Forensic Biology Section Administrative Policy and Procedure

1.0 Purpose - The purpose of the document is to ensure the following:

1.1 The Forensic Biology Section meets the standards set forth in the State Crime Laboratory Quality Manual and the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.

1.2 The Forensic Biology Section provides the North Carolina Criminal Justice System services for identification of Body Fluids and DNA typing and ensures that these procedures are operating within established performance criteria.

1.3 The quality and integrity of the data are maintained and are sound scientifically**.**

1.4 The Forensic Biology Section provides the North Carolina Criminal Justice System with laboratory services for identification and genetic typing of biological materials that pertain to a particular criminal investigation.

1.5 Corrective actions are documented.

1.6 The Forensic Biology Section provides guidelines to employees so they are aware of performance expectations.

1.7 Personnel performing these tests have the appropriate level of training and education.

1.8 The Forensic Biology Section adheres to FBI Quality Assurance Standards for Forensic DNA Testing Laboratories, ISO 17025 and supplemental requirements.

1.9 Forensic Scientists are competent in performing the testing and interpreting the results through a series of proficiency tests.

2.0 Scope - This procedure applies to all personnel assigned to the State Crime Laboratory Forensic Biology Section.

3.0 Responsibilities

3.1 Organization Overview

3.1.1 The Forensic Biology Section performs testing in the following areas: DNA Casework (STR and YSTR) and Body Fluid Casework.

3.1.2 The organizational chart for the Section reflects the management structure and responsibilities (e.g., technical leader, CODIS state administrator, safety officer etc.). Areas in which the Forensic Scientist has shown competency is documented on the work authorization record. The date of qualification (as documented on the work authorization) will be used to define the applicable version of QAS used to access education, experience, and training.

3.1.2.1 If the Technical Leader position is vacated, the laboratory procedure for selection will be followed. If there is no qualified personnel within the laboratory system, then a contingency plan will be submitted to the FBI. No casework analyses will be initiated until FBI approval is granted.

3.1.2.2 If the number of qualified analysts falls below two, the Laboratory's Continuity of Operations Plan (COOP) will be followed.

3.1.2.3 Notification of the TL vacancy or the number of qualified analysts falling below two as assigned to each laboratory facility (e.g., Raleigh or Western sites) will be made as required in the QAS audit document and the NDIS Operational Procedures Manual.

3.1.2.4 The laboratory shall not upload DNA profiles to NDIS in the event that the casework CODIS administrator position is unoccupied.

4.0 Procedure

4.1 Section Obligations

4.1.1 Continuing Education

4.1.1.1 Qualified Section Forensic Scientists shall complete a minimum of 8 hours of continuing education each calendar year. This requirement does not apply to Forensic Scientists in training status and may be prorated for the year. This requirement shall be met one of the following ways: by attending seminars, college courses, professional meetings or by taking on-line courses. DNA on-line courses shall be submitted to the DNA–TL for review and approval prior to participation. Section Forensic Scientists shall stay current of developments within the field by reading current scientific literature and signing the appropriate acknowledgement sheet as documentation. Forensic Scientists shall have access to the internet and local university libraries for reading scientific literature. The TL or designee shall circulate literature when pertinent scientific literature is published.

4.1.1.2 Records

4.1.1.2.1 Documentation of continuing education training records (e.g., certificates, BDAs) shall be stored in the Forensic Biology Section according to the record retention schedule as set forth by the North Carolina Department of Cultural Resources or for five years, whichever is longer.

4.1.1.2.2 Documentation shall be incorporated into a master training log for each Forensic Scientist.

4.2 Facilities

4.2.1 Section secure areas:

- Areas designated by the DNA QC procedure as being limited access.
- Areas where evidence is actively being stored/analyzed to include evidence vault, personal evidence lockers, refrigerators and freezers.

4.3 Validation

4.3.1 This Laboratory shall use only validated methods and procedures for the analysis of forensic cases.

4.3.2 Developmental and Internal Validation of the DNA Analysis Procedures

All developmental and internal validation studies will be performed according to the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories (Standard 8).

4.3.3 Internal Validation of Body Fluid Identification Procedures

Prior to initiation of new Body Fluid typing procedures, studies shall be conducted by this Laboratory to ensure reproducibility and precision of the procedure as well as define and/or establish limitations to the procedure. These studies shall be performed by the Body Fluid Technical Leader or designee. The procedure shall be tested using known samples and may include (but not be limited to) the following tests: reproducibility, sensitivity, species study (if applicable) and sample stability.

4.3.4 Validation studies, population studies, and research project results shall be maintained in hard copy and on the Forensic Biology Section shared drive by the Forensic Scientist Manager or designee.

4.3.5 Documentation for historical procedures

The following procedures are used as a part of the Forensic Biology Section and have undergone the audit process numerous times. These procedures have been utilized in-house and verified by multiple analysts over time. This verification is documented in the training files, which are available upon request. These procedures were in place before increased validation requirements were made under ISO 17025 standards. References are available for each of these procedures.

- Kastle-Meyer Test
- Acid Phosphatase Test
- Christmas Tree Stain

4.4 Proficiency Tests

4.4.1 All Forensic Scientists shall follow the procedure for proficiency testing as outlined in the Laboratory Procedure for Ensuring the Quality of Test Results. In addition, all proficiency vendors shall meet FBI Quality Assurance Standards for Forensic DNA Testing Laboratories. DNA Forensic Scientists shall complete an external proficiency test twice a year (every 180 days, based upon the due date set by the vendor). If a Forensic Scientist is on extended leave during the period of time when the proficiency test is to be analyzed, they shall complete an internal competency test prior to returning to the bench for analysis.

4.4.2 DNA Proficiency tests shall be reviewed and recorded on a Proficiency Test Evaluation Form which contains the elements required by the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories (Standard 13).

4.4.3 All final reports shall be graded as satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data. Administrative errors shall be documented and actions taken to minimize the error in the future. The Casework CODIS Administrator will be notified in the event of non-administrative discrepancies that affect the typing results and/or conclusions.

4.4.4 All proficiency test participants shall be given feedback which shall be documented.

4.4.5 The vendor due date for DNA External Proficiency Tests shall be the date used to monitor the semi-annual tests for DNA Forensic Scientists.

4.4.6 Each Body Fluid proficiency test shall be evaluated to determine if:

4.4.6.1 The correct body fluid(s) have been identified.

4.4.6.2 All results reported are consistent with written Laboratory guidelines.

4.4.6.3 All final reports shall be graded satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors made. Administrative errors shall be documented and corrective actions taken to minimize the error in the future.

4.4.6.4 All proficiency test participants shall be given feedback which shall be documented.

4.4.7 Storage of Proficiency tests - For storage and retention schedule, see the State Crime Laboratory Procedure for Ensuring the Quality of Test Results.

4.5 Corrective Action – See State Crime Laboratory Procedure for Corrective Actions and Non-Conformities. The plan must be approved by the Technical Leader prior to implementation and when the non-conformity impacts DNA records entered into CODIS, the casework CODIS administrator must also be notified.

4.6 Audits -The Laboratory Procedure for Conducting Audits and Management Reviews shall be referred to for Section wide internal audits. For the purpose of DNA audits, the Forensic Biology section shall adhere to the FBI Quality Assurance Standards for Forensic DNA testing laboratories standard 15. As a part of the annual internal audit, a representative sample of cases worked will be reviewed. The scope of this review will be defined by the Technical Leader as a part of the internal review process.

4.7 Subcontracting

4.7.1 Body Fluid – refer to the applicable Laboratory Procedures.

4.7.2 DNA

4.7.2.1 Use of a Subcontractor Laboratory for Forensic Cases is permitted. Most often this will take place as part of a coordinated outsourcing program to specific laboratories chosen for this work.

4.7.2.2 Criteria for Subcontractor Selection

4.7.2.2.1 The DNA Technical Leader shall approve the technical specifications of the outsourcing agreement and/or document the approval of acceptance of the ownership of the DNA data prior to uploading or accepting data to upload or search in CODIS from any vendor laboratory or agency.

4.7.2.2.2 The criteria for evaluating prospective subcontractor labs may include, but not be limited to, the following: compliance with the proposal, adherence to quality standards (audit report and responses), personnel, equipment/materials/facilities, security, evidence handling procedures, proficiency testing, documentation, validation, safety, analytical procedures, data interpretation and reporting, etc.

On-site visits: When samples are outsourced to a vendor laboratory for DNA analysis, an on-site visit of the vendor laboratory shall be performed or the laboratory may elect to accept information/documentation generated from an on-site visit conducted of the vendor laboratory by an NDIS laboratory using the same

technology, platform, and typing amplification test kit as long as it was conducted within the past twelve months. Alternatively, the technical leader of the NDIS participating laboratory may accept an on-site visit conducted by a designated FBI employee. The site visit will be performed by the technical leader or designee from the Forensic Biology Section and will verify that the laboratory meets or exceeds the FBI Quality Assurance Standards. A memorandum should be generated by the employee(s) conducting the site visit and that documentation shall be retained by the Forensic Biology Section. The memorandum shall include the date the on-site visit was performed, a summary of the visit, and documentation of the employee who performed the on-site. Initial and on-site visits will follow the requirements from the most current version of QAS Section 17.

4.7.2.2.3 The Forensic Biology Section and the contracting laboratory shall ensure that an appropriate chain of custody is maintained at all times.

4.8 Uncertainty of Measurement – The Forensic Biology Section acknowledges that its measurements have a level of uncertainty. Since there are no quantitative results reported from the Section, it has no measurements that need an uncertainty measurement formula applied to them. Additional discussion of uncertainty will be discussed within the individual section procedures if applicable.

4.9 Reviews

4.9.1 Stop-work cases – For stop work cases with a generated case report, only a combined technical/administrative review is required.

4.9.2 Swabbing only – Swabbing only examinations are performed to facilitate transfer of evidence to other sections for analysis prior to the completion of the applicable Forensic Biology request. A verification review must be completed to document that the appropriate documentation (e.g., serology workbook, CV, photographs, etc.) is present in the FA Case Record OR. No other reviews are required at this step. Additional reviews will be completed as needed based on the results of the additional analysis.

4.9.3 Body Fluid only cases – For case records where only body fluid analysis is performed (no DNA), only a combined technical/administrative review is required.

4.9.4 Stop at quant cases – For case records where the analyses for all samples stop at the quantification step and no samples are amplified, only a combined technical/administrative review is required.

4.9.5 The case records for cases where additional standards are submitted for comparison to previously worked unknowns with no additional interpretation performed (e.g., CODIS hit comparisons), and statistics only records require a combined technical/administrative review only.

4.9.6 Cases with amplified samples – For case records where the analysis for any sample continues past the quantification step, a separate technical and combined technical/administrative review must be completed prior to the case record being released.

4.9.7 Other case reports (e.g., , outsourcing, familial searching, etc.) – Reviews for these reports will be performed as documented in the applicable Forensic Biology procedures.

4.9.8 Batch verification reviews are performed for DNA cases. The analysis documentation for the batch of cases analyzed as a set is reviewed to streamline the overall review process. The batch verification may be combined with the technical review process. A batch verification review will be scheduled in

Forensic Advantage (FA) for one of the cases in the batch. The FA case record object repository for each case within the batch will contain the batch verification review form and be approved by the analyst of record once complete.

4.9.9 Additional technical review is needed if during combined technical/administrative review changes are made to interpretation (e.g., number of contributors, inclusion/exclusion), additional analysis is performed or changes to CODIS entry.

5.0 Safety – Refer to the State Crime Laboratory Safety Manual.

6.0 References

State Crime Laboratory Quality Manual

ISO 17025

State Crime Laboratory Procedure for Ensuring the Quality of Test Results

State Crime Laboratory Procedure for Conducting Audits and Management Reviews

State Crime Laboratory Safety Manual

State Crime Laboratory Document Control and Management Procedure

Federal Bureau of Investigation "QUALITY ASSURANCE STANDARDS FOR FORENSIC DNA TESTING LABORATORIES." *September 1, 2011*.

7.0 Records

- Forensic Biology Proficiency Test Evaluation Form
- Key inventory
- Duty list
- Reviewer list
- Work Authorization
- Vendor list
- Forensic Biology section equipment inventory

8.0 Attachments – N/A

Revision History

Effective Date	Version Number	Reason
05/24/2024	7	4.9.5 – add additional case types that require a combined review; 4.9.7 Clarify wording regarding scheduling of batch verification reviews; 4.9.8 – added wording for additional review scheduling, 4.9.9 – wording for additional required technical review