Connecticut Department of Public Safety Forensic Science Laboratory

278 Colony Street, Meridan, CT 06451

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

Conducted on July 11-13, 2011

Lucy A. Davis	NFSTC Lead Auditor
Kathy Guenther	NFSTC Technical Auditor
Mark Losko	NFSTC Technical Auditor

This audit was performed under Cooperative Agreement #2007–MU–BX–K008
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

DNA DATABASING LABORATORIES

IN ACCORDANCE WITH

THE QUALITY ASSURANCE STANDARDS

FOR

DNA DATABASING LABORATORIES

EFFECTIVE JULY 1, 2009

An Audit of: Connecticut Department of Public Safety Forensic Science Laboratory

Dates of Audit: July 11-13, 2011

Auditor(s):

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(Name)	(Signature)
Kathy Guenther	
(Name)	(Signature)
Mike Losko	
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Last Updated: July, 21, 2010

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Checklist of General Laboratory Information

1. Name of Laboratory: Connecticut Department of Public Safety Forensic Science Laboratory

☐ ☑ ☐ ☐ ☐ ☐

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

3. Approximate Population Size Served: 3.5 million

4. Uses a Contract Laboratory: Yes ☑ No ☐
   Name of Contract Laboratory(i s): LabCorp

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: 5
   DNA trainees: 0
   DNA technicians: 1
   Laboratory support personnel: 0
   DNA technical leader: Carll Ladd
   On site: Yes ☑ No ☐
   CODIS administrator: Mike Bourke

9. Last audit conducted on: December 2008 (Internal audits conducted in 2009 and 2010)
   External Audit ☑ Internal Audit ☐ (Choose one)
   Audit Document Discussion Used (Revision Date): July 2009

10. Uses an expert system: Yes ☐ No ☑
    Name & Version of Expert System, Test Kit, Instrument and version of Data Collection _____
11. Does the database laboratory process casework known reference samples? Yes ☑ No ☐

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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		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	Sample control?	☑	☐	☐
3.1.1.6	Validation?	☑	☐	☐
3.1.1.7	Analytical procedures?	☑	☐	☐
3.1.1.8	Equipment calibration and maintenance?	☑	☐	☐
3.1.1.9	Documentation/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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Standards 3.1.1, 3.1.1.4 and 3.1.1.15 - See Findings Section

		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. Analytical Results?	Yes	☑	No	☐
c. Sample receipt and processing records?	Yes	☑	No	☐
d. Sample retention?	Yes	☑	No	☐
e. Hit confirmation?	Yes	☑	No	☐
f. Corrective action?	Yes	☑	No	☐
g. Audits?	Yes	☑	No	☐
h. Training records?	Yes	☑	No	☐
i. Continuing education?	Yes	☑	No	☐
j. 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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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 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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Standards 4.1, 4.1.2, 4.1.3. and 4.1.5 - See Findings Section

Standard 4.1.2.a is marked N/A 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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Standard 5.1 - See Findings Section

		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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Standard 5.1.1 - See Findings Section

		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 DNA methodologies used in the laboratory's database program?	☑	☐	☐
	5.1.2.1.1 If the databasing laboratory is processing known or casework reference sample(s) as evidence, does the laboratory's training program also include evidence handling and courtroom testimony?	☑	☐	☐
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 or DNA database 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 database analysis 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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Standards 5.1.2.2.2.a and 5.1.2.2.2.b are rated N/A as no analysts or technicians with previous forensic experience were hired and put through a modified training program 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, 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 5.1.3.2.a - See Findings Section

		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 ☑ ☐			
	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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Standard 5.2.1.4 was rated N/A since the current Technical Leader does not posses a waiver from ASCLD; the current Technical Leader meets the degree requirements of 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, databasing or human identification DNA laboratory experience obtained at a laboratory where DNA testing was conducted for identification, databasing or forensic purposes?	☑	☐	☐
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 database or 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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	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 database 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 database 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 database 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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Standards 5.2.3.1.2, 5.2.3.2.1, 5.2.3.2.2, 5.2.3.2.3, 5.2.3.2.4 and 5.2.3.2.5 - See Findings Section

		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 database DNA analysis 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.b was rated N/A as the Technical Leader does not oversee a system of separate laboratories.

Standards 5.2.4.1.1.a, 5.2.4.1.1.b and 5.2.4.1.1.c are marked N/A because the technical leader position has not been vacant since the last external audit.

Standards 5.2.5.1 and 5.2.5.2 are marked N/A because the technical leader was hired prior to July 1, 2009.

		Yes	No	N/A
5.3	Is the CODIS administrator an employee of the laboratory and does he or she meet the following qualifications?	☑	☐	☐
5.3.1	Education:			
	Does the CODIS administrator meet the minimum education requirements?	☑	☐	☐
	a. Does the CODIS administrator meet the minimum education requirements as defined in Standard 5.4 or	☑	☐	☐
	b. Was the CODIS administrator appointed or hired prior to July 1, 2009, with supporting documentation from the FBI?	☐	☐	☑
5.3.2	Experience:			
	Does the CODIS administrator meet the experience requirements?	☑	☐	☐
	a. Is a current or previously qualified casework or database DNA analyst with documented mixture interpretation training, or	☑	☐	☐
	b. Was the 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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Standards 5.3.1.b and 5.3.2.b were rated as N/A as the CODIS administrator meets the minimum education requirements as defined in Standard 5.4 and has documented mixture interpretation training.

		Yes	No	N/A
5.3.3	Has the 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 CODIS administrator responsible for the following:	☐	☑	☐
5.3.4.1	Administering the laboratory's CODIS network?	☑	☐	☐
5.3.4.2	Scheduling and documenting the CODIS computer training of database 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 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?	☐	☑	☐
5.3.5.1	Does the state CODIS administrator have the authority over all CODIS sites under his/her jurisdiction to terminate an analyst's or laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with data is identified?	☐	☐	☑
5.3.6	If the 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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Standards 5.3.4, 5.3.4.2, 5.3.4.3, 5.3.4.4, 5.3.4.5 and 5.3.5 - See Findings Section

Standard 5.3.5.1 is marked N/A because this is the only CODIS laboratory in the state.

Standard 5.3.6 was rated N/A as the CODIS Administrator position has not be unoccupied since the last external 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, human-DNA laboratory experience with at least three months in a forensic or database DNA laboratory?	☑	☐	☐
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 database analysis?	☑	☐	☐
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?	☑	☐	☐
5.6	Do all laboratory technical support personnel have documented training specific to their job function(s)?	☐	☐	☑

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Standard 5.6 was rated N/A as the laboratory does not utilize technical support personnel for DNA analysis.

Standard 6. Facilities

		Yes	No	N/A
6.1	Is the laboratory designed to ensure the integrity of the analyses and the samples?	☑	☐	☐
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 sample accessioning, 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 sample accessioning, 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 (if applicable), 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 sample accessioning? ☐ ☐ ☑

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Standards 6.1.4 and 6.1.4.a were marked N/A as the laboratory only uses robotics systems for DNA extractions.

		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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STANDARD 7. Sample Control

		Yes	No	N/A
7.1	Does the laboratory have and follow a documented sample inventory control system to ensure the integrity of database and known samples?	☑	☐	☐
7.1.1	For evidence and sample identification:			
	a. Are all database, known and casework reference samples marked with a unique identifier?	☑	☐	☐
	b. Does the laboratory have and follow a method to distinguish each sample throughout processing?	☑	☐	☐

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		Yes	No	N/A
7.1.2	Does the laboratory maintain documentation of sample identity, collection, receipt, storage, and disposition?	☑	☐	☐
	7.1.2.1 If the databasing laboratory is processing known or casework reference sample(s) as evidence, does the laboratory document and maintain a chain of custody in hard or electronic format, to include the following:	☑	☐	☐

a. Signature or initials or the electronic equivalent of each individual receiving or transferring the known or casework reference sample(s)?
Yes ☑ No ☐

b. The corresponding date for each transfer?
Yes ☑ No ☐

c. The known or casework reference sample(s) transferred?
Yes ☑ No ☐

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	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 samples and work product in progress?	☑	☐	☐
7.1.4 Does the laboratory have secure, controlled-access areas for sample storage, including environmental control, consistent with the form or nature of the sample?	☑	☐	☐

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	Yes	No	N/A
7.2 Does the laboratory retain the database sample for retesting for quality assurance and sample confirmation purposes where possible?	☑	☐	☐

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Standard 8. Validation

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

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Standard 8.1 - See Findings Section

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

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		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.	Database-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. Database type samples? Yes ☑ No ☐ N/A ☐			
	2. Reproducibility and precision? Yes ☑ No ☐ N/A ☐			
	3. Sensitivity and stochastic studies? Yes ☑ No ☐ N/A ☐			
	4. 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 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?	☑	☐	☐
8.3.4	If the NDIS laboratory has validated an expert system, was it validated in accordance with applicable NDIS operational procedures?	☐	☐	☑
8.3.5	If the laboratory has validated the use of robotics, was the validation conducted and documented to the extent	☑	☐	☐

they are used by the database laboratory?

8.4	Has the analyst or examination team successfully completed a competency test using the DNA analysis procedure prior to its incorporation into database applications?	☐	☐	☑

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Comment

Standards 8.3.1.b, 8.3.1.b.4, and 8.3.2 - See Findings Section

Standards 8.3.1.1.a and 8.3.1.1.b were rated N/A as the laboratory is not part of a multi-laboratory system.

Standard 8.3.4 is rated N/A since the laboratory has not validated an expert system.

		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 database applications?	☐	☑	☐
8.6	Has the laboratory evaluated each additional or modified critical instrument by conducting a performance check prior to its use in databasing?	☐	☑	☐
8.7	Has the laboratory evaluated software upgrades by conducting a performance check prior to use in databasing?	☐	☐	☑
	a. Has new software or significant software modifications been documented and subjected to validation testing prior to use in databasing?	☐	☐	☑

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Comment

Standards 8.5 and 8.6 - See Findings Section

Standards 8.7 and 8.7.a were rated N/A as there were no upgrades, modifications or new software implemented in the laboratory 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?	☐	☑	☐

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Standards 9.1, 9.1.a, 9.1.1, and 9.1.1.a - See Findings Section

		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 databasing? ☐ ☑ ☐

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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Standards 9.3.a, 9.3.b, 9.3.1, and 9.3.1.a - See Findings Section

Standards 9.3.2.b, and 9.3.2.c were rated N/A as the laboratory tests these items as part of the test kit components.

		Yes	No	N/A
9.4	Does the laboratory have and follow a documented procedure for the resolution, verification and reporting/notification of database matches?	☑	☐	☐

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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	Where quantitation is performed, are quantitation standards used?	☑	☐	☐
9.5.2	For positive and negative amplification controls:			
	a. Are the positive and negative amplification controls associated with the samples being typed amplified concurrently in the same instrument with the samples at all loci using the same primers as the database, known and casework reference samples?	☑	☐	☐
	b. Are the positive and negative amplification controls associated with the 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 sample(s)? Yes ☑ No ☐			
	b. The same instrument model as the sample(s)? Yes ☑ No ☐			
	c. The same concentration conditions as required by the sample(s) with the most sensitive volume conditions of the extraction set?			

☑ No ☐

9.5.3.3 Are the reagent blanks typed using: ☑ ☐ ☐

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

Yes ☑ No ☐

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

Yes ☑ No ☐

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

Yes ☑ No ☐

9.5.4 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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Standard 9.5.5 - See Findings Section

		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 data to be entered into CODIS?	☑	☐	☐

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

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Comment

Standard 9.7 - See Findings Section

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 verification 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 system where utilized?	☑	☐	☐
	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?	☑	☐	☐
10.2.2	The following critical equipment requires quarterly recertification:			
	10.2.2.1 Expert systems approved for use at NDIS.	☐	☐	☑
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 database analysis?	☐	☑	☐
10.4.1	At a minimum, are the following critical instruments or equipment performance-checked and/or recertified 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 quantitative-PCR where utilized?	☐	☑	☐
10.4.1.5 Expert systems approved for use at NDIS?	☐	☐	☑

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Standards 10.2, 10.2.1, 10.2.1.3, 10.2.1.6,10.3, 10.4, 10.4.1.3 and 10.4.1.4 - See Findings Section

Standards 10.2.1.5 and 10.4.1.1 are rated N/A since the laboratory does not use electrophoresis detection systems other than genetic analyzers.

Standards 10.2.2.1 and 10.4.1.5 are rated N/A since the laboratory does not use an expert system.

Standard 11. Documentation/Reports

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

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		Yes	No	N/A
11.2	Does the laboratory have and follow written procedures to ensure the confidentiality of the database, known or casework reference samples and the information in DNA databases and DNA records, except as otherwise provided by applicable state or federal law?	☑	☐	☐
11.2.1	Does the laboratory have and follow written procedures for the release of the DNA records and database, known or casework reference samples in accordance with applicable state or federal law?	☑	☐	☐
11.2.2	Does the laboratory have and follow written procedures for the release of personally identifiable information relating to DNA records in accordance with applicable state or federal law?	☑	☐	☐
	11.2.2.1 Does the laboratory have and follow a procedure for the release of personally identifiable information in connection with a database hit?	☑	☐	☐

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Standard 12. Review

		Yes	No	N/A
12.1	Does the laboratory have and follow written procedures for reviewing DNA records and DNA database information, including the verification and resolution of database matches?	☑	☐	☐
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 prior to uploading or searching in SDIS, and does it include the following elements:	☐	☑	☐
12.2.1	A review of all notes, all worksheets, and all electronic data (or printed electropherograms or images) supporting the results?	☐	☑	☐
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 controls, internal lane standards, and allelic ladders to verify that the expected results were obtained?	☑	☐	☐
12.2.4	A review to confirm that reworked samples have appropriate controls?	☑	☐	☐

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Standards 12.2 and 12.2.1 - See Findings Section

		Yes	No	N/A
12.3	a. Does the laboratory conduct an administrative review of official correspondence related to database hits containing personally identifiable information?	☑	☐	☐
	b. 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 supporting administrative documentation and the correspondence for clerical errors?	☑	☐	☐
12.3.2	A review of the individual's biographical data, qualifying offense, and DNA profile generated from reanalysis, as applicable?	☑	☐	☐
12.3.3	Does the laboratory have and follow 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?	☐	☑	☐
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 a system in place to ensure that the correct CODIS specimen categories have been assigned?	☑	☐	☐

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Standard 12.4 - See Findings Section

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

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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 database analysis?	☑	☐	☐

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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 database analysis?	☑	☐	☐
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 (if applicable) correct?	☐	☑	☐
	b. Are all reported exclusions (if applicable) 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 CODIS administrator of all nonadministrative discrepancies that affect the typing results and/or conclusions at the time of discovery?	☐	☐	☑

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		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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Comment

Standards 13.1.7, 13.1.7.1.a, 13.1.7.1.b, and 13.1.7.1.c - See Findings Section

Standards 13.1.7.2 and 13.1.7.2.1 were rated N/A as no proficiency test results have been reported as inconclusive or not interpretable since the last external audit

Standard 13.1.7.3 was rated N/A as there were no discrepancies/errors since the last external audit.

Standard 13.1.7.4.1.1 was rated N/A as there were no administrative errors or corrective actions since the last external audit.

Standard 13.1.9.a was rated N/A as there were no non-administrative discrepancies since the last external audit.

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 database 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?	☑	☐	☐

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Standards 14.1.a, 14.1.b, 14.1.b.1, 14.1.b.2, 14.1.b.3, 14.1.b.4, and 14.1.b.5 - See Findings Section

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:	☑	☐	☐
	a. A qualified auditor? Yes ☑ No ☐			
	b. A current or previously qualified analyst in the laboratory's current DNA technologies and platform? Yes ☑ No ☐			
	c. One team member that is a currently or previously qualified analyst from a databasing laboratory? Yes ☑ No ☐			
15.2	Has an external audit been conducted at least once every two years?	☐	☑	☐
15.2.1	Has the laboratory maintained audit documentation of those individuals (i.e., 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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Standards 15.1, 15.2, 15.3 and 15.3.b - See Findings Section

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 plan been reviewed annually?	☑	☐	☐
	a. Has such review been documented?	☑	☐	☐

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Standard 16.1 - See Findings Section

STANDARD 17. Outsourcing

		Yes	No	N/A
17.1	Has the vendor laboratory complied with the FBI Quality Assurance Standards for DNA Databasing Laboratories and the accreditation requirements of federal law?	☑	☐	☐
17.1.1	Has the NDIS laboratory that outsources DNA sample(s) for entry into or search in CODIS required and maintained the following documentation from the vendor laboratory:	☑	☐	☐
	a. Compliance with the FBI Quality Assurance Standards for DNA Databasing 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 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, follow and document appropriate quality assurance procedures to verify the integrity of the data received from the vendor laboratory including but not limited to the following:	☑	☐	☐

17.4.1	Random reanalysis of database, known or casework reference samples	☑	☐	☐
17.4.2	Inclusion of QC samples	☑	☐	☐
17.4.3	For an on site visit:			
	a. Does the NDIS laboratory have and follow a procedure for the performance of an on-site visit?	☐	☐	☑
	b. Does the procedure include, at a minimum, the following elements?	☐	☐	☑
	17.4.3.1 A documented on-site visit prior to the initiation of analysis?	☐	☐	☑
	17.4.3.2 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?	☐	☐	☑
	17.4.3.3 If the NDIS laboratory's outsourcing agreement extended beyond one year, was an annual on-site visit conducted?	☑	☐	☐
	17.4.3.3.1 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?	☑	☐	☐
17.5	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?	☑	☐	☐
17.5.1	Does the technical review of DNA data prior to upload to or search of DNA data in SDIS 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	Verification of the DNA types, eligibility, and the correct specimen category for entry into CODIS.	☑	☐	☐
17.5.2	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?	☑	☐	☐
	b. Was a portion of this review accomplished through the use of an NDIS approved and internally validated expert system?	☐	☐	☑

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Standards 17.2, 17.2.1, 17.3.a, 17.4.3.1, and 17.4.3.2 are marked N/A since the contractual outsourcing agreement with LabCorp was in effect prior to July 1, 2009, and had an extended expiration date of January 31, 2010.

Standards 17.4.3.a and 17.4.3.b are marked N/A since the outsourcing agreement went into effect prior to 7/1/2009.

Standard 17.5.2.b. is rated N/A since the laboratory does not use an expert system.

Appendix A: Findings and Responses

Findings:

Standard 3.1.1 Is the quality system documented in a manual that includes or references the following elements:
Standard 3.1.1.4 Facilities?

Objective Proof for the Finding:

The Quality Manual, version 3 (Revised 04/2007) that was in effect until April 1, 2011, did not define, establish, or reference the laboratory's practices or procedures for laboratory security and its approach for maintaining the integrity of DNA analyses and evidence examination.

The Technical Leader provided the audit team with a memo dated 7/13/2011 stating that he had conducted annual reviews in 2009 and 2010 of the quality system as required by standard 3.3 and that the review encompassed a review and approval of all written analytical DNA procedures as well as elements required in standards 5.2.5.1and 5.2.5.2, and no protocol modifications were made. This requirement was from the July 2009 QAS and was not updated in a laboratory manual until April 2011.

Standard 3.1.1 Is the quality system documented in a manual that includes or references the following elements:
Standard 3.1.1.15 Outsourcing?

Objective Proof for the Finding:

The Quality Manual, version 3 (Revised 04/2007) that was in effect until April 1, 2011, did not reference the laboratory's practices or procedures for outsourcing.

The The Technical Leader provided the audit team with a memo dated 7/13/2011 stating that he had conducted annual reviews in 2009 and 2010 of the quality system as required by standard 3.3 and that the review encompassed a review and approval of all written analytical DNA procedures as well as elements required in standards 5.2.5.1 and 5.2.5.2, and no protocol modifications were made. This requirement was from the July 2009 QAS and was not updated in a laboratory manual until April 2011.

Appendix A: Findings and Responses

Findings:

Standard 4.1 Does the laboratory have:
Standard 4.1.2 A technical leader who is accountable for the technical operations?

Objective Proof for the Finding:

The discussion under this standard states, 'Standard 5.2.3.1 and its subcategories must be satisfied in order to demonstrate that the Technical Leader is accountable for the technical operations.'

The Technical Leader's job description defined in Appendix VIII - DNA Unit Job Functions that was in effect until April 1, 2011, does not state that the Technical Leader has the authority to initiate, suspend, and resume DNA database operations for the laboratory or an individual. Standard 5.2.3.1.2 (a subcategory of 5.2.3.1) is marked NO and therefore this standard is also marked NO.

This requirement was from the July 2009 QAS and was not updated in a laboratory manual until April 2011. (See findings under standards 3.1.1 and 5.2.3.1).

Standard 4.1 Does the laboratory have:
Standard 4.1.3 A CODIS administrator who is accountable for CODIS on-site at each individual laboratory facility using CODIS?

Objective Proof for the Finding:

The discussion under this standards states, 'Standard 5.3.5 must be satisfied in order to demonstrate that the casework CODIS administrator is accountable for CODIS operations on-site at each individual laboratory facility using CODIS.' The CODIS administrator's job description defined in Appendix VIII - DNA Unit Job Functions that was in effect until April 1, 2011, does not state that the CODIS Administrator is 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. Standard 5.3.5 is marked NO and therefore this standard is also marked NO.

This requirement was from the July 2009 QAS and was not updated in a laboratory manual until April 2011. See findings under standards 3.1.1 and 5.3.5).

Appendix A: Findings and Responses

Findings:

Standard 4.1 Does the laboratory have:
Standard 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?

Objective Proof for the Finding:

The laboratory has an organizational chart (June 2011) however the chart does not reference specific personnel by name with their specific assignments (Technical Leader, casework or CODIS administrator) or reference the specific position assignments (Technical Leader or casework CODIS administrator).

The DNA Job Unit Functions Appendix VIII revised 12/01/2008 includes an organizational chart that lists position titles; however it is outdated and it doesn't reflect that there is only one DNA Technical Leader (as of August 2009) for the laboratory and still shows a separate DNA Technical Leader for the mtDNA section. The DNA Section Job Functions, Appendix 7, issued April 2011 does reflect only one DNA Technical Leader.

The Technical Leader provided the audit team with a memo dated 7/13/2011 stating that he had conducted annual reviews in 2009 and 2010 of the quality system as required by standard 3.3 and that the review encompassed a review and approval of all written analytical DNA procedures as well as elements required in standards 5.2.5.1 and 5.2.5.2, and no protocol modifications were made. The DNA Job Unit Functions was not updated in a laboratory manual until April 2011.

Standard 5.1 Do laboratory personnel have the education, training, and experience commensurate with the examination and testimony provided?

Note:
To successfully satisfy Standard 5.1, compliance must be demonstrated with all of the subcategories of Standard 5. There is no separate finding against this standard, only that the lab was not in compliance for Standards 5.1.1, 5.1.3.2.a, 5.2.3.1.2, 5.2.3.2.1, 5.2.3.2.2, 5.2.3.2.3, 5.2.3.2.4, 5.2.3.2.5, 5.3.4, 5.3.4.2, 5.3.4.3, 5.3.4.4, 5.3.4.5, and 5.3.5.

Appendix A: Findings and Responses

Findings:

Standard 5.1.1 Does the laboratory have written job descriptions for all personnel to include responsibilities, duties, and skills?

Objective Proof for the Finding:

The DNA Technical Leader and CODIS Administrator job descriptions do not specify all of the responsibilities, duties and skills for this position as described in these standards.

Note:
The following was a finding from the last external audit conducted December 2008:
While the laboratory did provide the assessment team with general job descriptions for laboratory scientists and technicians and did specify and document the responsibility, authority and interrelation of the Technical Leader and CODIS administrator, they did not provide the assessors with job descriptions, responsibilities and relevant authority of nuclear DNA analysts and nuclear DNA technicians.

This finding was addressed by the laboratory and submitted to NDIS but was not included in the laboratory manuals until April 2011, in the DNA Section Job Functions Appendix 7 issued April 2011. The Technical Leader provided the audit team with a memo stating that he had conducted annual reviews in 2009 and 2010 of all processes and that no changes were needed. Please refer to Standard 3.1.1.

Standard 5.1.3.2 For the review of scientific literature:
Standard 5.1.3.2.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?

Objective Proof for the Finding:

The laboratory's DNA SOP-1, section 1.14.3 states, "All DNA analysts will attend at least one continuing education unit (8 hours) and read at least one relevant scientific paper each year as outlined in the FBI QAS (Standard 5). This record will be documented in the analyst's personnel file." Most analysts are only documenting the reading of one scientific article per year, which is not sufficient to stay abreast of new developments and issues in the field of DNA analysis. The Technical Leader stated that most analysts are reading more than one article per year, but the audit team was given no documentation to support this. Additionally, there is no documentation to demonstrate that the Technical Leader is approving the reading of scientific literature.

Appendix A: Findings and Responses

Findings:

Standard 5.2.3 Does the technical leader of the laboratory have responsibility for the following:
Standard 5.2.3.1 Does the technical leader have the following general duties and authority:
Standard 5.2.3.1.2 Authority to initiate, suspend, and resume DNA analytical operations for the laboratory or an individual?

Objective Proof for the Finding:

The Technical Leader's job description listed in the DNA Job Unit Functions Appendix VIII revised 12/01/2008 does not state that the Technical Leader has the authority to initiate, suspend, and resume DNA operations for the laboratory or an individual. This was not updated in the laboratory manuals until April 2011, in the DNA Section Job Functions Appendix 7 issued April 2011. This requirement was new to the July 2009 QAS and was not updated in a laboratory manual until April 2011.

Standard 5.2.3 Does the technical leader of the laboratory have responsibility for the following:
Standard 5.2.3.2 Does the technical leader perform the following specific responsibilities:
Standard 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?

Objective Proof for the Finding:

The Technical Leader's job description listed in the DNA Job Unit Functions Appendix VIII revised 12/01/2008 does not state that the Technical Leader is responsible for evaluating and documenting approval of all validations and methods used by the laboratory. This was not updated in the laboratory manuals until April 2011, in the DNA Section Job Functions Appendix 7 issued April 2011. This requirement was modified in the July 2009 QAS and was not updated in a laboratory manual until April 2011.

Appendix A: Findings and Responses

Findings:

Standard 5.2.3 Does the technical leader of the laboratory have responsibility for the following:
Standard 5.2.3.2 Does the technical leader perform the following specific responsibilities:
Standard 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?

Objective Proof for the Finding:

The Technical Leader's job description listed in the DNA Job Unit Functions Appendix VIII revised 12/01/2008 does not state that the Technical Leader is responsible for reviewing and documenting the review of the academic transcripts and training records for newly qualified analysts and approve their qualifications prior to their conducting independent casework analysis. This was not addressed in the updated laboratory manual issued April 2011, in the DNA Section Job Functions Appendix 7 issued April 2011. This requirement was new to the July 2009 QAS and was not updated in a laboratory manual until April 2011.

Additionally, several analysts were qualified and began casework on or after 7/1/2009 and the Technical Leader did not approve their academic transcripts until 6/27/2011.

Standard 5.2.3 Does the technical leader of the laboratory have responsibility for the following:
Standard 5.2.3.2 Does the technical leader perform the following specific responsibilities:
Standard 5.2.3.2.3 Approve the technical specifications for outsourcing agreements?

Objective Proof for the Finding:

The Technical Leader's job description listed in the DNA Job Unit Functions Appendix VIII revised 12/01/2008 does not state that the Technical Leader is responsible for approving the technical specifications for outsourcing agreements. This was not addressed in the updated laboratory manual issued April 2011, in the DNA Section Job Functions Appendix 7 issued April 2011. This requirement was new to the July 2009 QAS and was not updated in a laboratory manual until April 2011.

Appendix A: Findings and Responses

Findings:

Standard 5.2.3 Does the technical leader of the laboratory have responsibility for the following:
Standard 5.2.3.2 Does the technical leader perform the following specific responsibilities:
Standard 5.2.3.2.4 Review and document the review of internal and external DNA audit documents and, if applicable, approve corrective action(s).

Objective Proof for the Finding:

The Technical Leader's job description listed in the DNA Job Unit Functions Appendix VIII revised 12/01/2008 does not state that the Technical Leader is responsible for reviewing and documenting the review of internal and external DNA audit documents and, if applicable, approve corrective action(s). This was not updated in the laboratory manuals until April 2011, in the DNA Section Job Functions Appendix 7 issued April 2011. The 2011 revisions state the Technical Leader's responsibility is for oversight and approval of validation, internal and external audits The new manual does not state that the Technical Leader must approve corrective action(s). This requirement was new to the July 2009 QAS and was not updated in a laboratory manual issued April 2011.

Standard 5.2.3 Does the technical leader of the laboratory have responsibility for the following:
Standard 5.2.3.2 Does the technical leader perform the following specific responsibilities:
Standard 5.2.3.2.5 Review annually the procedures of the laboratory and document such review?

Objective Proof for the Finding:

The Technical Leader's job description listed in the DNA Job Unit Functions Appendix VIII revised 12/01/2008 does not state that the Technical Leader is responsible for annually reviewing the procedures of the laboratory and documenting these reviews. This was not addressed in the updated laboratory manual issued April 2011, in the DNA Section Job Functions Appendix 7 issue April 2011. This requirement was new to the July 2009 QAS and was not updated in a laboratory manual issued April 2011.

Appendix A: Findings and Responses

Findings:

Standard 5.3.4 Is the casework CODIS administrator responsible for the following:
Standard 5.3.4.2 Scheduling and documenting the CODIS computer training of casework analysts?

Objective Proof for the Finding:

The CODIS administrator's job description listed in the DNA Job Unit Functions Appendix VIII revised 12/01/2008 does not state that the CODIS administrator is responsible for scheduling and documenting the CODIS computer training of casework analysts. This was not updated in the laboratory manuals until April 2011, in the DNA Section Job Functions Appendix 7 issued April 2011. This requirement for CODIS Administrators was not updated in a laboratory manual until April 2011.

Standard 5.3.4 Is the CODIS administrator responsible for the following:
Standard 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?

Objective Proof for the Finding:

The CODIS administrator's job description listed in the DNA Job Unit Functions Appendix VIII revised 12/01/2008 does not state that the CODIS administrator is responsible for assuring that the security of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures. This was not updated in the laboratory manuals until April 2011, in the DNA Section Job Functions Appendix 7 issued April 2011. This requirement for CODIS Administrators was not updated in a laboratory manual until April 2011.

Standard 5.3.4 Is the CODIS administrator responsible for the following:
Standard 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?

Objective Proof for the Finding:

The CODIS administrator's job description listed in the DNA Job Unit Functions Appendix VIII revised 12/01/2008 does not state that the CODIS administrator is responsible for assuring that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures. This was not updated in the laboratory manuals until April 2011, in the DNA Section Job Functions Appendix 7 issued April 2011. This requirement for CODIS Administrators was new to the July 2009 QAS and was not updated in a laboratory manual until April 2011.

Appendix A: Findings and Responses

Findings:

Standard 5.3.4 Is the CODIS administrator responsible for the following:
Standard 5.3.4.5 Assuring that matches are dispositioned in accordance with NDIS operational procedures?

Objective Proof for the Finding:

The CODIS administrator's job description listed in the DNA Job Unit Functions Appendix VIII revised 12/01/2008 does not state that the CODIS administrator is responsible for assuring that matches are dispositioned in accordance with NDIS operational procedures. This was not updated in the laboratory manuals until April 2011, in the DNA Section Job Functions Appendix 7 issued April 2011. This requirement for CODIS Administrators was new to the July 2009 QAS and was not updated in a laboratory manual until April 2011.

Standard 5.3.5 Is the 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?

Objective Proof for the Finding:

The CODIS administrator's job description listed in the DNA Job Unit Functions Appendix VIII revised 12/01/2008 does not state that the CODIS administrator is 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. This was not updated in the laboratory manuals until April 2011, in the DNA Section Job Functions Appendix 7 issued April 2011. Please refer to the discussion under 5.1.1.This requirement for CODIS Administrators was not updated in a laboratory manual until April 2011.

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

Note:
To successfully satisfy Standard 8.1, compliance must be demonstrated with all of the subcategories of Standard 8. There is no separate finding against this standard, only that the lab was not in compliance for Standards 8.3.1.b, 8.3.1.b.4, 8.3.2, 8.5, and 8.6.

Appendix A: Findings and Responses

Findings:

Standard 8.3.1 For Internal Validation Studies:
Standard 8.3.1.b Have all internal validation studies conducted on or after July 1, 2009, included, as applicable:
Standard 8.3.1.b.4 Contamination assessment?

Objective Proof for the Finding:

The laboratory conducted internal validation studies for the Quantifiler® Duo Kit which were approved by the Technical Leader on 8/27/2009. This validation study encompassed precision/stability, reproducibility/sensitivity, mixtures, degradation and specificity. A contamination assessment was not included in the validation summary or noted anywhere in the validation data provided for review.

Standard 8.3.2 Have quality assurance parameters and interpretation guidelines been defined pursuant to internal validation?

Objective Proof for the Finding:

The Biomek 2000 validation (SN 1321-001) was signed off on 7/28/2009 validating the use of Promega DNA IQ chemistry to extract reference buccal swabs and FTA samples.

The discussion under this standard states that studies summarized after July 1, 2009, shall define the quality assurance parameters and interpretation guidelines to support their use in database applications. The internal validation documentation for the Biomek® 2000 robotic workstation using the Promega DNA IQ™ extraction chemistry does not define the quality assurance parameters.

Appendix A: Findings and Responses

Findings:

Standard 8.5 Have modified procedures been evaluated by comparison with the original procedures using similar DNA samples prior to their incorporation into database applications?

Objective Proof for the Finding:

A material modification was conducted to allow the diluted standards (buffer and concentrated standard) from the Quantifiler® Duo Kit to be used with the primers and reaction mix from the Quantifiler® Human Kit. Analysts also have the option of using the Quantifiler® Human Kit to quantitate known/reference samples. This modification allowed the laboratory to generate one set of diluted standards to be used for both kits rather than generating a diluted set of standards for the Quantifiler® Duo Kit and one for the Quantifiler® Human Kit. A comparison study was conducted and summarized in a memo dated 12/21/2009. The audit team requested supporting data and analysis documentation to support the summary conclusion that the use of reagents from the Quantifiler® Duo kit gave comparable results when compared to those in Quantifiler® Human kit.

No documentation regarding the approval date by the Technical Leader could be located or provided to the audit team except the material modification process that was added to the SOP 3.3.5 dated 4/1/11. Therefore, although a comparison study was conducted, no evidence of the evaluation of the data and approval by the Technical Leader was provided prior to incorporation into casework (Also see finding under Standard 9.1).

Data was provided to the audit team by the analyst that performed the validation. A comparison study was performed and the summary stated the modification was comparable to current methods; however, no supportive data was found in the binder and additional documentation provided to the audit team did not contain the specific data used in the evaluation. The analyst stated that the Y-intercept was used in the analysis, but the data provided to the audit team did not include Y-intercept information. Additionally, the data set had no identifiers (date/title) that could be used to link the data set to this particular material modification. Please see finding under standard 8.3.1.a.

Appendix A: Findings and Responses

Findings:

Continued from the previous page:

Standard 8.5 Have modified procedures been evaluated by comparison with the original procedures using similar DNA samples prior to their incorporation into casework applications?

Objective Proof for the Finding - continued:

Additionally, a modification of the expiration date for a diluted set of quantitation standards from the Quantifiler® Duo kit was evaluated. The manufacturer states that the diluted set of standards can be stored up to two weeks at 2-8°C and longer storage is not recommended.

A comparison study was conducted at the laboratory and it was determined that a two month storage period did not have a negative effect on the quality of the standard curve. Data was generated, but no statistical analysis was conducted to support the conclusion that the data sets were comparable. In SOP 3.0 Quantitation, the SOP states that "The diluted DNA quantitation standards may be stored for longer than 2 weeks at 2 to 8°C…" No set expiration date was documented in the SOP and appears to be infinite and at the analyst's discretion and is not supported by the material modification conducted by the laboratory.

Standard 8.6 Has the laboratory evaluated each additional or modified critical instrument by conducting a performance check prior to its use in databasing?

Objective Proof for the Finding:

If a laboratory currently uses one instrument and adds other instruments of the same model number, it is necessary to conduct a performance check on the new instruments. This laboratory currently utilizes injection times on the Applied Biosystems' 3130xl Genetic Analyzer ranging from 2-60 seconds. Using the Applied Biosystems' Identifiler® kit, performance checks were conducted on the new AB 3130xl -3 and 3130xl -4 instruments. The only injection time used for the performance check on the 3130xl -3 instrument was 10 seconds and the only injection times used for the performance check on the 3130xl -4 instrument were 5 and 10 seconds.

Appendix A: Findings and Responses

Findings:

Standard 9.1 Does the laboratory have and follow written analytical procedures approved by the technical leader?

Objective Proof for the Finding:

A material modification was conducted to allow the diluted standards (buffer and concentrated standard) from the Quantifiler® Duo Kit to be used with the primers and reaction mix from the Quantifiler® Human Kit. Analysts also have the option of using the Quantifiler® Human Kit to quantitate known/reference samples. This modification allowed the laboratory to generate one set of diluted standards to be used for both kits rather than generating a diluted set of standards for the Quantifiler® Duo Kit and one for the Quantifiler® Human Kit. A comparison study was conducted and summarized in a memo dated 12/21/2009. The audit team requested supporting data and analysis documentation to support the summary conclusion that the use of reagents from the Quantifiler® Duo kit gave comparable results when compared to those in Quantifiler® Human kit. Documentation of the approval of the modification by the Technical Leader consisted of initials at the top of the Quantifiler Human & Y DNA Worksheets but did not include a date indicating when the method was officially approved for use. No documentation regarding the approval date by the Technical Leader could be located or provided to the audit team except the material modification process that was added to the SOP 3.3.5 dated 4/1/11. Prior to 4/1/11, this modification did not appear in any DNA SOP. (Also see finding under Standard 8.3.1.a).

Standard 9.1.a Are the laboratory's standard operating procedures reviewed annually by the technical leader, and is this review documented?

Objective Proof for the Finding:

The laboratory could not provide documentation of the Technical Leader's annual review of the analytical procedures. A memo was drafted by the Technical Leader during the audit stating that the Technical Leader conducted the quality review of the DNA process pursuant to "Standard 3.3"; however it did not mention or include analytical procedures. The team was provided with a modified memo dated 7/13/2011 stating that this review included all written analytical DNA procedures as well as the elements required in standards 5.2.5.1 and 5.2.5.2.

The analytical procedures provided to the audit team had a revision date of 12-01-2008.

Appendix A: Findings and Responses

Findings:

Continued from previous page:

Standard 9.1.a Are the laboratory's standard operating procedures reviewed annually by the technical leader, and is this review documented?

Objective Proof for the Finding - continued:

Although "Work Instructions" were provided for the procedure, the standard operating procedures were not up-dated with currently used procedures until April 1, 2011. The Technical Leader approved the Quantifiler® Duo DNA Quantification Kit "Work Instructions" 8/27/2009 to allow the diluted standards (buffer and concentrated standard) from the Quantifiler® Duo Kit to be used with the primers and reaction mix from the Quantifiler® Human Kit. The audit team requested supporting data and analysis documentation to support the summary conclusion that the use of reagents from the Quantifiler® Duo kit gave comparable results when compared to those in Quantifiler® Human kit to allow the Quantifiler® Duo Quantification Kit dilution buffer to dilute the Quantifiler® Human Quantification Kit standard DNA. The "Work Instruction" provided to the audit team does not include this material modification.

The annual review, which the Technical Leader stated he conducted, did not result in changes to the standard operating procedures to reflect the current practices employed by the laboratory and in fact, the memo provided by the Technical Leader (referenced above - dated 7/13/2011) specifically stated, 'This Quality system review for 2009 and 2010 encompassed a review (and approval) by the Technical Leader of all written analytical DNA procedures as well as the elements required in Standard 5.2.5.1 & 5.2.5.2. As a result, no protocol modifications were made.' Protocol modifications were made in practice, but they were not identified in the annual reviews or included as revisions to the written protocols.

Appendix A: Findings and Responses

Findings:

Standard 9.1.1 Does the laboratory have a documented standard operating procedure for each analytical method used?

Objective Proof for the Finding:

The laboratory's Quality Manual 5.0 Technical Procedures Section (Revision 3, 04/2007) does not include any information concerning the existence of "Work Instructions", how "Work Instructions" relate to the laboratory's Standard Operating Protocols or methods for up-date and revision of "Work Instructions". The Standard Operating Protocols provided to the audit team had revision dates of 12/1/2008. The laboratory provided "Work Instructions" for the Biomek® 2000 robotic workstation using the Promega DNA IQ™ extraction chemistry (approved 7/28/2009) and the Quantifiler® Duo DNA Quantification Kit (approved 8/27/2009) as the analytical procedures for these methods. These Work Instructions provided to the audit team for these methods contained the Technical Leader's initials and the date 8/27/09. The "Work Instructions" did not contain revision dates or documentation of annual review. A QR 5-1 form is the form required by the laboratory's Quality Manual (ver. 2007)". The laboratory did not provide documentation of a notation made in the front of the technical manual listing the modifications, date of modification and reason or a copy of the QR 5-1 form.

The Technical Leader approved the Quantifiler® Duo DNA Quantification Kit "Work Instructions" 8/27/2009. A material modification was validated 12/2009 to allow the diluted standards (buffer and concentrated standard) from the Quantifiler® Duo Kit to be used with the primers and reaction mix from the Quantifiler® Human Kit. The "Work Instruction" provided to the audit team does not include this material modification.

As noted above, the annual review did not result in changes to the standard operating procedures to reflect the current practices employed by the laboratory (to include work instructions) in fact, the memo provided by the technical leader (referenced above - dated 7/13/2011) specifically stated, 'This Quality system review for 2009 and 2010 encompassed a review (and approval) by the TL of all written analytical DNA procedures as well as the elements required in Standard 5.2.5.1 & 5.2.5.2. As a result, no protocol modifications were made.' Protocol modifications were made in practice, but they were not identified in the annual reviews or included as revisions to the written protocols until April 2011.

Appendix A: Findings and Responses

Findings:

Standard 9.1.1.a Do the analytical procedures specify reagents, sample preparation, extraction methods, equipment, and controls that are standard for DNA analysis and data interpretation?

Objective Proof for the Finding:

The laboratory provided "Work Instructions" for the Biomek® 2000 robotic workstation using the Promega DNA IQ™ extraction chemistry (approved 7/28/2009) and the Quantifiler® Duo DNA Quantification Kit (approved 8/27/2009) but did not provide analytical procedures for these methods.

Standard 9.3 Critical reagents shall include, but are not limited to, the reagents listed in Standards 9.3.1 and 9.3.2.
Standard 9.3.a Has the laboratory identified critical reagents?
Standard 9.3.b Has the laboratory evaluated critical reagents prior to use in casework?

Objective Proof for the Finding:

The list of Critical Reagents documented in the 2008 Standard Operating Procedures Section 8 Appendices (Revised 12-01-2008) Appendix V - 8.5.3 does not list the Quantifiler® Duo DNA Quantification Kit as a critical reagent. The laboratory procedures do not include written procedures detailing the acceptable range of results, procedures for addressing unacceptable data, and mechanisms used for documentation and subsequent approval/rejection of quality control data of the defined critical reagents. The Quantifiler® Duo kit was approved and subsequently used for casework on 8-27-09 but was not identified as a critical reagent until the approval of DNASOP-6, section 5.3 on 4-1-11. Through the evaluation of case files, the Quantifiler® Duo kit was in use on casework between the period of 8-27-09 and 4-1-11.

The Quantifiler® Duo DNA Quantification Kit reagent log documenting the analysis on a new lot performed June 6, 2011 stated that the lot passed the quality check. Review of the data in the reagent log showed that the slope of the standard curve was outside of the -3.0 to -3.6 requirement listed on the log sheet (actual result was -3.8). The analysts stated in interviews that the lot quality check was repeated. The repeated analysis was not documented in the reagent log. The date of the repeat analysis is not available.

Appendix A: Findings and Responses

Findings:

Standard 9.3.1 Has the laboratory identified and evaluated the following:
Standard 9.3.1.a Test kits or systems for performing quantitative PCR?

Objective Proof for the Finding:

Although the laboratory has evaluated and implemented the use of the Quantifiler® Duo kit, it was not identified as a critical reagent in the 2008 Standard Operating Procedures Section 8 Appendices (Revised 12-01-2008) Appendix V - 8.5.3 which was in place from 8-27-09 through 4-1-11.

Standard 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?

Objective Proof for the Finding:

The laboratory did not run a NIST traceable sample for autosomal STR kits in 2009, 2010, or 2011. The laboratory used a sample, RKO (lot # 2-24-09) in 2009 and 2010 and RKO (lot # 3-28-11) in 2011 as the NIST traceable standards. These RKO samples were not directly traceable to the NIST SRM 2391b and/or 2395. The laboratory traced these RKO samples to previous RKO lots that were directly traceable to the NIST SRM 2391b and/or 2395; however in doing so, they are not direct NIST traceable samples.

Standard 9.7 Does the laboratory have and follow a documented policy for detecting and controlling contamination?

Objective Proof for the Finding:

The laboratory does not have policy for detecting contamination. There is no documentation that describes whether peaks above and/or below the laboratory's analytical threshold are assessed as potential contamination.

Standard 10.2 Does the laboratory have and follow a documented program for conducting performance checks and calibrating equipment and instruments?

Note:
To successfully satisfy Standard 10.2, compliance must be demonstrated with all of the subcategories of Standard 10.2. There is no separate finding against this standard, only that the laboratory was not in compliance for Standards 10.2.1,10.2.1.3, and 10.2.1.6.

Appendix A: Findings and Responses

Findings:

Standard 10.2.1 At a minimum, are the following critical instruments or equipment performance-checked at least annually:
Standard 10.2.1.3 Thermal cycler temperature-verification system?

Objective Proof for the Finding:

The laboratory routinely does a calibration of the thermal cycler temperature-verification system; however the laboratory could not provide a written protocol defining when or how the calibration of the thermal cycler temperature-verification system is performed.

Standard 10.2.1 At a minimum, are the following critical instruments or equipment performance-checked at least annually:
Standard 10.2.1.6 Robotic systems?

Objective Proof for the Finding:

The laboratory routinely performs a calibration of the Biomek® robotic workstation XY alignment after cleaning and preventive maintenance. The laboratory could not provide a written protocol defining the minimum requirements for the performance check or when the alignment of the XY axis of the Biomek® robotic workstation is performed.

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:

The laboratory did not provide a written protocol defining when the maintenance of the Biomek® robotic workstation is performed.

Standard 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 database analysis?

Note:
To successfully satisfy Standard 10.4, compliance must be demonstrated with all of the subcategories of Standard 10.4. There is no separate finding against this standard, only that the laboratory was not in compliance for Standards 10.4.1.3 and 10.4.1.4.

Appendix A: Findings and Responses

Findings:

Standard 10.4.1 At a minimum, are the following critical instruments or equipment performance-checked following repair, service, or calibration:
Standard 10.4.1.3 Genetic analyzers?

Objective Proof for the Finding:

The AB 3130xl instrument (serial # 1606-006) had performance maintenance conducted on 03/01/08, 03/31/09 and 03/29/10; however, no performance checks were conducted after any maintenance.

Standard 10.4.1 At a minimum, are the following critical instruments or equipment performance-checked and/or recertified following repair, service, or calibration:
Standard 10.4.1.4 Thermal cycler including quantitative PCR where utilized?

Objective Proof for the Finding:

On 02/09/2011 9700-1 Serial No. 805S9020449, 9700-7 Serial No. 805S7020902 and 9700-11 Serial No 805S0160183 were found to be out of tolerance and the calibration was rejected. The thermal cyclers were sent to Life Technologies for repair and passed 3/31/2011. There were no corrective actions or documentation concerning how the issue of the “out of tolerance” was handled. The laboratory did not produce documentation of a performance check conducted after the instrumentation was put back into service.

Standard 12.2 Does the laboratory document the completion of the technical review prior to uploading or searching in SDIS, and does it include the following elements:
Standard 12.2.1 A review of all notes, all worksheets, and all electronic data (or printed electropherograms or images) supporting the results?

Objective Proof for the Finding:

The DNA 2008 Standard Operating Procedures Section 12 DNA Database Evidence Collection and Analysis Guidelines (Revised 12-01-2008) states that all results obtained from the analysis of a convicted offender sample will be reviewed according to standard forensic biology protocols. The standard forensic biology protocols state that “the cases/reports are administratively and technically reviewed by at least one DNA analyst in addition to the primary examiner. STR gels must be second analyzed by at least one DNA examiner.” Although the analysts described during interviews the process of conducting technical and administrative reviews to include a review of all notes, all worksheets, and all electronic data supporting the results, the case notes do not include the appropriate initials documenting the review of the notes and worksheets. The case notes do include documentation of the electronic data review. Additionally, the procedure appears to be outdated. The laboratory no longer conducts STR analysis on gels.

Appendix A: Findings and Responses

Findings:

Standard 12.4 Does the laboratory document the elements of a technical and administrative review?

Objective Proof for the Finding:

The DNA 2008 Standard Operating Procedures Section 12 DNA Database Evidence Collection and Analysis Guidelines (Revised 12-01-2008) states that all results obtained from the analysis of a convicted offender sample will be reviewed according to standard forensic biology protocols. The DNA 2008 Standard Operating Procedures Section 7.0 PCR Interpretation of Results (Revised 12-01-2008) 7.14.2.8 states that the second analysis of Identifiler Convicted Offender DNA profiles is limited to a review of the following data parameters using the first analyst's data files: All required size standard peaks were called, all included alleles are called in the ladder(s) used, all controls performed as expected and all offender profiles are correctly called. Although the analysts described during interviews the process of conducting technical and administrative reviews to include a review of all notes, all worksheets, and all electronic data supporting the results, the review does not document all the required elements of a technical and administrative review.

Standard 13.1.7 Does the laboratory include, at a minimum, the following criteria for evaluating proficiency test results:
Standard 13.1.7.1 Evaluation:
Standard 13.1.7.1.a Are all reported inclusions correct?
Standard 13.1.7.1.b Are all reported exclusions correct?
Standard 13.1.7.1.c Are all reported genotypes and/or phenotypes correct or incorrect according to consensus results or within the laboratory's interpretation guidelines?

The Quality Manual, Section 9.0 Proficiency Testing Procedures (Version 4, Revised 04/2007) does not state that the review of the DNA proficiency tests will be evaluated to confirm that all reported inclusions (if applicable) correct, all reported exclusions (if applicable) correct, or that all reported genotypes and/or phenotypes correct or incorrect according to consensus results or within the laboratory's interpretation guidelines.

Appendix A: Findings and Responses

Findings:

Standard 14.1 For a corrective action plan:
Standard 14.1.a Has the laboratory established and followed a corrective action plan that addresses discrepancies detected in proficiency tests and casework analysis?
Standard 14.1.b Does the corrective action plan, at a minimum, address the following:
Standard 14.1.b.1 Define what level/type of discrepancies are applicable to this practice?
Standard14.1.b.2 Identify (when possible) the cause of the discrepancy?
Standard14.1.b.3 Effect of the discrepancy?
Standard14.1.b.4 Corrective actions taken?
Standard14.1.b.5 Preventative measures taken (where applicable) to minimize its reoccurrence?

Objective Proof for the Finding:

The laboratory has a corrective action plan (QA Program, Section 8.1-Rev. 4); however the plan does not address discrepancies detected in casework analysis. In addition, the plan does not define level/type of discrepancies, identify causes and effects of discrepancies, corrective actions, and preventative measures taken to minimize reoccurrences. There is also no documentation to show that they are doing this in practice.

The laboratory does not define when an incident will be handled using the corrective action plan outlined in the QA Program.

For example, as of December 2010, the laboratory was out of compliance with the QAS because they did not have an external audit. This was noted in the internal audit they conducted in 2010; however they did not start a corrective action report until June 2011. The laboratory did not have any other documented corrective actions since the December 2008 external audit.

Appendix A: Findings and Responses

Findings:

Standard 15.1 Has the laboratory been audited annually in accordance with the FBI DNA Quality Assurance Standards?
Standard 15.2 Has an external audit been conducted at least once every two years?

Objective Proof for the Finding:

The laboratory's Quality Manual, Section 8.2.1 (d) Rev. 4 states "The DNA Unit procedures shall also be reviewed by an external auditor approximately once every two years (minimum), in accordance with FBI NDIS/CODIS requirements". The laboratory had their last external audit in December 2008. There was no documentation to demonstrate the laboratory had an external audit in 2010.

Standard 15.3 For internal audits, has the laboratory maintained documentation that the auditor(s) for this inspection include:
Standard 15.3.b A current or previously qualified analyst in the laboratory's current DNA technologies and platform?

Objective Proof for the Finding:

The laboratory did not complete Appendix C of the 2009 FBI Quality Assurance Standards Audit Document related to the internal audits conducted in 2009 or 2010. The audit team was unable to determine if a current or previously qualified analyst in the laboratory's current DNA technologies and platforms were included on the internal audit team.

Standard 16.1 Does the laboratory have and follow a documented environmental health and safety program that includes, at a minimum, the following:

Objective Proof for the Finding:

The laboratory's Safety Manual, Section 5.8A (Rev. 3) states "The Laboratory Safety Officer will meet with the safety committee on a quarterly basis to discuss any non-emergency issues/concerns that have risen since the previous meeting". According to the Quality Manager/Safety Officer, there have never been any safety committee meetings.

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: CT State Div. of Scientific Services Laboratories-CODIS (DB) As of [date] June 28, 2011

Technologies currently in use: Identifiler, PowerPlex Y

Platforms currently in use: ABI 3130xl

Validations needing to be memorialized: Quantifiler Human + Y, Duo; DNA, IQ on Biomek 2000,BSD Duet

Outsourcing agreements in place or in process: NA

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: Mark D. Losko

Auditor's Employer: Ohio BCI&I

Auditor's Title or Position: Forensic Scientist / Forensic Science Coordinator

Qualified Auditor[1]: Yes ☑ No ☐ (Check One)

Year Completed FBI DNA Auditor Class: 2003, 2007 (refresher course)

Current or Previously Qualified DNA Analyst: Yes ☑ No ☐ (Check One)

Current or Previously Qualified in Casework, Database Analysis, or Both[2]:

Casework ☐ Database ☐ Both ☑ (Check 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[3] ; and
I have no conflicts of interest with the laboratory being audited; and

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

[2] 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.

[3] 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."

The information contained in Section 2 above is correct.

Signed By Mark E. Jakubs **Date** 6/30/11

Appendix C - Auditor Self-Certification for QAS Audits

Section 1 - to be completed by the laboratory being audited:
Laboratory being audited: CT State Div. of Scientific Services Laboratories-COD I S (DB) As of [date] June 28, 2011

Technologies currently in use: Identifiler, PowerPlex Y
Platforms currently in use: ABI -3130xl
Validations needing to be memorialized: Quantifiler Human + Y, Duo; DNA IQ on Biomek 2000, BSD Duet
Outsourcing agreements in place or in process: NA

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: Kathy M. Guenther
Auditor's Employer: NFSTC (retired from LVMPD Forensic Lab 4/30/2011)
Auditor's Title or Position: Contract Assessor/Auditor (retired FS II-CODIS Administrator)
Qualified Auditor[1] **Yes √** No (Check One)
Year Completed FBI DNA Auditor Class: Current Document--2010; prior 2001 (2004 &2007ref)
Current or Previously Qualified DNA Analyst: **Yes √** No (Check One)
Current or Previously Qualified in Casework, Database Analysis, or Both[2]:
Casework Database **Both √** (Check 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 15.23 ; and
I have no conflicts of interest with the laboratory being audited; and
The information contained in Section 2 above is correct.
Signed By Kathy M. Guenther **Date** 29th June 2011

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

2 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.

3 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."

D

Appendix C – Auditor Self-Certification for QAS Audits

Section 1 – to be completed by the laboratory being audited:

Laboratory being audited: CT State Div. of Scientific Services Laboratories-CODIS (DB) As of [date] June 28, 2011

Technologies currently in use: Identifiler, PowerPlex Y

Platforms currently in use: ABI 3130xl

Validations needing to be memorialized: Quantifiler Human + Y, Duo; DNA, IQ on Biomek 2000,BSD Duet

Outsourcing agreements in place or in process: NA

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: Lucy A Davis

Auditor's Employer: LDH Consultants

Auditor's Title or Position: Forensic DNA Consultant

Qualified Auditor[1]: Yes ☒ No ☐ (Check One)

Year Completed FBI DNA Auditor Class: 2009

Current or Previously Qualified DNA Analyst: Yes ☒ No ☐ (Check One)

Current or Previously Qualified in Casework, Database Analysis, or Both[2]?

Casework ☐ Database ☐ Both ☒ (Check 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):

Gel based / CE

I verify that:

I understand the requirements of Standard 15.2[3] ; and

I have no conflicts of interest with the laboratory being audited; and

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

[2] 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.

[3] 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."

The information contained in Section 2 above is correct.

Signed By _____ **Date** 6/29/2011

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):

Kristen Madel (6/2006 & 12/2008)
Kristin Sasinouski (6/2006 & 12/2008)

Approvals after July 1, 2004 and this audit makes two successive, separate external audits:

Angela Przech (12/2008 & 7/ 2011)

Technical Leader(s):

Technical Leader:

Carll Ladd (6/2006 & 12/2008)

CODIS Administrator:

Michael Bourke (6/2006 & 12/2008)

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):

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):

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):

Cheryl Civitello
Adrianne Schoefer

CODIS administrator(s):

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:

The Biomek 2000 validation (SN 1321-001) was signed 7/28/2009 validated the use of Promega DNA IQ chemistry to extract reference buccal swabs and FTA samples. The validation specifies protocols and programs provided by Promega within the Biomek 2000. This included studies noted under standard 8..3.1.b (1-4).