual assault kit evidence require additional laboratory equipment, reagents, and sample preprocessing before being placed in a Rapid DNA instrument/System. If additional reagents are involved, reagent blanks are needed for each lot of specialized reagents at a minimum. The laboratory procedures may establish that positive sample controls and negative sample controls are not incorporated in each run of the Rapid DNA instrument/System.

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Forensic Standard 18.9	Database Standard 18.8

To successfully satisfy **Forensic Standard 18.9/Database Standard 18.8**, compliance must be demonstrated with all of the substandards of **Forensic Standard 18.9/Database Standard 18.8**.

For **Forensic Standard 18.9.1/Database Standard 18.8.1**, the minimum requirements for a performance check are to process a positive sample control before, or in parallel with, database, known, casework reference, or forensic samples analyzed on the Rapid DNA instrument, unless otherwise noted below. Positive sample controls should only be run in parallel with forensic samples in instances where an abundance (enough sample to run multiple analyses) of forensic sample is available for processing using non-Rapid DNA laboratory methods, if needed. If a laboratory processes the positive control in parallel with samples, the data shall only be searched and/or uploaded to CODIS after the controls have successfully met the laboratory's criteria. Laboratories must have written procedures for handling sample data processed in parallel with sample controls if the control quality data fails. A negative control is required upon instrument installation and prior to the use of each lot of Rapid DNA cartridges/chips, including primary cartridge if applicable, on casework or databasing samples. Performance checks of new lots must be specific to the Rapid DNA cartridge/chip type being checked. Other performance checks may use any Rapid DNA cartridge/chip type.

For **Forensic Standard 18.9.1.1/Database Standard 18.8.1.1**, the minimum requirements for a performance check of an NDIS approved Rapid DNA System upon installation requires running a positive sample control in each sample position prior to the initial use of the Rapid DNA instrument/System for the analysis of database, known, casework reference, or forensic samples. The minimum requirements for a performance check of a new Rapid DNA instrument where the laboratory previously validated modified Rapid DNA requires running a positive sample control in each sample position prior to the initial use of the Rapid DNA instrument/System for the analysis of database, known, casework reference, or forensic samples. The laboratory shall identify and document the acceptable results for the positive sample control prior to the use of the Rapid DNA instrument/System. A negative control is also required upon installation as well as on new lot numbers of Rapid DNA cartridges/chips, including primary cartridge if applicable, prior to use in casework or databasing.

For **Forensic Standard 18.9.1.2/Database Standard 18.8.1.2**, all updates to instrument software and software associated with running the instrument, including updates to the instrument firmware, require a performance check after installation and prior to use in casework or databasing. Major software revisions as defined in **Standards 8.5.2** and guidance under **Forensic Standard 18.7/Database Standard 18.6** may require additional validation or NDIS approval.

For **Forensic Standard 18.9.1.3/Database Standard 18.8.1.3**, a laboratory must perform a performance check of a Rapid DNA instrument/System if the instrument is idle longer than the period recommended in the instrument specifications or as

established by the laboratory. If the laboratory determines an acceptable idle time period that exceeds the length recommended by the instrument's specifications, the laboratory must have validation data to support that determination.

Forensic Standard 18.9.1.4, a performance check is required when relocating an instrument to a mobile/temporary location unless validation data supports a performance check is not required (see guidance under **Forensic Standard 18.6**).

Latest Revision: 07/01/2025

Forensic Standard 18.10	
Forensic samples require the use of NDIS approved Rapid DNA cartridges/chips for CODIS entry. Because Rapid DNA instruments can utilize at least two different sample cartridge/chip types, one designed for reference samples, and one designed for forensic sample use, laboratory casework reports shall include the cartridge/chip type used.	
Latest Revision: 07/01/2025	

Forensic Standard 18.11	**Database Standard 18.9**
Verification of DNA types conducted by two independent concordant assessments by a qualified analyst or technical reviewer is required before a forensic sample can be uploaded and/or searched in CODIS. A review of all analytical controls, internal size standards, and allelic ladders to verify that the expected results were obtained (**Standard 12.2.2**) and a review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images) (**Standard 12.2.3**) does not apply for laboratories using an NDIS approved Rapid DNA System on database, known, or casework reference samples or an NDIS approved Rapid DNA System on single source forensic samples (once Rapid DNA Systems for forensic samples are approved by NDIS), but do apply to laboratories using Rapid DNA instruments to perform modified Rapid DNA analysis on any of the above samples. All other aspects of **Standard 12.2** and its substandards apply. For **Database Standard 18.9**, the technical review of database, known, or casework reference samples using modified Rapid DNA analysis must include the verification of DNA types conducted by two independent concordant assessments by a qualified analyst or technical reviewer prior to upload or search in CODIS.	
Latest Revision: 07/01/2025	

Forensic Standard 18.12	**Database Standard 18.10**
Proficiency testing requirements do not apply to the use of a Rapid DNA System; however, analysts qualified to perform modified Rapid DNA analysis must be proficiency tested. Technicians are not required to proficiency test in Rapid DNA. Rapid DNA utilizes STR technology and capillary electrophoresis platform. The interpretation parameters for data developed using a Rapid DNA instrument/System are different than the interpretation parameters of data developed in the laboratory using non-Rapid DNA techniques, even if the PCR typing kit has the same name.	

Rapid DNA cartridge/chip types (reference vs forensic) are considered different PCR typing kits. Proficiency testing for modified Rapid DNA analysis must be in accordance with **Standard 13**.

If the analyst is qualified to perform modified Rapid DNA analysis with multiple Rapid DNA instrument models using the same or different Rapid DNA cartridges/chips (reference vs forensic), then data generated by each Rapid DNA cartridge/chip on each instrument model must be tested at least once per year.

For Rapid DNA, it is imperative to select proficiency tests containing a sufficient amount of DNA. Low level DNA samples and samples containing mixtures may not be appropriate. All samples contained within a particular proficiency test may not be appropriate for Rapid DNA testing and inappropriate samples should not be attempted. It is important to note that blood samples containing EDTA may inhibit the Rapid DNA process.

Latest Revision: 07/01/2025

Forensic Standard 18.13	**Database Standard 18.11**
The laboratory's **Standard 14** nonconformity procedures shall apply to all Rapid DNA applications identified in **Standard 18.1**.	
Latest Revision: 07/01/2025	

Forensic Standard 18.14	**Database Standard 18.12**
To successfully satisfy **Forensic Standard 18.14/Database Standard 18.12**, compliance must be demonstrated with all of the substandards of **Forensic Standard 18.14/Database Standard 18.12**. **Forensic Standard 18.14/Database Standard 18.12** apply only to sample data generated by a vendor laboratory using an NDIS approved Rapid DNA System. For an NDIS participating laboratory that outsources to a vendor laboratory performing modified Rapid DNA analysis on database, known, casework reference and/or forensic samples, all elements of **Standard 17** apply.	
Latest Revision: 07/01/2025	

Standard 19. Rapid DNA Partner Agency Forensic Rapid DNA Program

Forensic Standard 19	
Forensic Standard 19 applies to a laboratory that implements a Forensic Rapid DNA Program with a Rapid DNA partner agency(ies). The Rapid DNA partner agency's location must be accredited under the laboratory's scope of accreditation. The laboratory is the lead agency for any Forensic Rapid DNA Program established with a Rapid DNA partner agency under **Standard 19**. **Standard 19** works in conjunction with **Forensic Standard 18** as all Rapid DNA data submitted to the laboratory under **Standard 19** must be reported by the laboratory.	

There is no **Standard 19** in the QAS for DNA Databasing Laboratories. Forensic Rapid DNA Programs located under the supervision of the database section of a laboratory shall be audited to the Forensic Rapid DNA **Standards 18** and **19**.

Booking Station implementation of Rapid DNA is not under the scope of **Standard 19** as booking station implementation has their own separate national Standards and Procedures (see *Standards for the Operation of Rapid DNA Booking Systems by Law Enforcement Agencies* and *National Rapid DNA Booking Operational Procedures Manual* at https://le.fbi.gov/science-and-lab/biometrics-and-fingerprints/codis/rapid-dna).

Latest Revision: 07/01/2025

Forensic Standard 19.1	

To successfully satisfy **Standard 19.1**, compliance must be demonstrated with all of the substandards of **Standard 19.1**.

For **Standard 19.1**, an agreement, such as a Memorandum of Understanding (MOU) or other legal agreement, must be developed by the laboratory and executed between the laboratory and the Rapid DNA partner agency that includes, but is not limited to, defining the roles and responsibilities of each party, information technology requirements, sample acceptance criteria, Rapid DNA instrumentation and maintenance specifications, accreditation requirements, adherence to laboratory policies and procedures, and adherence to national forensic Rapid DNA Standards and Procedures. This agreement is required even when the Rapid DNA partner agency is the primary/parent agency of the laboratory. For example, if the crime scene unit of the laboratory's own agency becomes the partner, a laboratory-partner agency agreement is still required as operation and control of the Rapid DNA instrument is outside of the DNA laboratory.

The laboratory's Forensic Rapid DNA Program may have agreements with multiple Rapid DNA partner agencies, multiple locations within the same partner agency, or a combination of both.

For **Standard 19.1.1**, a laboratory's Forensic Rapid DNA Program that includes partner agencies must be audited to both **Forensic Standards 18 and 19**.

Latest Revision: 07/01/2025

Forensic Standard 19.2	

To successfully satisfy **Standard 19.2**, compliance must be demonstrated with all of the substandards of **Standard 19.2**.

For **Standard 19.2.1.1 and 19.2.1.2**, refer to **Forensic Standard 5.3.1** and **Forensic Standard 5.3.2** for guidance on the minimum educational and experience requirements.

For **Standard 19.2.1.3**, refer to **Forensic Standard 5.3.3** and **Forensic Standard 16.1** and its substandards for training and continuing education requirements of the Casework CODIS Administrator.

To successfully satisfy **Standard 19.2.2**, the laboratory must document the Laboratory Rapid DNA Administrator's duties, responsibilities, and authority. The Laboratory Rapid DNA Administrator could also have duties assigned to them under **Forensic Standard 18**, if designated by the laboratory. Refer to **Forensic Standard 18.2** and its substandards for the interrelationship between the Technical Leader, CODIS Administrator and the Laboratory Rapid DNA Administrator.

For **Standard 19.2.2.3**, the Laboratory Rapid DNA Administrator is responsible for the security of the forensic Rapid DNA data that is transferred to the laboratory.

For **Standard 19.2.2.4**, the Laboratory Rapid DNA Administrator is responsible for ensuring all the Rapid DNA partner agency casework documentation and Rapid DNA data, as outlined in **Standard 19.8** and guidance, is provided to the laboratory for modified Rapid DNA analysis and CODIS eligibility determination before the forensic Rapid DNA data is searched and/or uploaded in CODIS. The Rapid DNA data must be available electronically; other case documentation can be available by hard copy, electronic files, or a combination of both formats.

For **Standard 19.2.2.5**, the annual review of laboratory Rapid DNA procedures can be delegated to the Laboratory Rapid DNA Administrator by the Technical Leader. The Laboratory Rapid DNA Administrator is responsible for reviewing the Rapid DNA partner agency procedures to ensure they adhere to the requirements of the laboratory, *NDIS Operational Procedures* and these Standards.

For **Standard 19.2.2.6**, appropriate documentation includes all Rapid DNA partner agency documentation needed to show compliance with **Standard 19** and any laboratory requirements of the partner agency. Documentation can be available by hard copy, electronic files, or a combination of both formats.

Latest Revision: 07/01/2025

Forensic Standard 19.3	

To successfully satisfy **Standard 19.3**, compliance must be demonstrated with all of the substandards of **Standard 19.3**.

The laboratory must document the Forensic Rapid DNA Lead Operator's duties, responsibilities and authority. The Forensic Rapid DNA Lead Operator for each partner agency location must be documented in Appendix F of the QAS audit document.

For **Standard 19.3.1.4.4**, a separate reagent log is not necessary if all reagents are part of the cartridge/chip associated with the Rapid DNA instrument/System used at the partner agency.

Latest Revision: 07/01/2025

Forensic Standard 19.4	

To successfully satisfy **Standard 19.4**, compliance must be demonstrated with all of the substandards of **Standard 19.4**.

For **Standard 19.4**, Forensic Rapid DNA Operator training includes, at a minimum, the following: use of personal protective equipment (PPE), collection techniques for forensic Rapid DNA samples, identification of appropriate sample types for forensic Rapid DNA analysis (including sample consumption and retesting requirements), proper handling of evidence samples (to include sample cutting), instrument operation, instrument troubleshooting, CODIS eligibility specifications, submission of required data and case documentation to the laboratory and quality control requirements including: performance checks, QA/QC of Rapid cartridges/chips and primary cartridges, if applicable. The relevant aspects of Rapid DNA accreditation should also be covered. The laboratory's Rapid DNA training program must be approved by the Technical Leader. Appropriate sample types for forensic Rapid DNA use must be based on the laboratory's validation.

For **Standard 19.4.1**, if a partner agency has multiple locations with Rapid DNA instrument(s)/System(s), laboratory and partner agency procedures must outline if Forensic Rapid DNA Lead Operators/Operators can use Rapid DNA instrument(s)/System(s) at the alternate locations. All locations must be defined under the laboratory's scope of accreditation. Since Lead Operators are required to be trained as Rapid DNA Operators, **Standard 19.4.1** also applies to Lead Operators. Technicians and analysts from the laboratory authorized to operate the Rapid DNA instrument(s)/System(s) may also do so at the Rapid DNA partner agency without an additional authorization.

For **Standard 19.4.1.1**, sample types processed at a Rapid DNA partner agency location must not require additional extraction reagents and laboratory equipment (e.g., heat blocks, centrifuges) for preprocessing evidence samples. See **Forensic Standard 18.3.2** and **18.6.1** for additional guidance regarding these sample types being completed in a laboratory space and under laboratory control by a qualified laboratory technician.

For **Standard 19.4.1.1.1**, the initial Rapid DNA instrument/System training conducted at the Rapid DNA partner agency on their instrument shall include sample types routinely processed at that location and serves as the onsite validation for that location. Once a partner agency is online, instrument and Operator training can be centrally located, as determined by the laboratory. The same applies to the initial setup of a Rapid DNA partner agency mobile/temporary application. The initial instrument training must be completed using partner agency Rapid DNA instruments/Systems in a temporary/mobile capacity using sample types that would be routinely processed in the mobile/temporary application and serves as the onsite validation for the temporary/mobile application.

For **Standard 19.4.1.2**, competency tests can be produced by the laboratory or purchased from an external source, if available. Competency testing should include the types of samples that will be tested on a routine basis by the partner agency.

For **Standard 19.4.1.3.1**, examples of major changes that require refresher training include: changes to the operation or maintenance of the Rapid DNA instrument/System, and changes to the Rapid DNA workflow that may result in operator errors, affecting results or impacting chain of custody.

For **Standard 19.4.1.3.2**, infrequent use must be defined by the laboratory. The laboratory may define the frequency of refresher training by amount of time since last use, or a minimum number of times used over a defined period of time.

For **Standard 19.4.2**, the laboratory must document if the Technical Leader and/or the Rapid DNA Administrator is responsible for reviewing training records and approving qualification of Forensic Rapid DNA Operators/Lead Operators.

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Forensic Standard 19.5	

To successfully satisfy **Standard 19.5**, compliance must be demonstrated with all of the substandards of **Standard 19.5**.

For **Standard 19.5.1**, the Rapid DNA partner agency must document and follow the laboratory's policy for evidence sample consumption as samples may be entirely consumed when placed in Rapid DNA instruments.

The Rapid DNA partner agency must follow the laboratory's policy that identifies which samples can be collected and subjected to Rapid DNA analysis. Quantity, quality, potential mixtures, and sample consumption are considerations used in developing the laboratory policy.

In addition, the Rapid DNA partner agency must follow the laboratory's process for ensuring enough evidence remains for non-Rapid DNA laboratory forensic DNA analysis. (see guidance under **Forensic Standard 18.5**).

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Forensic Standard 19.6	

To successfully satisfy **Standard 19.6**, compliance must be demonstrated with all of the substandards of **Standard 19.6**.

For **Standard 19.6.2**, access to the Rapid DNA instrument/System must be limited to authorized Rapid DNA partner agency personnel and authorized laboratory personnel only. Access to the Rapid DNA instrument/System by laboratory personnel can be remote electronic access and/or escorted access.

For **Standard 19.6.3**, an uninterruptable power supply (UPS) capable of powering a run from start to finish is required in temporary/mobile applications. It is recommended

that a UPS is also used for partner agency applications when an instrument needs to maintain the temperature conditions of onboard reagents to prevent reagent degradation.

For **Standard 19.6.4**, operation of a Rapid DNA instrument/System outside of normal facilities may require shelter, heat, air-conditioning and/or humidity mitigation. Refer to manufacturer recommendations or specifications for instrument requirements. See guidance under **Forensic Standard 18.6** for additional information.

For **Standard 19.6.5**, separate unique logins, using advanced authentication, shall be required for each Forensic Rapid DNA Lead Operator/Operator accessing/utilizing a Rapid DNA instrument/System. The Forensic Rapid DNA Lead Operator/Operator who is logged into the Rapid DNA instrument/System shall be the same individual operating the Rapid DNA instrument/System. Advanced authentication, sometimes referred to as two-factor authentication is: 1) something you know such as a password, 2) something you have such as a unique user fob, a code sent to your phone, or an authenticator application, and 3) something you are such as a fingerprint, face, or retina. Two-factor authentication must meet two of the three methods listed above.

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Forensic Standard 19.7	

To successfully satisfy **Standard 19.7**, compliance must be demonstrated with all of the substandards of **Standard 19.7**.

For **Standard 19.7**, Rapid DNA instrument(s)/System(s) are considered critical equipment and must be maintained in accordance with manufacturer and laboratory requirements.

For **Standard 19.7.1**, NDIS approved Rapid DNA cartridges/chips for forensic sample use must contain internal quality controls that confirm successful PCR amplification, indicate the presence of potential PCR inhibitors, and include the ability to estimate the quantity of DNA in the forensic sample. These internal controls can also assist the analyst in determining if the sample may be degraded. Quantitation for forensic samples can be based on the nuclear DNA amplification on Rapid DNA instruments/Systems. Quantitation is not required for casework reference samples using Rapid DNA instruments/Systems.

For **Standard 19.7.2**, Rapid DNA instruments/Systems should be installed on a stable surface and movement of the Rapid DNA instrument/System should be minimized. The laboratory may require a performance check if the instrument is moved to a different location.

For **Standard 19.7.5**, the laboratory must establish procedures for the approval of performance checks conducted at the Rapid DNA partner agency in accordance with **Forensic Standard 18.9**. At minimum, a performance check consists of running a

positive sample control unless otherwise noted in the Standards and/or laboratory policies/procedures.

For **Standard 19.7.6.1 and 19.7.6.1.1**, the minimum requirements for a performance check of a Rapid DNA instrument/System upon installation at a Rapid DNA partner agency requires running a positive sample control in each sample position prior to the initial use of the Rapid DNA instrument/System for the analysis of casework reference and/or forensic samples. This performance check can be part of the initial training outlined in **Standard 19.4.1.1.1**. The laboratory shall identify and document the acceptable results for the positive sample control prior to the use of the Rapid DNA instrument/System. A negative control is also required upon installation as well as on new lot numbers of Rapid DNA cartridges/chips, including primary cartridges, if applicable, prior to use in casework. Performance checks of new lot numbers of Rapid DNA cartridges/chips and reagents can be centralized and/or coordinated by the laboratory.

For **Standard 19.7.6.2** service and/or maintenance includes software updates outlined in **Standard 18.9.1.2**. All updates to instrument software and software associated with running the instrument, including updates to the instrument firmware, require a performance check after installation and prior to use in casework or databasing. Major software revisions as defined in **Standards 8.5.2** and guidance under **Forensic Standard 18.7** may require additional validation or NDIS approval.

For **Standard 19.7.6.3**, the Rapid DNA partner agency must follow the performance check requirements of the laboratory when moving an instrument and for mobile/temporary applications, if applicable. A performance check is required when relocating an instrument to a mobile/temporary location unless laboratory validation data supports a performance check is not required (see guidance under **Forensic Standard 18.6**).

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Forensic Standard 19.8	

To successfully satisfy **Standard 19.8**, compliance must be demonstrated with all of the substandards of **Standard 19.8**.

For **Standard 19.8**, it is the responsibility of the laboratory to ensure all Rapid DNA data and documentation needed for the case file and reporting of results is provided by the Rapid DNA partner agency. The laboratory must define what Rapid DNA data and case documentation is required from the partner agency. The laboratory is responsible for making the final determination of CODIS eligibility prior to upload and/or search of any Rapid DNA data. Verification of DNA types conducted by two independent concordant assessments by a qualified analyst or technical reviewer is also required before a forensic sample can be uploaded and/or searched in CODIS. NDIS has not approved fully automated Rapid DNA Systems for use on single source forensic samples to date; if approved for use on single source forensic samples, the verification of DNA types may not be required in instances where no quality flags are present. Modified Rapid DNA is currently required on all forensic samples.

For **Standard 19.8.2**, the secure network must protect the confidential nature of the data being transferred. It is recommended that the laboratory consult with cyber security individuals within their agency for guidance. The CJIS Security Policy (https://le.fbi.gov/cjis-division/cjis-security-policy-resource-center) is an available cyber-security resource.

For **Standards 19.8.3 and 19.8.3.1**, the Federal DNA Identification Act ('Federal DNA Act'; 34 U.S.C. §12592) provides for limited disclosure of the DNA records in the National DNA Index System (NDIS) to criminal justice agencies for law enforcement identification purposes. NDIS participating laboratories comply with the provisions limiting access and disclosure to the DNA analyses and DNA samples maintained by federal, state and local criminal justice agencies (and the Secretary of Defense under 10 U.S.C. §1565) in accordance with the Federal DNA Act. Specifically, the Federal DNA Act provides for limited access to the DNA analyses and DNA samples to the following:

> "(A) to criminal justice agencies for law enforcement identification purposes;
> (B) in judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules;
> (C) for criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged; or
> (D) if personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes." 34 U.S.C. §12592(b) (3).

State laws on confidentiality of the DNA records are included in the respective state DNA database laws. Many state laws have provisions similar to those in the Federal DNA Act but for states with more expansive access and disclosure laws (such as, humanitarian purposes), the state has agreed, as a condition for its participation in NDIS, to comply with the more restrictive provisions of the Federal DNA Act. For those states having DNA database laws with more restrictive access and disclosure provisions than the Federal DNA Act, laboratories in those states are required to comply with their state laws. A Rapid DNA partner agency should have the applicable state law readily available and ensure that their disclosures of DNA records are in accordance with the Federal DNA Act and their state law and that their policies/procedures safeguard the confidentiality and privacy of the forensic Rapid DNA data and case documentation.

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Forensic Standard 19.9	

To successfully satisfy **Standard 19.9**, compliance must be demonstrated with all of the substandards of **Standard 19.9**.

For **Standard 19.9**, the inspection of the Rapid DNA partner agency's locations can be accomplished virtually during an internal or external QAS audit. All partner agency documentation to show compliance for **Standard 19** shall be available at the laboratory in hard copy, electronic files, or a combination of both formats. Video

and/or photographic documentation may be needed to document the partner agency facilities and location of the Rapid DNA instrumentation.

For **Standard 19.9.1** Appendix F shall be completed by auditors conducting external QAS audits for the Laboratory Rapid DNA Administrator's education, experience and required training.

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Appendices

Appendix A - Findings

Refer to **Standard 15.5**

For external audits of an NDIS participating laboratory, documentation demonstrating the remediation (e.g., corrective action) and/or the challenge/contesting of a finding must be submitted to QAS@fbi.gov. Refer to the *NDIS Operational Procedures Manual* for additional requirements pertaining to audit documentation.

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Appendix B - Contingency Plan Notification Form

Refer to **Standard 4.1.6**

Latest Revision: 07/01/2025

Appendix C - Auditor Self-Certification

Refer to **Standards 15.2 and 15.3**

Completed Appendix C are not required to be inserted into the audit document but must be submitted to QAS@fbi.gov along with the external audit documentation for an NDIS participating laboratory.

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Appendix D - Personnel

Refer to **Standard 5 and Standard 15.2.1**

Personnel who are not approved (e.g., do not meet the minimum requirements in **Standard 5**) will not be memorialized in Appendix D.

A recently appointed Technical Leader who has not completed the applicable QAS auditor training (**Standard 5.2.4**) and technology training (**Standard 5.2.3**) or a CODIS Administrator who has not completed the applicable QAS auditor training (**Standard 5.3.3**) and CODIS training (**Standard 5.3.3**) requirements will not be memorialized in Appendix D until these training requirements are complete.

Appendix D should include authorized individuals approved to meet the minimum requirements in **Standard 5** since the last external audit, even if no longer employed by the laboratory.
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Appendix E - Approved Validations
Refer to **Standard 8 and Standard 15.2.2** Validations, modified procedures evaluations, or software validation that are approved by the Technical Leader and provided to the audit team for review, but are not fully implemented (e.g., training and/or procedures in progress) can be memorialized in Appendix E. Validations, modified procedures evaluations, or software validation and testing that are reviewed by the auditors but not approved in their entirety (e.g., incomplete studies, contain findings) will not be memorialized in Appendix E and must be reviewed during a subsequent external audit.
Latest Revision: 07/01/2025

Appendix F – Forensic Rapid DNA Program
Refer to **Forensic Standard 18 and Forensic Standard 19**
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