Hassler, Michelle

From: Kimberly Erturk <kimberly.erturk@nfstc.org>
Sent: Tuesday, August 14, 2012 12:01 PM
To: Guroff, Steve
Cc: Abby Meyer
Subject: FINAL REPORT: CA_SanDiegoSD_SanDiego_07_12_DNA-CW

Importance: High

Dear Steve Guroff:

Your audit is complete and ready for download. Please click the link below to login and download your audit.

http://audits.nfstc.org/index.php?p=appendix_lab_login

You will need your e-mail address and the following Audit Key to log into the validation page.

Audit Key: ONPB-00108-QNT7

If you have any difficulties accessing your final report, please contact us at assessment@nfstc.org.

**Please, review this material in its entirety. The audit team has carefully reviewed this report; however, if you view any administrative errors, (i.e. misspelled names, grammatical errors, etc.), please let me know, and the appropriate corrections will be made. Because your audit has been completed, if you feel your final report findings need changes, additions or deletions, these must be remediated through NDIS. As always, please feel free to contact me with any questions.

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
DOUGLAS.HARES@IC.FBI.GOV

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.***

We appreciate your participation in the NFSTC Assessment Program. Should you have any questions or comments, please feel free to contact us.
~K

Kimberly G. Erturk
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San Diego Sheriff's Department Sheriff's 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: 07/23/2012 - 07/25/2012

Kelcey Reed, Lead Auditor

Beverly Himick, Technical Auditor

Jelena Myers, Technical Auditor

Jeremy Sanderson, Technical Auditor

NIJ

This audit was performed under Cooperative Agreement #2010-DN-BX-K210 with the National Institute of Justice and the National Forensic Science Technology Center

"This document is to be used for pre-decisional purposes only by the laboratory audited and NDIS in determining compliance with these standards."

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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 SEPTEMBER 1, 2011

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

Dates of Audit: From: 07/23/2012 - To: 07/25/2012

Auditor(s):

Kelcey Reed	(Name)	(Signature)
Beverly Himick	(Name)	(Signature)
Jelena Myers	(Name)	(Signature)
Jeremy Sanderson	(Name)	(Signature)

Table of Contents

Checklist of General Laboratory Information

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

☐ ☐ ☐ ☒ ☐ ☐

2. Federal / State / Regional / County / Local / Other: _____
   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: Staff: 15 Contract Employees: 0
   DNA trainees: Staff: 2 Contract Employees: 0
   DNA technicians: Staff: 0 Contract Employees: 0
   Laboratory support personnel: Staff: 1 Contract Employees: 0
   DNA technical leader: Michelle Hassler
   On Site: Yes ☒ No ☐
   Casework CODIS administrator: Shelley Webster

9. Last audit conducted on: November 9-10, 2011
   External Audit: ☐ Internal Audit: ☒ (Choose One)

10. Audit Document Discussion Used (Revision Date): September 2011

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?	☒	☐	☐

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?	☒	☐	☐

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 ☒	

Comment

Standard: 3.2 - See Finding Section Standard: 3.2.b - See Finding Section Standard: 3.2.c - See Finding Section Standard: 3.2.d - See Finding Section Standard: 3.2.e - See Finding Section Standard: 3.2.g - See Finding Section

		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?	☒	☐	☐

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?	☒	☐	☐

Comment

Standard 4.1.2.a was marked N/A because the laboratory 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?	☒	☐	☐

Comment

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

Comment

		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?	☒	☐	☐

Comment

Standard 5.1.2.2.2 was marked N/A because analysts with previous experience have not been qualified for DNA analysis since the last external audit.
Standard 5.1.2.2.2.a was marked N/A because analysts with previous experience have not been qualified for DNA analysis since the last external audit.
Standard 5.1.2.2.2.b was marked N/A because analysts with previous experience have not been qualified for DNA analysis since the last external audit.

		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: ☒ ☐ ☐

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? ☒ ☐ ☐

Comment

Standard 5.1.3.1.1 was marked N/A because the laboratory did not conduct internal training since the last external audit.
Standard 5.1.3.1.3 was marked N/A because there was not any continuing education based on multimedia or internet for delivery since the last external audit.

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

Comment

		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? ☒ ☐ ☐

Comment

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)? ☐ ☐ ☒

Comment

Standard 5.2.1.4 was marked N/A because the technical leader meets the educational requirement listed in Standard 5.2.1.

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? ☒ ☐ ☐

Comment

Standard 5.2.2.b was marked N/A because the technical leader was hired prior to 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?

5.2.3.2.7 Review requests by contract employees for employment by multiple NDIS participating and/or vendor laboratories and, if no potential conflict of interest exist, may approve such requests? ☐ ☐ ☒

Comment

Standard 5.2.3.2.3 was marked N/A because the laboratory does not outsource DNA casework.
Standard 5.2.3.2.7 was marked N/A because the laboratory does not have contract employees.

		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?	☒	☐	☐
	5.2.4.1.1.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?	☐	☐	☒
	5.2.4.1.1.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?	☐	☐	☒

Comment

Standard 5.2.4.b was marked N/A because the technical leader does not oversee a system of separate laboratories.
Standard 5.2.4.1.1.b was marked N/A because a qualified individual was available and appointed upon the temporary absence of the technical leader.
Standard 5.2.4.1.1.c was marked N/A because a qualified individual has continuously been in the technical leader position without a break in service.
Standards 5.2.5, 5.2.5.1, and 5.2.5.2 were marked N/A because the technical leader was appointed / hired prior to 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?	☒	☐	☐

Comment

		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?	☐	☐	☒

Comment

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

		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?	☒	☐	☐
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?	☒	☐	☐

Comment

		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?	☒	☐	☐

Comment

		Yes	No	N/A
5.5	Is each technical reviewer an employee or contract employee of the laboratory and does he or she meet or exceed the following qualifications?	☒	☐	☐
5.5.1	Is each technical reviewer a current or previously qualified analyst in the methodologies being reviewed?	☒	☐	☐
5.5.2	Has each technical reviewer successfully completed a competency test prior to participating in the technical review of DNA data?	☒	☐	☐
5.5.3	Does each technical reviewer participate in an external proficiency testing program at an NDIS participating laboratory on the same technology, platform and typing amplification test kit used to generate the DNA data being reviewed?	☒	☐	☐

Comment

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

Comment

Standard 5.6 was marked N/A because the laboratory does not have a laboratory technician.
Standard 5.6.1 was marked N/A the laboratory does not have a laboratory technician.
Standard 5.6.2 was marked N/A because the laboratory does not have a laboratory technician.

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?	☒	☐	☐

Comment

		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?	☐	☐	☒

Comment

Standard 6.1.4.a was marked N/A because the laboratory does not have a robot that performs analysis through amplification.

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

Comment

Standard 7. Evidence Control

		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?
Yes ☒ No ☐

b. Does the laboratory clearly define what constitutes evidence and what constitutes work product?
Yes ☒ No ☐

c. Does the laboratory have and follow a method to distinguish each sample throughout processing?
Yes ☒ No ☐

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 ☐

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?	☒	☐	☐

Comment

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

Comment

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

Comment

Standard 8. Validation

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

Comment

Standard: 8.1 - See Finding Section

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

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? ☒ ☐ ☐

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?	☒	☐	☐

Comment

Standard 8.3.1.1.a was marked N/A because this laboratory is not part of a multi-laboratory system.
Standard 8.3.1.1.b was marked N/A because this laboratory is not part of a multi-laboratory system.
Standard: 8.3.2 - See Finding Section
Standard 8.3.3 was marked N/A because the laboratory has not had a change in the detection platform or test kit since the last external audit.

		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?	☒	☐	☐

Comment

Regarding Standard 8.5, Material modifications were performed on the following procedures:

Microcon concentration procedure to improve DNA recovery, approved March 28, 2011.
Regarding Standard 8.6, Performance checks were conducted prior to casework on the following critical instruments:

Tecan Freedom EVO 150 Liquid Handler, approved February 6, 2012.
Regarding Standard 8.7, Performance checks were conducted prior to casework on the following software upgrades:

1) Cal DOJ Mixture Tool v. 1.4 using YSTR database release 2.5, approved November 23,2011
2) Cal DOJ Mixture Tool v. 1.5 using YSTR database release 2.6, approved January 17, 2012
3) CODIS 7.0, approved July 25, 2012
Regarding Standard 8.7.a, Validation testing was performed on the following software:

1) Cal DOJ Mixture Tool v. 1.4 using YSTR database release 2.5, approved November 23,2011
2) Cal DOJ Mixture Tool v. 1.5 using YSTR database release 2.6, approved January 17, 2012

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?	☒	☐	☐

Comment

		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 [X] No [ ]

b. The date of the preparation or expiration or both?
Yes [X] No [ ]

c. The identity of the individual preparing the reagent?
Yes [X] 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? [X] [ ] [ ]

b. Has the laboratory evaluated critical reagents prior to use in casework? [X] [ ] [ ]

9.3.1 Has the laboratory identified and evaluated the following: [X] [ ] [ ]

a. Test kits or systems for performing quantitative PCR?
Yes [X] No [ ] N/A [ ]

b. Test kits or systems for performing genetic typing?
Yes [X] No [ ] N/A [ ]

9.3.2 Has the laboratory identified and evaluated the following: [ ] [ ] [X]

a. Thermostable DNA polymerase (if not tested as test kit components under Standard 9.3.1)?
Yes [ ] No [ ] N/A [X]

b. Primer sets (if not tested as test kit components under Standard 9.3.1)?
Yes [ ] No [ ] N/A [X]

c. Allelic ladders used for genetic analysis (if not tested as test-kit components under Standard 9.3.1)?
Yes [ ] No [ ] N/A [X]

Comment

Standard 9.3.2 was marked N/A because 9.3.2.a, 9.3.2.b and 9.3.2.c were rated N/A.
Standard 9.3.2.a was marked N/A because the thermostable DNA polymerase is part of the test kit.
Standard 9.3.2.b was marked N/A because the primer set is part of the test kit.
Standard 9.3.2.c was marked N/A because the allelic ladders are part of the 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?	[X]	[ ]	[ ]

Comment

		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 in the same instrument 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 [X] No [ ]

		Yes	No	N/A
9.5.4	Does the laboratory use allelic ladders and internal size markers for VNTR sequence PCR- based systems?	[X]	[ ]	[ ]

Comment

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?	[X]	[ ]	[ ]

Comment

		Yes	No	N/A
9.6	Does the laboratory have and follow written guidelines for the interpretation of data?	[ ]	[X]	[ ]
9.6.1	Does the laboratory verify that all control results meet the laboratory's interpretation guidelines for all reported results?	[X]	[ ]	[ ]
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?	[X]	[ ]	[ ]
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?	[X]	[ ]	[ ]
9.6.4	Does the laboratory have and follow documented procedures for mixture interpretation to include the following:	[X]	[ ]	[ ]

a. Major and minor contributors? Yes ☒ No ☐

b. Inclusions and exclusions? Yes ☒ No ☐

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

Comment

Standard: 9.6 - See Finding Section

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

Comment

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?	☒	☐	☐

Comment

Standard 10.2.1.5 was marked N/A because the laboratory does not use an electrophoresis detection system other than a genetic analyzer.
Standard: 10.3 - See Finding Section
Standard 10.4.1.1 was marked N/A because the laboratory does not use an electrophoresis detection system other than a genetic analyzer.

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?	☒	☐	☐
11.1.b	Does the laboratory maintain all analytical documentation generated by analysts related to case analyses?	☒	☐	☐
11.1.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?	☒	☐	☐

Comment

		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?	☒	☐	☐

Comment

		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?	☒	☐	☐

Comment

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?	☒	☐	☐

Comment

		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 assessments 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 ☐

Comment

		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?	☒	☐	☐

Comment

		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?	☒	☐	☐

Comment

		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?	☒	☐	☐

Comment

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?	☒	☐	☐

Comment

		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?	☐	☐	☒

Comment

Standard 13.1.2 was marked N/A because the laboratory has not had newly qualified individuals since the last external audit.
Standard 13.1.4.1 was marked N/A because the laboratory does not use the team approach for DNA casework.
Standard 13.1.7.2 was marked N/A because the laboratory did not have proficiency results that were reported as inconclusive or not interpretable since the last external audit.
Standard 13.1.7.2.1 was marked N/A because the laboratory did not have proficiency results that were reported as inconclusive since the last external audit.
Standard 13.1.7.4.1.1 was marked N/A because the laboratory didn't identify any administrative errors in the proficiency tests since the last external audit.
Standard 13.1.9.a was marked N/A because there were not any nonadministrative discrepancies that affected typing results and/or conclusions since the last external audit.

		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?	☒	☐	☐

Comment

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?	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?	☒	☐	☐

Comment

Standard 15. Audits

		Yes	No	N/A
15.1	Has the laboratory been audited annually in accordance with the FBI DNA Quality Assurance Standards?	☒	☐	☐
	For this audit, has the laboratory maintained documentation that the auditor(s):	☒	☐	☐
	a. Is qualified? Yes ☒ No ☐			
	b. Is a current or previously qualified analyst in the laboratory's current DNA technologies and platform? Yes ☒ No ☐			
15.2	Has an external audit been conducted at least once every two years by a second agency?	☒	☐	☐
	For this audit, has the laboratory maintained documentation that the auditor(s):	☒	☐	☐
	a. Is qualified? Yes ☒ No ☐			
	b. Is a current or previouly 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):	☒	☐	☐
	a. Is qualified? Yes ☒ No ☐			
	b. Is 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?	☒	☐	☐

Comment

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?	☒	☐	☐

Comment

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 or searching in 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 profiles generated by a vendor laboratory for upload to CODIS?	☐	☐	☒
	a. Prior to the NDIS laboratory's uploading or accepting data to upload to 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 search of DNA data in SDIS, did an analyst, casework CODIS administrator, or technical reviewer employed by an NDIS participating laboratory review the DNA data to verify specimen eligibility and the correct specimen category for entry into CODIS? ☐ ☐ ☒

17.6 Prior to the upload of the data generated by the vendor laboratory to SDIS or the reporting of search results, did an NDIS laboratory perform a technical review of the vendor laboratory's data? ☐ ☐ ☒

a. Was the technical review performed by an NDIS laboratory 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 an NDIS laboratory's proficiency-test program? ☐ ☐ ☒

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

17.6.1.1 A review of all DNA types to verify that they are supported by the raw and/or analyzed data? ☐ ☐ ☒

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

17.6.1.3 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 ☐

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

17.7 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?	☐	☐	☒
17.7.1	A documented on-site visit prior to the initiation of analysis?	☐	☐	☒
17.7.1.1	a. Has the on-site visit been performed by the technical leader or designated employee of an NDIS laboratory that uses the same technology, platform, and typing amplification test kit; or b. Has an on-site visit performed by a designated FBI employee been accepted by the technical leader?	☐	☐	☒
17.7.2	If the NDIS laboratory's outsourcing agreement extended beyond one year, was an annual on-site visit conducted?	☐	☐	☒
17.7.2.1	If an on-site visit conducted by the FBI, or another NDIS laboratory was used by the NDIS laboratory, did the technical leader document the review and acceptance of that on-site visit?	☐	☐	☒

Comment

Standard 17.1 and all its subcategories were marked N/A because the laboratory has not outsourced samples or accepted profiles generated by a vendor laboratory for upload to CODIS since their last external audit.

Appendix A: Findings and Responses

Findings:

Standard: 3.2 - Does the laboratory maintain and follow a procedure regarding document retention that specifically addresses:

Objective Proof for the finding:

See Standards 3.2.b, 3.2.c, 3.2.d, 3.2.e and 3.2.g.

Standard: 3.2.b - Corrective action?

Objective Proof for the finding:

Standard 3.2.b was rated No because there was not a documented record retention policy specifically for corrective action records.

Standard: 3.2.c - Audits?

Objective Proof for the finding:

Standard 3.2.c was rated No because there was not a documented record retention policy specifically for audit documents.

Standard: 3.2.d - Training records?

Objective Proof for the finding:

Standard 3.2.d was rated No because there was not a documented record retention policy specifically for training records.

Standard: 3.2.e - Continuing education?

Objective Proof for the finding:

Standard 3.2.e was rated No because there was not a documented record retention policy specifically for continuing education.

Standard: 3.2.g - Court testimony monitoring?

Objective Proof for the finding:

Standard 3.2.g was rated No because there was not a documented record retention policy specifically for court testimony monitoring records.

Standard: 8.1 - Does the laboratory use validated methods for DNA analyses?

Objective Proof for the finding:

See Standard 8.3.2.

Standard: 8.3.2 - Have quality assurance parameters and interpretation guidelines, including, as applicable, guidelines for mixture interpretation, been defined pursuant to internal validation?

Objective Proof for the finding:

Standard 8.3.2 was rated No because, the casework data for Quantifiler DUO and Quantifiler Human does not support the data produced in the validation as there are multiple instances of human DNA below 250 pg in casework (01061001 and 94076729) that produced full profiles. The Forensic Biology Technical Procedures Manual revision 4, dated March 20, 2012 section 4.4.2 states that amplification of less than 250 pg total DNA should only be attempted with extreme caution and analyst discretion, which is allowing analysts to stop processing samples at this level that has been shown to produce full profiles.

Standard: 9.6 - Does the laboratory have and follow written guidelines for the interpretation of data?

Objective Proof for the finding:

Standard 9.6 was rated No, because the Forensic Biology Technical Procedures Manual revision 4 dated March 20, 2012 states in section 4.5.5.1 that the Popstats statistical program should be used for autosomal STR calculations; however there are not any statistical formulas or procedures present for manual calculations if Popstats is inoperable. Several analysts were not certain where to locate the statistical formulas to conduct manual calculations.

Standard: 10.3 - Does the laboratory have a schedule and follow a documented program to ensure that instruments and equipment are maintained properly?

Objective Proof for the finding:

Standard 10.3 is rated No because although the Tempsys temperature monitoring system does provide a computer alert when temperatures fall outside of the tolerance range; there is not a procedure in place detailing what should be done if temperatures fall out of the acceptable range.

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 Department Sheriff's Regional Crime Laboratory
As of [date]: 05/23/2012

Technologies currently in use:

Autosomal STRs [X] YSTR [X] MtDNA [ ]

Other [ ]

Platforms currently in use: Identifiler
YFiler

Validations needing to be memorialized: YFiler
Automated quantitation setup using Tecan EVO-150

Outsourcing agreements in place or in process: Bode Technology Group (CODIS upload only)

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: Kelcey Reed
Auditor's Employer: City of Phoenix
Auditor's Title or Position: Forensic Scientist

Qualified Auditor [2] Yes: [X] No: [ ]

Year Completed FBI DNA Auditor Class: 2009

Current or Previously Qualified DNA Analyst: Yes No Yes: [X] No: [ ]
Current or Previously Qualified in Casework, Database Analysis, or Both [3]
Casework: [X] Database: [ ] Both: [ ]

Technologies Currently or Previously Qualified in: (e.g. STR, mtDNA)
Please List: rnAutosomal STRs

Platforms Currently or Previously Qualified in: (e.g. Gel Based/CE)
Please List: CE-ABI310, 3100, 3130

I verify:
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: Kelcey Reed **Date: 05/23/2012**

[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 platforms.

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 Department Sheriff's Regional Crime Laboratory
As of [date]: 05/23/2012

Technologies currently in use:

Autosomal STRs [X] YSTR [X] MtDNA [ ]

Other [ ]

Platforms currently in use: Identifiler
YFiler

Validations needing to be memorialized: YFiler
Automated quantitation setup using Tecan EVO-150

Outsourcing agreements in place or in process: Bode Technology Group (CODIS upload only)

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 Laboratory- Seattle
Auditor's Title or Position: Supervising Forensic Scientist

Qualified Auditor [2] Yes: [X] No: [ ]

Year Completed FBI DNA Auditor Class: 2003

Current or Previously Qualified DNA Analyst: Yes No Yes: [X] No: [ ]
Current or Previously Qualified in Casework, Database Analysis, or Both [3]
Casework: [X] Database: [ ] Both: [ ]

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:
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:** 05/23/2012

[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 platforms.

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 Department Sheriff's Regional Crime Laboratory
As of [date]: 05/23/2012

Technologies currently in use:

Autosomal STRs [X] YSTR [X] MtDNA [ ]

Other [ ] _____

Platforms currently in use: Identifiler
YFiler

Validations needing to be memorialized: YFiler
Automated quantitation setup using Tecan EVO-150

Outsourcing agreements in place or in process: Bode Technology Group (CODIS upload only)

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: Jelena Myers
Auditor's Employer: Tucson Police Department Crime Lab
Auditor's Title or Position: DNA Technical Leader

Qualified Auditor [2] Yes: [X] No: [ ]

Year Completed FBI DNA Auditor Class: 2004

Current or Previously Qualified DNA Analyst: Yes No Yes: [X] No: [ ]
Current or Previously Qualified in Casework, Database Analysis, or Both [3]
Casework: [X] Database: [ ] Both: [ ]

Technologies Currently or Previously Qualified in: (e.g. STR, mtDNA)
Please List: STR, Y-STR

Platforms Currently or Previously Qualified in: (e.g. Gel Based/CE)
Please List: GEL BASED, CE

I verify:
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: Jelena Myers **Date: 05/23/2012**

[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 platforms.

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 Department Sheriff's Regional Crime Laboratory

As of [date]: 05/24/2012

Technologies currently in use:

Autosomal STRs [X] YSTR [X] MtDNA [ ]

Other [ ] _____

Platforms currently in use: Identifiler
YFiler

Validations needing to be memorialized: YFiler
Automated quantitation setup using Tecan EVO-150

Outsourcing agreements in place or in process: Bode Technology Group (CODIS upload only)

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: [X] No: [ ]

Year Completed FBI DNA Auditor Class: 2010

Current or Previously Qualified DNA Analyst: Yes No Yes: [X] No: [ ]

Current or Previously Qualified in Casework, Database Analysis, or Both [3]

Casework: [X] Database: [ ] Both: [ ]

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:

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: 05/24/2012**

[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 platforms.

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 Standard 15.1 and 15.2.1, this form shall be used to document the evaluation and approval of analysts, casework 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 successsive 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[1]:

Analyst(s):

Michelle Hassler (10/2005 & 11/2007)
STRs

Connie Milton (10/2005 & 11/2007)
STRs

Renee Montgomery (10/2005 & 11/2007)
STRs

Ashlie Robinson (10/2005 & 11/2007)
STRs

Lauren Sautkulis (11/2007 & 11/2008)
STRs

[1] Laboratory personnel qualified by the technical leader on or before June 30, 2009, and evaluated after July 1, 2009, should be listed in this section.

AnneMarie Shafer (10/2005 & 11/2007)
STRs

Byron Sonnenburg (10/2005 & 11/2007)
STRs

Shelley Webster (10/2005 & 11/2007)
STRs

Emily Campbell (Williams) (10/2005 & 11/2007)
STRs

Technical Leader(s):

Michelle Hassler (11/2007 & 11/2008)

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 Forensic DNA Testing Laboratories:

Analyst(s):

Kelly Ledbetter (11/2010 & 7/2012)
STRs, YSTRs (2012)

Michael Palermo (11/2010 & 7/2012)
STRs

Scott Zoll (11/2010 & 7/2012)
STRs

Rebekah Neyhart (11/2010 & 7/2012)
STRs

Monica Ammann (11/2008 & 11/2010)
STRs

Kelly Brockhohn (11/2008 & 11/2010)
STRs

Cathy Chang (11/2008 & 11/2010)
STRs

Casework CODIS Administrator(s):

None

Technical Leader(s):

Section 2 documents those personnel who are receiving the first external audit approval of their education, experience, and training qualifications.

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):

()

()

Technical Leader(s):

None

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 Forensic DNA Testing Laboratories:

Analyst(s):

None

Casework CODIS Administrator(s):

Shelley Webster (7/2012)

Technical Leader(s):

None

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 Yfiler
Approved by DNA Technical Leader on September 7, 2011
Precision and Match Criteria
Sensitivity and Stochastic Studies
Amplification Target Amount
Analytical Threshold
Stutter
Reproducibility and NIST Samples
Proficiency Test Samples
Non-probative Case Samples
Female Samples
High Female Samples
Male/Female Mixtures
Two Male Mixtures
Three Male Mixtures
DYS385A/b Peak Height Ratio
Inheritance
Contamination

Validation of Tecan Freedom EVO 150 with HID EVOlution Software for Quantitation Set Up of Applied Biosystems Quantifiler Human DNA Kit and Applied Biosystems Quantifiler Duo DNA Kit
Approved by Technical Leader on February 6, 2012
Minimum Volume Handling
Reproducibility, Reliability and Concordance with Manually Processed Samples
Sensitivity
NIST
Non-Probative Casework Samples
Contamination Monitoring
Sample Tracking

Validation of Tecan Freedom EVO 150 with HID EVOlution Software for Normalization and Amplification Set Up of Applied Biosystems AmpFISTR Identifiler STR Amplfications Kit
Approved by Technical Leader on February 6, 2012
Evaluation of Normalization
Reproducibility

Sensitivity
NIST SRM Study
Non-Probative Casework Samples
Contamination Monitoring
Concordance/Known Samples
Sample Tracking