Deviation Request Form (DRF)

Directions: The Initiator will complete Sections A through C. Additional continuation pages can be included if necessary.

Initiator	MA Hannon	**Date**	6/23/2020

A. Requested deviation applies to (Technical Procedure – include specific section):

Procedure for DNA Data Acceptance from a Vendor Laboratory sections 3 and 5.6

B. Requested deviation:

Section 3 - update definitions list. See attached
Section 5.6 Add wording to indicate that a vendor laboratory has generated a DNA profile and made comparisons regarding known standards. See attached. The remainder of this section to be renumbered appropriately

C. Necessity for the deviation:

Section 3 - Update with new QAS guidelines
Section 5.6 - Current procedures do not include working for NCSCL reports to indicate to the investigating agency that a comparison has been made in a vendor laboratory report

D. Technical review and Authorization (to be completed by the Quality Manager and/or Technical Leader)
Comments(to include merits and impacts):

Section 3 - Additional wording specifies additional definitions for clarification.
Section 5.6 - Additional report wording clarifies role NCSCL has in the outsourced cases and clearly states in the generated report.

Approved	☑	Yes	☐	No	Duration	until next version
Signature	Mackenzie DeHaan Digitally signed by Mackenzie DeHaan DN: C=US, OU=Forensic Biology, O=NCSCL, CN=Mackenzie DeHaan, E=mdehaan@ncdoj.gov Reason: I have reviewed this document Location: Date: 2020-06-23 17:00:00 Foxit PhantomPDF Version: 9.3.0				Date	06/23/2020

E. Quality Assurance Authorization (to be completed by the Quality Manager, Forensic Scientist Manager or designee)

Acceptable within general QA guidelines and good laboratory practice?	☑	Yes	☐	No
Significant negative impact to Crime Laboratory Quality System?	☐	Yes	☑	No

Restrictions/limitations:

Effective 07/01/2020

☑	Authorized	☐	Rejected	Signature	Jody H. West Digitally signed by Jody H. West DN: cn=Jody H. West, o=DOJ, ou=State Crime Laboratory, email=jwest@ncdoj.gov, c=US Date: 2020.06.25 09:08:08 -04'00'	Date	6/25/20

- Audit – is an on-site inspection used to evaluate, conform, and/or determine the extent to which specified requirements are fulfilled.
- Auditor – is an individual who has successfully completed the FBI's DNA auditor training course
- Outsourcing – is the utilization of a vendor laboratory to provide DNA services in which the NDIS participating laboratory takes or retains ownership of the DNA data. Outsourcing does not require the existence of a contractual agreement or the exchange of funds.
- Ownership is the process by which the responsibility for the products of DNA analyses provided by a vendor laboratory may pass to an NDIS participating laboratory. It applies if any of the following will occur:
    - The NDIS participating laboratory will use any samples, extracts or materials from the vendor laboratory for the purposes of DNA testing
    - The NDIS participating laboratory will interpret the DNA data generated by the vendor laboratory
    - The NDIS participating laboratory will issue a report describing or drawing conclusions on the results of the DNA analysis performed by the vendor laboratory; or
    - The NDIS participating laboratory will enter or search a DNA profile in CODIS from the data generated
- Ownership review – is the technical review of outsourced DNA data required by Standard 17. This review is to be distinguished from the technical and administrative reviews required. For outsourcing DNA data, the vendor laboratory is responsible for conductions the technical and administrative reviews required.
- Technical reviewer – is an employee who is qualified by the laboratory in the technology, platform, and typing test kit used to generate the data. The reviewer must participate in the Laboratory's external proficiency testing program to the extent necessary to be proficient in the technology, platform, and typing test kit under review in the outsourced data
- Vendor laboratory – is a governmental or private laboratory that provides DNA analysis services to another laboratory or agency and does not take ownership of the DNA data for the purposes of entry into CODIS.

5.6.2 If it is determined that a DNA profile generated by a vendor laboratory is utilized in deduction or a mixture DNA profile, the following wording shall be used to notify the investigating agency.

5.6.2.1 The DNA profile obtained from (Item) (as provided by) is an assumed contributor to this mixture.

5.6.3 If it is determined that a DNA profile generated by a vendor laboratory from a known reference (other than the DNA profile from the intimate sample donor) has been compared to a DNA profile in which the NCSCL has taken ownership, the following wording shall be used to notify the investigating agency.

5.6.3.1 The DNA profile obtained from ___ (Item) (as provided by [vendor laboratory]) was analyzed and reported by a laboratory other than the NCSCL. Please refer to the vendor laboratory report in regards to any results and conclusions involving this item.

Procedure for DNA Data Acceptance from a Vendor Laboratory

1.0 Purpose – The purpose of this document is to address the requirements and specifications that must be met in order for the North Carolina State Crime Laboratory's (NCSCL) Forensic Biology Section to take possession of DNA data generated by a vendor laboratory for the purpose of search or entry into CODIS database. In addition, the procedures contained herein are established to comply with the *Quality Assurance Standards for Forensic DNA Testing Laboratories*.

2.0 Scope – This document applies to the DNA Technical Leader (DNA TL), the CODIS Administrator, and any Forensic Scientist in the Forensic Biology Section qualified to perform a technical review.

3.0 Definitions

- **Amplification Test Kit -** a preassembled reagent set that allows the user to conduct a specific DNA amplification.
- **On-Site Visit -** a scheduled or unscheduled visit to the vendor laboratory work site by one or more representatives from an NDIS participating laboratory who is (are) a qualified or previously qualified DNA analyst(s) in the technology, platform and typing amplification test kit used to generate the DNA data, or designated FBI employee(s), to assess and document the vendor laboratory's ability to perform analysis on outsourced casework.
- **On-Site Vendor Laboratory Visit Program (OVP)** – Program facilitated by the FBI in order to provide NDIS-participating labs with a completed, standardized on-site visit checklist/summary. The on-site visit summaries and supplemental materials are not an approval/endorsement by the FBI of a particular vendor laboratory.
- **Platform** - the type of analytical system used to generate DNA profiles, such as capillary electrophoresis.
- **Qualified Analyst** - an employee who successfully completed the laboratory's training requirements for casework sample analysis, passed a competency test, and has entered into a proficiency testing program according to Quality Assurance Standards. This individual conducts and/or directs the analysis of forensic samples, interprets data, and reaches conclusions.
- **Technical Reviewer** - an employee who is a currently or previously qualified analyst in the methodology being reviewed.
- **Technology -** the type of forensic DNA analysis performed in the laboratory, such as STR, YSTR, or mitochondrial DNA.
- **Vendor Laboratory -** a governmental or private laboratory that provides DNA analysis services to another laboratory or agency and does not take ownership of the DNA data for purposes of entry into CODIS.

4.0 Equipment, Materials, and Reagents – Forensic Advantage (FA), CODIS software

5.0 Procedure –

5.1 Procedure for Vendor Laboratory Approval

5.1.1 Prior to uploading or accepting data to upload to CODIS from any vendor laboratory, the DNA TL shall document prior approval of the technical specifications and/or the acceptance of ownership of the DNA data.

5.1.2 The documentation of DNA TL approval shall be either a signed Memorandum of Agreement, a signed Private Lab Pre-Approval Form, or a signed On-site Vendor Laboratory Visit Program (OVP) Summary. This documentation shall be maintained on the Forensic Biology Section's shared drive.

5.1.3 The DNA TL shall review and approve all mandatory documentation that is submitted to the NCSCL prior to granting approval to the vendor laboratory. This supporting documentation shall be maintained on the Forensic Biology Section's shared drive, with the exception of the supplemental document provided by the OVP, which can be accessed by an approved CODIS user on the CODIS secure website.

5.1.4 The DNA TL shall not approve the upload or acceptance of DNA data if the vendor laboratory fails to notify the NCSCL of any updates to the mandatory documentation that is required to be submitted to the NCSCL. This includes, but is not limited to, a change in accreditation status, any findings as a result of a QAS Audit, any procedural changes, or changes in technical specifications.

5.1.4.1 The NCSCL, as owner of any DNA profile entered/searched in CODIS on behalf of a vendor laboratory, shall remove any such profile from CODIS upon the failure of the vendor laboratory to disclose any updates to the mandatory documentation that is required to be submitted to the NCSCL.

5.1.5 DNA TL approval of a vendor laboratory is site specific. Any additional locations of a vendor laboratory shall be treated as a separate vendor laboratory. In addition, if any vendor laboratory has multiple sections/units that function separately under different protocols, procedures, and validations shall be treated as a separate vendor laboratory.

5.2 Mandatory Documentation to be submitted to the NCSCL

5.2.1 The DNA TL shall maintain the following documentation to ensure the vendor laboratory's compliance with:

5.2.1.1 FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.

5.2.1.2 Federal law accreditation requirements.

5.2.2 The DNA TL shall maintain documentation of an on-site visit that occurred prior to the initiation of analysis by the vendor laboratory.

5.2.2.1 The on-site visit shall be performed and/or accepted by the DNA TL, a designated employee of an NDIS-participating laboratory that uses the same

technology, platform, and typing amplification test kit, or a designated FBI employee.

5.2.2.2 For an on-site visit by an employee of the NCSCL, see the Procedure for Conducting an On-site Visit within this document.

5.2.3 If the signed Memorandum of Agreement between the NCSCL and the vendor laboratory is extended beyond one year, an annual on-site visit must be performed and/or accepted by the DNA TL.

5.2.4 The DNA TL shall maintain the most recent version of the vendor laboratory's Quality Assurance Manuals and Laboratory Procedures.

5.2.4.1 This may be limited to the specific procedures used for data that is being submitted.

5.2.5 The DNA TL shall maintain any validation summaries for the procedures used for data that is being submitted.

5.3 Procedure for Conducting an On-Site Visit by an Employee of the NCSCL (not part of OVP)

5.3.1 The DNA TL (or designee) shall, at a minimum, review or directly examine the following:

5.3.1.1 The most recent accreditation certificates and audit documentation.

5.3.1.2 Adequacy of laboratory space for evidence storage, screening, extraction, quantitation, STR amplification, electrophoresis, and review of data.

5.3.1.3 Security and access control of the laboratory space.

5.3.1.4 Adherence to procedures, reagent labeling, QC logs for equipment and reagents, tidiness of examination areas, and flow of evidence through the laboratory.

5.3.1.5 Proper sealing and storage of evidence.

5.3.1.6 Proficiency tests from the most recent cycle for all analysts, technical reviewers, technicians, and other personnel designated by the technical leader.

5.3.1.7 Any corrective action documentation from the last year.

5.3.1.8 An organizational chart and *curriculum vitae* for analysts and technicians.

5.3.1.9 Three case files from each person conducting DNA analysis (to include any documentation created by technician and technical reviewer).

5.3.1.10 All applicable validations and performance checks.

5.3.2 The DNA TL (or designee) shall complete the NCSCL Vendor Laboratory On-Site Visit Checklist.

5.3.3 Upon approval of the vendor laboratory, the DNA TL shall sign and maintain the NCSCL Vendor Laboratory On-Site Visit Checklist on the Forensic Biology Section's shared drive.

5.3.3.1 A copy of the on-site documentation may be provided to another NDIS-participating lab that uses the same technology, platform, and amplification testing kit as the NCSCL, upon request, as permitted by federal guidelines.

5.4 Procedure for Receipt of Vendor Data

5.4.1 The Forensic Scientist (or designee) in receipt of the vendor data shall create a new submission in FA. Refer to State Crime Laboratory Procedure for Evidence Management.

5.4.2 All data returned from a vendor laboratory shall be uploaded into the FA case object repository and approved.

5.5 Procedure for Review of Outsourced Data

5.5.1 A qualified analyst/technical reviewer shall conduct a technical review of all of the vendor laboratory's data prior to uploading the data in CODIS (see Outsourcing Tech Review Checklist).

5.5.1.1 A qualified analyst/technical reviewer shall review, at a minimum, the following:

5.5.1.1.1 All DNA types to verify that they are supported by the raw and/or analyzed data.

5.5.1.1.2 All associated controls, ladders, and internal lane standards to verify that the expected results were obtained.

5.5.1.1.3 The DNA data to verify specimen eligibility and the correct specimen category for entry into CODIS.

5.5.1.1.4 The final report (if provided) to verify that the results/conclusions are supported by the data and that each tested item (or probative fraction) is addressed.

5.6 Notification of CODIS Entry

5.6.1 If it is determined that a DNA profile generated by a vendor lab is eligible for search or entry into the CODIS database, the CODIS administrator (or designee) shall use the following wording to notify the investigating agency.

5.6.1.1 *The DNA profile obtained from_____(Item) (as provided by_____) has been entered into the Combined DNA Index System (CODIS) in accordance with state and national regulations, where regular searches will be performed.*

Notification will be issued if there is a hit in the database or if the profile is removed from CODIS at any time in the future.

5.6.2 If it is determined that a DNA profile generated by a vendor laboratory is eligible for a one time search, refer to the Procedure for CODIS Reports for report wording.

5.6.3 If it is determined that a DNA profile generated by a vendor laboratory does not meet eligibility requirements for search or entry into the CODIS database, the CODIS Administrator (or designee) shall use the following wording to notify the investigating agency.

5.6.3.1 *The DNA profile obtained from (Item) (as provided by_____) is not suitable for search or entry in the CODIS (Combined DNA Index System) Database.*

5.6.4 The Forensic Scientist performing the technical review of the vendor data/report shall issue the Notification of CODIS Entry report.

5.6.5 The notification report shall go through a combined technical/administrative review.

5.6.6 The search/entry of a DNA profile in the CODIS database implies acceptance of ownership of the DNA data.

6.0 Limitations – N/A

7.0 Safety – N/A

8.0 References

State Crime Laboratory Procedure for Evidence Management

Forensic Biology Section Procedure for CODIS – DNA Casework

Forensic Biology Section Procedure for CODIS Reports

NDIS Operational Procedures, CODIS Website

9.0 Records – N/A

10.0 Attachments – N/A

Revision History		
Effective Date	Version Number	Reason
08/29/2014	1	Original Document
12/28/2015	2	5.1.2 – changed from Understanding to Agreement; 5.2.3 – annual on-site requirement; 5.5.1 – added reference to form
12/20/2016	3	5.6 – added Notification of CODIS Entry (previously in Casework Report Writing); 8.0 – removed references to Interp, Report Writing and Doc and Review; added reference to CODIS Reports.
03/12/2018	4	Added OVP to Definitions; 5.1.2 – added signed OVP summary as documentation of TL approval; 5.1.3 – document retention of OVP supplement; 5.3 – clarified title; 5.6.1.1 – updated wording