North Carolina State Bureau of Investigation Laboratory

121 East Tryon Rd, Raleigh, NC 27603

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

Conducted on 11/29/2010 - 12/1/2010

Lynn Langford NFSTC Lead Auditor

Cara Lupino 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: North Carolina SBI Laboratory

Dates of Audit: November 29 - December 1, 2010

Auditor(s): Lynn Langford (Name) (Signature)

Cara Lupino (Name) (Signature)

Last Updated: July, 21, 2010

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Checklist of General Laboratory Information

1. Name of Laboratory: North Carolina State Bureau of Investigation Laboratory

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

3. Approximate Population Size Served: ~9.1 million

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

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: 8
   - DNA trainees: _____
   - DNA technicians: 1
   - Laboratory support personnel: 4
   - DNA technical leader: A. Chris Parker
     - On site: Yes ☑ No ☐
   - CODIS administrator: Amanda F. Overman

9. Last audit conducted on: October 26-28, 2010 (Kentucky group) October 19-21, 2009 (NFSTC)
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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		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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Standard 4.1.2.a - This standard is marked N/A because the laboratory is not a multi-laboratory system.

Standard 5. Personnel

		Yes	No	N/A
5.1	Do laboratory personnel have the education, training, and experience commensurate with the examination and testimony provided?	☑	☐	☐

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

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		Yes	No	N/A
5.1.2	Does the laboratory have a documented training program for qualifying all analyst(s) and technician(s)?	✓		
5.1.2.1	Does the training program contain at a minimum the following components:			
	a. A training manual that covers all applicable DNA analytical procedures that the analyst/technician will perform?	✓		
	b. Practical exercises that include the 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 5.1.2.1.1 - This standard is marked N/A because the database laboratory does not process known or casework reference samples.

Standards 5.1.2.2.2.(a & b) - These standards are marked N/A because the database laboratory did not hire any personnel with previous forensic or DNA database experience since the last external assessment.

		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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Standards 5.1.3.1.1 - is marked N/A because the database laboratory did not conduct continuing education internally since the last external audit.

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

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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 - This standard is rated N/A because the technical leader does not possess a waiver form ASCLD.

	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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		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 is rated N/A because the Technical leader does not oversee a system of laboratories. This is not a multi- system laboratory.

Standards 5.2.4.1.1.a, 5.2.4.1.1.b and 5.2.4.1.1.c are rated N/A as the Technical Leader position has not been vacant since the last external audit.

		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 are marked N/A because the CODIS Administrator is a currently qualified casework analyst with documented mixture interpretation training and meets the educational requirements described in standard 5.4.

		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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Standard 5.3.6 is marked N/A as the CODIS administrator position has not been vacant 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 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 are marked N/A because the database laboratory does not use the robotic workstation as described in the discussion for these criteria.

		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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Standard 7.1.2.1 is marked N/A because the database laboratory does not process casework known or reference samples.

		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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Comment

		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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		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

Standard 8.3.1.b (1-4) are marked N/A because the internal validation studies were not conducted on or after July 1, 2009. Standard 8.3.1.1.(a &b) is marked N/A because the database laboratory is not a multilaboratory system. Standard 8.3.3 is marked N/A because the database laboratory has not had a change in detection platform or test kit since last external audit. Standard 8.3.4 is marked N/A because the database laboratory has not validated an expert system. Standard 8.4 is marked N/A because the database laboratory has not had any new validations since the last external audit.

		Yes	No	N/A
8.5	Have modified procedures been evaluated by comparison with the original procedures using similar DNA samples prior to their incorporation into 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

Standard 8.5 is marked N/A because procedures have not been modified since last external audit.

Standards 8.7 and 8.7.a are marked N/A because the database laboratory has not evaluated any software upgrades since last external audit.

Standard 8.6
Performance Checks were performed on the following instruments: ABI Prism® 3130XL Genetic Analyzer (Serial number 1455-010, GeneMapper ID software v 3.2.1) ABI Prism® 3130XL Genetic Analyzer (Serial number 1352-020, GeneMapper ID software v 3.2.1) and Qiagen BioRobot 8000 (Serial number SN#A4178)

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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Comment

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

Yes ☑ 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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Comment

Standard 9.3.1.a is marked N/A because the laboratory does not conduct quantitative PCR.

Standards 9.3.2. (a, b and c) are marked N/A because these are tested as part of the test kit in 9.3.1.b.

		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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Comment

		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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Comment

Standard 9.5.1 is marked N/A because quantitation is not performed on database samples.

	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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Comment

		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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Comment

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

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Comment

Standard 10. Equipment Calibration and Maintenance

		Yes	No	N/A
10.1	Does the laboratory use equipment that is suitable for the methods employed?	☑	☐	☐
10.2	Does the laboratory have and follow a documented program for conducting performance checks and calibrating equipment and instruments?	☑	☐	☐
10.2.1	At a minimum, are the following critical instruments or equipment performance-checked at least annually:	☑	☐	☐
	10.2.1.1 A thermometer that is traceable to national or international standard(s) and is used for conducting performance 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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Comment

Standards 10.2.2.1 and 10.4.1.5 are marked N/A because the database laboratory does not have an expert system.

Standards 10.2.1.5 and 10.4.1.1 are marked N/A because the database laboratory does not use an electrophoresis detection system other than genetic analyzers.

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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Comment

		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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Comment

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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Comment

		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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Comment

		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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Comment

		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?	☑	☐	☐

Comment

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

Comment

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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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Comment

		Yes	No	N/A
13.1.1	Are individuals using both manual and automated methods proficiency-tested in each, at least once per year, to the full extent in which they participate in 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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Comment

Standard 13.1.4.1 is marked N/A because the database laboratory does not use the team approach. Standard 13.1.7.2 and 13.1.7.2.1 are marked N/A because the database laboratory did not have any results reported as inconclusive or not interpretable since the last external audit. Standard 13.1.7.3 is marked N/A because the database laboratory did not have any discrepancies/errors for corrective actions to be documented since the last external audit.. Standard 13.1.7.4.1.1 is marked N/A because the database laboratory did not have any administrative errors and corrective actions to document since the last external audit Standard 13.1.9.a is marked N/A because the database laboratory did not have any non-administrative discrepancies to report to the CODIS administrator since the last external audit.

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

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Comment

Standard 14. Corrective Action

		Yes	No	N/A
14.1	For a corrective action plan:			
	a. Has the laboratory established and followed a corrective action plan that addresses discrepancies detected in proficiency tests and 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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Comment

Standard 15. Audits

		Yes	No	N/A
15.1	Has the laboratory been audited annually in accordance with the FBI DNA Quality Assurance Standards?	☑	☐	☐
	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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Comment

Standard 15.3 is marked as N/A due to all QAS audits have been external each year.

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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Comment

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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Comment

Standard 17.2.1 is marked N/A because there is not a vendor laboratory performing DNA analysis for a law enforcement agency or entity other than the NDIS laboratory.
Standard 17.4.3.3.1 is marked N/A because the laboratory conducted all their on-site visits to the vendor laboratory.
Standard 17.5.2.b is marked N/A because the laboratory does not have an expert system for reviewing database data.

Appendix A: Findings and Responses

Findings:

No findings were identified by the audit team.

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: NCSBI Crime Lab - Raleigh, Database As of [date] 10/25/10
Technologies currently in use: STRs
Platforms currently in use: Capillary Electrophoresis
Validations needing to be memorialized: None
Outsourcing agreements in place or in process: Bode Technology
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: Lynn Langford
Auditor's Employer: Georgia Bureau of Investigation
Auditor's Title or Position: Laboratory Manager of Northeastern Regional Lab
Qualified Auditor[2]: Yes No (Circle One)
Year Completed FBI DNA Auditor Class: 2002 with refreshers in 2004, 2006, 2007, 2009
Current or Previously Qualified DNA Analyst: Yes No (Circle One)
Current or Previously Qualified in Casework, Database Analysis, or Both[3]:
Casework Database Both (Circle One)
Technologies Currently or Previously Qualified In (e.g., STR, mtDNA) (Please List): STR
Platforms Currently or Previously Qualified In (e.g., Gel based/CE) (Please List): CE

I verify that:
I understand the requirements of Standard 15.2[4] ; and
I have no conflicts of interest with the laboratory being audited; and
The information contained in Section 2 above is correct.
Signed By Lynn Langford **Date** 11/8/2010

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

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

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

Appendix C – Auditor Self-Certification for QAS Audits

Section 1 – to be completed by the laboratory being audited:
Laboratory being audited: NCSBI Crime Lab - Raleigh, Database As of [date] 10/25/10
Technologies currently in use: STRs
Platforms currently in use: Capillary Electrophoresis
Validations needing to be memorialized: None
Outsourcing agreements in place or in process: Bode Technology
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: Cara Lupino
Auditor's Employer: Rhode Island Dept of Health
Auditor's Title or Position: Supervisor, Forensic Biology
Qualified Auditor[2]: Yes No (Circle One)
Year Completed FBI DNA Auditor Class: 2010
Current or Previously Qualified DNA Analyst: Yes No (Circle One)
Current or Previously Qualified in Casework, Database Analysis, or Both[3]:
Casework Database Both (Circle One)
Technologies Currently or Previously Qualified In (e.g., STR, mtDNA) (Please List): STR's
Platforms Currently or Previously Qualified In (e.g., Gel based/CE) (Please List): CE

I verify that:
I understand the requirements of Standard 15.2[4] ; and
I have no conflicts of interest with the laboratory being audited; and
The information contained in Section 2 above is correct.
Signed By Cara Lupino **Date** 11/9/10

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

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

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

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

To be completed by the audit team.

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

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

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

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

Analyst(s):

Janis Matthews (12/06, 10/07)
Gina Autry (12/06, 10/07)
Jessica K. (Badger) Rotenberg (10/09, 10/10)
Stephen Henderson (10/09, 10/10)
Tonya Rush (10/09, 10/10)
Jessica a. Posto (10/09, 10/10)

Technical Leader(s):

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):

Robin C. Bridges (10/10, 11/10)
Laura S. Clements (10/10, 11/10)

CODIS administrator(s):

Amanda Fox Overman(10/09, 11/10)

Technical Leader(s):

Chris Parker (10/10, 11/10)

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):

-

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:

No validations have been conducted by this laboratory since the last external audit; therefore, this audit team did not evaluate or approve any validations.