

THE FBI QUALITY ASSURANCE STANDARDS

AUDIT FOR

FORENSIC DNA TESTING LABORATORIES

IN ACCORDANCE WITH THE QUALITY ASSURANCE STANDARDS
FOR FORENSIC DNA TESTING LABORATORIES
EFFECTIVE JULY 1, 2020

An Audit of: San Diego County Sheriff Regional Crime Laboratory

Address of Laboratory: 5590 Overland Ave, San Diego, CA, 92123

Dates of Audit: 8/5/2024-8/7/2024

Type of Audit: External ☒ Internal ☐

Was the audit done in conjunction with an accreditation assessment? Yes ☐ or No ☒

Revision Date of Guidance Document referenced 1/1/2023

Does the Audit Document include findings? Yes ☐ or No ☒

Audit Team: Anna JB Wilson

Allison Heard [Click here to enter name of auditor.](#)

[Click here to enter name of auditor.](#)

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For Laboratory:

Date Final Audit Report Received: [Click here to enter a date](#)

Date Audit Documentation Sent to NDIS: [Click here to enter a date](#) or N/A ☐

FORENSIC QAS AUDIT DOCUMENT

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 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 (SWGDM).

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 the QAS Guidance Document. The Guidance Document clarifies standards, as needed, and provides additional guidance to assist the laboratory and auditors in determining compliance.

The Forensic and Databasing QAS and QAS Guidance Document will take effect on January 1, 2020 and are not to be applied retroactively. The Forensic and Databasing QAS are the primary resource for the definitions and quality assurance standards and take precedence over the QAS Guidance Document which should be consulted only for additional clarification as a secondary resource.

The Forensic and Databasing Audit Documents now contain only the checklists for assessing compliance with each standard. In this Audit Document, the rating system for assessing the laboratory with respect to each standard contains the choices of "Yes" or "No", and, where appropriate, "Not Applicable (N/A)." In Appendix A, the findings associated with the audit will be detailed and summarized by the auditor, with an area available for response to such findings by the laboratory. Notes or comments, including observations and recommendations, are better suited to be mentioned during the exit briefing with laboratory personnel or in a separate letter/memorandum to the laboratory so that these comments are not confused with comments relating to a finding or an explanation of why a particular standard is not applicable.

Instructions to Audit Team

Thank you for participating in this important process intended to evaluate compliance with minimum standards for a quality program for performing forensic DNA analysis.

Starting with audits conducted in accordance with the Quality Assurance Standards effective July 1, 2009, separate Audit Documents are used for forensic and databasing laboratories. If a laboratory performs both functions, each Audit Document must be completed and submitted to the laboratory at the conclusion of the audit process.

Once an external audit has been scheduled, the laboratory being audited should provide the audit team with the Checklist contained on the following pages as soon as possible. The Lead Auditor shall also request a certification (contained in Appendix C) from each auditor on the team and provide them to the laboratory prior to the beginning of the audit. The Lead Auditor shall review the checklist completed by the laboratory and the laboratory shall review the Appendix C for each auditor to ensure that the audit team contains the appropriate number of members to audit the laboratory and that the team members possess the necessary expertise required to audit that laboratory. An auditor or his or her employer who has a contractual relationship (exclusive of audits) with the laboratory being audited shall disclose this fact and recuse himself or herself from performing the audit. The laboratory shall review the auditors' certifications for any potential conflicts of interest.

As a general rule, compliance with a standard is assessed through a review of the laboratory's documentation and interviews with laboratory staff. Documents may be in hard copy, electronic or a combination of both formats. Certificates of qualifications shall not be considered documentation of compliance with these standards. Laboratory personnel's compliance with these standards shall be documented by the auditor(s) in Appendix D. A review of case reports for the laboratory shall include a number of case files randomly selected for each DNA analyst. As appropriate, a minimum of three to five cases per DNA analyst should be reviewed.

When conducting an audit, please keep in mind the following general guidelines:

- Potential issues concerning compliance should be directed to the laboratory's designated points of contact.
- Comments on the laboratory's operations should be reserved for the audit document if a "No" or "N/A" is marked and/or the exit interview with laboratory management; comments should not be made to laboratory staff.
- Contested or contentious issues should be brought to the attention of your Lead Auditor for follow-up, as necessary.

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As a general rule,

- Issues deemed minor by the audit team that are addressed during the course of an audit (for example: date or position revisions of a laboratory's organizational chart) may be determined by the auditor to satisfy a non-compliance so that a "Yes" is marked for that standard.
- Non-compliance with a standard identified by the laboratory prior to the audit should be assessed by the audit team for adequate documentation and/or corrective action. If determined to have been appropriately addressed, the auditor may mark the corresponding standard as "Yes".
- Comments should not be included for standards marked "Yes".
- Comments shall be included for standards marked "No" or "N/A".
 - For a standard marked "No", the comment shall describe the non-compliance with sufficient detail so that the laboratory can develop an appropriate corrective action for compliance.
 - For a standard marked "N/A", the comment shall describe why that standard is not applicable to that laboratory.

For additional information pertaining to the interpretation of each standard refer to the QAS Guidance Document. Questions concerning this Audit Document or a specific standard should be directed to the FBI's Combined DNA Index System (CODIS) Unit at QAS@fbi.gov.

After the audit is completed, the Lead Auditor or auditor(s) briefs DNA laboratory management and the DNA technical leader regarding the results. This briefing should verbally detail specific findings (non-compliances) and observations (general comments and/or recommendations), as well as recognize commendable performances. The written report should be prepared by the Lead Auditor and/or auditor(s) and sent to the laboratory within 30 days of the audit. The Audit Document Report consists of the completed Audit Document Checklist, with any areas of non-compliance listed under the Findings Section of Appendix A. All findings of non-compliance must be clearly identified and referenced to the appropriate standard.

Recommendations shall not be included in the Audit Document Report. Notes or comments, including observations and recommendations are better suited to be mentioned during the exit briefing with laboratory personnel or in a separate letter/memorandum to the laboratory so that these comments are not confused with comments relating to a finding of non-compliance or an explanation of why a particular standard is not applicable.

General Laboratory Information

For an External Audit, to be completed by the laboratory and provided to the audit team prior to the on-site visit.

1. Name of Laboratory: San Diego County Sheriff Regional Crime Laboratory
2. Jurisdiction: Local If Other: [Click here to explain.](#)
3. Uses a Vendor Laboratory: ☐ Yes ☒ No
If Yes, [Click here to enter Vendor Laboratory\(ies\)](#)
4. Uses contract employees: ☐ Yes ☒ No
5. NDIS Participant: ☒ Yes ☐ No
If No, applying for NDIS Participation: ☐ Yes ☐ No
6. Technologies Used: (Choose those that apply)
☒ Autosomal STR ☒ Y STR ☐ Mito ☐ SNP
☐ Other: [Click here to enter text.](#)
☐ Other: [Click here to enter text.](#)
7. Test Typing Kits Used: PowerPlex Fusion 6C, YFiler Plus
8. Platform Instrument Models Used: CE: 3500 Genetic Analyzer
9. Validations requiring review under Std 15: ☒ Yes ☐ No
10. Staff (to include contract employees)
 - a. Total # of qualified DNA Analysts/Technical Reviewers: 15
 - i. # of DNA Analysts requiring review under Std 15: 4
 - b. # of DNA Technicians: 0
 - c. # of Laboratory Support Personnel: 1
 - d. DNA Technical Leader: Michelle Hassler
 - i. On Site: ☒ Yes ☐ No
 - ii. Hired or Appointed since last external audit: ☐ Yes ☒ No
 - e. Casework CODIS Administrator: Cathy Chang
 - i. Hired or Appointed since last external audit: ☒ Yes ☐ No
11. Date of Last Audit: 7/14/2023
 - a. ☐ External ☒ Internal
 - b. If Internal, Date of Last External Audit: 7/15/2022
 - c. Revision Date of Audit Guidance Document Used: 7/1/2020
12. Uses an Expert System: ☐ Yes ☒ No
 - a. Name & Version of Expert System: [Click here to enter text.](#)
 - b. Test Kit and Instrument: [Click here to enter text.](#)
 - c. Version of Data Collection: [Click here to enter text.](#)
13. Uses a Rapid DNA System: ☐ Yes ☒ No
 - a. Name of Rapid DNA System and Instrument: [Click here to enter text.](#)
 - b. Typing Kit and Cartridge: [Click here to enter text.](#)
 - c. System Software: [Click here to enter text.](#)
 - d. Expert System Software: [Click here to enter text.](#)

Standard 1. Scope

No Auditable Requirements

Standard 2. Definitions

No Auditable Requirements

Standard 3. Quality Assurance Program

		Yes	No	N/A
3.1	Does the laboratory have, follow, and maintain a documented quality system:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	a. Is the quality system appropriate to the testing activities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	b. Is the quality system equivalent to or more stringent than what is required by these Standards?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
NOTE: To successfully satisfy Standard 3.1, compliance must be demonstrated with all of the substandards of Standard 3.1.1.				
3.1.1	Is the quality system documented in a manual that includes or references the following elements:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.1.1.1	Goals and objectives?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.1.1.2	Organization and management?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.1.1.3	Personnel?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.1.1.4	Training?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.1.1.5	Facilities and evidence control?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.1.1.6	Validation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.1.1.7	Analytical procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.1.1.8	Equipment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.1.1.9	Reports?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.1.1.10	Review?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.1.1.11	Proficiency testing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.1.1.12	Corrective action?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

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3.1.1.13	Audits?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1.1.14	Professional Development?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1.1.15	Outsourcing Ownership?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1.2	Does the laboratory maintain and have available on-site any documents referenced within the quality manual?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		Yes	No N/A
3.2	Does the laboratory have and follow a policy regarding document retention that specifically addresses:	<input checked="" type="checkbox"/>	<input type="checkbox"/>
a.	Proficiency tests? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
b.	Corrective action? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
c.	Audits? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
d.	Training records? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
e.	Continuing education? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
f.	Case files? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
g.	Court testimony monitoring? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
3.3	Does the laboratory perform annual review of its DNA quality system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
a.	Is the review independent of the audit required by Standard 15?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b.	Is the review completed under the direction of the technical leader?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c.	Is the review approved by the technical leader?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.4	Does the laboratory annually review case files determined by the technical leader to be a representative sample of the cases worked?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
a.	Is the review independent of an external audit required by Standard 15?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b.	Is the scope of the review defined prior to each annual review and approved by the technical leader?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Comment

See attached document for comments.

Standard 4. Organization and Management

		Yes	No	N/A
4.1	Does the laboratory have:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4.1.1	A managerial staff with the authority and resources needed to discharge its duties and meet the requirements of the Standards in this document?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4.1.2	A technical leader who is accountable for the technical operations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	a. Have at least one technical leader in a multi - laboratory system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4.1.3	A casework CODIS administrator who is accountable for CODIS on-site at each individual laboratory facility using CODIS?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1.4	At least two full-time employees who are qualified DNA analysts?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4.1.5	Documentation that specifies the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the validity of the DNA analysis?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4.1.6	A documented contingency plan that is approved by laboratory management if the technical leader position is vacated or if the number of qualified DNA analysts falls below the two full-time analyst requirement?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	a. If applicable, did the laboratory follow the documented contingency plan?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NOTE: For an NDIS participating lab, refer to Appendix B for the Contingency Plan Notification Form.				
4.2	Does the laboratory define whether the date of hire/appointment/promotion or date of qualification will be used by the laboratory for determining the applicable QAS version for education, experience and training requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Comment

See attached document for comments.

Standard 5. Personnel

		Yes	No	N/A
5.1	Do laboratory personnel have the education, training, and experience commensurate with the examination and testimony provided?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
NOTE:	<i>To successfully satisfy Standard 5.1, compliance must be demonstrated with all of the substandards of Standard 5.</i>			
5.1.1	Does the laboratory have written job descriptions for all personnel to include responsibilities, duties, and skills?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5.1.2	Does the laboratory maintain records on the relevant qualifications, training, skills, and experience of all technical personnel?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
		Yes	No	N/A
5.2	Is the technical leader a full-time employee of the laboratory or multi-laboratory system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
NOTE:	<i>To successfully satisfy Standard 5.2, compliance must be demonstrated with all of the substandards of Standard 5.2.</i>			
NOTE:	<i>Standard 5.2 and Standards 5.2.1 through 5.2.4 may be marked "Yes" for a TL who has been reviewed and memorialized in at least 2 prior external audit documents.</i>			
5.2.1	Does the technical leader of the laboratory meet or exceed the following degree/educational requirements or have a waiver as allowed for in 5.2.1.4?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NOTE:	<i>The substandards of Standards 5.2.1 through 5.2.1.3 will be marked "N/A" for a TL who has a waiver as allowed for in 5.2.1.4</i>			
	a. A master's degree in a biology-, chemistry-, or forensic science-related area?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. Twelve semester hours or equivalent credit hours including a combination of graduate and undergraduate coursework or classes covering the following subject areas:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1. Biochemistry?	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>

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2. Genetics?	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>
3. Molecular biology?	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>
4. Statistics / population genetics?	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>
5.2.1.1 Of the 12 semester or equivalent credit hours required, do they include at least one graduate-level course registering 3 or more semester or equivalent credit hours?		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2.1.2 Do each of the specific subject areas listed in Standard 5.2.1 constitute an integral component of any coursework used to demonstrate compliance with this Standard?		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2.1.3 For individuals who have completed coursework with titles other than those listed in Standard 5.2.1, have they successfully demonstrated compliance with this Standard through a combination of pertinent materials such as a syllabus, letter from the instructor, or other documentation that supports the course content?		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.2.1.4 If the degree requirements of Standard 5.2.1 are not met, does the technical leader possess a waiver from the American Society of Crime Laboratory Directors (ASCLD)?		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		Yes	No	N/A
5.2.2 Does the technical leader meet or exceed one of the following minimum experience requirements?		<input checked="" type="checkbox"/>	<input type="checkbox"/>	
a. If the technical leader was appointed prior to July 1, 2009, does the technical leader have three years of forensic DNA laboratory experience obtained at a laboratory where forensic DNA testing was conducted for the identification and evaluation of biological evidence in criminal matters?		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. If the technical leader was appointed on or after July 1, 2009, does the technical leader have a minimum of three years human DNA experience (current or previous) as a qualified analyst on forensic samples?		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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NOTE: Standards 5.2.3 and 5.2.4 may be marked "N/A" if the technical leader has been in the position for less than one year.

5.2.3	If the technical leader was appointed on or after July 1, 2020, was the technical leader a currently or previously qualified analyst in each technology or have documented training in each technology utilized in the laboratory within one year of appointment?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.2.4	Has the technical leader successfully completed the FBI-sponsored auditor training within one year of appointment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Yes	No	N/A
5.2.5	Does the technical leader of the laboratory have the following authority and minimum responsibilities:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5.2.5.1	Oversee the technical operations of the laboratory?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5.2.5.2	Authority to initiate, suspend, and resume DNA analytical operations for the laboratory or an individual?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5.2.5.3	Evaluate and approve of all validations and new or modified methods used by the laboratory?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5.2.5.4	Review the training records for newly qualified analysts, technicians and technical reviewers and approve their qualifications prior to independent casework analysis and review, verify, and approve the academic transcripts for newly qualified analysts and technical reviewers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5.2.5.5	Approve the technical specifications for outsourcing agreements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5.2.5.6	Review internal and external DNA audit documents and, if applicable, approve corrective action(s)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5.2.5.7	Review annually the procedures of the laboratory?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5.2.5.8	Review and approve the training, quality assurance, and proficiency testing programs in the laboratory?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

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5.2.5.9 Review potential conflicts of interest when contract employees are employed by multiple NDIS participating and/or vendor laboratories?		<input checked="" type="checkbox"/>	<input type="checkbox"/>	
		Yes	No	N/A
5.2.6	Is the technical leader accessible to the laboratory to provide on-site, telephonic, or electronic consultation as needed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	a. If the technical leader oversees a system of separate laboratories, has the technical leader conducted and documented semi-annual on-site visits of each of the laboratories?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NOTE:	<i>Standards 5.2.7, 5.2.7.1 and 5.2.7.2 may be marked "N/A" if the technical leader has been in the position for less than one year.</i>			
5.2.7	Has a newly appointed technical leader documented a review of the following within one year of appointment?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	5.2.7.1 Validation studies and analytical procedures currently used by the laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	5.2.7.2 Educational qualifications and training records of currently qualified analysts and technical reviewers?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		Yes	No	N/A
5.3	Is the casework CODIS administrator an employee of the laboratory and does he or she meet the following qualifications?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NOTE	<i>For an audit of a vendor laboratory, Standard 5.3 and all of its substandards will be marked "N/A".</i>			
NOTE	<i>To successfully satisfy Standard 5.3, compliance must be demonstrated with all of the substandards of Standard 5.3.1 through 5.3.3.</i>			
NOTE	<i>Standard 5.3 and Standards 5.3.1 through 5.3.3 may be marked "Yes" if the casework CODIS administrator has been reviewed and memorialized in at least 2 prior external audit documents.</i>			
NOTE	<i>Standard 5.3.1 shall be marked "Yes" if the casework CODIS administrator was appointed prior to July 1, 2020.</i>			

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5.3.1 Does the casework CODIS administrator meet or exceed the degree and educational requirements in Standard 5.4? ☒ ☐ ☐

NOTE: *Standard 5.3.2 shall be marked "Yes" if the CODIS administrator was appointed prior to July 1, 2009.*

5.3.2 Is the casework CODIS administrator a current or previously qualified analyst with documented mixture interpretation training? ☒ ☐ ☐

NOTE: *Standard 5.3.3 a may be marked "N/A" if the casework CODIS administrator has been in the position for less than six months. Standard 5.3.3 and 5.3.3 b may be marked "N/A" if the casework CODIS administrator has been in the position for less than one year.*

5.3.3 Has the casework CODIS administrator successfully completed the following training requirements? ☒ ☐ ☐

a. FBI-sponsored CODIS software training within six months of appointment, if not previously completed such training? ☒ ☐ ☐

b. FBI DNA auditor training within one year of appointment, if not previously completed such training? ☒ ☐ ☐

5.3.4 Is the casework CODIS administrator responsible for the following: **Yes** **No** **N/A**
☒ ☐ ☐

5.3.4.1 Administer the laboratory's local CODIS network? ☒ ☐ ☐

5.3.4.2 Schedule and document the CODIS computer training of casework analysts? ☒ ☐ ☐

5.3.4.3 Ensure that the security of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures? ☒ ☐ ☐

5.3.4.4 Ensure that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures? ☒ ☐ ☐

5.3.4.5 Ensure that matches are dispositioned in accordance with NDIS operational procedures? ☒ ☐ ☐

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5.3.5 Is the casework CODIS administrator authorized to terminate an analyst's or the laboratory's participation in CODIS until the reliability and security of the computer data can be assured if an issue with the data is identified? ☒ ☐ ☐

5.3.6 If the casework CODIS administrator position has been unoccupied since the last audit, has the laboratory refrained from uploading new DNA profiles to NDIS during the vacancy? ☐ ☐ ☒

Yes No N/A

5.4 Is each analyst an employee or contract employee of the laboratory and does he or she meet or exceed the following qualifications? ☒ ☐

NOTE: To successfully satisfy Standard 5.4, compliance must be demonstrated with all of the substandards of Standards 5.4.1 through 5.4.2.

NOTE: Complete Standards 5.4.1 through 5.4.2 for analysts under review. Standard 5.4 and Standards 5.4.1 through 5.4.2 may be marked "Yes" if all analysts have been reviewed and memorialized in at least 2 prior external audit documents.

5.4.1 Does each analyst reviewed meet or exceed the following degree and educational requirements: ☒ ☐ ☐

a. B.A./B.S. or advanced degree or its equivalent in a biology-, chemistry-, or forensic science- related area? ☒ ☐ ☐

b. College coursework covering the subject areas of: ☒ ☐ ☐

1. Biochemistry? Yes ☒ No ☐

2. Genetics? Yes ☒ No ☐

3. Molecular biology? Yes ☒ No ☐

c. For analysts hired/appointed/promoted or qualified (as defined by the laboratory per Standard 4.2) prior to July 1, 2020, college coursework or training that covers the subject areas of statistics and/or population genetics as it applies to forensic DNA analysis? or ☒ ☐ ☐

For analysts hired/appointed/promoted or qualified (as defined by the Laboratory per Standard 4.2) on

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or after July 1, 2020, successful completion of coursework covering statistics and/or population genetics?

5.4.1.1 Does each of the specific subject areas listed in Standard 5.4.1 constitute an integral component of any coursework used to demonstrate compliance with this Standard? ☒ ☐ ☐

5.4.1.2 For analysts appointed or hired on or after July 1, 2009, do the required subject areas of biochemistry, genetics, and molecular biology consist of nine or more cumulative semester or equivalent hours? ☒ ☐ ☐

5.4.1.3 For individuals who have completed coursework with titles other than those listed in Standard 5.4.1, has compliance with this Standard been demonstrated through a combination of pertinent materials such as a syllabus, letter from the instructor, or other documentation that supports the course content, and has the technical leader approved compliance with this Standard? ☒ ☐ ☐

5.4.2 Does each analyst have six months of forensic human DNA laboratory experience? ☒ ☐ ☐

a. Has each analyst successfully completed the laboratory's required training? ☒ ☐ ☐

Yes No N/A

5.5 Is each technical reviewer an employee or contract employee of the laboratory and meet the education and experience requirements of Standard 5.4? ☒ ☐ ☐

NOTE: *To successfully satisfy Standard 5.5, compliance must be demonstrated with Standards 5.5.1 and 5.5.2.*

NOTE: *Complete Standards 5.5.1 through 5.5.2 for technical reviewers under review. For qualified analysts under review that are authorized to conduct technical reviews, Standards 5.5 through 5.5.2 will be marked "Yes" if compliance with Standard 5.4 was demonstrated.*

5.5.1 Is each technical reviewer a current or previously qualified analyst? ☒ ☐ ☐

5.5.2 Has each technical reviewer successfully completed documented training? ☒ ☐ ☐

		Yes	No	N/A
5.6	Is each technician an employee or contract employee of the laboratory and successfully completed laboratory's documented training program?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

		Yes	No	N/A
5.7	Has the technical leader verified and approved the education, to include a review of academic transcripts, of each analyst and technical reviewer?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment

See attached document for comments.

Standard 6. Training

		Yes	No	N/A
6.1	Does the laboratory have a training program documented in a training manual for qualifying all analyst(s) and technician(s)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

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

Does the laboratory's training program:

6.1.1	Address all DNA analytical, interpretation, and/or statistical procedures used in the laboratory?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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6.1.2	Include practical exercises encompassing the examination of a range of samples routinely encountered in casework?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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6.1.3	Teach and assess the technical skills and knowledge required to perform DNA analysis?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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6.1.3.1	Does the laboratory's training program for analysts include the skills and knowledge required to conduct a technical review?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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6.1.4	Include an assessment of oral communication skills and/or a mock court exercise?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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6.1.5	Include requirements for competency testing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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		Yes	No	N/A
6.2	Did the technical leader approve any modifications to an analyst's, technical reviewer's, technician's, or laboratory support personnel's required training based on a documented assessment of the individual's previous training and experience?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.3	Prior to participating in independent casework, did all analysts and technicians, regardless of previous experience, successfully complete competency testing covering the routine DNA methods, interpretation, and/or statistical procedures to be used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
NOTE:	<i>Complete Standards 6.3.1 through 6.3.2 for analysts under review and technicians that completed the training program since the last external audit. Standards 6.3 through 6.3.2 may be marked "Yes" if all analysts have been reviewed and memorialized in at least 2 prior external audit documents and no technicians have completed training since the last external audit.</i>			
6.3.1	Did the competency testing for a new analyst include a practical component, and written and/or oral components?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.3.2	Did the competency testing for a new technician include a practical component?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		Yes	No	N/A
6.4	For an analyst or technician (currently or previously qualified within the laboratory) to be qualified in a new or additional method:			
	Did the laboratory teach and assess the technical skills and knowledge required to perform the additional method?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.4.1	Before the use of a new or additional method on forensic samples or casework reference samples:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	a. Did the analyst and/or technician successfully complete competency testing to the extent of his/her participation in casework analyses?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	b. Did the competency testing include a practical component?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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6.5	For an analyst (currently or previously qualified within the laboratory) to be qualified to interpret data and generate reports for a new or additional technology, typing test kit, platform, or interpretation software:			
	Did the laboratory teach and assess the technical skills and knowledge required to interpret data, reach conclusions, and generate reports using the additional technology, typing test kit, platform, or interpretation software?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.5.1	Before the use of a new or additional technology, typing test kit, platform or interpretation software on forensic samples or casework reference samples:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. Did the analyst successfully complete competency testing using the additional technology, typing test kit, platform or interpretation software to the extent of his/her participation in casework analyses?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. Did the competency testing include a practical component?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Yes	No	N/A
NOTE:	<i>Standard 6.6 may be marked "N/A" for a laboratory that does not have individuals that solely conduct technical reviews.</i>			
6.6	Did a technical reviewer, who is not currently qualified as an analyst in the laboratory, receive training on the case notes, data analysis, interpretation, and reporting criteria for any method, technology, typing test kit, platform, or interpretation software or the legacy technology, typing test kit, platform and/or interpretation software on which they were not previously qualified as an analyst in the laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.6.1	Did the technical reviewer successfully complete competency testing before completing a technical review of data and/or reports using the additional method, technology, typing test kit, platform or interpretation software used in casework analyses?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	6.6.1.1 For a contract technical reviewer conducting reviews for an NDIS participating laboratory, was the competency testing administered by the NDIS participating laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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		Yes	No	N/A
NOTE:	<i>Standards 6.7 through 6.8 may be marked "N/A" for a laboratory that does not reinterpret legacy data.</i>			
6.7	For an analyst to be qualified in reinterpretation of legacy data, for which they were not previously qualified within the laboratory, did the analyst demonstrate the technical skills and knowledge required to interpret data, reach conclusions, and generate reports in the legacy technology, typing test kit, and/or platform?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.7.1	Did the analyst successfully complete competency testing in the legacy technology, typing test kit, and/or platform to the extent of his/her participation in casework analyses?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	a. Did the competency testing include practical components of reinterpretation?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.8	Does the laboratory have and follow procedures for maintaining or reestablishing the technical skills and knowledge of analysts and technical reviewers who reinterpret legacy data for which they are qualified or previously qualified and whose external proficiency testing does not include a legacy technology, typing test kit or platform?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.8.1	Does the technical leader review the documentation of an analyst's or technical reviewer's maintenance or reestablishment of the technical skills and knowledge and authorize the analyst or technical reviewer to reinterpret legacy data for no more than a two year period?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Yes	No	N/A
6.9	Does the technical leader review the training records for each analyst, technician, and/or technical reviewer and approve his/her qualifications prior to independent casework responsibilities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
6.10	Are each analyst, technician, and/or technical reviewer authorized to independently perform the assigned job responsibilities and the date(s) documented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

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|---|--|-------------------------------------|--------------------------|--------------------------|
| 6.11 | Do laboratory support personnel have documented training specific to their job function(s)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.12 | Does the laboratory have and follow a policy for addressing retraining of personnel when necessary? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| | a. Is the technical leader responsible for evaluating the need for and assessing the extent of retraining and approving the retraining plan? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| NOTE: <i>Standard 6.12.1 will also be completed for any individual on extended leave for a period that takes them out of the proficiency test cycle.</i> | | | | |
| 6.12.1 | Did the individual successfully complete competency testing prior to his/her return to participation in casework analyses? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | a. Did the competency testing include a practical component? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.13 | Does the laboratory maintain records on the training, including successful completion of competency testing, of the laboratory personnel? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

Comment

See attached document for comments.

Standard 7. Facilities and Evidence Control

- | | | Yes | No | N/A |
|--|--|-------------------------------------|--------------------------|-----|
| 7.1 | Does the laboratory physical space ensure the integrity of the analyses and the evidence? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| NOTE: <i>To successfully satisfy Standard 7.1, the laboratory must demonstrate compliance with all of the substandards of Standard 7.1.</i> | | | | |
| 7.1.1 | Does the laboratory have secure, controlled access areas for evidence storage? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 7.1.2 | Except as provided in Standard 7.1.3.1, are techniques performed prior to polymerase chain reaction (PCR) amplification, such as evidence examinations, DNA extractions, and PCR setup, conducted at separate times or in separate spaces from each another? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

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7.1.3	Except as provided in Standard 7.1.3.1, is amplified DNA product, including real-time PCR, generated, processed, and maintained in a room(s) separate from the evidence examination, DNA extractions, and PCR-setup areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
a.	Are the doors between rooms containing amplified DNA and other areas closed at all times except for passage?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
7.1.3.1	Is a Rapid DNA instrument/System used for processing casework reference samples maintained in rooms outside of evidence examination areas or those containing amplified DNA?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.2	Does the laboratory have and follow written procedures for laboratory security?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
7.2.1	Is access to the laboratory controlled and limited in a manner that prevents access to the operational areas by unauthorized personnel?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
a.	Do all exterior entrance/exit points have security control that limits entry and access into the operational areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
b.	Is the distribution of all keys, combinations, and other security devices, documented and limited to the personnel designated by laboratory management?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
		Yes	No	N/A
7.3	Does the laboratory have and follow a documented evidence control program to ensure the integrity of physical evidence?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
NOTE:	<i>To successfully satisfy Standard 7.3, the laboratory must demonstrate compliance with all of the substandards of Standard 7.3.</i>			
7.3.1	For evidence and sample identification:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
a.	Is all evidence marked with a unique identifier on the evidence package?			
	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			
b.	Does the laboratory clearly define what constitutes evidence and what constitutes work product?			
	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			
c.	Does the laboratory have and follow a method to distinguish each sample throughout processing?			

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		Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>	
7.3.2	Does the laboratory document and maintain a chain of custody, in written, printed, or electronic format, for all evidence, to include the following:		<input checked="" type="checkbox"/>		<input type="checkbox"/>	
	a. Signature, initials, or the electronic equivalent of each individual receiving or transferring the evidence?	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>	
	b. The corresponding date for each transfer?	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>	
	c. Evidentiary item(s) transferred?	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>	
7.3.3	Does the laboratory have and follow procedures for handling and preserving the evidence and work product designed to minimize loss, contamination, and/or deleterious change of evidence and work product?		<input checked="" type="checkbox"/>		<input type="checkbox"/>	
7.3.3.1	Does the laboratory have and follow procedures for securing evidence and work product in progress?		<input checked="" type="checkbox"/>		<input type="checkbox"/>	
7.3.3.2	Does the laboratory have and follow procedures for properly sealing evidence?		<input checked="" type="checkbox"/>		<input type="checkbox"/>	
		Yes		No		N/A
7.4	Does the laboratory have a policy on sample consumption?		<input checked="" type="checkbox"/>		<input type="checkbox"/>	
7.4.1	Does the laboratory retain or return a portion of the evidence sample and/or extract, where possible?		<input checked="" type="checkbox"/>		<input type="checkbox"/>	
7.5	Does the laboratory have and follow documented policies for the disposition of evidence?		<input checked="" type="checkbox"/>		<input type="checkbox"/>	

Comment

See attached document for comments.

Standard 8. Validation

		Yes	No	N/A
8.1	Does the laboratory use validated methods for DNA analyses?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

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NOTE: To successfully satisfy Standard 8.1, the laboratory must demonstrate compliance with all of the substandards of Standard 8.

		Yes	No	N/A
NOTE: Standards 8.2 and 8.3 and all of the substandards may be marked "N/A" if there are no validations to review since the last external audit. Ensure Standard 8.3.3 is "N/A" prior to marking all Standards of 8.3 as "N/A".				
8.2	Have developmental validation studies preceded the use of any new methods implemented for forensic DNA analysis since the last external audit?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.2.1	For all validations under review: Have developmental validation studies been performed and documented to include, where applicable:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. Characterization of the genetic marker?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	b. Species specificity?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	c. Sensitivity studies?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	d. Stability studies?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	e. Case-type samples?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	f. Population studies?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	g. Mixture studies?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	h. Precision and accuracy studies?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	i. PCR-based studies to include?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	1. Reaction conditions?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	2. Assessment of differential and preferential amplification?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	3. Effects of multiplexing?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	4. Assessment of appropriate controls?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	

5. Product detection studies?

Yes ☒ No ☐

8.2.2 Are peer-reviewed publication(s) of the underlying scientific principle(s) of a method available? ☒ ☐ ☐

Yes No N/A

8.3 Except as provided in Standard 8.3.1.1, have internal validation of all manual and robotic methods been conducted by each laboratory? ☒ ☐ ☐

a. Were the appropriate sample number and type to demonstrate the reliability and potential limitations of the method used? ☒ ☐ ☐

NOTE: To successfully satisfy Standard 8.3, the laboratory must demonstrate compliance with all of the substandards of Standard 8.3.

8.3.1 Have internal validation studies included, as applicable: ☒ ☐ ☐

1. Known and non-probative evidence samples or mock evidence samples?

Yes ☒ No ☐ N/A ☐

2. Precision and Accuracy studies?

Yes ☒ No ☐ N/A ☐

3. Sensitivity and stochastic studies?

Yes ☒ No ☐ N/A ☐

4. Mixture studies?

Yes ☒ No ☐ N/A ☐

5. Contamination assessment studies?

Yes ☒ No ☐ N/A ☐

8.3.1.1 For multi-laboratory systems:

a. Are the summaries of all shared validation data available at each site? ☐ ☐ ☒

b. Has each laboratory in a multi-laboratory system completed, documented, and maintained applicable site-specific studies: ☐ ☐ ☒

1. Precision studies?

Yes ☐ No ☐ N/A ☒

2. Sensitivity studies?

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Yes ☐ No ☐ N/A ☒

3. Contamination assessment studies?

Yes ☐ No ☐ N/A ☒

8.3.2 Have quality assurance parameters and interpretation guidelines been defined pursuant to internal validation? Including, as applicable: ☒ ☐ ☐

a. Guidelines for mixture interpretation?

Yes ☒ No ☐ N/A ☐

b. Application of appropriate statistical calculations?

Yes ☒ No ☐ N/A ☐

8.3.2.1 Do mixture interpretation validation studies include: ☒ ☐ ☐

a. A range of the number of contributors?

Yes ☒ No ☐ N/A ☐

b. A range of template amounts?

Yes ☒ No ☐ N/A ☐

c. Mixture ratios expected to be interpreted in casework?

Yes ☒ No ☐ N/A ☐

8.3.3 If a laboratory has had a change in platform instrument model or typing test kit (or laboratory assembled equivalent), have internal validation studies been performed? ☐ ☐ ☒

8.3.4 Have internal validation studies been documented and summarized? ☒ ☐ ☐

a. Were internal validation studies reviewed and approved by the laboratory's technical leader prior to implementation? ☒ ☐ ☐

Yes No N/A

8.4 Have newly validated DNA methods (from amplification through characterization), typing test kit, or platform instrument model been checked against an appropriate and available certified reference material (or sample made traceable to the certified reference material) prior to the implementation of the method? ☒ ☐ ☐

8.5 Have modified procedures been evaluated by comparison with the original procedures using similar DNA samples? ☒ ☐ ☐

a. Was the evaluation documented? ☒ ☐ ☐

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| | b. Was the evaluation reviewed and approved by the technical leader prior to the implementation of the modified procedure into casework applications? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8.6 | Were Rapid DNA instruments used for modified Rapid DNA analysis on casework reference samples validated in accordance with Standard 8? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 8.7 | Have NDIS approved Rapid DNA Systems undergone a performance check prior to use on casework reference samples? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

- | | | Yes | No | N/A |
|------------|--|-------------------------------------|--------------------------|--------------------------|
| 8.8 | Is new software or new modules of existing software and modifications to software evaluated to assess the suitability of the software for its intended use in the laboratory and to determine the necessity of validation studies or software testing? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | a. Is the evaluation documented and does it include the determination of which studies will and will not be conducted? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

NOTE: *Standards 8.8.1 through Standards 8.8.2 and all of the substandards may be marked "N/A" if there are no software validations to review since the last external audit.*

- | | | | | |
|----------------|--|--------------------------|--------------------------|-------------------------------------|
| 8.8.1 | Is new software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations subject to developmental validation prior to implementation in forensic DNA analysis? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 8.8.1.1 | With the exception of legally protected information, are the underlying scientific principle(s) utilized by software with an impact on the analytical process, interpretation, or statistical calculations publicly available for review or published in a peer-reviewed scientific journal? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 8.8.1.2 | Do the developmental software validation studies for new software or new modules of existing software used <u>as a component of instrumentation</u> include, at a minimum: | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | a. Functional testing? | | | |
| | | Yes | <input type="checkbox"/> | No <input type="checkbox"/> |

b. Reliability testing?

Yes ☐ No ☐

8.8.1.3 Do the developmental software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data include: ☐ ☐ ☒

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

c. Accuracy studies (as applicable)?

Yes ☐ No ☐ N/A ☒

d. Precision studies (as applicable)?

Yes ☐ No ☐ N/A ☒

e. Sensitivity studies (as applicable)?

Yes ☐ No ☐ N/A ☒

f. Specificity studies (as applicable)?

Yes ☐ No ☐ N/A ☒

8.8.1.4 Do the developmental software validation studies for new software or new modules of existing software for statistical calculations include: ☐ ☐ ☒

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

c. Accuracy studies (as applicable)?

Yes ☐ No ☐ N/A ☒

d. Precision studies (as applicable)?

Yes ☐ No ☐ N/A ☒

8.8.2 Is new software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for

Yes	No	N/A
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

statistical calculations subject to internal validation
specific to the laboratory's intended use prior to
implementation in forensic DNA analysis?

8.8.2.1 Do the internal software validation studies for new software or new modules of existing software used as a component of instrumentation include: ☐ ☐ ☒

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

8.8.2.2 Do the internal software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data include: ☐ ☐ ☒

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

c. Precision and accuracy studies (as applicable)?

Yes ☐ No ☐ N/A ☒

d. Sensitivity studies (as applicable)

Yes ☐ No ☐ N/A ☒

e. Specificity studies (as applicable)?

Yes ☐ No ☐ N/A ☒

8.8.2.3 Do the internal software validation studies for new software or new modules of existing software for statistical calculations include: ☐ ☐ ☒

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

c. Precision and accuracy studies (as applicable)?

Yes ☐ No ☐ N/A ☒

8.8.2.4 Does software that does not impact the analytical process, interpretation, or statistical ☐ ☐ ☒

calculations undergo, at a minimum, a functional test?

	Yes	No	N/A
NOTE: Standards 8.8.3 and all of the substandards may be marked "N/A" if there are no modifications to software since the last external audit.			
8.8.3 Are any modifications to software as described in Standards 8.8.1 and 8.8.2 evaluated to determine if the modifications result in major or minor revisions to the software?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.8.3.1 Are any major revisions to software used <u>as a component of instrumentation</u> validated prior to implementation, to include:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
a. Functional testing?			
Yes <input type="checkbox"/> No <input type="checkbox"/>			
b. Reliability testing?			
Yes <input type="checkbox"/> No <input type="checkbox"/>			
c. Regression testing?			
Yes <input type="checkbox"/> No <input type="checkbox"/>			
8.8.3.2 Are any major revisions to software used <u>for the analysis and/or interpretation of DNA data</u> validated prior to implementation, to include:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. Functional testing?			
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			
b. Reliability testing?			
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			
c. Regression testing?			
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			
d. Precision and accuracy studies (as applicable)?			
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>			
e. Sensitivity studies (as applicable)?			
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>			
f. Specificity studies (as applicable)?			
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>			

8.8.3.3 Are any major revisions to software used for statistical calculations validated prior to implementation, to include: ☒ ☐ ☐

a. Functional testing?

Yes ☒ No ☐

b. Reliability testing?

Yes ☒ No ☐

c. Regression testing?

Yes ☒ No ☐

d. Precision and accuracy studies (as applicable)?

Yes ☒ No ☐ N/A ☐

8.8.3.4 Do any minor revisions to software that does not impact the analytical process, interpretation, or statistical calculations undergo, at a minimum, a functional test? ☒ ☐ ☐

8.8.4 For multi-laboratory systems:

- a. Are the summaries of shared software validation and software testing data available at each site?
b. Has each laboratory in a multi-laboratory system completed, documented, and maintained applicable site-specific reliability testing?

Yes No N/A

☐ ☐ ☒

☐ ☐ ☒

☐ ☐ ☒

8.8.5 Is all software validation and testing documented and reviewed and approved by the technical leader prior to implementation?

☒ ☐ ☐

Yes No N/A

8.9 Are developmental validation studies, internal validation studies, modified procedure evaluations, and software testing, including the documented approval of the technical leader, available for review?

☒ ☐ ☐

Comment

See attached document for comments.

Standard 9. Analytical Procedures

	Yes	No	N/A
9.1 Does the laboratory have and follow written analytical procedures supported by the internal validations and approved by the technical leader?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

NOTE: To successfully satisfy Standard 9.1, the laboratory must demonstrate compliance with all of the substandards of Standard 9.1.

9.1.1 Does the laboratory have and follow a documented standard operating procedure for each analytical method used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
a. Do the analytical procedures include the appropriate analytical controls required for DNA analysis and data interpretation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

	Yes	No	N/A
9.2 Does the laboratory use reagents that are suitable for the methods employed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

NOTE: To successfully satisfy Standard 9.2, the laboratory must demonstrate compliance with all of the substandards of Standard 9.2.

9.2.1 Does the laboratory have written procedures for documenting commercial reagents and for the formulation of in-house reagents?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
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9.2.2 Are commercial reagents labeled with:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. The identity of the reagent?			
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			
b. The expiration date as provided by the manufacturer or as determined by the laboratory?			
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			

9.2.3 Are in-house reagents labeled with:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. The identity of the reagent?			
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			
b. The date of the preparation and/or expiration?			
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			
c. The identity of the individual preparing the reagent?			
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			

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		Yes	No	N/A
9.3	Does the laboratory identify critical reagents and evaluate them prior to use in casework?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
9.3.1	Has the laboratory identified and evaluated the following:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. Test kits (or systems) for performing quantification?			
	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>			
	b. Test kits (or systems) for performing amplification?			
	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>			
9.3.2	If not tested as test kit components under Standard 9.3.1, has the laboratory identified and evaluated the following:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	a. Thermostable DNA polymerase?			
	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>			
	b. Primer sets?			
	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>			
	c. Allelic ladders used for genetic analysis?			
	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>			
9.3.3	Has the laboratory identified and evaluated Rapid DNA cartridges?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.3.4	Has the laboratory identified and evaluated other laboratory defined critical reagents?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Yes	No	N/A
9.4	Except as provided in Standard 9.4.1, does the laboratory quantify or otherwise calculate the amount of human DNA in forensic samples prior to nuclear DNA amplification?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.4.1	If quantification of human DNA for casework reference samples is not performed, does the laboratory have a validated system demonstrated to reliably yield successful DNA amplification and typing without prior quantification?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.5	With all analytical procedures except Rapid DNA instruments/Systems used to analyze casework reference samples pursuant to Standards 9.7 and 9.8, does the laboratory monitor the analytical procedures using appropriate controls and standards?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

NOTE: *The use of Rapid DNA instruments/Systems to analyze casework reference samples is pursuant to Standards 9.7 and/or 9.8.*

- 9.5.1** Are reagent blank controls associated with each extraction set being analyzed as follows: ☒ ☐
- 9.5.1.1** Extracted concurrently and treated with the most sensitive conditions as the samples? ☒ ☐
- 9.5.1.2** Are the reagent blanks amplified using: ☒ ☐
- a. The same typing test kit as the sample(s)?
Yes ☒ No ☐
- b. The same instrument model as the sample(s)?
Yes ☒ No ☐
- c. The same sensitivity conditions as required by the sample(s) containing the least amount of DNA?
Yes ☒ No ☐
- 9.5.1.3** Are the reagent blanks typed using: ☒ ☐
- a. The same instrument model as the sample(s)?
Yes ☒ No ☐
- b. The same injection conditions as the sample(s)?
Yes ☒ No ☐
- c. The most sensitive volume conditions of the extraction set?
Yes ☒ No ☐
- 9.5.2** When quantification is used, are standards used? ☒ ☐ ☐
- a. If a virtual or external standard curve is utilized, is a calibrator run concurrently with the samples? ☒ ☐ ☐
- 9.5.3** Are the positive and negative amplification controls associated with the samples being typed amplified concurrently using the same typing test kit and on the same instrument as the samples? ☒ ☐
- 9.5.3.1** Except as provided in 9.5.4.1, are the positive and negative amplification controls associated with the samples typed? ☒ ☐
- 9.5.4** For laboratories performing sequencing, are positive and negative sequencing controls concurrently sequenced using the same typing test kit on the same instrument as the samples? ☐ ☐ ☒

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9.5.4.1	If the positive amplification control is not used as the positive sequencing control, does the laboratory have and follow procedures for the evaluation of the positive amplification control?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.5.5	Are allelic ladders and internal size standards used for PCR-based systems?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Yes	No	N/A
9.6	Does the laboratory have and follow written guidelines for the interpretation of data that are based on and supported by internal validation studies? Does the laboratory:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
9.6.1	Have criteria to evaluate quantification standards, internal size standards, allelic ladders, and analytical controls?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
9.6.2	Have criteria for the interpretation of non-allelic peaks/signal?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.6.3	Have criteria for the interpretation of allelic peaks/signal?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.6.4	Define the thresholds used for interpretation? As appropriate to the interpretation model utilized, does the laboratory establish the following thresholds:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	9.6.4.1 Analytical Threshold?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	9.6.4.2 Stochastic Threshold?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.6.5	Define criteria for uninterpretable data?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
9.6.6	Have and follow procedures for mixture interpretation to include the following:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. Assessment of the number of contributors?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. Separation of contributors (e.g. major versus minor)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	c. Criteria for deducing potential contributors?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Yes	No	N/A
9.7	For modified Rapid DNA analysis, does the laboratory:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.7.1	Have and follow written guidelines for the manual interpretation of data?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	9.7.1.1 Does the laboratory verify that the internal size standard and allelic ladder results meet the laboratory's interpretation guidelines?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.7.2	Have and follow procedures to address the use of positive sample controls and negative sample controls?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.8	For Rapid DNA analysis, does the laboratory have and follow procedures to address the use of positive sample	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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controls and negative sample controls?

9.8.1 Does the Rapid DNA cartridge include an internal size standard with each sample? ☐ ☐ ☒

Yes No N/A

9.9 Does the laboratory define criteria for the formulation of inclusionary, exclusionary, and inconclusive conclusions? ☒ ☐

9.10 Does the laboratory have and follow procedures for statistical calculations and the reporting of results and conclusions that address the following: ☒ ☐

9.10.1 The assumptions that can be made when formulating conclusions? ☒ ☐

9.10.2 Performing statistical analysis in support of any inclusion that is determined to be relevant in the context of the case? ☒ ☐

9.10.3 Documenting of the genetic loci and assumptions used for statistical calculations, at a minimum, in the case notes? ☒ ☐

9.10.4 Not using uninterpretable data in statistical calculations? ☒ ☐

9.10.5 The approaches to performing statistical calculations? ☒ ☐

9.10.5.1 For autosomal STR typing, does the procedure address: ☒ ☐ ☐

a. Homozygous and heterozygous typing results?
Yes ☒ No ☐

b. Multiple locus profiles?
Yes ☒ No ☐

c. Mixtures?
Yes ☒ No ☐

d. Minimum allele frequencies?
Yes ☒ No ☐

e. Where appropriate, biological relationships?
Yes ☒ No ☐ N/A ☐

9.10.5.2 For lineage marker testing, does the procedure address parameters specific for the applicable lineage marker statistical calculations? ☒ ☐ ☐

9.10.5.3 Does the laboratory use loci that are shown to be in Hardy-Weinberg equilibrium and ☒ ☐ ☐

	statistically unlinked, when using the product rule for statistical calculations?			
9.10.6	The source of the population database(s) used in any statistical calculations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
9.10.7	The criteria for source attribution declarations, when applicable?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		Yes	No	N/A
9.11	Does the laboratory have and follow a procedure to address the reinterpretation of legacy data?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
9.12	Does the laboratory have and follow a procedure for the detection and control of contamination?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
9.12.1	Does the laboratory have and follow procedures for cleaning and decontaminating facilities and equipment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Comment

See attached document for comments.

Standard 10. Equipment Calibration and Maintenance

		Yes	No	N/A
10.1	Does the laboratory use equipment that is suitable for the methods employed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
NOTE: To successfully satisfy Standard 10.1, the laboratory must demonstrate compliance with all of the substandards of Standard 10.				
10.2	Does the laboratory identify critical equipment or instruments and have and follow a program to ensure they are maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
10.2.1	At a minimum, are the following identified as critical:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
10.2.1.1	Handheld mechanical pipettes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.1.2	A thermometer traceable to national or international standard(s)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.1.3	Incubator/Heat block, used in analytical procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.1.4	Robotic systems?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.1.5	Thermal cycler, including quantitative-PCR?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.1.6	Thermal cycler temperature verification system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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10.2.1.7	Electrophoresis detection systems, including Genetic Analyzers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.1.8	Rapid DNA instruments/Systems?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10.2.1.9	Any additional instruments or equipment that produce DNA typing results?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		Yes	No	N/A
10.3	Does the laboratory have procedures for conducting performance checks and evaluating results of critical equipment or instruments?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
10.3.1	Does the laboratory performance check new critical equipment or instruments, not requiring validation, before use in casework analysis?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. Does the laboratory performance check each additional critical instrument, of the same instrument model validated for use in the laboratory, prior to use in casework analysis?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NOTE:	<i>Equipment or instruments that require validation will be assessed under Standard 8.</i>			
10.3.2	Are the following critical equipment or instruments performance-checked at least annually:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
10.3.2.1	Handheld mechanical pipettes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.3.2.2	Incubator/Heat block, used in analytical procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.3.2.3	Robotic systems?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.3.2.4	Thermal cycler, including quantitative-PCR?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.3.2.5	Thermal cycler temperature verification system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.3.2.6	Electrophoresis detection systems, including Genetic Analyzers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.3.2.7	Any additional instruments or equipment that produce DNA typing results?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10.3.2.8	Other critical equipment or instruments defined by the laboratory as needing annual performance check?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10.3.3	Are the following critical equipment or instruments performance-checked after repair or service:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
10.3.3.1	Robotic systems?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10.3.3.2	Thermal cycler, including quantitative-PCR?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.3.3.3	Electrophoresis detection systems, including Genetic Analyzers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.3.3.4	Rapid DNA instruments/Systems?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10.3.3.5	Any additional instruments or equipment that produce DNA typing results?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10.3.3.6	Other critical equipment or instruments defined by the laboratory as needing performance check after repair or service?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10.3.4	Are Rapid DNA instruments/Systems performance-checked upon installation?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10.3.5	Are Rapid DNA instruments/Systems performance-checked if the Rapid DNA instrument remains idle longer than the period recommended in the instrument specifications or as established by the laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		Yes	No	N/A
10.4	Does the laboratory maintain documentation of maintenance, service, repair, and performance checks?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Comment

See attached document for comments.

Standard 11. Reports

		Yes	No	N/A
11.1	Does the laboratory have and follow written procedures for taking and maintaining casework notes to support the conclusions drawn in laboratory reports?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
a.	Does the laboratory maintain all analytical documentation generated by technicians and/or analysts related to case analyses?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
b.	Does the laboratory retain, in written, printed, or electronic format, sufficient documentation for each technical analysis to support the report conclusions such that another qualified individual can evaluate what was done and interpret the data?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

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	Yes	No	N/A
11.2 Do casework reports include the following elements:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.2.1 Case identifier?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.2.2 Description of evidence examined and identification of samples tested?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.2.3 Technology used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.2.4 Loci, sequence region, or amplification system(s)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.2.5 Results and/or conclusions for each forensic sample tested?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.2.6 A quantitative or qualitative interpretative statement to support all inclusions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.2.7 Date of the report?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.2.8 Disposition of evidence?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.2.9 Signature and title, or equivalent identification, of the person accepting responsibility for the content of the report?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

	Yes	No	N/A
11.3 Does the laboratory maintain the confidentiality of reports, case files, DNA records, and databases, except as otherwise provided by applicable state or federal law?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
NOTE: <i>To successfully satisfy Standard 11.3, the laboratory must demonstrate compliance with all of the substandards of Standard 11.3.</i>			
11.3.1 Does the laboratory have and follow policies and/or procedures to ensure the privacy of reports, case files, DNA records, and databases?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.3.2 Does the laboratory have and follow policies and/or procedures for the release of reports, case files, DNA records, and databases in accordance with applicable state or federal law?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.3.3 Does the laboratory have and follow policies and/or procedures for the release of personally identifiable information in accordance with applicable state and federal law?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Comment

See attached document for comments.

Standard 12. Review

		Yes	No	N/A
12.1	Does the laboratory have and follow a procedure to conduct and document technical and administrative reviews of all case files and reports to ensure that conclusions and supporting data are reasonable and within the constraints of scientific knowledge?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.1.1	Are all technical reviews conducted by an analyst or technical reviewer that is qualified in the method, technology, typing test kit, platform, and interpretation software being reviewed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
		Yes	No	N/A
12.2	Does the laboratory document the completion of the technical review of forensic casework, and does it include the following elements:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.2.1	A review of all case notes, all worksheets, and the electronic data (or printouts of such data) supporting the results and/or conclusions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.2.2	A review of all analytical controls, internal size standards, and allelic ladders to verify that the expected results were obtained, except when using an NDIS approved Rapid DNA System on casework reference samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.2.3	A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images), except when using an NDIS approved Rapid DNA System on casework reference samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.2.4	A review of all data to verify conclusions (i.e., inclusions, exclusions, inconclusive) are in compliance with laboratory guidelines?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.2.5	A review of statistical analysis, if applicable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.2.6	A review of the final report's content to verify compliance with Standard 11.2 and that the results and/or conclusions are supported by the data?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.2.7	Verification that all profiles entered into CODIS are eligible, have the correct DNA types, and correct specimen category?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<p>12.2.7.1 Prior to upload to SDIS, entry of a DNA profile into a searchable category of SDIS, or search of SDIS, were the following criteria verified by two concordant assessments by a qualified analyst or technical reviewer:</p> <p>a. Eligibility for CODIS? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p>b. Correct DNA types? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p>c. Appropriate specimen category? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Yes No N/A	
<p>12.3 Does the laboratory document the completion of the administrative review and does it include the following elements, any or all of which may be included within the technical review process:</p> <p>12.3.1 A review of the case file and final report for clerical accuracy and compliance with Standard 11.2?</p> <p>12.3.2 A review of the chain of custody and disposition of evidence?</p>	<p><input checked="" type="checkbox"/> <input type="checkbox"/></p> <p><input checked="" type="checkbox"/> <input type="checkbox"/></p> <p><input checked="" type="checkbox"/> <input type="checkbox"/></p>
Yes No N/A	
<p>12.4 Does the laboratory have and follow policy and/or procedure to address unresolved discrepant conclusions between analysts and reviewer(s)?</p>	<p><input checked="" type="checkbox"/> <input type="checkbox"/></p>
<p>NOTE: Standard 12.5 shall be marked "N/A" for non-NDIS participating laboratories.</p>	
<p>12.5 Does the laboratory have and follow a documented procedure for the verification and resolution of database matches?</p>	<p><input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>

Comment
See attached document for comments.

Standard 13. Proficiency Testing

<p>13.1 Do analysts, technical reviewers, technicians, and other personnel designated by the technical leader undergo semi-annual external proficiency testing?</p>	<p><input checked="" type="checkbox"/> <input type="checkbox"/></p>
Yes No N/A	

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- | | | | | |
|-----------------|---|-------------------------------------|--------------------------|-------------------------------------|
| 13.1.1 | Are analysts proficiency tested in each technology at least once per calendar year? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 13.1.1.1 | Has the typing of all CODIS core loci or CODIS core sequence ranges been attempted for each technology performed at least once per calendar year? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 13.1.2 | Are analysts proficiency tested in each typing test kit at least once per calendar year? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 13.1.2.1 | Are analysts that are qualified to perform modified Rapid DNA analysis externally proficiency tested on the interpretation of data generated by each Rapid DNA instrument model for each PCR STR typing test kit at least once per calendar year? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 13.1.3 | Are individuals that perform analytical procedures on forensic samples or casework reference samples proficiency tested on at least one method in each methodology at least once per calendar year? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 13.1.4 | Except as provided in Standard 13.1.4.1, is each external proficiency test assigned to and completed by one analyst? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 13.1.4.1 | If technicians and/or a team approach is used for casework examinations, has each analyst been assigned a proficiency test to complete the interpretation and report the results? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| NOTE: | <i>Standard 13.1.5 and the substandards may be marked "N/A" for a laboratory that does not have individuals that solely conduct technical reviews.</i> | | | |
| 13.1.5 | Are individuals whose sole responsibility is technical review proficiency tested in the technical review of each technology and typing test kit at least once per calendar year? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13.1.5.1 | Does the proficiency testing cover the CODIS core loci or CODIS core sequence ranges attempted for each technology at least once per calendar year? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13.1.5.2 | Are technical reviewers qualified to review modified Rapid DNA analysis externally proficiency tested on the technical review of data generated by a Rapid DNA instrument model for each PCR STR typing test kit at least once per year? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

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13.1.5.3	If the technical reviewer is a contract employee conducting technical review for an NDIS participating laboratory, is the proficiency testing administered by an NDIS participating laboratory and reviewed and approved by the technical leader of the NDIS participating laboratory for which the technical reviewer is conducting reviews?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
13.1.6	Have newly qualified individuals undergone semi-annual external proficiency testing within eight months of the date of their authorization?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Yes	No	N/A
13.2	Does the laboratory use an external proficiency test provider that is accredited to the current applicable standard of the International Organization for Standardization and is the applicable test included on the proficiency test provider's scope of accreditation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	a. Is the external proficiency testing an open proficiency testing program and is it submitted to the proficiency testing provider in order to be included in the provider's published external summary report?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
13.3	For purposes of tracking compliance with the proficiency testing requirements, does the laboratory define and consistently use the date that the proficiency test is performed as the received date, assigned date, submitted date, or the due date?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
		Yes	No	N/A
13.4	Are the following records maintained by the laboratory for proficiency tests:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.4.1 The test set identifier?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.4.2 Identity of the analyst, and other participants, if applicable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.4.3 Date of analysis and completion?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.4.4 Copies of all data and notes supporting the conclusions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.4.5 The proficiency test results?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.4.6 Any discrepancies noted?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.4.7 Corrective actions taken?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

		Yes	No	N/A
13.5	Does the laboratory evaluate proficiency test results? At a minimum, are the following criteria included in the evaluation of proficiency test results:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.5.1 Are all reported genotypes, phenotypes, and/or sequences correct or incorrect according to consensus results or are compliant with the laboratory's interpretation guidelines?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.5.2 Are inclusions and exclusions correct or incorrect?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.5.3 Are all reported uninterpretable results and/or inconclusive conclusions compliant with written laboratory guidelines?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.5.3.1 Has the technical leader reviewed any inconclusive conclusion for compliance with laboratory guidelines?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	13.5.4 Have all final reports been graded as satisfactory or unsatisfactory?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.5.4.1 Have all discrepancies/errors and subsequent corrective actions, as applicable, been documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		Yes	No	N/A
13.6	Have the following been informed of the results of the proficiency test:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.6.1 The proficiency test participant(s)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.6.2 The technical leader?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	13.6.3 The casework CODIS administrator in the event of non-administrative discrepancies that affect the typing results and/or conclusions?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Comment

See attached document for comments.

Standard 14. Corrective Action

		Yes	No	N/A
14.1	Does the laboratory have and follow a policy and/or procedure to address nonconformities detected in	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

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	casework analysis, proficiency tests, testimony, and audits?			
	a. Does the laboratory policy and/or procedure define when a nonconformity requires documentation and/or a corrective action plan?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
14.1.1	Are corrective action plans documented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Yes	No	N/A
14.2	Does the laboratory's documented corrective action plan include the following:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. The identification (when possible) of the cause(s) of the nonconformity?			
	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>			
	b. The corrective actions taken with time frames (where applicable)?			
	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>			
	c. Preventative measures taken (where applicable) to minimize its reoccurrence?			
	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>			
14.2.1	Are corrective action plans approved by the technical leader prior to implementation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.2.2	Is the casework CODIS administrator notified when the nonconformity impacts DNA records entered into CODIS?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Comment

See attached document for comments.

Standard 15. Audits

		Yes	No	N/A
15.1	Has the laboratory been audited annually in accordance with the Quality Assurance Standards for Forensic DNA Testing Laboratories?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. Have the annual audits occurred every calendar year at least six months and no more than 18 months apart?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.2	Has an external audit been conducted at least once every two years?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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a. Was the external audit conducted by one or more auditor(s) who has successfully completed the FBI's DNA auditor training course from a second agency(ies)? ☒ ☐ ☐

b. Was at least one auditor a current or former analyst previously qualified in the laboratory's current DNA technologies and platforms? ☒ ☐ ☐

NOTE: Auditor(s) and their applicable qualifications will be documented in Appendix C.

15.2.1 Has the laboratory maintained audit documentation of those analysts, technical reviewers, casework CODIS administrator(s), and technical leader(s) that have had their education, experience, and training qualifications evaluated and approved during two successive, separate external audits? ☒ ☐ ☐

NOTE: Approval of an individual's education, experience, and training qualifications shall be documented in Appendix D.

15.2.1.1 As of July 1, 2020, has the laboratory maintained audit documentation of those individuals that have had their additional qualification in an additional technology(ies), typing test kit(s), or platform(s) evaluated and approved during one external audit? ☒ ☐ ☐

15.2.2 Has the laboratory maintained the audit documentation for validation studies previously evaluated and approved during one external audit? ☒ ☐ ☐

NOTE: Approved validation studies shall be documented in Appendix E.

15.3 For internal audits, was the internal audit conducted by an audit team with at least one auditor(s) who has successfully completed the FBI's DNA auditor training course? ☒ ☐ ☐

a. Was at least one audit team member a current or former analyst previously qualified in the laboratory's current DNA technologies and platforms? ☒ ☐ ☐

NOTE: Auditor team member(s) and their applicable qualifications will be documented in Appendix C.

	Yes	No	N/A
15.4 Have the internal and/or external audits performed pursuant to Standard 15.1 been conducted using the FBI DNA Quality Assurance Standards Audit Document in effect at that time?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

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- | | | | | |
|---------------|---|-------------------------------------|--------------------------|--------------------------|
| 15.5 | Have internal and external DNA audit documentation and, if applicable, corrective action(s) been reviewed by the technical leader to ensure that findings, if any, were appropriately addressed and has the review been documented? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15.5.1 | Have internal and external audit documentation, and if applicable, corrective action(s) been provided to the casework CODIS administrator? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15.5.2 | For NDIS participating laboratories, did the laboratory provide all external audit documentation and laboratory responses to the FBI within 30 days of the laboratory's receipt of the audit document or report? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15.6 | Are previous internal and external audit documents retained and available for inspection during subsequent audits? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comments

See attached document for comments.

Standard 16. Professional Development

- | | | Yes | No | N/A |
|---------------|---|-------------------------------------|--------------------------|-----|
| 16.1 | Does the laboratory have and follow a documented program to ensure that technical qualifications are maintained through participation in continuing education? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 16.1.1 | Does the technical leader, casework CODIS administrator, and each analyst and technical reviewer stay abreast of topics relevant to the field of forensic DNA analysis by having documented attendance at seminars, courses, professional meetings, or documented lectures or classes in relevant subject areas for a minimum of eight cumulative hours each calendar year? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| | 16.1.1.1 Have continuing education hours been documented? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| NOTE: | <i>Attendance at regional, national, or international, conferences with content including topics relevant to the field of forensic DNA analysis shall be deemed to provide a minimum of eight hours of continuing education.</i> | | | |

	16.1.1.2 Has the laboratory maintained documentation of attendance through a mechanism such as certificates, attendance lists, or travel documentation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	16.1.1.3 With the exception of a regional, national, or international conference, has the laboratory maintained documentation of content through a mechanism such as agenda/syllabus, record of presentation content, or curriculum vitae of the presenter?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16.1.1.4 Has continuing education based on multimedia or internet delivery received approval of the technical leader?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.1.2	Does the laboratory have and follow a program approved by the technical leader for the annual review of scientific literature that documents the analysts' ongoing reading of scientific literature?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	16.1.2.1 Does the laboratory maintain or have physical or electronic access to a collection of current books, reviewed journals, or other literature applicable to DNA analysis?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
		Yes	No	N/A
16.2	Does the laboratory have and follow a program that documents the annual review of the testimony of each analyst?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
16.2.1	Does this program define elements and mechanisms for testimony review?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
16.2.2	Is the testimony review documented and provided to the testifying individual?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16.2.2.1 Are any deficiencies and subsequent corrective actions, as applicable, documented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment

See attached document for comments.

STANDARD 17. Outsourcing Ownership

		Yes	No	N/A
17.1	Has the vendor laboratory complied with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories and the accreditation requirements of federal law?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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NOTE: For a vendor laboratory, Standards 17.1.1, 17.2, 17.2.2, and Standards 17.3 and 17.4 and their substandards shall be marked "N/A."

NOTE: For an NDIS participating laboratory, if a contract for outsourcing is in place or outsourcing is occurring without a contractual agreement, Standard 17 must be assessed even if no samples were outsourced.

NOTE: For an NDIS participating laboratory, Standard 17 may be marked "N/A" if the NDIS participating laboratory has not outsourced any DNA-related services for the purposes of taking ownership in the scope of the audit.

- | | | | | |
|---------------|---|--------------------------|--------------------------|-------------------------------------|
| 17.1.1 | Has the NDIS participating laboratory that outsources to a vendor laboratory acquired the following documentation from the vendor laboratory, and has this documentation been reviewed by the NDIS participating laboratory's technical leader for:
a. Compliance with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories?
Yes <input type="checkbox"/> No <input type="checkbox"/>
b. Compliance with the accreditation requirements of federal law?
Yes <input type="checkbox"/> No <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 17.2 | Except as provided in Standard 17.2.1 and 17.2.2, since the laboratory's last external audit, did the NDIS participating laboratory's technical leader approve the technical specifications of the outsourcing agreement before it was awarded? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 17.2.1 | For a vendor laboratory that is performing forensic DNA analysis on behalf of a law enforcement agency or other entity for the purposes of ownership by an NDIS participating laboratory, was documented approval obtained by the vendor laboratory from the appropriate NDIS participating laboratory's technical leader prior to the initiation of analysis? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 17.2.2 | For the rare instances where the NDIS participating laboratory is requested to take ownership and no outsourcing agreement exists between either the law enforcement agency, the vendor laboratory or that NDIS participating laboratory, prior to acceptance of ownership of product(s) of forensic DNA analyses from the vendor laboratory has the following been documented by the requested NDIS participating laboratory's technical leader: | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

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	17.2.2.1 Approval of the casework CODIS administrator and written permission from the NDIS Custodian for any scenario that involves CODIS entry or searching?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	17.2.2.2 Approval of the technical specifications of testing?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	17.2.2.3 Review of the documentation of an on-site visit that has occurred within 18 months of the conducted analysis or conduct an on-site visit of the vendor laboratory within 18 months of the conducted analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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17.3.3.1	A review of all DNA types of which the NDIS participating laboratory will take ownership to verify that they are supported by the raw and/or analyzed data (electropherograms or images)?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
17.3.3.2	A review of all associated analytical controls, internal size standards and allelic ladders to verify that the expected results were obtained?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
17.3.3.3	A review of the final report (if provided) to verify that the results/conclusions are supported by the data?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
17.3.3.4	For samples to be entered into CODIS, verification of the DNA types, eligibility, and the correct specimen category?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
17.3.3.4.1	Is verification of eligibility performed by a current CODIS user?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
17.3.4	For an NDIS participating laboratory that outsources to a vendor laboratory performing Rapid DNA analysis on casework reference samples using an NDIS approved Rapid DNA System, does the ownership review for data generated by the Rapid DNA System include:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
17.3.4.1	A review of the final report (if provided) to verify that the results/conclusions are supported by the Rapid DNA System data?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
17.3.4.2	For samples to be entered into CODIS, verification of the eligibility and the correct specimen category?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
17.3.4.2.1	Is verification of eligibility performed by a current CODIS user?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
17.3.4.3	A review of the data associated with applicable Rapid DNA System performance checks?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		Yes	No	N/A
17.4	Does the NDIS participating laboratory or multi-laboratory system outsourcing DNA sample(s) to a vendor laboratory or accepting ownership of DNA data from a vendor laboratory have and follow a procedure to perform an on-site visit(s) of the vendor laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NOTE:	<i>An on-site visit is not required when only technical review services are being provided.</i> Does the procedure to perform an on-site visit include, at a minimum:			

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- | | | | | |
|-----------------|--|--------------------------|--------------------------|-------------------------------------|
| 17.4.1 | A documented initial on-site visit, to assess the vendor laboratory's ability to perform analysis on outsourced casework, prior to the vendor laboratory's beginning of casework analysis for the NDIS laboratory? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 17.4.1.1 | Has the on-site visit been performed by the technical leader or designated employee of an NDIS participating laboratory who is a qualified or previously qualified analyst in the technology, platform and typing test kit used to generate the DNA data or has an on-site visit coordinated by a designated FBI employee been evaluated and approved by the NDIS participating laboratory's technical leader? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 17.4.2 | An annual on-site visit if the NDIS participating laboratory's outsourcing agreement extends beyond one year? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| a. | Did an annual on-site visit occur every calendar year, with each visit at least six months but no more than 18 months apart? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 17.4.2.1 | If an on-site visit conducted by another NDIS participating laboratory using the same technology, platform and typing test kit used to generate the DNA data or coordinated by a designated FBI employee was accepted, did the technical leader of the NDIS participating laboratory document the review and approval of that on-site visit? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

Comments

See attached document for comments.

Appendix A: Findings and Responses

To be completed by the audit team (Findings) and laboratory (Responses).

Auditors shall reference any standard found to be in non-compliance in the Findings below. Following the standard, a detailed description of the non-compliance shall be provided.

Comments and/or recommendations shall **not** be included in Appendix A.

Additional pages may be attached, as needed.

Findings:

No Findings

Responses:

Appendix B: Contingency Plan Notification Form

To be completed by the NDIS participating laboratory in the event of:

1. A vacancy in the technical leader position when there is no qualified individual available to serve as the technical leader.
2. The number of qualified analysts falls below two full-time employees who are qualified analysts.

This form shall be used to document various actions relating to the laboratory's contingency plan. In accordance with the FBI Quality Assurance Standards and the NDIS Operational Procedures Manual, the FBI's NDIS Custodian shall be notified of such vacancy within 5 days and provided with the laboratory's contingency plan within 14 days of the vacancy.

Date technical leader position vacated or number of qualified analysts fell below two full-time employees:	
Date NDIS Custodian and, if applicable, State CODIS Administrator Notified: (must be within 5 days of the vacancy)	
Date contingency plan submitted to the FBI: (must be within 14 days of the vacancy)	
Date FBI approval received:	

Contingency plan attached:

FBI conditions for approval attached, if applicable:

Date new casework/database analysis initiated:

Laboratory:

Signed by: _____
(Name and Signature of Person Completing Form)

Date: _____

Appendix C – Audit Team Self-Verification for QAS Audits

To be completed by each auditor/audit team member who will be conducting a QAS audit and/or completing the QAS Audit Document.

For external audits, return to the laboratory prior to the scheduled audit date.

For internal audits, maintain in the laboratory's files.

Name: Anna J.B. Wilson

Employer: Washington State Patrol Crime Laboratory

Title or Position: Supervising Forensic Scientist (FS5)

Qualifications:

A. Completed FBI DNA Auditor Course: ☒ Yes ☐ No

If yes: (*Required for all external auditors*)

Year (If multiple, list at least the most recent.): 2020

B. Current or Previously Qualified DNA Analyst: ☒ Yes ☐ No

If yes:

1. Was the qualification as a Casework and/or Database Analyst? Enter the qualifying laboratory(ies).

(If multiple, list at least the most recent for each applicable category.)

☒ Casework: Washington State Patrol Crime Laboratory

☐ Database:

2. Technologies Currently or Previously Qualified In (e.g., STR, mtDNA):
STR, Y-STR

3. Platforms Currently or Previously Qualified In (e.g., Gel based, CE):
CE

I verify that:

The information contained above is correct; and

I have read the *Instructions to Audit Team* contained in the applicable Audit Document; and

For External Audits, I understand the requirements of Standard 15.2 and

I have no conflicts of interest with the laboratory being audited.

Signed By Anna Wilson Date 03/20/2024

Appendix C – Audit Team Self-Verification for QAS Audits

To be completed by each auditor/audit team member who will be conducting a QAS audit and/or completing the QAS Audit Document.

For external audits, return to the laboratory prior to the scheduled audit date.

For internal audits, maintain in the laboratory's files.

Name: Allison Heard

Employer: Texas Department of Public Safety

Title or Position: Section Supervisor III

Qualifications:

A. Completed FBI DNA Auditor Course: ☒ Yes ☐ No

If yes: *(Required for all external auditors)*

Year (If multiple, list at least the most recent.): 2020

B. Current or Previously Qualified DNA Analyst: ☒ Yes ☐ No

If yes:

1. Was the qualification as a Casework and/or Database Analyst? Enter the qualifying laboratory(ies).

(If multiple, list at least the most recent for each applicable category.)

☒ Casework: Texas Department of Public Safety-Austin

☐ Database:

2. Technologies Currently or Previously Qualified In (e.g., STR, mtDNA):
STR; YSTR

3. Platforms Currently or Previously Qualified In (e.g., Gel based, CE):
CE

I verify that:

The information contained above is correct; and

I have read the *Instructions to Audit Team* contained in the applicable Audit Document; and

For External Audits, I understand the requirements of Standard 15.2 and

I have no conflicts of interest with the laboratory being audited.

Signed By Allison Heard Date 3/7/24

Appendix D – Personnel Meeting Minimum Education, Experience, and Training Qualifications As Assessed By External Audit

To be completed by the audit team. In accordance with Standards 15.2.1 and 15.2.1.1, this form shall be used to document the evaluation and approval of analysts, technical reviewers, casework CODIS administrators and technical leaders during an external audit. **Such personnel shall be assessed in accordance with the applicable Quality Assurance Standards for Forensic DNA Testing Laboratories (QAS)¹ in effect at the time of their hire/appointment or qualification².** Analysts, technical reviewers, casework CODIS administrators and technical leaders who have previously undergone two successive external audit reviews in his/her current role and those reviews have been captured in the corresponding external audit documents do not need to be continuously captured in Appendix D.

Section 1 is for documenting personnel who are receiving the **first** external audit approval of their education, experience, and the initial training qualifications in this external audit.

Section 2 is for documenting personnel who are receiving the **second successive** external audit approval of their education, experience, and the initial training qualifications in this external audit.

Section 3 is for documenting personnel whose **additional training** in new technologies, typing test kits, and/or platforms is receiving external audit approval in this external audit.

Section 1. The following personnel have been evaluated and approved for the first time as meeting the education, experience, and initial training qualifications required under QAS Standard 5.1:

Analysts/Technical Reviewers ³	Casework CODIS Administrator	Technical Leader
NA	NA	NA

¹ Applicable Quality Assurance Standards for Forensic DNA Testing Laboratories may include those that took effect in 2004, 2009 2011, and 2019.

² As defined by the laboratory in accordance with Standard 4.2.

³ For individuals whose initial training qualification in the laboratory is for Technical Review only (i.e., is not currently or previously qualified as an analyst in the laboratory for which they are performing technical reviews), indicate these individuals as “TR only” in the table.

Section 2. The following personnel have been previously evaluated once in their current role and are receiving the second successive external audit approval of their education, experience, and initial training qualifications required under QAS Standard 5.1:

Analysts/Technical Reviewers ³	Casework CODIS Administrator	Technical Leader
Mike Yakoo	Cathy Chang Alexis Meeker	NA

Section 3. The training of Analyst(s)/Technical Reviewer(s) in additional technologies, typing test kits, platforms, and interpretation software for the following personnel have been evaluated and are receiving external audit approval required under QAS Standards 6.5 through 6.6: [please include the technology, typing test kit, or platform]

Kelly Hensley, YFiler Plus
Monica McCall, YFiler Plus
Kelly Ledbetter, YFiler Plus

Appendix E: Approved Validations

This form may be used to document the evaluation and approval of validations by the external audit team according to **Standard 8**; this documentation to be maintained by the audited laboratory to comply with **Standard 15.2.2**. Modified procedure evaluations and software testing reviewed during the audit will also be listed below.

Validations reviewed during an external audit but not approved in their entirety may be listed in this Appendix with a notation of the study(ies) requiring additional review and approval in order for the validation to be approved.

To be completed by the external audit team:

Were new developmental and/or internal validations evaluated during this audit?

Yes ☒

No ☐

List of validations approved during this audit:

YFiler Plus

List of modified procedure evaluations reviewed during this audit:

VeritPro Thermal Cyclor


List of software testing reviewed during this audit:

STRmix v2.7 (8.8.3.2, 8.8.3.3)

YMix v4.6 (8.8.3.4)

YHRD v69 (8.8.3.4)

CODIS v11 (8.8.3.4)

The FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories-Comments			
FM 3165	Authority: Director of Accreditation	Effective: 2021/06/01	

FORENSIC DNA TESTING LABORATORIES QAS AUDIT for: San Diego County Sheriff Regional Crime Laboratory

Dates of Audit: 8/5/24 to 8/7/24

Instructions:

- All Standards marked “N/A” or “No” should include a comment in the corresponding standards below.
- If the standard does not have any comments, please write, “No Comments.”
- As a reminder- all “No” comments are to be captured in the Appendix A as well.

Standard 3. Quality Assurance Program

No comments

Standard 4. Organization and Management

Standard 4.1.2a was marked N/A because the laboratory is not part of a multi-laboratory system.

Standard 4.1.6a was marked N/A because the technical leader position was not vacated nor did the lab fall below the two full-time analyst requirement. A contingency plan was not needed.

Standard 5. Personnel

Standard 5.2.1.3 was marked N/A because the technical leader’s coursework had the titles stated in 5.2.1.

Standard 5.2.1.4 was marked N/A because the technical leader meets the degree requirements of Standard 5.2.1.

Standard 5.2.2b was marked N/A because the technical leader was appointed before July 1, 2009.

Standard 5.2.3 was marked N/A because the technical leader was appointed before July 1, 2020.

Standard 5.2.6a was marked N/A because the technical leader does not oversee a system of separate laboratories.

Standards 5.2.7, 5.2.7.1, and 5.2.7.2 were marked N/A because a new technical leader has not been appointed since the last external audit.

Standard 5.3.6 was marked N/A because the CODIS administrator position has not been unoccupied since the last external audit.

Standard 5.6 was marked N/A because the laboratory does not use technicians or contract employees.

Standard 6. Training

Standard 6.3.2 was marked N/A because the laboratory does not use technicians.

Standards 6.4, 6.4.1, 6.4.1a, and 6.4.1b were marked N/A because no analysts or technicians were qualified in a new or additional method since the last external audit

Standards 6.6 was marked N/A because the laboratory does not have individuals who solely conduct technical reviews who were not previously qualified in this laboratory.

Standard 6.6.1.1 was marked N/A because the laboratory does not have contract technical reviewers.

Standard 6.7, 6.7.1, and 6.7.1a was marked N/A because all analysts were previously qualified in the interpretation of legacy data to be reviewed.

Standard 7. Facilities and Evidence Control

Standard 7.1.3.1 was marked N/A because the laboratory does not use a Rapid DNA Instrument or System.

Standard 8. Validation

Standards 8.3.1.1a, 8.3.1.1b, and all subcategories were marked N/A because the laboratory is not a multi-laboratory system.

Standard 8.3.3 was marked N/A because the laboratory was not changed platform instrument model or typing test kit since the last external audit.

Standard 8.6 and 8.7 were marked N/A because the laboratory does not use Rapid DNA instruments or systems.

Standard 8.8.1 through 8.8.2 and all substandards were marked N/A because the laboratory has not conducted any developmental or internal software validations since the last external audit.

Standard 8.8.3.1 was marked as N/A because no major revisions to software used as a component of instrumentation were conducted since the last external audit.

Standard 8.8.4, 8.8.4a, and 8.8.4b were marked N/A because the laboratory is not part of a multi-laboratory system.

Standard 9. Analytical Procedures

Standard 9.3.2, 9.3.2a, 9.3.2b, and 9.3.2c were marked N/A because the thermostable DNA polymerase, primer sets, and allelic ladders are tested as kit components under Standard 9.3.1.

Standard 9.3.3 was marked N/A because the laboratory does not use Rapid DNA instruments or Systems.

Standard 9.4.1 was marked N/A because the laboratory performs quantification of casework reference samples.

Standard 9.5.4 and 9.5.4.1 were marked N/A because the laboratory does not perform DNA sequencing.

Standard 9.7, 9.8 and all subcategories were marked N/A because the laboratory does not perform Rapid or Modified Rapid DNA analysis.

Standard 9.10.7 was marked N/A because the laboratory does not make source attribution declarations.

Standard 10. Equipment Calibration and Maintenance

Standard 10.2.1.8, 10.3.3.4, 10.3.4, and 10.3.5 were marked N/A because the laboratory does not use Rapid DNA instruments or Systems.

Standard 10.2.1.9, 10.3.2.7 and 10.3.3.5 were marked N/A because the laboratory does not use other equipment or instruments that produce DNA typing results.

Standard 10.3.2.8 and 10.3.3.6 were marked N/A because the laboratory does not define any other critical equipment or instruments.

Standard 11. Reports

No Comments

Standard 12. Review

No Comments

Standard 13. Proficiency Testing

Standards 13.1.2.1 and 13.1.5.2 were marked N/A because the laboratory does not perform modified Rapid DNA analysis.

Standard 13.1.4.1 was marked N/A because technicians and/or a team approach is not used for casework examinations.

Standard 13.1.5.3 was marked N/A because the technical reviewer is not a contract employee.

Standard 13.5.3.1 was marked N/A because no inconclusive conclusions were reported on the proficiency tests taken since the last external audit.

Standard 13.5.4.1 was marked N/A because no discrepancies or errors were identified in proficiency tests taken since the last external audit.

Standard 13.6.3 was marked N/A because no non-administrative discrepancies were identified that affect the typing results since the last external audit.

Standard 14. Corrective Action

Standard 14.2.2 was marked N/A because no nonconformities were identified that would have impacted DNA records entered into CODIS since the last external audit.

Standard 15. Audits

No comments

Standard 16. Professional Development

No comments

Standard 17. Outsourcing Ownership

Standard 17 and all subcategories were marked N/A because the laboratory has not outsourced any DNA-related services for the purposes of taking ownership in the scope of the audit, has a contract for outsourcing in place, or outsourced without a contractual agreement since the last external audit.