Addendum to the Quality Assurance Standards Audit for DNA Databasing Laboratories performing Rapid DNA Analysis and Modified Rapid DNA Analysis Using a Rapid DNA Instrument

IN ACCORDANCE WITH

THE QUALITY ASSURANCE STANDARDS

FOR

DNA DATABASING LABORATORIES

EFFECTIVE DECEMBER 1, 2014

An Audit of: _____

Dates of Audit: _____

Auditor(s):

_____ **(Name)**	_____ **(Signature)**
_____ **(Name)**	_____ **(Signature)**
_____ **(Name)**	_____ **(Signature)**

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QUALITY ASSURANCE AUDIT DOCUMENT ADDENDUM

INTRODUCTION

This addendum to the Quality Assurance Standards describes the quality assurance requirements that accredited laboratories performing Rapid DNA analysis or modified Rapid DNA analysis using a Rapid DNA instrument on reference samples (i.e. offender, arrestee, detainee or casework reference sample) for inclusion in the Combined DNA Index System (CODIS) or are performing Rapid DNA analysis or modified Rapid DNA analysis on casework reference samples for forensic casework comparison shall follow to ensure the quality and integrity of the data. These Standards also apply to vendor laboratories that perform Rapid DNA analysis or modified Rapid DNA analysis testing on reference samples (i.e. offender, arrestee, detainee or casework reference sample) in accordance with Standard 17. Consistent with the Quality Assurance Standards for DNA Databasing Laboratories, if the databasing laboratory is performing DNA analyses on known or casework reference samples considered evidence by that laboratory, the databasing laboratory shall either:

1. Follow the Quality Assurance Standards for Forensic DNA Testing Laboratories for the known or casework reference samples; or
2. Follow these Databasing Standards including the additional requirements for known and casework reference samples in 5.1.2.1.1 and 7.1.2.1.

This addendum to the Standards does not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

Laboratories performing Rapid DNA analysis or modified Rapid DNA analysis using a Rapid DNA instrument for the analysis of reference samples shall follow these Standards in conjunction with the publicly available minimum standards issued by the FBI Director (*Quality Assurance Standards for Forensic DNA Testing and DNA Databasing Laboratories* effective September 1, 2011.) For laboratories performing modified Rapid DNA analysis using a Rapid DNA instrument, the interpretation and technical review shall be conducted manually.

The revised discussions are not to be applied retroactively and will take effect December 1, 2014.

Instructions to Audit Team Leaders and Auditors

This addendum shall be completed in addition to the FBI Quality Assurance Standards Audit documents for laboratories performing Rapid DNA analysis or modified Rapid DNA analysis using a Rapid DNA instrument. This addendum is not required for laboratories not performing Rapid DNA analysis or modified Rapid DNA analysis using a Rapid DNA instrument.

Checklist of General Laboratory Information

1. Name of Laboratory: _____

2. Laboratory processes reference samples using a Rapid DNA instrument : Yes / No

   Rapid DNA analysis: Yes / No

   Modified Rapid DNA analysis: Yes / No / NA

Standard 1. Scope

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

Standard 2. Definitions

Except as noted below, the Standard shall be followed and applied as documented in the Quality Assurance Standards (QAS) for DNA Databasing Laboratories effective September 1, 2011.

As used in these Standards, the following terms shall have the meanings specified:

Cartridge lot number is an identification number assigned to a particular quantity or lot of material having uniform character and quality within specified limits from a single manufacturer.

Modified Rapid DNA analysis describes the automated (hands-free) process of developing a CODIS Core STR profile from a known reference sample. This "swab in – profile out" process consists of automated extraction, amplification, separation, and detection without human intervention but requires human interpretation and technical review.

Negative sample control is used to detect DNA contamination in all of the Rapid DNA reagents and consumables.

Positive sample control is an analytical control sample that is used to determine if the Rapid DNA instrument is performing all steps of the process properly. This control consists of a known DNA sample (biological material whose DNA type is known or established) that shows concordant results at all loci with a validated laboratory process.

Rapid DNA analysis describes the fully automated (hands-free) process of developing a CODIS Core STR profile from a known reference sample. The "swab in – profile out" process consists of automated extraction, amplification, separation, detection and allele calling without human intervention.

Rapid DNA cartridge is a preassembled set of reagents for performing extraction, amplification and/or separation on a Rapid DNA instrument.

Rapid DNA instrument describes the automated device that carries out the Rapid DNA analysis or modified Rapid DNA analysis.

Reference Samples are offender, arrestee, detainee or casework reference samples.

Standard 3. Quality Assurance Program

Discussion

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

Comment

Standard 4. Organization and Management

Discussion

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

Comment

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?	☐	☐	☐

Discussion

To successfully satisfy Standard 5.1, compliance must be demonstrated with all of the subcategories of Standard 5.

		Yes	No	N/A
5.1.2	Does the laboratory have a documented training program for qualifying all analyst(s) and technician(s)?	☐	☐	☐
5.1.2.2	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?	☐	☐	☐
	5.1.2.2.4 Does each analyst and technician have documented training for operating the Rapid DNA instrument?	☐	☐	☐
	5.1.2.2.5 Prior to independently operating the Rapid DNA instrument, does each analyst and technician have documentation of successfully completing a competency test?	☐	☐	☐

Discussion

A laboratory's training program must teach and assess the skills and knowledge required to achieve the minimum standards of competence and good laboratory practice in operating the Rapid DNA instrument.

The laboratory must have available for review documentation of successful completion of a competency test for operating the Rapid DNA instrument for each analyst and technician. At a minimum, the competency test for a Rapid DNA instrument shall include a practical examination.

The measure of an individual's competency should be defined within the laboratory's training program.

Comment

Standard 6. Facilities

		Yes	No	N/A
6.1.6	If a Rapid DNA instrument is used to process reference samples, has the laboratory validated the analytical process in accordance with Standard 8?	☐	☐	☐
	a. Is the Rapid DNA instrument housed in a pre-amplification room?	☐	☐	☐

Discussion

Due to the design of the Rapid DNA instruments, they are not considered robotic workstations.

The laboratory shall operate the Rapid DNA instrument within a pre-amplification room in the laboratory. A laboratory shall not operate a rapid DNA instrument in a post-amplification room.

Comment

STANDARD 7. Sample Control

Discussion

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

Comment

Standard 8. Validation

Discussion

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

Comment

Standard 9. Analytical Procedures

		Yes	No	N/A
9.1	Does the laboratory have and follow written analytical procedures approved by the technical leader?	☐	☐	☐

Discussion

To successfully satisfy Standard 9.1, the laboratory must demonstrate compliance with Standard 9.1.1.

Comment

		Yes	No	N/A
9.3	Critical reagents shall include, but are not limited to, the reagents listed in Standard 9.3.3.			
	b. Has the laboratory evaluated critical reagents prior to use in the laboratory?	☐	☐	☐
9.3.3	Has the laboratory identified and evaluated the following:	☐	☐	☐

a. Rapid DNA Cartridge(s)?

Yes ☐ No ☐

Discussion

Cartridge lot number is an identification number assigned to a particular quantity or lot of material having uniform character and quality within specified limits from a single manufacturer.

Negative sample control is used to detect DNA contamination in all of the Rapid DNA reagents and consumables.

Positive sample control is an analytical control sample that is used to determine if the Rapid DNA instrument is performing all steps of the process properly. This control consists of a known DNA sample (biological material whose DNA type is known or established) that shows concordant results at all loci with a validated laboratory process.

Rapid DNA cartridge is a preassembled set of reagents for performing extraction, amplification and/or separation on a Rapid DNA instrument.

For each new rapid DNA cartridge(s), the laboratory shall evaluate at least one rapid DNA cartridge(s) from the cartridge(s) lot number. A positive sample control and negative sample control shall be processed and analyzed for each new Rapid DNA cartridge(s) lot number, before or in parallel with reference samples analyzed on the Rapid DNA instrument. If a laboratory processes the positive sample control and negative sample control in parallel with reference samples, the data shall only be searched and/or uploaded to CODIS after the controls are interpreted and meet the laboratory's criteria for successful approval of the quality control data. Laboratories must have written procedures for handling data processed in parallel with sample controls if the control quality data fails.

Comment

	Yes	No	N/A
9.5.5.1 Does the laboratory check its Rapid DNA analysis and/or modified Rapid DNA analysis procedures either	☐	☐	☐

annually or whenever upgrades or changes are made to the procedure against an appropriate and available NIST standard reference material (SRM) or standard traceable to a NIST standard?

Discussion

The laboratory must demonstrate performance through an annual check of its Rapid DNA analysis and/or modified Rapid DNA analysis procedures to generate typing results using an appropriate and available NIST standard reference material (SRM) or standard traceable to a NIST standard.

A laboratory must demonstrate a designated NIST SRM laboratory check of its Rapid DNA analysis and/or modified Rapid DNA analysis procedure annually or whenever an upgrade or change is made to the instrument.

Comment

		Yes	No	N/A
9.5.6	For a laboratory performing Rapid DNA analysis or modified Rapid DNA analysis, does the laboratory have and follow documented procedures to address the use of positive sample controls and negative sample controls for Rapid DNA instruments?	☐	☐	☐
	9.5.6.1 Does the laboratory use standards to monitor the Rapid DNA process?	☐	☐	☐

9.5.6.1.1 Internal Lane Standard (ILS) in each sample?

Yes ☐ No ☐

9.5.6.1.2 Allelic ladder included in each instrument run?

Yes ☐ No ☐

Discussion

Negative sample control is used to detect DNA contamination in all of the Rapid DNA reagents and consumables.

Positive sample control is an analytical control sample that is used to determine if the Rapid DNA instrument is performing all steps of the process properly. This control consists of a known DNA sample (biological material whose DNA type is known or established) that shows concordant results at all loci with a validated laboratory process.

The laboratory is not required to analyze quantitation standards, reagent blank controls, positive amplification controls and negative amplification controls on a Rapid DNA instrument.

For Rapid DNA analysis or modified Rapid DNA analysis, the laboratory shall have and follow documented procedures to address the use of positive sample controls and negative sample controls for the Rapid DNA instrument. These procedures shall identify the acceptable results for controls and the verification and documentation of their use.

The laboratory shall have and follow documented procedures for the use of standards to monitor the Rapid DNA process. These procedures shall identify the acceptable results for standards and the verification and documentation of their use. Each sample must contain an Internal Lane Standard (ILS).

The laboratory shall include an allelic ladder with each Rapid DNA instrument run. The laboratory shall have and follow documented procedures for the use of allelic ladders to monitor the Rapid DNA process. These procedures shall identify the acceptable results for allelic ladders and the verification and documentation of their use.

The laboratory shall have and follow documented procedures for the use of any controls that are incorporated by the manufacturer into the Rapid DNA cartridge or if additional controls are processed by the laboratory.

Comment

Yes No N/A

9.6.2	For a laboratory performing modified Rapid DNA analysis:	☐	☐	☐
9.6.2.1	Does the laboratory verify the Internal Lane Standard (ILS) and allelic ladder results meet the laboratory's interpretation guidelines prior to data being reported and/or entered into CODIS?	☐	☐	☐
9.6.2.2	Does the laboratory perform manual interpretation of the data generated?	☐	☐	☐

Discussion

For laboratories that do not perform modified Rapid DNA analysis, Standard 9.6.2 and its subcategories shall be marked "N/A."

A laboratory shall verify that all ILS and allelic ladder results meet the laboratory's interpretation guidelines for all reported results. A documented method must exist to demonstrate that standard values are verified when used (e.g., check-off, technical review).

For Standard 9.6.2.2, the manual interpretation of data generated shall be performed by a qualified DNA analyst or the laboratory may rely upon an NDIS-approved expert system.

Comment

Standard 10. Equipment Calibration and Maintenance

		Yes	No	N/A
10.2	Does the laboratory have and follow a documented program for conducting performance checks and calibrating equipment and instruments?	☐	☐	☐
10.2.2	The following critical equipment requires quarterly recertification and/or performance checks:			

	10.2.2.2 Rapid DNA instrument.	☐	☐	☐
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 DNA analysis?	☐	☐	☐
10.4.1	At a minimum, are the following critical instruments or equipment performance-checked and/or recertified following repair, service, or calibration:	☐	☐	☐
	10.4.1.6 Rapid DNA instrument?	☐	☐	☐
10.4.2	At a minimum, are the Rapid DNA instrument(s) performance checked and/or recertified if the Rapid DNA instrument remains idle longer than the period recommended in the instrument specifications or as established by the laboratory?	☐	☐	☐

Discussion

To successfully satisfy Standards 10.2 and 10.4, the laboratory must demonstrate compliance with all of the subcategories of both Standards.

The minimum requirements of a performance check of a Rapid DNA instrument requires running a positive sample control in each lane prior to the analysis of reference samples. The Laboratory shall identify and document the acceptable results for the positive sample control prior to the use of the Rapid DNA instrument.

For Standard 10.2.2.2, laboratories must performance check and/or recertify their Rapid DNA instrument quarterly.

The critical instruments and equipment identified in Standard 10.4.1 require additional (beyond annual) performance checks after repair, service or calibration. At a minimum, the Rapid DNA instrument shall be performance-checked and/or recertified after repair, service, or calibration.

For Standard 10.4.2, a laboratory must perform a performance check and/or recertify a Rapid DNA instrument if the instrument is idle longer than the period recommended in the instrument specifications or as established by the laboratory. If the laboratory determines a time period that exceeds the recommended instrument specifications time period, the laboratory must have validation data to support that determination.

Comment

Standard 11. Documentation/Reports

Discussion

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

Comment

Standard 12. Review

	Yes	No	N/A
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?	☐	☐	☐
12.2.5 For laboratories performing modified Rapid DNA analysis, manual review of the data generated?	☐	☐	☐

Discussion

For NDIS participating laboratories, the review of the DNA types in Standards 12.2.2 and 12.2.3 may be accomplished by an NDIS approved and internally validated expert system or an internally validated Rapid DNA instrument that uses an NDIS-approved expert system.

For Standard 12.2.3, a review of all controls is applicable for controls that are incorporated by the manufacturer into the rapid DNA cartridge(s) or if additional controls are processed by the laboratory. A review of the controls is not required if the laboratory does not use rapid DNA cartridge(s) with controls incorporated by the manufacturer or does not run additional controls; however, the laboratory shall review

the internal lane standards and allelic ladders to verify that the expected results were obtained.

For Standard 12.2.5, the review may be accomplished by a qualified DNA analyst or an NDIS approved and internally validated expert system.

Comment

Standard 13. Proficiency Testing

		Yes	No	N/A
13.1.1.1	If an analyst or technical reviewer is interpreting data or performing the technical review for modified Rapid DNA analysis, have all analysts and technical reviewers been external proficiency-tested on the interpretation of data generated by a Rapid DNA instrument at least once per year?	☐	☐	☐

Discussion

For individuals performing Rapid DNA analysis using a Rapid DNA instrument with an NDIS approved STR typing kit and the Rapid DNA instrument applies an NDIS-approved and internally validated expert system, Standards 13.1.1 and 13.1.1.1 do not apply. The individual is not required to be proficiency tested on Rapid DNA Analysis using a Rapid DNA instrument.

Analysts and technical reviewers who complete the interpretation or technical reviews for modified Rapid DNA analysis shall be externally proficiency tested in the interpretation of the data generated by a Rapid DNA instrument at least once per year. Analysts and technical reviewers who only complete the interpretation or technical reviews for modified Rapid DNA analysis and do not participate in other scheduled DNA

proficiency tests shall be externally proficiency tested twice per year in accordance with Standard 13.1.

Comment

Standard 14. Corrective Action

Discussion

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

Comment

Standard 15. Audits

Discussion

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

Comment

Standard 16. Safety

Discussion

Standard shall be followed and applied as documented in the Quality Assurance Standards for DNA Databasing Laboratories effective September 1, 2011.

Comment

STANDARD 17. Outsourcing

		Yes	No	N/A
17.1.2	For a vendor laboratory that is performing Rapid DNA analysis using a Rapid DNA instrument with an approved STR typing kit and NDIS-approved and internally validated expert system, was the correct specimen category verified as part of the technical review under Standard 12?	☐	☐	☐
17.7.1	Does the technical review of DNA data include, at a minimum, the following elements:	☐	☐	☐
17.7.1.4	A review of all notes, all worksheets, and the electronic data (or printed electropherograms or images) to verify the results, for data generated by a vendor laboratory that performs modified Rapid DNA analysis?	☐	☐	☐
17.7.1.5	A review of all the data associated with applicable Rapid DNA instrument performance checks for vendor laboratory's using a Rapid DNA instrument?	☐	☐	☐

Discussion

To comply with Standard 17.1.2, a vendor laboratory must document that the correct specimen category was verified as part of the technical review under Standard 12.

For vendor laboratories, Standards 17.7.1 and its subcategories, shall be marked "N/A."

Comment

Appendix A: Findings and Responses

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

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

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

Additional pages may be attached, as needed.

Findings:

Responses: