U.S. Department of Justice

Federal Bureau of Investigation

Washington, D. C. 20535-0001

January 26, 2011

Byron Sonnenberg
CODIS Manager
San Diego County Sheriff's Office Crime Laboratory
5255 Mount Etna Drive
San Diego, California 92117-6912

Dear Mr. Sonnenberg:

This is to acknowledge receipt of your DNA Quality Assurance Standards (QAS) Audit Report for the San Diego Sheriff's Office Crime Laboratory, San Diego, California dated November 8 to 10, 2010, for the 2010 external audit. As you are aware, participation in the National DNA Index System (NDIS) requires an external audit bi-yearly. Copies of the audit report will be submitted to an audit committee for review. Upon completion of this review, the committee's copies of the audit documents will be destroyed by the FBI. The original will be returned to you.

For tracking purposes, the audit has been assigned number 2011007. Please refer to this number if you have any inquiries concerning this particular audit document.

Thank you for your assistance in this matter. If you have any questions, please call me at (703) 632-8315.

Sincerely,

Douglas Hares /CT

Douglas R. Hares, PhD
NDIS Custodian
CODIS Unit
Laboratory Division

1 - Mr. Linton von Beroldingen (information only)

Fink, Marilyn

From: Guroff, Steve
Sent: Thursday, December 23, 2010 8:46 AM
To: Fink, Marilyn
Subject: FW: Final DNA Audit Report: CA_SDSO_SanDiego_11_10_DNA-CW
Importance: High
Attachments: CA_SDSO_SanDiego_11_10_DNA-CW_KGE(locked)_FINAL.pdf

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From: Kimberly G. Erturk [mailto:Kimberly.Erturk@nfstc.org]
Sent: Wednesday, December 15, 2010 10:29 AM
To: Guroff, Steve
Cc: Kashtan, Patricia; CSobieralski@isp.in.gov; jeremy.sanderson@wsp.wa.gov; Beverly.Himick@wsp.wa.gov; jpasternak@mt.gov; Stephenie.Winter-Sermeno@wsp.wa.gov
Subject: Final DNA Audit Report: CA_SDSO_SanDiego_11_10_DNA-CW
Importance: High

Please, find attached the final DNA Audit Report(s) for your laboratory(ies). Please, review this material in its entirety. The audit team has carefully reviewed this (these) report(s); however, if we have left a standard un-rated, or if we missed something important, please let me know, and the appropriate corrections will be made.

Laboratory Director:	**Please use the "Reply to All" feature on your email application to confirm to all parties that this (these) report(s) have been received and reviewed.**

The attached document(s) is (are) a secure signed electronic version of your laboratory report(s). Please print a hardcopy for your records and/or copy it (them) to a CD. It is the responsibility of the laboratory to forward the reports directly to the FBI.

DOUGLAS HARES – NDIS CUSTODIAN
FBI LABORATORY
2501 INVESTIGATION PARKWAY
QUANTICO, VA 22135
PHONE: (703) 632-8315

Note: ***Mail received by the FBI is x-rayed and it can take months for them to receive first class mail. I would suggest that you use an overnight carrier to get you report to the NDIS Custodian.***

Audit Team Members:	**Upon receipt of the return email confirming that this (these) laboratory's final report(s) have been received and reviewed, please destroy any hard copy or electronic data you may have pertaining to this audit.**

We remind all auditors of the confidentially agreement that you signed. Should you be contacted by ANYONE about his audit, you must tell them of your confidentiality agreement and refer any questions to the audited laboratory's director.
The only exceptions to the terms of the confidentiality agreement are:

- If you are contacted by a member of the NDIS Board and questioned as to why you rated a standard the way you did or are asked to clarify a finding statement; or
- If you are contacted by a member of the Office of the Inspector General (OIG) and asked to sign a simple statement indicating that you conducted an audit of a laboratory on a particular set of dates and whether you have any conflict of interest with the audited laboratory (OIG employees will not ask you specific questions about the audit itself or the ratings assigned).

If applicable, GPA assessment report(s) are forwarded directly to the NIJ. You will receive a copy of each report and letter from the NIJ within a few weeks.
We appreciate your participation in the NFSTC Assessment Program. Should you have any questions or comments, please feel free to contact us.

Kimberly

nberly G. Erturk
Assessments Specialist
National Forensic Science Technology Center®
Science Serving Justice
www.NFSTC.org

San Diego Sheriff's Department Regional Crime Laboratory

5255 Mt. Etna Drive, San Diego, CA 92117

External DNA Audit
Report on Compliance with the FBI Director's Quality Assurance Standards for Forensic DNA Testing Laboratories

Conducted on November 8-10, 2010

Carl Sobieralski	NFSTC Lead Auditor
Beverly Himick	NFSTC Technical Auditor
Joseph Pasternak	NFSTC Technical Auditor
Stephenie Winter Sermeno	NFSTC Technical Auditor
Jeremy Sanderson	NFSTC Technical Auditor

NIJ

This audit was performed under Cooperative Agreement #2007–MU–BX–K008
with the
National Institute of Justice
and the
National Forensic Science Technology Center

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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, 2009

An Audit of: San Diego Sheriff's Department Regional Crime Laboratory

Dates of Audit: November 8-10, 2010

Auditor(s):

Carl Sobieralski	
(Name)	(Signature)
Beverly Himick	
(Name)	(Signature)
Joseph Pasternak	
(Name)	(Signature)
Stephenie Winter Sermeno	
(Name)	(Signature)
Jeremy Sanderson	
(Name)	(Signature)

Last Updated: July, 21, 2010

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Checklist of General Laboratory Information

1. Name of Laboratory: San Diego Sheriff's Department Regional Crime Laboratory

☐ ☐ ☐ ☑ ☐ ☐

2. Federal / State / Regional / County / Local / Other: county
   Laboratory (Choose one)

3. Approximate Population Size Served: 1,500,000

4. Uses a Contract Laboratory: Yes ☐ No ☑
   Name of Contract Laboratory(ies): _____

5. NDIS Participant: Yes ☑ No ☐

6. Applying for NDIS Participation: Yes ☐ No ☐ NA ☑ (Choose one)

7. Technologies Used: (Choose those that apply)
   - ☑ STRs
   - ☐ YSTRs
   - ☐ MtDNA
   - ☐ Other: _____

8. Number of staff:
   DNA analysts: 18
   DNA trainees: 0
   DNA technicians: 0
   Laboratory support personnel: 1
   DNA technical leader: Michelle Hassler
   On site: Yes ☑ No ☐
   Casework CODIS administrator: Byron Sonnenberg

9. Last audit conducted on: November 9-10, 2009
   External Audit ☐ Internal Audit ☑ (Choose one)

10. Audit Document Discussion Used (Revision Date): July 2009

Standard 3. Quality Assurance Program

		Yes	No	N/A
3.1	For the DNA laboratory's quality assurance program:	☑	☐	☐
	a. Does the DNA laboratory have an established and maintained documented quality system that is appropriate to the testing activities?	☑	☐	☐
	b. Is the quality system equivalent to or more stringent than what is required by these Standards?	☑	☐	☐

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Comment

		Yes	No	N/A
3.1.1	Is the quality system documented in a manual that includes or references the following elements:	☑	☐	☐
	3.1.1.1 Goals and objectives?	☑	☐	☐
	3.1.1.2 Organization and management?	☑	☐	☐
	3.1.1.3 Personnel?	☑	☐	☐
	3.1.1.4 Facilities?	☑	☐	☐
	3.1.1.5 Evidence control?	☑	☐	☐
	3.1.1.6 Validation?	☑	☐	☐
	3.1.1.7 Analytical procedures?	☑	☐	☐
	3.1.1.8 Equipment calibration and maintenance?	☑	☐	☐
	3.1.1.9 Reports?	☑	☐	☐
	3.1.1.10 Review?	☑	☐	☐
	3.1.1.11 Proficiency testing?	☑	☐	☐
	3.1.1.12 Corrective action?	☑	☐	☐

3.1.1.13 Audits?	☑	☐	☐
3.1.1.14 Safety?	☑	☐	☐
3.1.1.15 Outsourcing?	☑	☐	☐

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Comment

	Yes	No	N/A
3.2 Does the laboratory maintain and follow a procedure regarding document retention that specifically addresses:	☑	☐	☐
a. Proficiency tests?	Yes ☑	No ☐	
b. Corrective action?	Yes ☑	No ☐	
c. Audits?	Yes ☑	No ☐	
d. Training records?	Yes ☑	No ☐	
e. Continuing education?	Yes ☑	No ☐	
f. Case files?	Yes ☑	No ☐	
g. Court testimony monitoring?	Yes ☑	No ☐	

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		Yes	No	N/A
3.3	Is the quality system as applicable to DNA reviewed annually (calendar year) independent of the audit required by Standard 15, and is the review performed under the direction and documented approval of the technical leader?	☑	☐	☐

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Comment

Standard 4. Organization and Management

		Yes	No	N/A
4.1	Does the laboratory have:	☑	☐	☐
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?	☑	☐	☐
4.1.2	A technical leader who is accountable for the technical operations?	☑	☐	☐
	a. Have at least one technical leader in a multi - laboratory system?	☐	☐	☑
4.1.3	A casework CODIS administrator who is accountable for CODIS on-site at each individual laboratory facility using CODIS?	☑	☐	☐
4.1.4	At least two full-time employees who are qualified DNA analysts?	☑	☐	☐
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?	☑	☐	☐
4.1.6	A documented contingency plan that is approved by laboratory management if the technical leader position is vacated?	☑	☐	☐

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Standard 4.1.2 (a) was marked NA because this is not a multi-laboratory system.

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?	☑	☐	☐

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Comment

		Yes	No	N/A
5.1.1	Does the laboratory have written job descriptions for all personnel to include responsibilities, duties, and skills?	☑	☐	☐

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		Yes	No	N/A
5.1.2	Does the laboratory have a documented training program for qualifying all analyst(s) and technician(s)?	☑	☐	☐
5.1.2.1	Does the training program contain at a minimum the following components:			
	a. A training manual that covers all applicable DNA analytical procedures that the analyst/technician will perform?	☑	☐	☐
	b. Practical exercises that include the examination of a range of samples routinely encountered in casework?	☑	☐	☐

5.1.2.2	Does the laboratory's training program teach and assess the technical skills and knowledge required to perform DNA analysis and include, at a minimum, the following?	☑	☐	☐
5.1.2.2.1	Does the training program require the documentation of the successful completion of a competency test(s)?	☑	☐	☐
5.1.2.2.2	For an analyst or technician with previous forensic experience:			
	a. Did the technical leader assess and document the adequacy of the previous training of the analyst and/or technician?	☑	☐	☐
	b. Did the analyst and/or technician complete a modified training program that was assessed and documented by the technical leader?	☑	☐	☐
5.1.2.2.3	Prior to participating in independent casework did all analysts and technicians, regardless of previous experience, successfully complete a competency test(s) covering the routine DNA methodologies to be used?	☑	☐	☐

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		Yes	No	N/A
5.1.3	Does the laboratory have a documented program to ensure that technical qualifications are maintained through continuing education?	☑	☐	☐
5.1.3.1	Does the technical leader, casework CODIS administrator, and each analyst have documented attendance at seminars, courses, professional meetings, or documented training sessions/classes that consist of:	☑	☐	☐

a. Subject areas relevant to the developments in DNA typing?

Yes ☑ No ☐

b. Cumulative minimum of eight hours per calendar year?

Yes ☑ No ☐

5.1.3.1.1 For continuing education conducted internally, does the laboratory's retained documentation include the following: ☑ ☐ ☐

a. Title of the program? Yes ☑ No ☐

b. A record of the presentation? Yes ☑ No ☐

c. Date of the training? Yes ☑ No ☐

d. Attendance list? Yes ☑ No ☐

e. Curriculum vitae of the presenter(s)? Yes ☑ No ☐

5.1.3.1.2 For continuing education conducted externally, does the laboratory's retained documentation include one or more of the following: ☑ ☐ ☐

a. Certificate of attendance?

b. Program agenda/syllabus?

c. Travel documentation?

5.1.3.1.3 For continuing education that is based on multimedia or Internet delivery: ☐ ☐ ☑

a. Was the training subject to the review of, and approved by, the technical leader?

Yes ☐ No ☐

b. Was the time required to complete the program formally recorded in the laboratory's retained document?

Yes ☐ No ☐

c. Was the completion submitted to the technical leader for review and approval?

Yes ☐ No ☐

5.1.3.2 For the review of scientific literature:

a. Does the laboratory have a program, approved by the technical leader, for the annual review of scientific literature that documents the ongoing reading of scientific literature? ☑ ☐ ☐

b. 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? ☑ ☐ ☐

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standard 5.1.3.1.3 was rated NA because the laboratory did not use multimedia training for their 8 hours of continuing education.

		Yes	No	N/A
5.1.4	Does the laboratory maintain records on the relevant qualifications, training, skills, and experience of all technical personnel?	☑	☐	☐

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		Yes	No	N/A
5.2	Does the technical leader satisfy the requirements for degree/education, experience, and duties listed in Standards 5.2.1 through 5.2.4.1?	☑	☐	☐
5.2.1	Does the technical leader of the laboratory meet or exceed the following degree/educational requirements?	☑	☐	☐
	a. A master's degree in a biology-, chemistry-, or forensic science-related area or have a waiver as stated in Standard 5.2.1.4?	☑	☐	☐

b. Twelve semester hours or equivalent credit hours including a combination of graduate and undergraduate course work or classes covering the following subject areas: ☑ ☐ ☐

1. Biochemistry? Yes ☑ No ☐
2. Genetics? Yes ☑ No ☐
3. Molecular biology? Yes ☑ No ☐
4. Statistics or population genetics? Yes ☑ No ☐

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? ☑ ☐ ☐

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? ☑ ☐ ☐

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 transcript, syllabus, letter from the instructor, or other documentation that supports the course content? ☑ ☐ ☐

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		Yes	No	N/A
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)?	☐	☐	☑

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Comment

Standard 5.2.1.4 was rated NA because the technical leader does not possess a wavier from ASCLD.

		Yes	No	N/A
5.2.2	Technical leader minimum experience requirements:			
	a. 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?	☑	☐	☐
	b. Does any technical leader, appointed or hired on or after July 1, 2009, have a minimum of three years human-DNA experience (current or previous) as a qualified analyst on forensic samples?	☐	☐	☑
	c. Has the technical leader successfully completed, or will successfully complete within one year of appointment, the FBI-sponsored auditor training?	☑	☐	☐

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Standard 5.2.2.b was marked NA because the technical leader was hired before July 1, 2009.

	Yes	No	N/A
5.2.3 Does the technical leader of the laboratory have responsibility for the following:			
5.2.3.1 Does the technical leader have the following general duties and authority:			
5.2.3.1.1 Oversee the technical operations of the laboratory?	☑	☐	☐
5.2.3.1.2 Authority to initiate, suspend, and resume DNA analytical operations for the laboratory or an individual?	☑	☐	☐
5.2.3.2 Does the technical leader perform the following specific responsibilities:			
5.2.3.2.1 Evaluate and document approval of all validations and methods used by the laboratory and propose new or modified analytical procedures to be used by analysts?	☑	☐	☐
5.2.3.2.2 Review and document the review of the academic transcripts and training records for newly qualified analysts and approve their qualifications prior to their conducting independent casework analysis?	☑	☐	☐
5.2.3.2.3 Approve the technical specifications for outsourcing agreements?	☑	☐	☐
5.2.3.2.4 Review and document the review of internal and external DNA audit documents and, if applicable, approve corrective action(s).	☑	☐	☐
5.2.3.2.5 Review annually the procedures of the laboratory and document such review?	☑	☐	☐
5.2.3.2.6 Review and approve the training, quality assurance, and proficiency testing programs in the laboratory?	☑	☐	☐

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		Yes	No	N/A
5.2.4	Technical leader accessibility:			
	a. Is the technical leader accessible to the laboratory to provide on-site, telephonic, or electronic consultation as needed?	☑	☐	☐
	b. If the technical leader oversees a system of separate laboratories, has the technical leader conducted semiannual on-site visits of each of the laboratories?	☑	☐	☐
5.2.4.1	Is the technical leader a full-time employee of the laboratory or laboratory system?	☑	☐	☐
5.2.4.1.1	a. If the technical leader position of the laboratory had been vacant since the last audit, was there a qualified individual immediately appointed as technical leader?	☐	☐	☑
	b. If a qualified individual was not available/ appointed, did the laboratory immediately contact the FBI and submit its contingency plan within 14 days of the vacancy for the FBI's approval?	☐	☐	☑
	c. Was all new casework suspended until the plan was approved by the FBI?	☐	☐	☑
5.2.5	Did each technical leader appointed or hired on or after July 1, 2009, document a review of the following:			
	5.2.5.1 Validation studies and methodologies currently used by the laboratory?	☐	☐	☑
	5.2.5.2 Educational qualifications and training records of currently qualified analysts?	☐	☐	☑

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Standard 5.2.4.1.1 and its subcategories were rated NA because the technical leader position was not vacant since the last audit.

Standard 5.2.5 and its subcategories was marked NA because the technical leader was hired before July 1, 2009.

		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?	☑	☐	☐
5.3.1	Education:			
	Does the casework CODIS administrator meet the minimum education requirements?	☑	☐	☐
	a. Does the casework CODIS administrator meet the minimum education requirements as defined in Standard 5.4 or	☑	☐	☐
	b. Was the casework CODIS administrator appointed or hired prior to July 1, 2009, with supporting documentation from the FBI?	☐	☐	☑
5.3.2	Experience:			
	Does the casework CODIS administrator meet the experience requirements?	☑	☐	☐
	a. Is a current or previously qualified casework DNA analyst with documented mixture interpretation training, or	☑	☐	☐
	b. Was the casework CODIS administrator appointed or hired prior to July 1, 2009 with documented mixture-interpretation training and completion of FBI-sponsored CODIS training?	☐	☐	☑

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Standard 5.3.1.b was marked NA because the technical leader was hired before July 1, 2009 and was a qualified casework analyst.

Standard 5.3.2 (b) was marked NA because the casework CODIS administrator is a qualified analyst with documented mixture interpretation training.

		Yes	No	N/A
5.3.3	Has the casework CODIS administrator:			
	a. Successfully completed the FBI auditor training within one year of appointment, if not previously attended such training?	☑	☐	☐
	b. Participated in the FBI sponsored CODIS software training within six months of appointment, if not previously attended such training?	☑	☐	☐
5.3.4	Is the casework CODIS administrator responsible for the following:	☑	☐	☐
	5.3.4.1 Administering the laboratory's local CODIS network?	☑	☐	☐
	5.3.4.2 Scheduling and documenting the CODIS computer training of casework analysts?	☑	☐	☐
	5.3.4.3 Assuring 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 Assuring 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 Assuring that matches are dispositioned in accordance with NDIS operational procedures?	☑	☐	☐
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?	☐	☐	☑

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Standard 5.3.6 was rated NA because the casework CODIS administrator position has not been unoccupied since the last audit.

		Yes	No	N/A
5.4	Is each analyst an employee of the laboratory and does he or she meet or exceed the following qualifications?	☑	☐	☐
5.4.1	Does each analyst 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 or classes covering the subject areas of:			
	1. Biochemistry? Yes ☑ No ☐			
	2. Genetics? Yes ☑ No ☐			
	3. Molecular biology? Yes ☑ No ☐			
	c. College course work or training that covers the subject areas of 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 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:			
	a. Have they successfully demonstrated compliance with this Standard through a combination of pertinent materials such as a transcript, syllabus, letter from the instructor, or other documentation that supports the course content?	☑	☐	☐
	b. Has the technical leader documented his or her approval of compliance with this Standard?	☑	☐	☐

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		Yes	No	N/A
5.4.2	Does each analyst have six months of documented, forensic human-DNA laboratory experience?	☑	☐	☐
5.4.2.1	Prior to independent work using DNA technology, has each analyst completed the analysis of a range of samples routinely encountered in forensic casework?	☑	☐	☐
5.4.2.2	Has each analyst successfully completed a competency test before beginning independent DNA analysis?	☑	☐	☐

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		Yes	No	N/A
5.5	Has each technician successfully completed each of the following:			
5.5.1	Documented training specific to his or her job function(s)?	☐	☐	☑
5.5.2	A competency test before participating in DNA analysis on evidence?	☐	☐	☑
5.6	Do all laboratory technical support personnel have documented training specific to their job function(s)?	☑	☐	☐

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Standards 5.5.1; and 5.5.2 were rated NA because the laboratory does not have technicians.

Standard 6. Facilities

		Yes	No	N/A
6.1	Is the laboratory designed to ensure the integrity of the analyses and the evidence?	☑	☐	☐
6.1.1	Is access to the laboratory controlled and limited in a manner that prevents access by unauthorized personnel?	☑	☐	☐
	a. Do all exterior entrance/exit points have security control?	☑	☐	☐
	b. Is the distribution of all keys, combinations, and other security devices, documented and limited to the personnel designated by laboratory management?	☑	☐	☐

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		Yes	No	N/A
6.1.2	Except as provided in Standard 6.1.4, are techniques performed prior to polymerase chain reaction (PCR) amplification-- to include evidence examinations, DNA extractions, and PCR setup-- conducted at separate times or in separate spaces from one another?	☑	☐	☐
6.1.3	Except as provided in Standard 6.1.4, 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?	☑	☐	☐
	a. Are the doors between rooms containing amplified DNA and other areas closed at all times except for passage?	☑	☐	☐

6.1.4	If a robotic workstation is used to carry out DNA extraction, quantification, PCR setup, and/or amplification in a single room, has the laboratory validated the analytical process in accordance with Standard 8?	☐	☐	☑
	a. If the robot performs analysis through amplification, is the robot housed in a separate room from that used for initial evidence examinations?	☐	☐	☑

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Standards 6.1.4 and 6.1.4.a were rated NA because the laboratory does not use a robot to carry out DNA extraction, quantification, PCR setup, and/or amplification in a single room.

		Yes	No	N/A
6.1.5	Does the laboratory have and follow written procedures for cleaning and decontaminating facilities and equipment?	☑	☐	☐

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Comment

STANDARD 7 Evidence

		Yes	No	N/A
7.1	Does the laboratory have and follow a documented evidence control system to ensure the integrity of physical evidence?	☑	☐	☐
7.1.1	For evidence and sample identification:			
	a. Is all evidence marked with a unique identifier on the evidence package?	☑	☐	☐
	b. Does the laboratory clearly define what constitutes evidence and what constitutes work product?	☑	☐	☐
	c. Does the laboratory have and follow a method to distinguish each sample throughout processing?	☑	☐	☐

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Comment

		Yes	No	N/A
7.1.2	Does the laboratory document and maintain a chain of custody, in hard or electronic format, for all evidence, to include the following:	☑	☐	☐
	a. Signature or initials or the electronic equivalent of each individual receiving or transferring the evidence?	Yes ☑	No ☐	
	b. The corresponding date for each transfer?	Yes ☑	No ☐	
	c. Evidentiary item(s) transferred?	Yes ☑	No ☐	

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Comment

		Yes	No	N/A
7.1.3	Does the laboratory have and follow documented procedures designed to minimize loss, contamination, and/or deleterious change of evidence and work product in progress?	☑	☐	☐
7.1.4	Does the laboratory have secure, controlled-access areas for evidence storage and work product in progress?	☑	☐	☐

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Comment

		Yes	No	N/A
7.2	Does the laboratory retain or return a portion of the evidence sample or extract where possible?	☑	☐	☐

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Comment

		Yes	No	N/A
7.3	Does the laboratory have and follow documented policies for the disposition of evidence and sample consumption?	☑	☐	☐

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Comment

Standard 8. Validation

		Yes	No	N/A
8.1	Does the laboratory use validated methods for DNA analyses?	☑	☐	☐

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Comment

		Yes	No	N/A
8.2	Have developmental validation studies preceded the use of a novel methodology for forensic DNA analysis?	☑	☐	☐

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Comment

	Yes	No	N/A
8.2.1 Have developmental validation studies been performed and documented to include, where applicable:	☑	☐	☐

a. Characterization of the genetic marker? Yes ☑ No ☐ N/A ☐

b. Species specificity? Yes ☑ No ☐ N/A ☐

c. Sensitivity studies? Yes ☑ No ☐ N/A ☐

d. Stability studies? Yes ☑ No ☐ N/A ☐

e. Reproducibility? Yes ☑ No ☐ N/A ☐

f. Case-type samples? Yes ☑ No ☐ N/A ☐

g. Population studies? Yes ☑ No ☐ N/A ☐

h. Mixture studies? Yes ☑ No ☐ N/A ☐

i. Precision and accuracy studies? Yes ☑ No ☐ N/A ☐

j. PCR-based studies to include? Yes ☑ No ☐ N/A ☐

1. Reaction conditions? Yes ☑ No ☐
2. Assessment of differential and preferential amplification? Yes ☑ No ☐
3. Effects of multiplexing? Yes ☑ No ☐
4. Assessment of appropriate controls? Yes ☑ No ☐
5. Product detection studies? Yes ☑ No ☐

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

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Comment

		Yes	No	N/A
8.3	Except as provided in Standard 8.3.1.1, have internal validation of all manual and robotic methodologies been conducted by each laboratory and reviewed and approved by the laboratory's technical leader prior to use?	☑	☐	☐
8.3.1	For Internal Validation Studies:			
	a. Have internal validation studies been documented and summarized?	☑	☐	☐
	b. Have all internal validation studies conducted on or after July 1, 2009, included, as applicable:	☑	☐	☐
	1. Known and non probative evidence samples or mock evidence samples? Yes ☑ No ☐ N/A ☐			
	2. Reproducibility and precision? Yes ☑ No ☐ N/A ☐			
	3. Sensitivity and stochastic studies? Yes ☑ No ☐ N/A ☐			
	4. Mixture studies? Yes ☑ No ☐ N/A ☐			
	5. Contamination assessment? Yes ☑ No ☐ N/A ☐			
8.3.1.1	For multilaboratory systems:			
	a. Has each laboratory in a multi-laboratory system completed, documented, and maintained applicable site-specific precision, sensitivity, and contamination assessment studies?	☐	☐	☑
	b. Are the summaries of all applicable validation data available at each site?	☐	☐	☑
8.3.2	Have quality assurance parameters and interpretation guidelines, including, as applicable, guidelines for mixture interpretation, been defined pursuant to internal validation?	☑	☐	☐
8.3.3	If a laboratory has had a change in detection platform or test kit, have internal validation studies been performed?	☐	☐	☑
8.4	Has the analyst or examination team successfully completed a competency test using the DNA analysis procedure prior to its incorporation into casework applications?	☑	☐	☐

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Standard 8.3.1.1 and its subcategories were marked NA because this is not a multi-laboratory system.

Standard 8.3.3 was rated NA because the laboratory did not have a change in detection platform or test kit.

		Yes	No	N/A
8.5	Have modified procedures been evaluated by comparison with the original procedures using similar DNA samples prior to their incorporation into casework applications?	☑	☐	☐
8.6	Has the laboratory evaluated each additional or modified critical instrument by conducting a performance check prior to its use in casework?	☑	☐	☐
8.7	Has the laboratory evaluated software upgrades by conducting a performance check prior to use in casework?	☐	☐	☑
	a. Has new software or significant software modifications been documented and subjected to validation testing prior to use in casework?	☐	☐	☑

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Standard 8.5 : ABI 3130 plate set-up with a 10ul volume; Modified sample prep for the ABI 3130 with a reduced volume of LIZ GS-500.

Standard 8.6: ABI 3130 (instrument B) which included sensitivity, reproducibility, precision, and threshold compared to instrument A; ABI 3130 (instrument C) which included sensitivity, reproducibility, precision, and threshold compared to instrument A and B; EZ1 Advanced XL robot for DNA extraction which included sensitivity, contamination, and precision.

Standards 8.7 and 8.7.a were rated NA because the laboratory has not evaluated or modified their software since the last external audit.

Standard 9. Analytical Procedures

		Yes	No	N/A
9.1	Does the laboratory have and follow written analytical procedures approved by the technical leader?	☑	☐	☐
	a. Are the laboratory's standard operating procedures reviewed annually by the technical leader, and is this review documented?	☑	☐	☐
9.1.1	Does the laboratory have a documented standard operating procedure for each analytical method used?	☑	☐	☐
	a. Do the analytical procedures specify reagents, sample preparation, extraction methods, equipment, and controls that are standard for DNA analysis and data interpretation?	☑	☐	☐
	b. Does the laboratory have a procedure for the differential extraction of stains that contain sperm?	☑	☐	☐

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		Yes	No	N/A
9.2	Does the laboratory use reagents that are suitable for the methods employed?	☐	☑	☐
9.2.1	Does the laboratory have written procedures for documenting commercial reagents and for the formulation of in-house reagents?	☑	☐	☐
9.2.2	Are commercial reagents labeled with:	☑	☐	☐
	a. The identity of the reagent? Yes ☑ No ☐			
	b. The expiration date as provided by the manufacturer or as determined by the laboratory? Yes ☑ No ☐			
9.2.3	Are in-house reagents labeled with:	☑	☐	☐

a. The identity of the reagent?

Yes ☑ No ☐

b. The date of the preparation or expiration or both?

Yes ☑ No ☐

c. The identity of the individual preparing the reagent?

Yes ☑ No ☐

9.3 Critical reagents shall include, but are not limited to, the reagents listed in Standards 9.3.1 and 9.3.2.

a. Has the laboratory identified critical reagents? ☑ ☐ ☐

b. Has the laboratory evaluated critical reagents prior to use in casework? ☑ ☐ ☐

9.3.1 Has the laboratory identified and evaluated the following: ☑ ☐ ☐

a. Test kits or systems for performing quantitative PCR?

Yes ☑ No ☐ N/A ☐

b. Test kits or systems for performing genetic typing?

Yes ☑ No ☐ N/A ☐

9.3.2 Has the laboratory identified and evaluated the following: ☑ ☐ ☐

a. Thermostable DNA polymerase (if not tested as test kit components under Standard 9.3.1)?

Yes ☑ No ☐ N/A ☐

b. Primer sets (if not tested as test kit components under Standard 9.3.1)?

Yes ☐ No ☐ N/A ☑

c. Allelic ladders used for genetic analysis (if not tested as test-kit components under Standard 9.3.1)?

Yes ☐ No ☐ N/A ☑

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Standard 9.2 see findings section

Standards 9.3.2.b and 9.3.2.c were rated NA because the components are evaluated as part of a test kit.

		Yes	No	N/A
9.4	Does the laboratory quantify the amount of human DNA in forensic samples prior to nuclear DNA amplification?	☑	☐	☐

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		Yes	No	N/A
9.5	Does the laboratory monitor the analytical procedures using appropriate controls and standards?	☑	☐	☐
9.5.1	Are standards used during quantification procedures?	☑	☐	☐
9.5.2	For positive and negative amplification controls:			
	a. Are the positive and negative amplification controls associated with the forensic samples being typed amplified concurrently with the samples at all loci using the same primers as the forensic samples?	☑	☐	☐
	b. Are the positive and negative amplification controls associated with the forensic samples being typed?	☑	☐	☐
9.5.3	Are reagent blank controls associated with each extraction set being analyzed as follows:			
	9.5.3.1 Extracted concurrently?	☑	☐	☐
	9.5.3.2 Are the reagent blanks amplified using:	☑	☐	☐
	a. The same primers as the forensic sample(s)? Yes ☑ No ☐			
	b. The same instrument model as the forensic sample(s)? Yes ☑ No ☐			
	c. The same concentration conditions as required by the forensic sample(s) containing the least amount of DNA? Yes ☑ No ☐			
	9.5.3.3 Are the reagent blanks typed using:	☑	☐	☐

a. The same instrument model as the forensic sample(s)?

Yes ☑ No ☐

b. The same injection conditions as the forensic sample(s)?

Yes ☑ No ☐

c. The most sensitive volume conditions of the forensic extraction set?

Yes ☑ No ☐

9.5.4 Does the laboratory use allelic ladders and internal size markers for VNTR sequence PCR- based systems? ☑ ☐ ☐

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	Yes	No	N/A
9.5.5 Does the laboratory check its DNA procedures either annually or whenever substantial changes are made to a procedure against an appropriate and available NIST standard reference material (SRM) or standard traceable to a NIST standard?	☑	☐	☐

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		Yes	No	N/A
9.6	Does the laboratory have and follow written guidelines for the interpretation of data?	☑	☐	☐
9.6.1	Does the laboratory verify that all control results meet the laboratory's interpretation guidelines for all reported results?	☑	☐	☐
9.6.2	Has the 1996 National Research Council report and/or a court-directed method been used for the statistical interpretation of a DNA profile for a given population and/or hypothesis or relatedness, and are these calculations derived from an established population database(s) appropriate for the calculation?	☑	☐	☐
9.6.3	Does the laboratory have and follow specific documented statistical interpretation guidelines if genetic analyses that are not addressed by Standard 9.6.2 are being performed?	☑	☐	☐
9.6.4	Does the laboratory have and follow documented procedures for mixture interpretation to include the following:	☑	☐	☐

a. Major and minor contributors? Yes ☑ No ☐

b. Inclusions and exclusions? Yes ☑ No ☐

c. Policies for reporting results and statistics? Yes ☑ No ☐

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Comment

		Yes	No	N/A
9.7	Does the laboratory have and follow a documented policy for detecting and controlling contamination?	☑	☐	☐

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Standard 10. Equipment Calibration and Maintenance

		Yes	No	N/A
10.1	Does the laboratory use equipment that is suitable for the methods employed?	☑	☐	☐
10.2	Does the laboratory have and follow a documented program for conducting performance checks and calibrating equipment and instruments?	☑	☐	☐
10.2.1	At a minimum, are the following critical instruments or equipment performance-checked at least annually:	☑	☐	☐
10.2.1.1	A thermometer that is traceable to national or international standard(s) and is used for conducting performance checks?	☑	☐	☐
10.2.1.2	Balance/scale?	☑	☐	☐
10.2.1.3	Thermal cycler temperature-verification system?	☑	☐	☐
10.2.1.4	Thermal cycler including quantitative-PCR?	☑	☐	☐
10.2.1.5	Electrophoresis detection systems?	☐	☐	☑
10.2.1.6	Robotic systems?	☑	☐	☐
10.2.1.7	Genetic analyzers?	☑	☐	☐
10.2.1.8	Mechanical pipettes?	☑	☐	☐
10.3	Does the laboratory have a schedule and follow a documented program to ensure that instruments and equipment are maintained properly?	☑	☐	☐

	a. Has documentation been retained for maintenance, service, and/or calibration?	☑	☐	☐
10.4	Does the laboratory performance check new critical instruments and equipment, or critical instruments and equipment that have undergone repair, service or calibration, before their use in casework analysis?	☑	☐	☐
10.4.1	At a minimum, are the following critical instruments or equipment performance-checked following repair, service, or calibration:			
	10.4.1.1 Electrophoresis detection systems?	☐	☐	☑
	10.4.1.2 Robotic systems?	☑	☐	☐
	10.4.1.3 Genetic analyzers?	☑	☐	☐
	10.4.1.4 Thermal cycler including quantative-PCR?	☑	☐	☐

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Standards 10.2.1.5 and 10.4.1.1 are marked NA since the laboratory does not use electrophoresis detection systems other than genetic analyzers.

Standard 11 Reports

		Yes	No	N/A
11.1	a. Does the laboratory have and follow written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory reports?	☑	☐	☐
	b. Does the laboratory maintain all analytical documentation generated by analysts related to case analyses?	☑	☐	☐
	c. Does the laboratory retain, in hard copy or electronic format, sufficient documentation for each technical analysis to support the report conclusions such that another qualified individual could interpret and evaluate the data?	☑	☐	☐

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		Yes	No	N/A
11.2	Do the laboratory reports include the following elements:	☑	☐	☐
	11.2.1 Case identifier?	☑	☐	☐
	11.2.2 Description of evidence examined?	☑	☐	☐
	11.2.3 Description of technology?	☑	☐	☐
	11.2.4 Locus or amplification system?	☑	☐	☐
	11.2.5 Results and/or conclusions?	☑	☐	☐
	11.2.6 A quantitative or qualitative interpretative statement?	☑	☐	☐
	11.2.7 Date issued?	☑	☐	☐
	11.2.8 Disposition of evidence?	☑	☐	☐
	11.2.9 Signature and title, or equivalent identification, of the person accepting responsibility for the content of the report?	☑	☐	☐

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		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?	☑	☐	☐
11.3.1	Does the laboratory have and follow written procedures to ensure the privacy of reports, case files, DNA records, and databases?	☑	☐	☐
11.3.2	Does the laboratory have and follow written procedures for the release of reports, case files, DNA records, and databases in accordance with applicable state or federal law?	☑	☐	☐
11.3.3	Does the laboratory release personally identifiable information in accordance with applicable state and federal law?	☑	☐	☐

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Standard 12. Review

		Yes	No	N/A
12.1	Does the laboratory conduct and document administrative and technical reviews of all case files and reports to ensure that conclusions and supporting data are reasonable and within the constraints of scientific knowledge?	☑	☐	☐
12.1.1	Are all technical reviews conducted by an individual that is, or has been, a qualified analyst in the methodology being reviewed?	☑	☐	☐

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		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:	☑	☐	☐
12.2.1	A review of all case notes, worksheets, and electronic data (or printed electropherograms/images) that support the conclusions?	☑	☐	☐
12.2.2	A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images)?	☑	☐	☐
12.2.3	A review of all profiles to verify correct inclusions and exclusions (if applicable) as well as a review of any inconclusive result for compliance with laboratory guidelines?	☑	☐	☐
12.2.4	A review of all controls, internal lane standards, and allelic ladders to verify that the expected results were obtained?	☑	☐	☐
12.2.5	A review of statistical analysis, if applicable?	☑	☐	☐

12.2.6 A review of the final report to verify that the results/conclusions are supported by the data? ☑ ☐ ☐

a. Does the report address each tested item or its probative fraction? ☑ ☐ ☐

12.2.7 For verification of CODIS eligibility. Has there been verification that all profiles entered into CODIS are eligible and have the correct DNA types and correct specimen category? ☑ ☐ ☐

12.2.7.1 Prior to upload to or search of SDIS, have the following been verified for DNA profiles: ☑ ☐ ☐

a. Eligibility for CODIS? Yes ☑ No ☐

b. Correct DNA types? Yes ☑ No ☐

c. Appropriate specimen category? Yes ☑ No ☐

12.2.7.2 Prior to entry of a DNA profile into a searchable category of SDIS, were the following criteria verified by two concordant assessmetns by a qualified analyst or technical reviewer? ☑ ☐ ☐

a. Eligibility for CODIS? Yes ☑ No ☐

b. Correct DNA types? Yes ☑ No ☐

c. Appropriate specimen category? Yes ☑ No ☐

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		Yes	No	N/A
12.3	Does the administrative review include the following elements (any or all of which may be included within the technical-review process):			
12.3.1	A review of the case file and final report for clerical errors and for the presence and accuracy of the information specified in Standard 11.2?	☑	☐	☐
12.3.2	A review of the chain of custody and disposition of evidence?	☑	☐	☐
12.3.3	A procedure to document the completion of the administrative review?	☑	☐	☐

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		Yes	No	N/A
12.4	Does the laboratory document the elements of a technical and administrative review?	☑	☐	☐
	a. Are case files reviewed and documented according to the laboratory's procedures?	☑	☐	☐
12.5	Does the laboratory have and follow a documented procedure to address unresolved discrepant conclusions between analysts and reviewers?	☑	☐	☐
12.6	Does the laboratory have and follow a documented procedure for the verification and resolution of database matches?	☑	☐	☐

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		Yes	No	N/A
12.7	Does the laboratory have and follow a program that documents the annual monitoring of the testimony of each analyst?	☑	☐	☐

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Standard 13. Proficiency Testing

		Yes	No	N/A
13.1	Do analysts, technical reviewers, technicians, and other personnel designated by the technical leader undergo semiannual external proficiency testing in each technology performed to the full extent in which they participate in casework?	☑	☐	☐

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		Yes	No	N/A
13.1.1	Are individuals using both manual and automated methods proficiency-tested in each, at least once per year, to the full extent in which they participate in casework?	☑	☐	☐
13.1.2	Have newly qualified individuals entered the external proficiency-testing program within six months of the date of their qualification?	☑	☐	☐
13.1.3	Has the laboratory defined, documented, and consistently used the date that the proficiency test is performed as the received date, assigned date, submitted date, or due date?	☑	☐	☐
13.1.4	Except as provided in Standard 13.1.4.1, has each analyst been assigned and completed his or her own external proficiency test?	☑	☐	☐
	13.1.4.1 If a team approach is used, have all analysts, technicians, and technical reviewers been proficiency-tested according to Standard 13.1?	☐	☐	☑
13.1.5	Has the typing of all CODIS core loci or CODIS core sequence ranges been attempted for each technology performed as applicable?	☑	☐	☐
13.1.6	Does the laboratory maintain the following records for proficiency tests:			
	13.1.6.1 The test-set identifier?	☑	☐	☐
	13.1.6.2 Identity of the analyst, and other participants, if applicable?	☑	☐	☐
	13.1.6.3 Date of analysis and completion?	☑	☐	☐
	13.1.6.4 Copies of all data and notes supporting the conclusions?	☑	☐	☐
	13.1.6.5 The proficiency test results?	☑	☐	☐
	13.1.6.6 Any discrepancies noted?	☑	☐	☐
	13.1.6.7 Corrective actions taken?	☑	☐	☐
13.1.7	Does the laboratory include, at a minimum, the following criteria for evaluating proficiency test results:	☑	☐	☐
	13.1.7.1 Evaluation:			
	a. Are all reported inclusions correct?	☑	☐	☐
	b. Are all reported exclusions correct?	☑	☐	☐

	c. Are all reported genotypes and/or phenotypes correct or incorrect according to consensus results or within the laboratory's interpretation guidelines?	☑	☐	☐
	13.1.7.2 Are results that are reported as inconclusive or not interpretable consistent with written laboratory guidelines?	☑	☐	☐
	13.1.7.2.1 Has the technical leader reviewed any inconclusive result for compliance with laboratory guidelines?	☑	☐	☐
	13.1.7.3 Have all discrepancies/errors and subsequent corrective actions been documented?	☑	☐	☐
	13.1.7.4 Have all final reports been graded as satisfactory or unsatisfactory?	☑	☐	☐
	13.1.7.4.1 When a final report was graded satisfactory, was it shown that no analytical errors were observed for the DNA profile typing data?	☑	☐	☐
	13.1.7.4.1.1 If present, were administrative errors and corrective actions documented?	☑	☐	☐
13.1.8	Have all proficiency-test participants been informed of their final test results, and has this notification been documented?	☑	☐	☐
13.1.9	Has the technical leader been informed of the results of all participants, and has this notification been documented?	☑	☐	☐
	a. If applicable, did the technical leader inform the casework CODIS administrator of all nonadministrative discrepancies that affect the typing results and/or conclusions at the time of discovery?	☑	☐	☐

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Standard 13.1.4.1 was rated NA because the laboratory does not use a team approach.

	Yes	No	N/A
13.2 Does the laboratory use an external proficiency-test provider(s) that is in compliance with the current proficiency-testing manufacturing guidelines established by the American Society of Crime Laboratory Directors/Laboratory Accreditation Board or is in compliance with the current International Organization for Standardization?	☑	☐	☐

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Standard 14. Corrective Action

	Yes	No	N/A
14.1 For a corrective action plan:			
a. Has the laboratory established and followed a corrective action plan that addresses discrepancies detected in proficiency tests and casework analysis?	☑	☐	☐
b. Does the corrective action plan, at a minimum, address the following:	☑	☐	☐

1. Define what level/type of discrepancies are applicable to this practice?
   Yes ☑ No ☐ N/A ☐
2. Identify (when possible) the cause of the discrepancy?
   Yes ☑ No ☐ N/A ☐
3. Effect of the discrepancy?
   Yes ☑ No ☐ N/A ☐
4. Corrective actions taken?
   Yes ☑ No ☐ N/A ☐
5. Preventative measures taken (where applicable) to minimize its reoccurrence?

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Yes ☑ No ☐ N/A ☐

6. Is documentation of all corrective actions maintained in accordance with Standard 3.2?

Yes ☑ No ☐ N/A ☐

14.2	Prior to implementation do all corrective actions have the documented approval of the technical leader?	☑	☐	☐

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Standard 15. Audits

		Yes	No	N/A
15.1	Has the laboratory been audited annually in accordance with the FBI DNA Quality Assurance Standards?	☑	☐	☐
	Has the laboratory maintained documentation that the auditor(s) for this inspection include:	☑	☐	☐
15.2	Has an external audit been conducted at least once every two years?	☑	☐	☐
	a. By a qualified auditor? Yes ☑ No ☐			
	b. By a current or previously qualified analyst in the laboratory's current DNA technologies and platform? Yes ☑ No ☐			
15.2.1	Has the laboratory maintained audit documentation of those individuals (i.e., casework CODIS administrator, technical leader, and analysts) that have had their education, experience, and training qualifications evaluated and approved during two external audits?	☑	☐	☐
15.2.2	Has the laboratory maintained the documentation for those validations previously evaluated and approved during one external audit?	☑	☐	☐
15.3	For internal audits, has the laboratory maintained documentation that the auditor(s) for this inspection include:	☑	☐	☐

a. A qualified auditor? Yes ☑ No ☐

b. A current or previously qualified analyst in the laboratory's current DNA technologies and platform? Yes ☑ No ☐

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?	☑	☐	☐
15.5	Have internal and external DNA audit documents and, if applicable, corrective action(s) been submitted to the technical leader for review to ensure that findings, if any, were appropriately addressed?	☑	☐	☐
15.5.1	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 documents or report?	☑	☐	☐
15.6	Are previous internal and external audit documents retained and available for auditor inspection?	☑	☐	☐

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Standard 16. Safety

		Yes	No	N/A
16.1	Does the laboratory have and follow a documented environmental health and safety program that includes, at a minimum, the following:	☑	☐	☐
16.1.1	A bloodborne pathogen and chemical hygiene plan?	☑	☐	☐
16.1.2	Documented training on the bloodborne pathogen and chemical hygiene plan?	☑	☐	☐
16.2	Has the laboratory's environmental health and safety program been reviewed annually?	☑	☐	☐
	a. Has such review been documented?	☑	☐	☐

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STANDARD 17. Outsourcing

		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?	☐	☐	☑
17.1.1	Has the NDIS laboratory that outsources DNA sample(s) for entry into CODIS required and maintained the following documentation from the vendor laboratory: a. Compliance with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories? Yes ☐ No ☐ b. Compliance with the accreditation requirements of federal law? Yes ☐ No ☐	☐	☐	☑
17.2	Except as provided in Standard 17.2.1, since the laboratory's last external audit, did the NDIS laboratory's technical leader document and maintain the approval of the technical specifications of the outsourcing agreement before it was awarded?	☐	☐	☑
17.2.1	For a vendor laboratory that is performing forensic DNA analysis for a law enforcement agency or entity other than the NDIS laboratory, was documented approval obtained by the vendor laboratory from the technical leader of the NDIS laboratory, accepting ownership of the DNA data generated, prior to the initiation of analysis?	☐	☐	☑
17.3	Did the NDIS laboratory accept, upload to, or search in CODIS, profiles generated by a vendor laboratory?	☐	☐	☑

a. Prior to the NDIS laboratory's uploading or accepting data to upload or search in CODIS from any vendor laboratory or agency, did the technical leader of the NDIS laboratory document the prior approval of the technical specifications of the outsourcing agreement and/or document the approval of acceptance of ownership of the DNA data? ☐ ☐ ☑

17.4 Does the NDIS laboratory have and follow a procedure to verify the integrity of the data received from a vendor laboratory through the performance of a technical review? ☐ ☐ ☑

17.5 Prior to the upload or search of the data generated by the vendor laboratory to SDIS, did the NDIS laboratory perform a technical review of the vendor laboratory's data? ☐ ☐ ☑

a. Was the technical review performed by an NDIS laboratory-employed analyst or technical reviewer who is qualified, or was previously qualified, in the technology, platform, and typing amplification test kit used to generate the data and who participates in the NDIS laboratory's proficiency-test program? ☐ ☐ ☑

17.5.1 Do the technical review procedures include, at a minimum, the following elements:

17.5.1.1 A review of all DNA types to verify that they are supported by the raw and/or analyzed data? (electropherograms or images) ☐ ☐ ☑

17.5.1.2 A review of all associated controls, internal lane standards and allelic ladders to verify that the expected results were obtained? ☐ ☐ ☑

17.5.1.3 A review of the final report (if provided) to verify: ☐ ☐ ☑

a. That the results/conclusions are supported by the data?

Yes ☐ No ☐

b. That each tested item (or its probative fraction) submitted to the vendor laboratory is addressed?

Yes ☐ No ☐

17.5.1.4 Verification of the DNA types, eligibility, and the correct specimen category for entry into CODIS? ☐ ☐ ☑

17.6 For an on site visit:

a. Does the NDIS laboratory have and follow a procedure for performing an on-site visit? ☐ ☐ ☑

	b. Does the procedure include, at a minimum, the following elements?	☐	☐	☑
17.6.1	A documented on-site visit prior to the initiation of analysis?	☐	☐	☑
	17.6.1.1 Has the on-site visit been performed by either the technical leader or a designated employee of the NDIS laboratory who is a qualified or previously qualified analyst in the technology, platform, and typing amplification test kit used to generate the DNA data?	☐	☐	☑
17.6.2	If the NDIS laboratory's outsourcing agreement extended beyond one year, was an annual on-site visit conducted?	☐	☐	☑
	17.6.2.1 If an on-site visit conducted by another NDIS laboratory was used by the NDIS laboratory, did the technical leader document the review and acceptance of that on-site visit?	☐	☐	☑

Click Here For Discussion

Standard 17 and subcategories were rated NA because the laboratory does not outsource and the laboratory does not have a contract with a vendor laboratory.

Appendix A: Findings and Responses

Findings:

9.2 Does the laboratory use reagents that are suitable for the methods employed?

Objective Proof for the Finding:

The laboratory has no method to track some of the specific reagents used in casework. The technical reviewer cannot confirm that reagents were not expired. The laboratory keeps track of reagents made, but multiple lots of the same reagent can be in use at the same time. This means the multiple lots of the same reagent in use would have two different expiration dates. Different analysts can use different lots of solutions in casework at the same time. They keep the aliquot of the solution in their personal work area. The technical reviewer can not confirm which lot the analyst used and when it expires.

Appendix A: Findings and Responses

Responses:

Appendix C – Auditor Self-Certification for QAS Audits

Section 1 – to be completed by the laboratory being audited:
Laboratory being audited: San Diego Sheriff's Regional Crime Lab As of [date] 9/10/10
Technologies currently in use: Quantifiler and Quantifiler DUO, Identifiler
Platforms currently in use: ABI 7500, ABI 310, ABI 3130
Validations needing to be memorialized: Quantifiler DUO
Outsourcing agreements in place or in process: n/a
The laboratory being audited may request documentation for the information reported in Section 2 below.

Section 2 – to be completed by the auditor who will sign the attestation statement below the questions and (a) for external audits, return to the laboratory prior to the scheduled audit date; or (b) for internal audits, maintain in the laboratory's files.
Auditor Qualifications:
Name of Auditor: Carl Sabieralski
Auditor's Employer: Indiana State Police Lab
Auditor's Title or Position: DNA Supervisor / Technical Leader
Qualified Auditor[2]: (Yes) No (Circle One)
Year Completed FBI DNA Auditor Class: 2001, 2004, 2008, 2009
Current or Previously Qualified DNA Analyst: (Yes) No (Circle One)
Current or Previously Qualified in Casework, Database Analysis, or (Both)[3]:
Casework Database (Both) (Circle One)
Technologies Currently or Previously Qualified In (e.g., STR, mtDNA) (Please List):
STR
Platforms Currently or Previously Qualified In (e.g., Gel based/CE)
(Please List): FMBio CE
ABI 7500 & ABI 3130 & 3130xL

I verify that:
I understand the requirements of Standard 15.2[4] ; and
I have no conflicts of interest with the laboratory being audited; and
The information contained in Section 2 above is correct.
Signed By _____ **Date** 10-4-10

[2] A Qualified Auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor training course.

[3] If the laboratory being audited performs both casework and database analyses, then the audit team or auditor must be qualified in both casework and database analyses.

[4] Standard 15.2 requires that "at least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory's current DNA technologies and platform."

Appendix C – Auditor Self-Certification for QAS Audits

Section 1 – to be completed by the laboratory being audited:
Laboratory being audited; San Diego Sheriff's Regional Crime Lab As of [date] 9/10/10
Technologies currently in use: Quantifiler and Quantifiler DUO, Identifiler
Platforms currently in use: ABI 7500, ABI 310, ABI 3130
Validations needing to be memorialized: Quantifiler DUO
Outsourcing agreements in place or in process: n/a
The laboratory being audited may request documentation for the information reported in Section 2 below.

Section 2 – to be completed by the auditor who will sign the attestation statement below the questions and (a) for external audits, return to the laboratory prior to the scheduled audit date; or (b) for internal audits, maintain in the laboratory's files.
Auditor Qualifications:
Name of Auditor: Jeremy Sanderson
Auditor's Employer: Washington State Patrol
Auditor's Title or Position: Forensic Scientist 4
Qualified Auditor[2]: (Yes) No (Circle One)
Year Completed FBI DNA Auditor Class: 2010
Current or Previously Qualified DNA Analyst: (Yes) No (Circle One)
Current or Previously Qualified in Casework, Database Analysis, or Both[3]:
(Casework) Database Both (Circle One)
Technologies Currently or Previously Qualified In (e.g., STR, mtDNA) (Please List):
STR
Platforms Currently or Previously Qualified In (e.g., Gel based/CE)
(Please List): CE

I verify that:
I understand the requirements of Standard 15.2[4] ; and
I have no conflicts of interest with the laboratory being audited; and
The information contained in Section 2 above is correct.
Signed By Jeremy Sanderson **Date** 10/4/10

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[2] A Qualified Auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor training course.

[3] If the laboratory being audited performs both casework and database analyses, then the audit team or auditor must be qualified in both casework and database analyses.

[4] Standard 15.2 requires that "at least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory's current DNA technologies and platform."

Appendix C – Auditor Self-Certification for QAS Audits

Section 1 – to be completed by the laboratory being audited:
Laboratory being audited: San Diego Sheriff's Regional Crime Lab As of [date] 9/10/10
Technologies currently in use: Quantifiler and Quantifiler DUO, Identifiler
Platforms currently in use: ABI 7500, ABI 310, ABI 3130
Validations needing to be memorialized: Quantifiler DUO
Outsourcing agreements in place or in process: n/a
The laboratory being audited may request documentation for the information reported in Section 2 below.

Section 2 – to be completed by the auditor who will sign the attestation statement below the questions and (a) for external audits, return to the laboratory prior to the scheduled audit date; or (b) for internal audits, maintain in the laboratory's files.
Auditor Qualifications:
Name of Auditor: Beverly Himick
Auditor's Employer: Washington State Patrol Crime Lab - Seattle
Auditor's Title or Position: Supervising DNA Forensic Scientist
Qualified Auditor[2]: (Yes) No (Circle One)
Year Completed FBI DNA Auditor Class: 2003
Current or Previously Qualified DNA Analyst: (Yes) No (Circle One)
Current or Previously Qualified in Casework, Database Analysis, or Both[3]:
(Casework) Database Both (Circle One)
Technologies Currently or Previously Qualified In (e.g., STR, mtDNA) (Please List):
STR's
Platforms Currently or Previously Qualified In (e.g., Gel based/CE) (Please List): CE

I verify that:
I understand the requirements of Standard 15.2[4] ; and
I have no conflicts of interest with the laboratory being audited; and
The information contained in Section 2 above is correct.
Signed By Beverly Himick **Date** 10/04/10

[2] A Qualified Auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor training course.

[3] If the laboratory being audited performs both casework and database analyses, then the audit team or auditor must be qualified in both casework and database analyses.

[4] Standard 15.2 requires that "at least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory's current DNA technologies and platform."

Appendix C – Auditor Self-Certification for QAS Audits

Section 1 – to be completed by the laboratory being audited:
Laboratory being audited: San Diego Sheriff's Regional Crime Lab As of [date] 9/10/10
Technologies currently in use: Quantifiler and Quantifiler DUO, Identifiler
Platforms currently in use: ABI 7500, ABI 310, ABI 3130
Validations needing to be memorialized: Quantifiler DUO
Outsourcing agreements in place or in process: n/a
The laboratory being audited may request documentation for the information reported in Section 2 below.

Section 2 – to be completed by the auditor who will sign the attestation statement below the questions and (a) for external audits, return to the laboratory prior to the scheduled audit date; or (b) for internal audits, maintain in the laboratory's files.
Auditor Qualifications:
Name of Auditor: JOSEPH R. PASTERNAK
Auditor's Employer: STATE OF MONTANA FORENSIC SCIENCE DIVISION
Auditor's Title or Position: DNA ANALYST
Qualified Auditor[2]: (Yes) No (Circle One)
Year Completed FBI DNA Auditor Class: 3/2004 REFRESHER - 10/2009
(Current) or Previously Qualified DNA Analyst: (Yes) No (Circle One)
Current or Previously Qualified in Casework, Database Analysis, or Both[3]:
Casework Database (Both) (Circle One)
Technologies Currently or Previously Qualified In (e.g., STR, mtDNA) (Please List):
STR
Platforms Currently or Previously Qualified In (e.g., Gel based/CE) (Please List): CE

I verify that:
I understand the requirements of Standard 15.2[4] ; and
I have no conflicts of interest with the laboratory being audited; and
The information contained in Section 2 above is correct.
Signed By [signature] **Date** 10/4/10

[2] A Qualified Auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor training course.

[3] If the laboratory being audited performs both casework and database analyses, then the audit team or auditor must be qualified in both casework and database analyses.

[4] Standard 15.2 requires that "at least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory's current DNA technologies and platform."

Appendix C – Auditor Self-Certification for QAS Audits

Section 1 – to be completed by the laboratory being audited:
Laboratory being audited: San Diego Sheriff's Regional Crime Lab As of [date] 9/10/10
Technologies currently in use: Quantifiler and Quantifiler DUO, Identifiler
Platforms currently in use: ABI 7500, ABI 310, ABI 3130
Validations needing to be memorialized: Quantifiler DUO
Outsourcing agreements in place or in process: n/a
The laboratory being audited may request documentation for the information reported in Section 2 below.

Section 2 – to be completed by the auditor who will sign the attestation statement below the questions and (a) for external audits, return to the laboratory prior to the scheduled audit date; or (b) for internal audits, maintain in the laboratory's files.
Auditor Qualifications:
Name of Auditor: Stephenie Winter Sermeno
Auditor's Employer: Washington State Patrol
Auditor's Title or Position: Forensic Scientist 3
Qualified Auditor[2]: (Yes) No (Circle One)
Year Completed FBI DNA Auditor Class: 2015, refresher 2009
Current or Previously Qualified DNA Analyst: (Yes) No (Circle One)
Current or Previously Qualified in Casework, Database Analysis, or Both[3]:
(Casework) Database Both (Circle One)
Technologies Currently or Previously Qualified In (e.g., STR, mtDNA) (Please List):
STR
Platforms Currently or Previously Qualified In (e.g., Gel based/CE)
(Please List): AB 7000/7500, AB 310/3130

I verify that:
I understand the requirements of Standard 15.2[4] ; and
I have no conflicts of interest with the laboratory being audited; and
The information contained in Section 2 above is correct.
Signed By Stephenie Winter Sermeno Date 10/07/10

[2] A Qualified Auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor training course.

[3] If the laboratory being audited performs both casework and database analyses, then the audit team or auditor must be qualified in both casework and database analyses.

[4] Standard 15.2 requires that "at least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory's current DNA technologies and platform."

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 15.1 and 15.2.1, this form shall be used to document the evaluation and approval of analysts, CODIS administrators and technical leaders during an external audit. Section 1 is for documenting personnel who have received two successive separate external audit approvals of their education, experience, and training qualifications. Section 1 should be used to document all individuals who have received two successive separate audit approvals of their education, experience, and training qualifications, regardless of whether the individual is still employed by the laboratory. The date of the prior audit approvals should be noted in this Section, when known.

Section 2 is for documenting personnel who are receiving the **first** external audit approval of their education, experience, and training qualifications.

Section 1 documents those personnel who have received two successive external audit approvals of their education, experience, and training qualifications.

Section 1. (a) – Approvals Between July 1, 2004 and June 30, 2009
Laboratory personnel who have been evaluated after July 1, 2004, and approved under two successive, separate external audits as meeting the education, experience, and training qualifications required under Standard 5.1 of the 1998 Quality Assurance Standards for Forensic DNA Testing Laboratories:

Analyst(s):

Michelle Hassler (October 17-18, 2005 and November 13-14, 2007)
Connie Milton (October 17-18, 2005 and November 13-14, 2007)
Renee Montgomery (October 17-18, 2005 and November 13-14, 2007)
Ashlie Robinson (October 17-18, 2005 and November 13-14, 2007)
Lauren Sautkulis (November 13-14, 2007 and November 4-7, 2008)
AnneMarie Shafer (October 17-18, 2005 and November 13-14, 2007)
Byron Sonnenberg (October 17-18, 2005 and November 13-14, 2007)
Emily Williams (October 17-18, 2005 and November 13-14, 2007)
Shelley Webster (October 17-18, 2005 and November 13-14, 2007)

Monica Ammann (November 4-7, 2008)
Kelly Brockhohn (November 4-7, 2008)
Cathy Jakovich-Chang (November 4-7, 2008)

Technical Leader(s):

Michelle Hassler (November 13-14, 2007 and November 4-7, 2008)

Section 1. (b) – Approvals After July 1, 2009 Laboratory personnel who have been evaluated after July 1, 2009, and approved under two successive, separate external audits as meeting the education, experience, and training qualifications required under Standard 5.1 of the 2009 Quality Assurance Standards for DNA Databasing Laboratories:

Analyst(s):

Casework CODIS Administrator(s):

Technical Leader(s):

Section 2. (a) – For Personnel Appointed or Hired Prior to July 1, 2009

Laboratory personnel who were appointed or hired prior to July 1, 2009, and approved for the first time as meeting the education, experience, and training qualifications required under Standard 5.1 of the 1998 Quality Assurance Standards for Forensic DNA Testing Laboratories:

Analyst(s):

Kelly Ledbetter
Erin Forry
Erin Kilpatrick
Michael Palermo
Scott Zoll

Technical Leader(s):

Section 2. (b) – For Personnel Appointed or Hired On or After July 1, 2009 Laboratory personnel who have been evaluated after July 1, 2009, and approved for the first time as meeting the education, experience, and training qualifications required under Standard 5.1 of the 2009 Quality Assurance Standards for DNA Databasing Laboratories:

Analyst(s):

Rebekah Neyhart

Casework CODIS administrator(s):

Byron Sonnenberg

Technical Leader(s):

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.

To be completed by the audit team:

List of validations, if any, evaluated and approved during this audit:

Validation Quantifier Duo on the ABI 7500 which included
- Contamination assessment
- Known Sample comparison
- Sensitivity Study
- Stochastic study
- Reproducibility
- Precision
- Non-probative samples
- Amplification Target amount
- Mixture study