CMPD Crime Laboratory Biology

Quality Assurance Manual

Foreword

This manual is designed to ensure that CMPD Biology Laboratory produces scientifically valid and professionally acceptable casework analysis. It is designed to be used in conjunction with other safety, standard operating procedure, and training manuals to achieve this goal.

The CMPD Biology QA Manual is a compilation primarily of guidelines provided by SWGDAM, the FBI Quality Assurance Audit Document and the ANSI National Accreditation Board.

Throughout this document, references are made to other CMPD manuals in the laboratory and anyone consulting this manual for information regarding the function of the lab should have access to the other manuals. The other manuals include but are not limited to:

1. Biology SOP Manual
2. Biology Training Manual
3. CMPD Crime Laboratory Safety Manual
4. CMPD Crime Laboratory Quality Manual (QM)
5. CMPD Policy and Procedures, Directives and Field Volumes

If there are any questions regarding the contents of this or any Biology manual, they may be directed to the Biology Chief Criminalist or the DNA Technical Leader.

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1. Goals and Objectives

1.1 Goals

1. Provide the Charlotte Mecklenburg Police Department laboratory services for identification and genetic typing of biological materials that pertain to a particular criminal investigation.

2. Ensure the quality, integrity, and scientific accuracy of testing results through the implementation of a detailed Quality Assurance/Quality Control (QA/QC) program.

1.2 Scope

- The QA/QC program described in the following manual has two purposes: (1) to ensure that the identification and genetic typing procedures operate within established performance criteria and (2) to ensure that the quality and integrity of the data are maintained and are scientifically sound.

- The QA/QC program complies with the FBI QAS quality assurance requirements that laboratories performing forensic DNA testing or utilizing the Combined DNA Index System (CODIS) shall follow to ensure the quality and integrity of the data generated by the laboratory. DNA data generated from forensic DNA testing performed outside of the scope of these standards are prohibited from entry into CODIS. As it pertains to these standards, forensic DNA testing begins at sample lysis.

1.3 Program Objectives

- Ensure uniformity and accountability in records and analysis procedures
- Measure quality of performance with known standards and to be able to act on any differences encountered
- Ensure the accuracy of the data generated
- Document corrective actions taken
- Monitor personnel and equipment performance
- Eliminate non-conforming materials or work
- Prepare and/or verify all control materials used
- Ensure the use of documented and valid materials and procedures
- Ensure that identification and genetic typing results are technically sound
- Provide guidelines to employees so they will know what is expected of them
- Ensure that personnel have the appropriate level of training and education
- Ensure that analysts are competent in performing the testing and interpreting the results through a series of proficiency tests
- Provide for external audits to ensure that operating policies are followed and are adequate

- Provide for a safe workplace
- Provide guidelines for the outsourcing and review of DNA cases for CODIS entry

2. Organization and Management

2.1 Laboratory Management

Laboratory management is described in Laboratory QM 4.1.7. The appropriate levels of authority within the department but outside the Crime Lab Bureau are described in the CMPD Directive 100-003. These documents, along with QM Appendix C, outline the responsibilities, authority and interrelation of the staff.

2.2 Biology Section Contingency Plans

The Biology Section Contingency Plans outline how the laboratory will proceed if no one is qualified to fill the DNA Technical Leader vacancy, in the event the number of qualified analysts falls below two full-time employees who are qualified analysts, and if the casework CODIS Administrator position is unoccupied. The NDIS Custodian and State CODIS Administrator will be notified as required by the NDIS Operational Procedures Manual if either the DNA Technical Leader Contingency Plan or the Qualified Analysts Contingency Plan are enacted.

2.2.1 DNA Technical Leader Contingency Plan

a) If the DNA Technical Leader vacates the position, a qualified analyst will resume the responsibilities of the DNA Technical Leader until a replacement can be found. If no one is qualified to fill the technical leader role, DNA casework will cease until a qualified individual is hired or promoted. NDIS requires that within five business days the NDIS Custodian and State CODIS administrator are notified if the technical leader position is vacated and there is no one in the laboratory who meets the QAS qualifications and is available to serve in that position. The laboratory shall document such notification using the form entitled Notification Form for Technical Leader Contingency Plan in Appendix B of the FBI's QAS Audit document.

b) If an analyst has been designated a back-up technical leader in the technical leader's absence, a memo can be found in the Staff Qualifications folder. If the designated person is not qualified in all technologies, a separate technical leader will be designated as having ultimate authority for that technology.

c) A DNA Technical Leader must be assigned to the Biology section while DNA casework is being performed. Should the technical leader position be vacated, the Biology Section Contingency plan will be enforced.

2.2.2 Casework CODIS Administrator Contingency Plan

a) If the casework CODIS Administrator position is unoccupied, the laboratory shall not upload DNA profiles to NDIS until the position is filled by a qualified individual. Since the back-up CODIS administrator (alternate) is qualified to perform the activities of the CODIS administrator, that individual shall be designated as the CODIS administrator when the CODIS administrator is absent or unavailable. An alternate CODIS administrator shall be designated within ninety (90) days of a vacancy in the alternate CODIS administrator position.

b) A Casework CODIS Administrator must be assigned to the Biology section while DNA profiles are uploaded to NDIS. Should the CODIS Administrator position be vacated, the Biology Section Contingency plan will be enforced.

2.2.3 Qualified Analysts Contingency Plan

a) If the number of qualified DNA analysts in a specific technology falls below two full-time employees, DNA casework will cease until a full-time DNA analyst is hired and qualified in that technology. NDIS requires that within five business days the NDIS Custodian and State CODIS administrator are notified if fewer than two full-time employees are qualified as DNA analysts.

b) Two full-time qualified DNA analysts must be employed by the Biology section while DNA casework is being performed. Should the number of full-time qualified DNA analysts fall below two individuals, the Biology Section Contingency plan will be enforced.

3. Personnel

All laboratory technical personnel authorized in the recovery, evaluation, analysis, and interpretation of body fluid identification and/or DNA evidence shall have the education, training, and experience commensurate with their authorized responsibilities.

A current copy of all Biology Section job descriptions including responsibilities and qualifications will be maintained in the Laboratory QM Appendix C. Personnel qualifications and responsibilities specifically defined by the FBI Quality Assurance Document are included here to augment the Laboratory QM.

Each position within the laboratory has a defined function that is described in the official job descriptions. However, the general laboratory responsibilities are outlined here which do not necessarily contain all the functions of the individual. In addition to items listed, each analyst is responsible for following all safety, SOP, and QC regulations and guidelines. Each title may contain more than one individual at that position and each individual may have slightly different experience and abilities.

3.1 Qualifications and Responsibilities

3.1.1 Qualifications of DNA Analysts

a) The analyst shall have a bachelor's (or its equivalent) or an advanced degree in a biology-, chemistry-, or forensic science related area. Criminal justice degrees that do not include science coursework are not considered to be forensic science-related degrees
    - The analyst shall have successfully completed at least 9 credit hours of coursework in biology- or chemistry-related areas that provide an understanding of the foundation of DNA analysis.
    - Coursework that provides an understanding of the foundation of DNA analysis can include courses titled with terms such as molecular biology, genetics, biochemistry, biological chemistry, population genetics, molecular genetics, cell and molecular biology, genomics, and bioinformatics. This list is not exhaustive of all relevant courses that can be used to satisfy this standard. General education science courses cannot be used to satisfy the educational course requirements.
    - An analyst qualified prior to July 1, 2020, shall have coursework and/or training in statistics and/or population genetics as it applies to forensic DNA analysis. An analyst qualified on or after July 1, 2020, shall have successfully completed coursework covering statistics and/or population genetics.

- If prior minimum educational requirements as an analyst were accepted by the DNA Technical Leader, this shall be documented through prior external audit documentation and shall be retained by the laboratory.

b) The analyst shall have forensic human DNA laboratory experience commensurate with their authorized responsibilities. If prior forensic human DNA laboratory experience is accepted by a laboratory, the prior experience shall be documented and augmented by additional training, as needed. The analyst shall successfully complete the required training.

c) Qualified analysts that are hired at the CMPD will undergo a modified training/assessment to be determined and documented by the DNA Technical Leader based on their previous qualifications.

d) The DNA analyst training will cover the following:

- Evidence handling procedures
- Documentation and reporting procedures
- Safe lab practices
- Ethical practices
- DNA STR methodology
- Body fluid identification methodology (if applicable)
- DNA QA and QC systems and methods
- Equipment operation, monitoring, calibration and maintenance
- Buffer and solution preparation
- Quantitative and qualitative evaluation of DNA test results
- DNA case acceptance policies
- Interpretation of results
- Statistical evaluation of test results
- Technical review
- Oral assessment and/or expert testimony training

e) Successful completion of competency tests and authorization including a practical component and written and/or oral components is required before performing a method on an evidence item.
f) Supervised casework as applicable may be used as part of the training, retraining, and/or performance monitoring program once competency tested and authorized.
g) Independent casework as applicable will be authorized after the successful completion of supervised casework.
h) Authorization to perform technical reviews will be separate from the casework authorization and will be granted upon completion of instruction and documented training.

- A technical reviewer must meet the education and experience qualifications of an analyst and be a current or previously qualified analyst.

i) If retraining is needed, the technical leader shall be responsible for evaluating the need for and assessing the extent of retraining. The retraining plan shall be approved by the DNA Technical Leader.
   - The analyst shall successfully complete competency testing prior to resuming casework analyses. This competency testing shall include a practical component and written and/or oral components. Re-authorization will be documented after successful completion of retraining and competency requirements.
   - After an extended absence, the analyst may undergo retraining. If the analyst has missed a proficiency test during the absence, the analyst shall successfully complete competency testing prior to resuming casework analyses. This competency testing shall include a practical component.

3.1.2 Responsibilities of DNA Analysts

a) Examines evidence.

b) Operates complex laboratory equipment and uses advanced laboratory techniques.

c) Generates detailed documentation related to all examinations; completes reports of results of analyses and communicates results to appropriate department personnel.

d) Provides expert testimony relating to results of analyses; consults with and advises attorneys and other law enforcement officials in forensic matters.

e) Performs quality assurance and quality control checks and conducts laboratory analyses in accordance with laboratory procedures and ANAB requirements.

f) Assists in validation studies, performance checks and/or material modifications.

3.1.3 Qualifications of the DNA Technical Leader

a) In addition to the requirements for DNA analysts, the DNA Technical Leader shall have, at a minimum, a master's degree in a biology-, chemistry-, or forensic science-related area.

b) The Technical Leader shall have successfully completed at least 9 credit hours of coursework in biology- or chemistry-related areas that provide an understanding of the foundation of DNA analysis.

c) In addition, the Technical Leader shall have successfully completed coursework in statistics or population genetics.

d) The required coursework shall include at least one graduate level course.

e) If prior minimum educational requirements as a Technical Leader were accepted by the laboratory, this shall be documented through prior external audit documentation and shall be retained by the laboratory.

f) Any Technical Leader appointed on or after July 1, 2009, shall have a minimum of three years of human DNA (current or previous) experience as a qualified analyst testing forensic samples.

g) Any Technical Leader appointed on or after July 1, 2020 shall be a currently or previously qualified analyst in each technology utilized in the laboratory or have documented training in each technology utilized in the laboratory within one year of appointment.

h) The Technical Leader shall have previously completed or will successfully complete the current FBI’s DNA auditor training course within one year of appointment.

i) Within one year of being newly appointed, the Technical Leader shall be responsible for the review of the following:

- Validation studies and analytical procedures currently used by the laboratory
- Training records of currently qualified analysts and technical reviewers who have not yet been memorialized by an external audit.

3.1.4 Responsibilities of the DNA Technical Leader

A DNA Technical Leader oversees the DNA technical operations of the laboratory. The DNA Technical Leader is the Biology Section QA/QC Officer unless otherwise noted. The Biology Section QA/QC Officer works closely with the Biology Section Supervisor and the Laboratory Quality Assurance Manager

to ensure that the Biology Section is compliant with laboratory procedures, state and federal regulations, the FBI Quality Assurance Standards and the standards of the ANAB accreditation program. In addition to general technical and quality assurance responsibilities, the technical leader has the authority and responsibility for the following:

a) Evaluating all methods used by the laboratory and for proposing new or modified analytical procedures to be used by examiners.

b) Evaluating and approving all validations and new or modified methods used by the laboratory.

c) Technical problem solving of analytical methods.

d) Oversight of training, quality assurance, audits, safety and proficiency testing in the Biology section.

e) Accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

f) Initiating, suspending, and resuming DNA analytical operations for the laboratory or an individual, and, when applicable, a Rapid DNA partner agency.

g) Reviewing the training records for newly qualified analysts, technicians and technical reviewers and approving their qualifications prior to independent casework analysis.

h) Reviewing, verifying, and approving the education and experience for newly qualified analysts and technical reviewers.

i) Reviewing the internal and external DNA audit documents.

j) Approving the technical specifications for outsourcing agreements.

k) Approving all Corrective Actions in DNA prior to implementation.

l) Annually reviewing, documenting the review, and approving the review of the quality system as applicable to DNA (including the Biology SOP’s and Biology QA Manual).

m) Reviewing and approving the training, quality assurance, and proficiency testing programs in the DNA laboratory.

n) Reviewing requests by contract employees for employment by multiple NDIS participating laboratories and if no potential conflict of interest exists, approving such requests.

o) Determining and approving the scope of an annual case file review. This annual review will be independent of an external audit and will be a representative sample of the cases worked. The performance of the annual review will be conducted by the Technical Leader or an individual designated by the Technical Leader.

p) Ensuring that the data from the manufacturers and the testing of critical reagents is maintained.

q) Ensuring that all QA/QC protocols are performed on critical equipment and reagents prior to being used in casework.

r) Rejecting any chemical, solution, supply, reagent, or material that fails to meet specifications.

s) Evaluating the need for and assessing the extent of retraining and approving a retraining plan.

3.1.5 Qualifications of the CODIS Administrator and back-up Administrator(s)

Minimum educational requirements: The CODIS administrator and back-up CODIS administrator(s) shall meet the education requirements for an analyst as defined in FBI QAS Standard 5.4.

Minimum experience requirements: The CODIS administrator and back-up CODIS administrator(s) shall be current or previously qualified analysts as defined in QAS Standard 5.4 with documented mixture interpretation training.

Minimum CODIS training requirements: The CODIS administrator and back-up CODIS administrator(s) shall successfully complete the current FBI-sponsored training in CODIS software within six months of assuming CODIS administrator or back-up CODIS administrator duties if the administrator had not previously completed such training. The CODIS administrator and back-up CODIS administrator(s) shall successfully complete the current FBI's DNA auditor training course within one year of assuming his/her administrator duties if the administrator had not previously completed such training.

If prior minimum educational, experience, or training requirements as a Casework CODIS Administrator were accepted by the Technical Leader, this shall be documented through prior external audit documentation and shall be retained by the laboratory.

3.1.6 Responsibilities of the CODIS Administrator and back-up Administrator(s)

The CODIS administrator and back-up CODIS administrator(s) are responsible for administration and security of the laboratory's CODIS at a laboratory performing DNA analysis on forensic and casework reference samples. A back-up casework CODIS administrator must be designated by the laboratory as required by the NDIS operational procedures. A laboratory shall not upload DNA profiles to NDIS in the event that the Casework CODIS Administrator position is unoccupied. The CODIS Administrator and back-up CODIS administrator(s) are responsible for the following:

a) Administering the laboratory's local CODIS network.

b) Scheduling and documenting the CODIS computer training of the analysts.

c) Ensuring the security and quality of the data stored in CODIS is in accordance with state and federal laws and NDIS operational procedures.

d) Terminating an analyst's or laboratory's, and, when applicable, a Rapid DNA partner agency's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified.

e) Responsible for assuring that matches are dispositioned in accordance with NDIS operational procedures.

3.1.7 Qualifications of Forensic Biologists (FBI QAS Technicians)

Minimum education and experience requirements: The Forensic Biologist shall have at least a bachelor's degree or an advanced degree from an accredited college or university in a natural science or closely related field with coursework that meets the requirements of the FBI QAS for DNA Analysts.

Minimum training requirements: The Forensic Biologist shall successfully complete the laboratory's documented training program.

The Forensic Biologist's training will cover the following:

- Evidence handling procedures
- Documentation and reporting procedures (as needed)
- Safe lab practices
- Ethical practices

- DNA QA and QC systems and methods
- Monitoring, calibration and maintenance of instruments
- Buffer and solution preparation
- Inventory and sampling of SAK
- Screening and serological testing
- Operation of instruments to generate DNA profiles

3.1.8 Responsibilities of Forensic Biologists (FBI QAS Technicians)

The Forensic Biologists (FBI QAS Technicians) are responsible for clerical, administrative, and technical tasks in the laboratory. This is a technical and advanced professional level laboratory position responsible for processing physical evidence. The Forensic Biologist is responsible for the following:

- Achieving and maintaining proficiency in advanced laboratory techniques, methods, materials, and analytical instrumentation used in the forensic DNA and serological testing of biological evidence.

- Examining evidence for the presence of body fluids and making critical decisions about sampling from (swabbing/cutting) evidence items for trace DNA.

- Performing complex laboratory tests on biological evidence using specialized DNA methods to include DNA purification, DNA Quantitation, PCR amplification, and Genetic Analyzer setup following standard operating protocols.

- Following quality control procedures and ensuring that all work is performed in accordance with laboratory procedures, state and federal regulations, ANSI National Accreditation Board (ANAB) accreditation standards and the FBI’s Quality Assurance Standards for Forensic DNA Testing Laboratories (QAS).

- Generating and maintaining detailed and complete documentation of examinations and tests conducted.

- Operating and performing quality assurance and quality control checks of laboratory instrumentation.

- Assisting with the maintenance and calibration of laboratory equipment.

- Maintaining the integrity of all evidence and the associated chain of custody.

3.1.9 Qualifications of Laboratory Support Personnel (Crime Laboratory Technicians)

Minimum educational and experience requirements: The Laboratory Support Personnel (Crime Laboratory Technicians) shall have at least a high school diploma with three years of related laboratory experience or an Associate Degree in Forensic Science, Biology, Chemistry or a related field with one year of related experience.

Minimum training requirements: The Crime Laboratory Technician shall successfully complete the laboratory's documented training program.

The Crime Laboratory Technician's training will cover the following:

- Evidence handling procedures
- Documentation and reporting procedures (as needed)
- Safe lab practices
- Ethical practices
- DNA QA and QC systems and methods
- Equipment operation, monitoring, calibration and maintenance
- Buffer and solution preparation

3.1.10 Responsibilities of Laboratory Support Personnel (Crime Laboratory Technicians)

The Laboratory Support Personnel (Crime Laboratory Technicians) are responsible for clerical, administrative, and technical tasks in the laboratory. The Crime Lab Technician generally will not conduct analyses that require subjective opinions and/or the use of complex instrumentation. Tasks are performed under the general direction of the Biology Section Supervisor or a DNA Team Leader. The Crime Laboratory Technician is responsible for the following:

a) Assisting in the preparation of case files.

b) Entering case assignments and technical service requests into the Property and Laboratory Information Management System (PLIMS).

c) Maintaining the evidence flow through the section to include the receiving, releasing, or transferring of the evidence as determined by the section supervisor.

d) Receiving, routing, and disseminating reports and other information to detectives, attorneys, or other departments.

e) Maintaining laboratory files, maintenance logbooks, training records and data bases.

f) Ordering and maintaining laboratory and office supplies.

g) Managing and prioritizing requests for service.

h) Performing routine maintenance of complex lab instrumentation.

i) Maintaining safe conditions in the laboratory and conducts laboratory procedures in accordance with ANAB policies.

j) Preparing reagents and keeping the laboratory cleaned and stocked with critical supplies.

3.1.11 Technical Reviewer

The technical reviewer shall be an employee or contract employee of the laboratory and meet the following qualifications:

a) A currently or previously qualified analyst.
b) Successful completion of documented training.

3.2 Professional Development

1. The DNA Technical Leader, CODIS administrator, analysts, and technical reviewers must stay abreast of developments within the field by reading current scientific literature and attending Continuing Education (CE) sessions.

2. The Biology Section personnel will stay current on developments in the literature by reading documents on the internet, journals, etc as part of the Biology section's program for annual review of scientific literature. Journals are made available on the R drive by the Laboratory Director. Journal articles specifically pertaining to the Biology section may periodically be distributed by the Biology Section Supervisor or DNA Team Leaders and are then saved on the R drive. As new journals or articles are made available, the laboratory personnel are informed through email notification. By opening the email, the analyst will be indicating that they are responsible for reading the relevant portion of the journal or the assigned article. A copy of the email with a read-receipt is retained. The literature distributed by the laboratory director, Biology Section Supervisor, or a DNA Team Leader is considered approved by the Technical Leader as part of the annual review of scientific literature.

3. Additionally, the DNA Technical Leader, CODIS administrator, analysts, and technical reviewers, must attend seminars, courses, professional meetings, or other documented lectures or classes in relevant subject areas directly related to the analysis of DNA evidence for a minimum of eight cumulative hours each calendar year. This would include conferences, seminars, workshops, or courses which impart in-depth technical knowledge on forensic DNA testing.

Continuing education based on multimedia or internet delivery shall be subject to the approval of the DNA Technical Leader.

- The laboratory shall maintain documentation of attendance through a mechanism such as certificates, attendance lists, or travel documentation.

- With the exception of a regional, national, or international conference, the laboratory shall maintain documentation of content through a mechanism such as agenda/syllabus, record of presentation content, or curriculum vitae of the presenter.

4. The FBI online audit training course covering the Quality Assurance Standards, taken through the Learning Management System on the CODIS website or on the FBI Academy website, is approved by the technical leader to count for a minimum of 16 hours toward continuing education.

5. All Biology technical personnel must fill out a Training Action Report at the completion of a continuing education activity for retention in the laboratory Staff Qualification records. If grades or a certificate are given, this should be supplied for the record as well.

6. Each analyst will have their testimony review performed annually in accordance with QM 5.9.6 Testimony Monitoring. Additionally, at least one analyst performing DNA analysis testimony will annually have their testimony reviewed in accordance with QM 5.9.4.2 Testimony Technical Reviews.

3.3 Training and Qualification Records

1. Records of the completed qualification, training, skill, and experience of all Biology personnel involved in either the technical review or recovery, evaluation, analysis, and interpretation of body fluid identification and/or DNA evidence shall be maintained in the Section and/or with the Laboratory QA Manager according to the Crime Laboratory QM.

2. The date of qualification as documented on the qualification review memo generated by the DNA technical leader will used to determine the applicable version of the standards for education, experience, and training requirements.

4. Facilities

The CMPD Biology Laboratory was built as a part of the 1996 construction of the headquarters building and designed for DNA analysis. The laboratory is located on the fourth floor of the CMPD headquarters building.

4.1 Access to the Biology Laboratory

General laboratory security is addressed in Laboratory QM 5.3.4. Anyone with access to the laboratory or wishing to tour the laboratory will be required to give a buccal swab for the local database. Any outside entity wishing to view an analyst work on cases for court purposes must be proficiency tested in the technologies used by the CMPD laboratory.

4.2 Laboratory Layout

1. Separate lab coats will be dedicated and used for 1) evidence screening, 2) DNA extraction through PCR set-up, and 3) post-amplification. Lab coats are distinguished by their overall color or by their name tag stitching.

2. Evidence examination, DNA extraction, DNA quantitation, and DNA amplification are conducted at separate times or separate spaces. Areas in the laboratory are designated for each process and each phase of testing must be performed in the specified area.

4.2.1 DNA Extraction

DNA extraction of standards and unknowns must be performed at separate times or spaces.

4.2.2 Amplified Product

The following requirements are provided to limit the likelihood of a transfer of amplified DNA into the pre-amplified areas. (See Biology QA Section 15 for more information)

- Amplified DNA is generated, processed and maintained in a room separate from the evidence examination, DNA extraction, and PCR setup areas.

4.2.3 Post-Amplification Room

a. In general, items needing to be removed from the post-amplification room will be completely decontaminated using 10% bleach or commercial cleaner. Some exceptions to this rule are small items, biohazard waste, lab coats, case files, and worksheets.

b. All items may be brought into the PCR room for a limited purpose and a brief period of time and removed immediately provided that the item does not touch any surface in the room.

c. Biohazard waste will be taken directly from the biohazard area to the disposal area on the loading dock without being transferred to the pre-amplified areas.

d. Lab coats used in the amplified area will be taken directly to the cleaning bin without being transferred to the pre-amplified areas.

e. Any case files brought into the post-amplification room will be restricted to the areas adjacent to the CODIS terminals.

f. Sample set-up worksheets and maintenance worksheets will not be placed in the hood.

5. Evidence

- Evidence is an item submitted for DNA testing and/or a derivative of an item that is subject to a chain of custody and if disposed must adhere to proper legal disposal requirements and documentation.

  Evidence includes the parent item and all collected or inventoried sub-items from that item. Evidence is also the remaining DNA extract in the original DNA extraction tube and any remaining extraction material maintained from consumed items. If the item or the entirety of a stain is consumed and there is no remaining portions of the swab(s) or stain to re-test, then the cutting(s) will be retained as DNA# –M. Microscopic slides made during differential extraction that are not examined and retained for possible future examination are considered evidence.

  A stain may be sampled from a larger evidence item either as a portion or in its entirety. All cuttings taken should have a separate PLIMS item number created for the cutting and the DNA extract. The creation of the PLIMS item number for the cutting is necessary for documentation and reporting. The consumption of the cutting for DNA testing will be added to the Item Description in PLIMS. The cutting material does not need to be retained as DNA# –M unless the entirety of the stain is sampled.

- Work product is the material that is generated as a function of analysis that is not subject to a chain of custody and may be disposed of once the analysis has been performed and recorded.

  Work product includes the portion of the DNA extract transferred to a 96-well plate for automated processing on the QIAgility. Unless consumed, the cuttings used in the extraction process are considered work product. Amplified DNA is considered work product and will be disposed of properly once all technical review of those samples is complete. Microscopic slides made during serology or differential extraction are considered work product if they have been examined and the results recorded.

- Evidence submitted to the Biology Section will be accepted and handled per Laboratory QM 5.8. A tape seal with the analyst's INITIALS/ CMPD CODE/DATE must be placed on all outer packaging tape seals and as needed/applicable to inner packaging.

- Evidence that is received into the Biology section of the laboratory and is rejected due to the condition of the packaging requires notes or photo(s) documenting the condition of the packaging and reason for rejection. The notes or photo(s) may be taken by the assigned analyst, Section Supervisor, or one of the DNA Team Leaders. The closing of the assignment, approval for rejection of the evidence, and communication to the investigating officer must

be performed by the Section Supervisor or one of the DNA Team Leaders. If that item is the only item requested for testing, no report is necessary since no testing was performed. Defects to the packaging should be repaired with a tape seal if possible (INITIALS/CMPD CODE/DATE) or repackaged if necessary. Repackaged items should have the original packaging retained. The new outer packaging should have a note present indicating the repackaging. “Evidence Repackaged by INITIALS – DATE – CMPD CODE”

- A note such as “Rejected for DNA testing INITIALS/CMPD CODE/DATE” or “Due to packaging, DNA testing on body fluids only INITIALS/CMPD CODE/DATE” will be added to the Item Description in PLIMS to document the rejection of the evidence.

- No notes or report are required for evidence brought to the laboratory by Property Control Evidence Technicians that was not taken into an analyst's custody. This evidence may be returned to Property Control.

- Evidence will not be accepted for trace DNA analysis if the evidence is open or if the evidence has already been processed in another section of the laboratory. An exception can be made by the Chief Criminalist or a DNA Team Leader if the scenario permits and the Item is being considered for direct comparison and not CODIS entry. This exception will be documented as a communication attached in PLIMS or as a note on the printed Service Request scanned in with the case file.

- Evidence Packaging received into an analyst’s custody will be initialed and dated per Laboratory QM 5.8.2. DNA extract containers, DNA extract tubes, DNA extract material tubes, and sample cuttings tubes do not need to be initialed when taken into an analyst’s custody for additional processing.

- Evidence (including DNA extracts) taken into an analyst’s custody for a case that they are assigned will have, at a minimum, notes documenting the outer packaging description including labels.

    - This requirement may be met for internal evidence (items collected by Biology personnel and transferred to a DNA analyst) through verification of the label description and contents of packaging using the Sampling Worksheet – Internal Evidence.

- Cuttings of evidence items prepared for Direct to DNA (both SAKs and Firearm by Felon cases) processing do not require notes by the DNA analyst taking possession. The notes taken by the individual preparing the cuttings are reviewed and verified by the DNA analyst taking possession.

- If testing is performed, the notes will include the required information listed in Biology QA Section 12.1 in accordance with Laboratory QM 4.13.2. If

evidence is taken into the custody of Biology personnel, and the entire request is closed prior to testing being initiated, no notes or report are required.

- Evidence that is inadvertently rendered unusable will be documented in the case file. If no result can be reported, the final lab report will indicate that the quality control measures for that evidence item were not achieved, and no reportable data was obtained.

5.1 Sample Identification

- Each sample will be labeled with a unique identifier according to CMPD evidence guidelines outlined in the Laboratory QM 5.8.2.1. DNA extracts must be numbered by the DNA Number obtained in PLIMS.

- In accordance with North Carolina General Statute 114-65 as of October 1, 2018, all sexual assault evidence collection kits distributed to the hospitals are required to be barcoded for use in the North Carolina Sexual Assault Evidence Collection Kit Tracking and Information Management System (STIMS). All kits will have a barcode sticker affixed to the side of the box and will convey a unique “Kit Number” with a specific prefix.

- The “Kit Number” will be a required attribute field for all evidence entered in PLIMS as item type “Sexual Assault Kit” and will be recorded in the case file notes by the individual opening and inventorying the sexual assault evidence collection kit. Additionally, as required, information and tracking status will be updated in STIMS (see SOP 1.4 C. for further instruction).

5.2 Maintaining Integrity of Evidence

Evidence will be handled in a manner to prevent loss, alteration, contamination or mixing.

- Analysts will wear a mask, lab coat and gloves while handling, examining, and sampling evidence, both to protect the samples from contamination and for personal protection. Gloves will be changed often to prevent cross contamination.

- A hair net may also be worn when examining hair or collecting trace.

- A mask will be worn by all observing or consulting authorized individuals while around open evidence.

- All evidence should be air dried thoroughly. Wet evidence should never be packaged in plastic bags.

- Evidence should be kept in a dry location prior to submission to the laboratory.

- Liquid known blood samples should be kept under refrigeration prior to submission to the laboratory. A liquid blood sample should never be frozen.

- Evidence collection for DNA testing is occasionally performed in a section of the laboratory other than the Biology Section due to procedural or safety reasons. Proper precautions must be taken to limit exposure to potentially harmful substances, and any article of evidence suspected of having a lethal controlled substance associated with it will be processed through a coordinated approach with the Chemistry Section of the laboratory.

- Consultations with other laboratory sections will be noted in the case notes and initialed and dated by the consulting analyst/examiner.

- Only one DNA extraction tube will be open at a time unless noted in the Standard Operating Procedure.

- All microcentrifuge tubes will be opened in a manner to prevent cross contamination (e.g. decappers, Kimwipes).

5.3 Chain of Custody

5.3.1 Receiving Evidence from Property Control

- Laboratory personnel do not have direct access to Property Control. Therefore, evidence will only be obtained by laboratory personnel once transferred by Property Control personnel. All transfers will be recorded in the electronic chain of custody in PLIMS.

- Any item of evidence from which a biological sample is collected in another Section of the Crime Laboratory should first be electronically taken into custody in PLIMS by the collecting analyst. The analyst's notes will include the section of the laboratory in which the collection took place, the name of the individual in that section that had original custody of the Item (along with that person's initials), and a description of the packaging as received by Biology personnel.

5.3.2 Securing Evidence in the Laboratory

- Secure locations within the laboratory include the General Biology Cage (GBC), evidence lockers, locked screening rooms, and General Biology Storage (GBS).

- GBC is the secure location accessible by Property Control for transfer of evidence into and out of the Biology Section. Evidence should be inspected by the requesting analyst and transferred from this location in a timely manner. This is a temporary storage location intended for Property Control transfers.

- GBS is a combination of secure locations in the laboratory for both temporary and long-term storage. GBS includes Biology freezers, locked evidence drawers, and shelves in the caged laboratory storage area.

- Evidence lockers, locked screening rooms, or GBS may be used by the analyst to securely maintain evidence while it is in the laboratory. Evidence placed in these locations should be transferred in PLIMS to these locations.

- Evidence should only be in the personal custody of the analyst when the examination is started and should be transferred to a secure location when the examination is complete.

  Swabs drying overnight, DNA extracts while in laboratory testing, and prepared differential microscope slides prior to being viewed (if applicable) are all considered extensions of examination. Once the tape seals are placed on the envelopes of the drying swabs, the examination is complete. Once the review of the STR data has been performed by the analyst to verify no additional laboratory work is required, the examination is complete. Once the analyst reads the required microscope slide, the examination is complete.

  Cuttings taken for extraction are also considered extensions of examination and may remain in the analyst's custody until DNA analysis is complete. By the end of each day the analyst will create the subitems of the cuttings/extracts in PLIMS so the chain of custody is started and consistent with the analyst's laboratory notes.

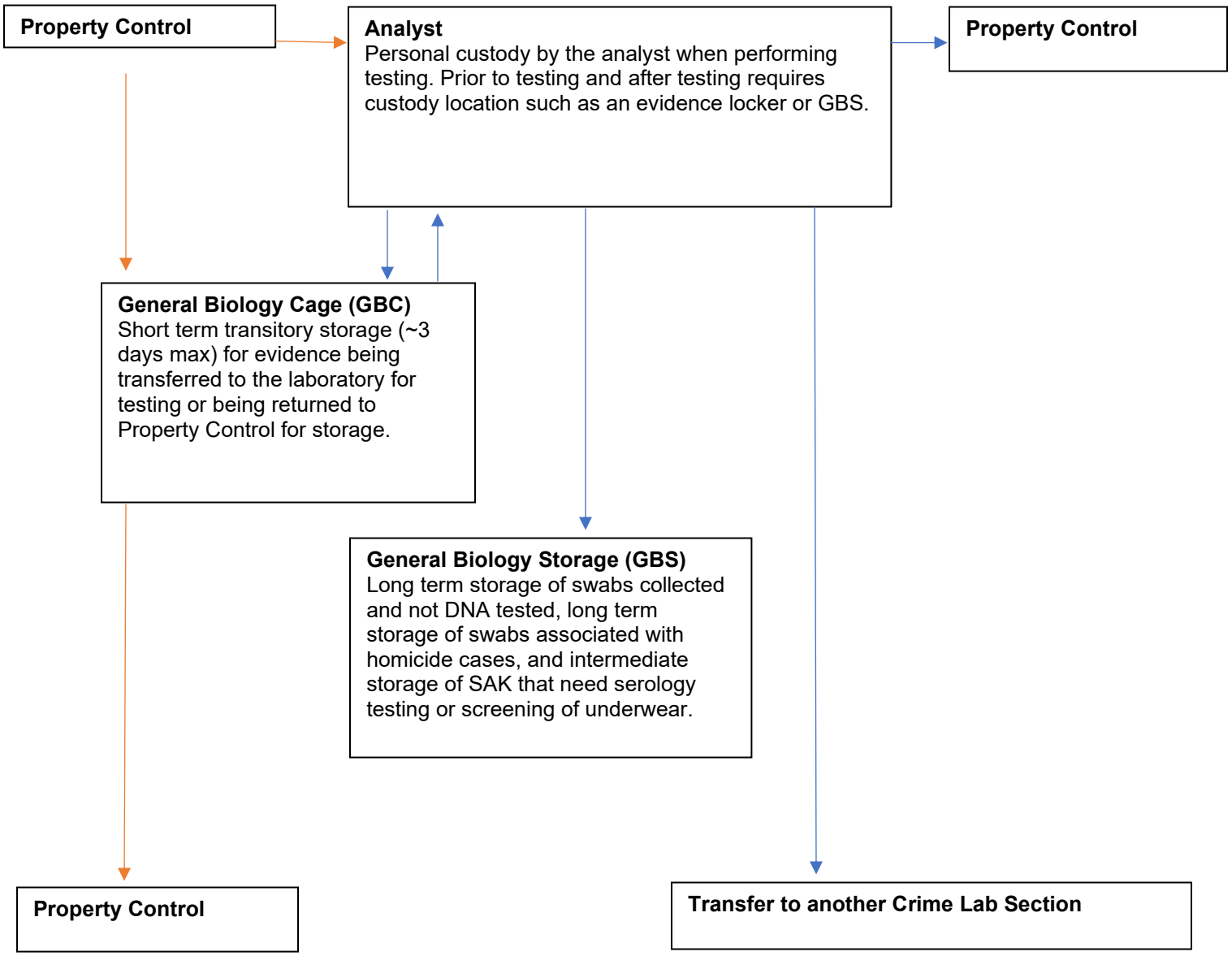
5.3.3 Retaining Evidence in the Laboratory

- Evidence to be retained in the laboratory, such as cuttings, swabs, DNA extracts, and remaining material will be created as sub-items in PLIMS and will be maintained in GBS.

5.3.4 Returning Evidence to Property Control

- Evidence to be returned to Property Control will be transferred to the GBC by Biology personnel once testing is completed.

General Evidence Workflow – Each Transfer is Reflected in PLIMS chain of custody



5.3.5 PLIMS

5.3.5.1 Biology Chain of Custody

- Chain of custody will be tracked electronically through the PLIMS system.

5.3.5.2 Sub-items

- Sub-items are made in PLIMS to either inventory contents of a parent item (e.g. sexual assault evidence collection kit) or to record a sampling collected from the parent item (e.g. swabs or cutting from clothing article).

- If the sub-item was created to record an inventory, then in PLIMS the "collected by", "date", "time", and "location" fields will all remain the same as the parent item.

- If the sub-item was created to record a sampling, then in PLIMS the "collected by" field will be changed to the name of the sampling analyst, the "date" and "time" it was sampled, and the "location" to 601 E. Trade St.

- DNA extracts will be created as sub-items in PLIMS from the swab or cutting.

- DNA extracts that are combined during DNA testing (typically in conjunction with the processing of discharged cartridge cases) will have a new PLIMS item number created.

- The analyst who creates sub-items in PLIMS is ultimately responsible for the accuracy of the information documented on both the evidence itself and the appropriate fields in PLIMS.

5.3.5.3 DNA Numbers

- A sequential numbering system will be employed for the analysis of DNA samples. Each DNA extract including reagent blanks will be assigned a unique number in PLIMS and will be maintained throughout the analysis and storage.

- Combined DNA extracts will be assigned a separate unique DNA number that is associated with the newly created corresponding PLIMS item.

5.4 Evidence Sampling

- For questioned samples, if there is more than one swab, (up to four swabs) a portion of each stained swab will be used for analysis. If more than four swabs, the swab selection will be at the analyst’s discretion and documented in the case file.

5.5 Evidence Preservation, Storage, and Final Disposition

Evidence will be stored in a manner to prevent loss, alteration, contamination or mixing.

5.5.1 Sample Storage

- All evidence (including samples derived from an evidence item) will be stored under the appropriate conditions to minimize degradation.

- Evidence items that are stored long-term in the Biology section will be stored frozen.

- All DNA extracts and any remaining material will be maintained frozen in General Biology Storage. After the review of the electronic data in GMID-X by the casework analyst, the DNA extract tubes, and DNA extract material tubes will be placed in the analyst's individual DNA extract box. The box will be labeled with a unique Bulk Container barcode and stored in the freezer.

To create a Bulk Container in PLIMS:

- Click Bulk Container from PLIMS Home Page
- Select New Bulk Container tab
- Fill in:
  Type = Box
  Custody Of = Biology
  Location = Freezer #
  Describe: “INITIALS DNA Extracts YEAR – Box #”

- Once full, the box will be sealed with evidence tape, and transferred to a long-term storage freezer. This will be documented by each analyst and reviewed by the Chief Criminalist or designee as part of the monthly cleaning. The documentation will be scanned to the R Drive.

- Amplified DNA from STR typing case samples will be stored refrigerated for up to two weeks, until the analysis has been completed, and/or the case file has been reviewed.

5.5.2 Final Disposition

- Evidence not stored long-term in the Biology section shall be returned to GBC to be returned to Property Control. Transfer of the evidence shall be documented electronically in PLIMS.

- Samples, DNA extracts, and extraction material retained and stored long-term by the Biology section are typically stored frozen. The storage location shall be documented electronically in the PLIMS chain of custody and documented in the report.

- The complete consumption of samples and/or DNA extracts shall be documented in the report.

- The complete consumption of any item created without any intermediary packaging and immediately consumed for testing will be transferred in PLIMS to Custody: “Biology” and Location “Sample Consumed” and dispositioned as consumed in the report. This applies to cuttings from a larger stain taken directly to DNA testing without the larger stain being collected or retained.

- DNA extracts and any remaining extraction material processed by an Outside Agency or Vendor Laboratory shall be maintained in appropriate storage conditions either in the Biology section or in Property Control. The storage location shall be documented electronically in the PLIMS chain of custody.

- The disposition of the evidence at the conclusion of testing shall be documented in the report. The disposition may be a general statement for all items with the same disposition but must convey the status of each of the items of evidence.

- Evidence transferred to another section of the laboratory for testing will be documented electronically in the PLIMS chain of custody and will be reflected in the final disposition in the Biology report. At times, evidence may be transferred to an alternate secure location for retrieval by another member of the crime lab. Transfers to designated secure evidence lockers and secure evidence storage locations are documented electronically in the PLIMS chain of custody and will be reflected in the final disposition in the Biology report. Required documentation will be included in the case file.

5.6 Data Handling and Storage

5.6.1 Photographs

Photographs may be taken and included in the case file to further document and describe the testing performed on an item of evidence. All photographs that are in the case file will be retained and uploaded to Evidence.com. Additional photographs taken, deemed to be of insufficient quality (e.g. blurry, dark, bright, etc.), and not used by the analyst, are not required to be retained. Photographs taken are not evidence and do not have an associated chain of custody requirement. Per QM 5.10.3.2 photographs are considered part of the analytical

case file and are generated to support the examination process similar to notes/drawings.

5.6.2 STR Data

After the run is complete all raw data files must be transferred from the 3500 instrument computer to the R drive following instructions found in the Biology SOP 6.8.

5.7 Evidence Sent to Outside Agency or Vendor Laboratory

Evidence workflow for shipping to an outside agency or vendor laboratory generally follows the process of 1) Receiving a request from Investigations, 2) Confirming and requesting the evidence in PLIMS, 3) Receiving and inspecting the evidence in the laboratory (rejecting the evidence if applicable), 4) Documenting the contents and repackaging the evidence, and 5) Shipping.

Records of communication, requests, and shipping are retained.

6. Validation

Validation of new methods must be performed before casework analysis. CMPD internal validation studies must be performed to ensure that the results are reliable and reproducible for casework. Developmental validation studies performed by the manufacturer are supplemental to the CMPD internal validation studies. Internal validation studies performed by other agencies may be used to aid in the design of CMPD validation studies. Internal validation studies may be performed onsite by an outside vendor. All validation studies must be reviewed and approved by the Technical Leader and the Biology Section Supervisor prior to use on casework. Prior to implementation of a procedure into forensic casework, the analyst shall successfully complete a qualifying test.

6.1 Documentation

Developmental validation studies, internal validation studies, modified method evaluations, and software testing, including the review and approval of the Technical Leader, shall be retained and available for review for as long as the methodology is being employed or may be testified to in court. Validation shall precede the implementation of any method used for forensic DNA analysis.

6.1.1 Developmental Validation

a) Developmental validation studies typically performed by the manufacturer prior to the internal validation shall be conducted for a new technology, typing test kit, or platform and shall include, where applicable, characterization of the genetic marker, species specificity, sensitivity studies, stability studies, case-type samples, population studies, mixture studies, precision and accuracy studies, and PCR based studies. PCR-based studies include reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and product detection studies. These studies shall be documented.

6.1.2 Internal Validation

a) Internal validation studies shall include as applicable: known and non-probative evidence samples or mock evidence samples, precision and accuracy studies, sensitivity and stochastic studies, mixture studies, and contamination assessment studies.

b) Internal validation studies shall be conducted by the laboratory with the appropriate sample number and type to demonstrate the reliability and potential limitations of the method.

c) Validation data shall define quality assurance parameters and interpretation guidelines, including, as applicable, guidelines for mixture interpretation and the application of appropriate statistical calculations.

d) Mixture interpretation validation studies shall include samples with a range of the number of contributors, template amounts, and mixture ratios expected to be interpreted in casework.

e) With the exception of a NDIS-approved Rapid DNA instrument/System, a new technology, typing test kit, or platform instrument model used to generate a DNA type shall be checked against an appropriate and available certified reference material (or sample made traceable to the certified reference material) prior to the implementation of the method for forensic analysis.

f) Each internal validation study will contain a summary of the interpretation of the results.

6.1.2.1 Material Modification of Methods

Material modifications to existing methods shall be evaluated by comparison to the original procedure using similar DNA samples and the evaluation documented. The evaluation shall be reviewed and approved by the DNA Technical Leader prior to the implementation of the modified method in casework.

6.1.2.2 Performance Checks

Performance checks of newly installed instruments to already validated procedures shall be checked by comparing the sensitivity, reproducibility and overall performance and comparison to already established data thresholds. The evaluation shall be reviewed and approved by the DNA Technical Leader prior to the use of the instrument in casework.

6.2 Software

Software used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations, shall be subject to validation prior to implementation in forensic DNA analysis. Software validation and testing shall be documented, reviewed, and approved by the DNA Technical Leader prior to implementation. The laboratory shall use software suitable for the intended use in the laboratory and within the limitations established during the internal validation. New software, new modules of existing software, or a major revision to software that is used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations shall be subject to internal validation specific to the laboratory's intended use prior to implementation in forensic DNA analysis.

6.2.1 Internal Validation/Testing

a) Internal software validation studies for new software or new modules of existing software used as a component of instrumentation shall

include functional testing and reliability testing. A major revision shall also require regression testing.

b) Internal software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data shall include functional testing, reliability testing, and, as applicable, precision and accuracy studies, sensitivity, and specificity studies. A major revision shall also require regression testing.

c) Internal software validation studies for new software or new modules of existing software for statistical calculations shall include functional testing, reliability testing, and, as applicable, precision and accuracy studies. A major revision shall also require regression testing.

d) A minor revision to software used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or statistical calculations shall require at a minimum, a functional test.

7. Analytical Procedures

7.1 Standard Operating Procedures

The Biology Standard Operating Procedures (SOPs) contain procedures for each analytical method used which are supported by internal validations and approved by the Technical Leader. These procedures include the use of appropriate controls and standards. All SOPs are accessible to Biology personnel electronically. All Biology SOPs will be retained by the Quality Assurance Manager according to the QM 4.13.1.2.3 Record Retention. Procedures are updated in accordance with QM 5.4.

7.2 Quality Control Measures for Consumables and Reagents

1. The laboratory will follow quality control measures for the use of consumables and reagents that are suitable for the methods employed. These measures ensure the quality of the data and reliability of the reagents used in casework.

2. The laboratory will maintain records of consumables, commercial reagents, in-house prepared reagents and critical reagents. An inventory of all laboratory supplies will be conducted monthly. All available purchasing and receiving documentation will be electronically stored.

3. Labeling of commercial reagents and in-house prepared reagents is specified in Laboratory QM 4.6.2.

4. Expiration dates represent the maximum date applied to an item and will not exceed the expiration date of any individual components. Unless otherwise stated by the manufacturer or in the SOP, expiration dates will be as follows: 1 year for DNA reagents, 2 years for liquids (nuclease-free water exempted), 5 years for solids, and 10 years for lyophilized substances.

5. Expired consumables, commercial reagents, in-house prepared reagents, and critical reagents are not used in evidence analyses; however, they can be used for research or training purposes. These must be clearly marked “Expired Do Not Use for Casework”. Exceptions may be made but must be documented and approved by either the Technical Leader or Biology Section Supervisor.

7.2.1 Consumables

The laboratory will use consumables appropriate for each analytical procedure. Records for consumables will include date received, receiver, and quantity. As applicable, manufacturer inserts and certificates of analysis will be attached.

7.2.2 Commercial Reagents

The laboratory will use commercial reagents appropriate for each analytical procedure. Records for these will include date received, receiver, lot number, expiration date, and quantity. As applicable, manufacturer's inserts and certificates of analysis will be attached.

7.2.3 Reagents prepared in-house

a) Reagent preparation instructions are found in the reagent logbook maintained in the laboratory. Adjustments to volume prepared may be made if the ratio of the components remains the same. Purified water will be used for reagent preparation when water is required. Only cleaned and sterilized (if applicable) lab-ware will be used for preparation and storage of reagents. Lot numbers for prepared reagents will be in the format “MMDDYY**” where MM is the two-digit month, DD is the two-digit day, YY is the two-digit year, and ** is initials of the person making the reagent (2-3 letters), and a letter designation for the reagent as outlined in the reagent logbook.

b) Records are not typically made for individual aliquots of reagents (such as formamide, cRNA, and DTT). Lot number, expiration date, and date passing QC are not found on individual aliquots but are instead noted on the storage box or rack.

7.2.4 Critical Reagents

The following are considered critical reagents:

- PHT stock solution, PHT working solution, LMG, AP Spot Test
- ABA card p30 and Hematrace
- Phadebas
- PrepFiler Express Kit, PrepFiler Express BTA Kit, QIAgen EZ1/EZ2 kit, ProK, DTT, Buffer MTL, and Buffer G2
- Quantifiler Trio kit
- GlobalFiler Kit, YFiler Plus Kit and Allelic Ladders
- Formamide, LIZ, and POP-4

Critical reagents will be quality control checked (QC’d) prior to use in casework. Upon receipt, critical reagents are stored in a designated area for non-QC'd reagents or are clearly labeled to indicate that QC has not been performed. Instructions for performing the QC, required paperwork, and passing criteria for each critical reagent are documented on the COQC (Certificate of Quality Control). The QC of multiple critical reagents may be performed together (e.g., extraction kit, amplification kit, and LIZ). All tested reagents will pass QC and may be used in casework if all the passing requirements are met for each reagent tested.

QC checks of a new lot of a critical reagent may be completed concurrently with casework providing the casework samples/batch were analyzed with a previously QC'd lot of the critical reagent.

QC checks may be performed by any trained and competency tested individual that is signed off to perform that test (qualified individuals may include technicians, serologists, or DNA analysts). Trainees may perform the QC tests under the supervision of a qualified individual; however, both the trainee and the qualified individual will initial the COQC field for analyst performing the QC.

If any component of a critical reagent changes, then the new reagent must be separately tested.

The extraction kits PrepFiler Express Kit and QIAgen EZ-1 kit are separated into their component parts after passing QC. Once separated, lot numbers from any kit may be used in the performance of the extraction. Each of these separated component lot numbers must be recorded on the extraction worksheet. At times, multiple kit lot numbers with different expiration dates will have the same lot numbers of component parts. Since the kit expiration date is applied to each of the components, duplicated component lot numbers will have a sequential letter designation to differentiate (e.g., A, B, C etc.) the component from the previous kit.

The PrepFiler BTA Kit and its associated lot #s should be used together as a discrete entity and recorded on the extraction worksheet.

Daily control checks of PHT working solution, LMG, Phadebas tests, ABAcards for p30 and Hematrace are only recorded in the applicable case record. Because AP Spot Test is prepared on the day of use, the manufacturer's lot requires initial QC before use in casework and a COQC. However, all subsequent daily preparations will only require entry in the preparation log and in the case record with no COQC.

Working solutions of PHT are recorded on the COQC, on the preparation log and in the case record. The working solution lot number is the Stock Lot Number followed by the next number in sequence (e.g. 092320KVHM1).

Failed QC checks may be retested to confirm that the first test was performed properly. If multiple critical reagents were tested together during the initial QC, the failing reagent will be retested. If it cannot be determined which reagent failed, then each critical reagent must be tested separately in the retest. The critical reagent may be accepted for use if it passes the retest. If the critical reagent fails the retest, the Technical Leader or the Biology Section Supervisor will be notified immediately. The second retest will be performed by the DNA Technical Leader or designee. Upon failure of the second retest, the reagent will not be accepted for use. Critical reagents will be discarded or returned to the manufacturer (if applicable).
The COQC must be approved prior to the critical reagent being used in casework. The approval is documented by signing and dating the COQC. Any trained and

competency tested individual that is signed off to use the method and evaluate the results in casework may be the person that approves the COQC prior to the critical reagent being used in casework. The approver may be the same individual as the performer of the QC if the passing criteria is verified by another qualified individual. The verification step is only a check of the lot numbers and the pass/fail criteria of the test and is required if the performer and approver are the same individual. Documentation of the verification (if applicable) will be recorded on the COQC. Prior to signing the COQC and finalizing the reagent to be used in casework, the approver will confirm the pass/fail requirements, lot #s, and expiration dates.

Once the reagent has passed QC, the approver is responsible for ensuring that:
1) the COQC paperwork is completed, signed, scanned, and filed,
2) there is an email notification of the passing QC sent to the applicable Biology personnel,
3) the reagent and necessary packaging are marked as passing QC with the date of passing or if the reagent is being unpacked that the laboratory QC logs of the component part lot numbers, expiration dates, and QC date are updated, and
4) the reagent record spreadsheet is accurately updated with the required information from the COQC.

The approver does not need to perform these tasks personally; however, will be responsible for their completion.

7.2.4.1 Modified Large Volume Extraction Procedure for EZ1/EZ2 Reagents QC

Sample preparation

1. Place cutting(s) of a NIST or NIST-traceable sample in a Lyse&Spin basket-tube assembly.

2. Add 600ul Qiagen buffer G2 to tube.

3. Proceed to pre-treatment prior to purification on the EZ1® Advanced XL instrument using the Large-Volume protocol.

Pre-treatment lysis procedure:

1. Create two reagent blanks (designated DNA#-A or B) by obtaining two Lyse&Spin basket-tube assemblies and add 600ul Qiagen buffer G2 to each tube.
2. For all samples and reagent blanks, add 20µl Qiagen Proteinase K (20mg/ml) to each basket-tube assembly.

3. Using the thermal mixer, incubate 1 hour at 56℃ at 750 rpm.

4. Centrifuge for 1.5 minutes at max speed to transfer liquid from basket to tube.
    a. Ensure no liquid remains in the basket. If liquid remains, repeat the centrifugation step until all liquid has passed through the membrane of the basket.
    b. Retain material and place in new microcentrifuge tube (or store basket in 2nd 2ml tube from Lyse&Spin package).

5. Add 300µl Buffer MTL and 1.0µl (1.0 µg/µl) carrier RNA to each tube.
    a. The carrier RNA will be reconstituted, aliquoted, and stored frozen. (Refer to the COQC for instructions).

6. Vortex and centrifuge briefly.

7. Cut the hinge of each Lyse&Spin tube prior to loading onto the instrument. Remove each cap as each sample is loaded into the rack.

8. Proceed to Large-Volume protocol.

Large Volume Protocol

Instrument Set-up for Purification

1. Switch on the EZ1 instrument (ensure that correct low elution card is inserted)

2. From the Main Menu, press 2 to display the “Manual” menu. Press 3 for Clean, and then press Start to lower the piercing unit. Open the instrument door. Wipe all prongs with a Kimwipe moistened with ethanol. Press ENT, then ESC to return to Main Menu.

3. Press Start, select “No” for “Create a Report File”, then select 3 for Large Volume protocol.

4. Choose the elution buffer and volume. Select 2 to elute in TE buffer. Select 1 to elute in 20µl.

5. Press any key to continue through the text on the display to begin worktable setup

6. Open the instrument door by pushing up, then remove the cartridge rack and tip and tube rack from the instrument.

7. Invert the reagent cartridges twice to resuspend the magnetic particles and then tap to deposit any particles or liquid from the foil to the bottom of the wells.

8. Load the cartridges into the rack by sliding each reagent cartridge along the groove towards the back of the rack until it clicks into place. Make sure that the notches in the cartridges align with those in the rack. You may have to put slight

pressure on the front tab of the cartridge once completely loaded to secure into rack.

9. Insert the loaded cartridge rack into the instrument.

10. Load the tip & tube rack:
    a. Fourth row: Load with sample tubes containing the lysate. These tubes must be placed in the rack gently. Avoid splashing of the contents.

    b. Third row: Leave empty.

    c. Second row: Load with tips inserted into tip holders.

    d. First row: Load with 1.5ml screw cap elution tubes. Remove caps prior to run start.

11. Insert the loaded tip & tube rack into the front of the instrument and close the door. (Do NOT slam the door—this may harm the UV lamp filament.)

12. Press Start to begin purification.

DO NOT OPEN THE DOORS ONCE THE RUN HAS STARTED.

13. Once run is completed, press ENT to unlock door. Open the instrument door.

14. Remove and cap the elution tubes containing your purified DNA.

15. Remove the cartridge rack and the tip & tube rack and discard sample preparation waste.

16. After each run clean the tip and tube rack and cartridge rack with di water followed by ethanol on a Kimwipe.

17. Close the instrument door.

18. Follow onscreen instructions to perform UV decontamination of worktable surfaces for 20 minutes (Selecting less than 20 minute lamp cycle may lead to reduction in lamp's lifetime).

7.2.4.2 Manual Standard Curve Procedure for Trio Reagents QC

1. Prepare the human DNA standards by labeling 5 tubes (1-5). Add 45 µl Dilution Buffer to tubes 2-5 and 12 µl Dilution Buffer to tube 1.

    a. Add 12 µl of Quantifiler Trio Standard to tube 1 and mix thoroughly.

b. Add 5 µl from the tube containing standard that was just prepared to the next tube in the series and mix thoroughly.

c. Repeat step “b” for tubes 3-5.

2. In triplicate pipette three sets of standard curves.

3. Create 1/10 and 1/50 calibrators.
   a. Add 45µl of dilution buffer to a 1.5ml tube followed by 5µl of Trio standard to make the 1/10 calibrator.

   b. In another 1.5ml tube, add 20ul of dilution buffer followed by 5µl of the 1/10 calibrator to make the 1/50 calibrator.

4. Load the plate according to the 7500 Quantifiler Trio VSC QC Worksheet including a negative control (diluent supplied in the kit).

5. Run the plate.

6. The calibrators should be analyzed three times by applying each manual standard curve separately. If the calibrator values fall in range, then that manual curve is used to calculate the average slope and y-intercept values. One replicate on up to two standard curves may be omitted. Additional omissions may be indicative of an issue with the run and should be re-setup. Be sure to press the green Analyze button with each curve being applied.

7. For each target (Small autosomal, Large autosomal, and Y), the slope and y-intercept values from the passing manual standard curves are averaged. The average target values from the manual curves will be used as the Virtual Standard Curve for that Trio lot number. Calculate the average Slope and Y-intercept for both Human and Male.

The Standard Curve for the small autosomal total human target typically falls in the range below.

Slope, Quantifiler	Y-intercept, Quantifiler	R^2 value
-3.1 to -3.5	26.5 to 27.5	>0.98

- Slope – Indicates the PCR amplification efficiency for the assay. A slope of -3.3 indicates 100% amplification efficiency.

- Y-intercept – Indicates the expected Ct value for a sample with Qty = 1 (for example, 1 ng/µl).
- R^2 value – Measure of the closeness of fit between the standard curve regression line and individual Ct data points of quantitation standard reactions.

A value of 1.00 indicates a perfect fit between the regression line and the data points.

The 1/10 and 1/50 calibrator should fall in the range below.

1/10 human range	1/50 human range	1/10 Y range	1/50 Y range
7.7--13.7	1.7 -- 2.5	8.4 -- 13.3	1.7 -- 2.3

8. Select the *Analysis tab* in the Experiment menu, then select the Virtual standard curve.

9. Select the *Add Virtual Standard Curve to Experiment* and input the averaged values, the applicable lot number of the Trio kit and the expiration date.

10. Then reanalyze the calibrators with the new VSC and ensure the quantitation results are consistent with the previous quantitation results of the calibrators from the manual standard curves. If all data passes according to the requirements specified on the COQC form, the Reagent Record will be updated with the QC date and the VSC slope and y-intercept values.

7.3 Reference Materials

7.3.1 Serological Controls

Preparation of stock positive controls for serological testing will be prepared in the laboratory and handled in a manner to prevent loss, alteration, contamination or mixing. Serological controls will be stored at -20ºC +/-5°C to minimize degradation. Storage will be separate from casework samples in a container labeled with the contents, lot number (date of preparation, followed by the initials of the preparer and the appropriate suffix - BL-blood, AA-amylase/saliva, and SE-semen). The expiration date will be 5 years from date of preparation.

- Blood controls: Submerge swabs in blood or spot blood on filter paper and allow to dry.
- Semen controls: Submerge swabs in semen or spot semen on filter paper and allow to dry.
- Amylase/saliva controls: Pipette alpha-amylase/saliva on filter paper and allow to dry.

Preparation and QC of serological controls may be performed by any trained and competency tested individual that is signed off to perform that test (qualified individuals may include technicians, serologists, or DNA analysts). Trainees may perform the preparation and QC tests under the supervision of a qualified individual; however, both the trainee and the qualified individual will initial the COQC field for analyst performing the QC.

Following preparation and prior to use in casework, the newly prepared stock positive control will be tested with the appropriate presumptive test and/or confirmatory test to verify the sample performs as expected. A negative control will also be run. Quality control checks will be completed with a previously QC'd reagent. Once approved, the serological control will be marked as passing QC with the date of the QC approval. A COQC recording the testing of the prepared control will be completed.

The COQC must be reviewed and approved prior to the critical reagent being used in casework. Any trained and competency tested individual that is signed off to use the method and evaluate the results in casework may be the person that approves the COQC prior to the prepared control being used in casework. The approver may be the same individual as the performer of the QC if the passing criteria is verified by another qualified individual. Verification requires either review of photographs of the test results or observation when the test is conducted. The QC analyst cannot be the verifier. Documentation of the verification will be recorded on the COQC.

7.3.2 Standard Reference Materials (SRMs)

Standard Reference Materials will be handled in a manner to prevent loss, alteration, contamination or mixing. Standard Reference Materials will be stored under the appropriate conditions to minimize degradation separate from casework samples. NIST Standards will be stored refrigerated in a container labeled with contents, date received, date opened, lot number and expiration date. The NIST Traceable Standard prepared in-house is assigned a unique lot number (MMDDYY**N) and stored frozen in a container labeled with at least the lot number, preparation date, expiration date and contents. The expiration date of the NIST-traceable will be the expiration date of the NIST SRM to which it was certified. Expiration dates may be updated by NIST or may be extended if the prepared NIST-traceable is retested to an unexpired NIST SRM. Documentation of the updated expiration date and any applicable retesting should be retained.

7.4 Data Not Meeting Quality Control Measures

If the final results from an evidence item are determined to be unusable, the reason will be documented in the case file by the Technical Leader or Biology Section Supervisor. The final lab report will indicate that the quality control measures for that sample were not achieved, and no reportable data was obtained.

7.5 Legacy Data

The laboratory will not reinterpret data generated from legacy technology, typing test kit, and/or platform. Reevaluating allele calls, genotype calls (to include potential allelic drop-out), a change in the assumptions used, or removing alleles (or entire loci) from statistical estimates from legacy amplification test kit data, are all considered reinterpretation.

Comparisons to legacy data may be performed if the interpretation of the DNA profile from a forensic sample has previously been documented regarding the genotypes that would be allowed for possible contributors. A comparison is not considered reinterpretation. The statistics, either already in the case file or newly calculated, will be based on the original interpretation and reported as an RMP statistic. During review of the legacy data, the analyst may recognize other case samples that may benefit from interpretation utilizing STRmix and a recommendation for re-testing can be made in the comparison case report.

The generation of a report for the comparison of two samples as a result of a CODIS high stringency match is not considered reinterpretation of legacy data.

Previously interpreted and reported GlobalFiler autosomal STR data generated on the 3500 is not considered legacy data; however, will require laboratory approval and a service request prior to reinterpretation with STRmix.

7.5.1 Known Standards

DNA profiles for questioned items generated under prior technology (e.g., Identifiler, Quantifiler, etc.) may be compared to standards generated using new technology. The analysts will follow guidance provided in the procedure and in the Legacy guidance document. If questions arise, consultation with the DNA Technical Leader will be documented.

For comparison to a forensic profile generated with the GlobalFiler amplification kit, the known reference should also be amplified in GlobalFiler.

If the known reference was previously amplified in a legacy amplification kit:

- The original analyst may re-quantitate and re-amplify from the DNA extract and associated reagent blank.
- A newly assigned analyst may re-quantitate and re-amplify from the DNA extract and associated reagent blank with approval from the DNA Technical Leader or designee.
- When possible, a newly assigned analyst should attempt to re-extract the known standard.
- If the re-extraction yields an incomplete profile, the previously generated DNA extract and associated reagent blank may be re-quantitated and re-amplified.
- If the original item has been destroyed, then the previously generated DNA extract may be re-quantitated and re-amplified.

- If the newly assigned analyst is reporting results for a previously generated DNA extract, a new buccal standard will be requested in the report.
- Exceptions may be made with approval from the DNA Technical Leader or designee.

8. Equipment

Monitoring of equipment is a quality assurance measure to assess the equipment functionality. A qualified individual will perform a scheduled procedure or observation and record the results.

Analysts are expected to verify that all required monitoring has been completed prior to using the equipment. When equipment is out of service, monitoring is not required. Any equipment that is beyond its service due date will be removed from service until the service is performed.

Operating manuals and documents provided by the manufacturer will be maintained in a file, near the equipment, or accessed online via a laboratory computer.

8.1 Critical Equipment

1. Critical equipment or instruments are those equipment/instruments whose accurate functionality directly affects the results of the analysis and requires calibration, certification, or performance check prior to use and periodically thereafter.

2. Critical monitoring is monitoring that, if not monitored as scheduled, could negatively affect the quality of casework. Any time service or maintenance is performed on an instrument, it will be recorded.

3. If applicable, a performance check will be performed on an instrument after preventative maintenance or repair work and prior to its use in casework. Any trained and competency tested individual that is signed off to use the equipment and evaluate the results in casework may be the person that approves the performance check paperwork.

4. Each instrument which needs to be monitored will be checked on an appropriate schedule. The performance checks of pipettes, the NIST-traceable thermometers, and the temperature verification system (Driftcon) are accomplished by certification by an outside vendor. The performance check records supplied by the vendor are reviewed by the DNA Technical Leader, Biology Section Supervisor, or designee.

5. NIST-traceable thermometers are not required to be checked annually but must have a valid certification before being used for annual performance check monitoring of the test thermometers associated with annual performance check of freezers, refrigerators, incubator/heat-block, and thermal mixers.

6. The Driftcon is not required to be checked annually but must have a valid certification before being used for annual performance check monitoring of the thermal cyclers or heat-block.

a) Per the Driftcon manual (Driftcon-DOC-001, 7.1) a probe requires calibration every 24 months or every 500 measurements.
b) The Driftcon result report indicates the expiration date of the probe used for the temperature verification.

7. Any instrument or equipment that is not monitored by its due date will be removed from service until the appropriate monitoring is performed.

8. The following equipment is designated as critical:
   - Automate
   - EZ-1 Advanced XL
   - QIAcube
   - QIAgility
   - 7500
   - Veriti
   - Driftcon as a Temperature Verification System
   - Genetic Analyzer (3500)
   - Thermometers (NIST Traceable and Driftcon)
   - Thermal Mixers/Heat-block/Incubator (Temperature Monitoring by Test Thermometers)
   - Refrigerators and Freezers (Temperature Monitoring by Test Thermometers)
   - Pipettes

8.2 Other Monitored Equipment

Non-critical monitoring (e.g., to extend the service life of an instrument) is expressly allowed to be non-compliant with the monitoring program. The following equipment is not designated as critical but will continue to be routinely monitored:

- DI Water Purification System
- Balances
- Hoods
- M-Vac
- Test thermometers
- Alternate light sources
- UV Crosslinkers

All equipment in the laboratory is also continually monitored through use by the analyst. Equipment such as centrifuges, vortexes, UV lights, drying cabinets, microscopes and other support equipment not listed above that are not performing as expected will be brought to the attention of the Technical Leader or Section Supervisor. The equipment will be evaluated and taken out of service if necessary. All equipment that has been

taken out of service is marked as such and a record of the equipment out of service is maintained. Once operating correctly, the equipment may be put back in service.

8.3 Maintenance Records

The following are included in the maintenance records through a combination of electronic logs, paper maintenance logs posted on the instrument, and monthly, biannual, calibration, and performance check paperwork maintained in the relevant log book.

1. The common name of the item, information, or event being monitored
2. Related information as applicable (e.g., manufacturer, model/catalog number, serial number, etc.)
3. The location of the monitoring or equipment, or storage location
4. Specifications to be met (e.g., test results, cleaning procedure, storage conditions)
5. The identity of the operator(s) responsible for the record & date(s)
6. The data required to demonstrate the specifications were either met or not met, or a note stating that the item is out of service
7. Expiration date of the item or monitoring interval

8.4 Maintenance Instructions for Critical Equipment

8.4.1 Automate DNA Extraction robots:

a) Maintenance: The O-Rings will be greased and the instrument cleaned once every month.

b) Diagnostic Testing: ***Note**: *It is recommended that this procedure be performed after allowing the instrument to return to room temperature.*

c) Once every 6 months, the axis, temperature, version and error tests will be performed. Any changes in the error test will be noted and the DNA Technical Leader or their designee will be notified. If the other tests are not passed, the instrument will be serviced by a qualified technician.

d) Performance Check: The Automates will be checked annually and after any repair or service by extracting and quantitating a NIST or NIST-traceable standard and a reagent blank. Upon QPCR, the standard must contain at least 0.075 ng/µL of DNA and the blank must not have any DNA. If a value up to 0.001 ng/uL is observed in the reagent blank, the analyst may either re-set up the Quant or amplify the reagent blank. If the amplification does not detect DNA then the QC has passed.

e) Preventative maintenance will be provided by a contract vendor annually and within 9-15 months of the previous preventative maintenance.

8.4.2 EZ-1 Advanced XL DNA Extraction robots:

a) Maintenance: Regular (before each run) and daily (after all the runs of the day) maintenance is performed as described in the EZ-1 extraction procedure. The O-Rings will be greased and the instrument cleaned once every month.

b) Performance Check: The EZ-1 will be checked annually and after any repair or service by extracting and quantitating a NIST or NIST-traceable standard and a reagent blank. The extraction is performed using the following modified Trace Protocol.

1. Place ~0.5cm^2 cutting of the NIST or NIST-traceable standard in 1.5 ml tube.

2. Bring the thermal shaker temperature to 56℃.

3. Prepare fresh lysis solution. Each sample requires 290µl DNA IQ Digest Buffer and 10µl QIAGEN Proteinase K (use kit supplied Proteinase K).
4. Add 300µl of the lysis solution to each sample tube and ensure lids are tightly closed.

5. Place sample tube in thermal shaker and incubate for 1 hour at 56℃ at 900 RPM.

6. Briefly centrifuge tube to remove condensation from inside the lid.

7. Use a sterile wood applicator stick or pipette tip to place the cutting in a spin basket.

8. Centrifuge at maximum speed for 2 minutes. Discard Spin basket.

9. Cut the hinge of each 1.5ml tube prior to loading onto the instrument. Remove each cap as each sample is loaded into the rack.

10. Switch on the EZ-1 instrument.

11. From the Main Menu, press 2 to display the “Manual” menu. Press 3 for Clean, and then press Start to lower the piercing unit. Open the instrument door. Wipe all prongs with a Kimwipe moistened with

ethanol. Press ENT, then ESC to return to Main Menu. Repeat piercing unit cleaning between fraction runs on the instrument.

12. Press Start, select 1 for Trace protocol.
13. Select “No” for “Create a Report File”.

14. Choose the elution buffer and volume. Select 2 to elute in TE buffer. Select 40µl as the elution volume.

15. Press any key to continue through the text on the display to begin worktable setup
16. Open the instrument door by pushing up, then remove the cartridge rack and tip and tube rack from the instrument.

17. Invert the reagent cartridges twice to resuspend the magnetic particles and then tap to deposit any particles or liquid from the foil to the bottom of the wells.

18. Load the cartridges into the rack by sliding each reagent cartridge along the groove towards the back of the rack until it clicks into place. Make sure that the notches in the cartridges align with those in the rack. It may be necessary to put slight pressure on the front tab of the cartridge once completely loaded to secure into rack.

19. Insert the loaded cartridge rack into the instrument.

20. Load the tip & tube rack:

    a. Fourth row: Load with sample tubes containing the lysate.
    b. Third row: Leave empty.
    c. Second row: Load with tips inserted into tip holders.
    d. First row: Load with labeled elution tubes.

21. Insert the loaded tip & tube rack into the front of the instrument and close the door.

22. Press Start to begin purification.

23. Once the run is complete, open the instrument door.

24. Remove and cap the elution tubes containing your purified DNA.

25. Remove the cartridge rack and the tip and tube rack and discard sample preparation waste.

26. After each run clean the tip and tube rack with di water followed by ethanol on a Kimwipe.

27. Close the instrument door.
28. Follow onscreen instructions to perform UV decontamination of worktable surfaces for 20 minutes.

Upon QPCR, the standard must contain at least 0.075 ng/µL of DNA and the blank must not have any DNA. If a value up to 0.001 ng/uL is observed in the reagent blank, the analyst may either re-set up the Quant or amplify the reagent blank. If the amplification does not detect DNA then the QC has passed.

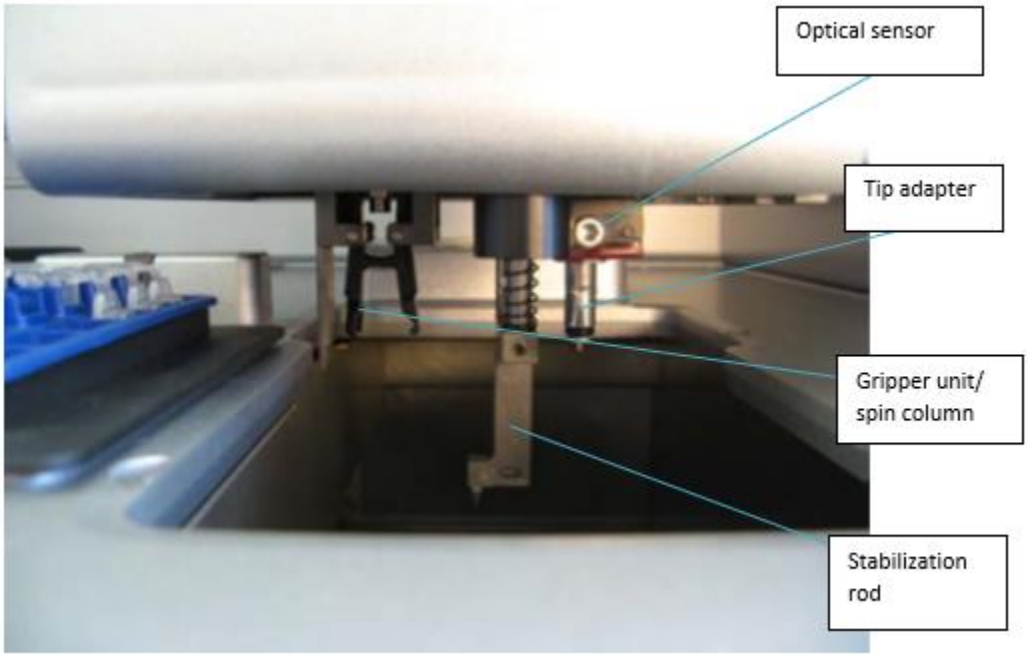
c) Preventative maintenance will be provided by a contract vendor annually and within 9-15 months of the previous preventative maintenance.

8.4.3 QIAcube:

a) Maintenance: Regular (after each run) and daily (after all the runs of the day) maintenance is performed as described in the QIAcube operating procedure.
<u>Monthly:</u> Clean the optical sensor, tip adapter, gripper unit/spin column lid holder, and stabilizing rod (indicated below) by wiping these modules with a lint-free wipe moistened with water.

To gain access to these areas:

- Tools → Maintenance → Cleaning position
- Be sure to remove the waste drawer and the labware tray to prevent robotic arm from crashing into tray.
- Visually and manually inspect the O-ring to make sure it is intact (not cracked and seated properly).



Wipe down the following with a lint-free wipe moistened with di water followed by ethanol. Wipe dry.

- Worktable
- Underneath centrifuge rotor
- Centrifuge, centrifuge gasket, and centrifuge lid
- Shaker rack, labware tray, heating adapter, reagent bottle rack, rotor plastic holder
- Waste drawer liner (and drawer, if needed)

Wipe the inside and outside of the QIAcube with distilled water.

- Do not use alcohol or alcohol-based disinfectants on the QIAcube door.
- Wipe the touchscreen with a lint-free wipe moistened with ethanol and then distilled water. Wipe dry with a paper towel.

<u>Biannually:</u> Perform the monthly cleaning and then follow the below instructions for the cleaning of the centrifuge and performance of a tightness test.

Cleaning the centrifuge: Access to the inside of the centrifuge is required. To open the lid if it is closed Tools → Maintenance → Open lid

- Switch off the QIAcube at the power switch.
- Remove the buckets from the rotor. Undo the rotor nut on rotor top using the rotor key and lift the rotor off the rotor shaft.

- Rinse the rotor, buckets, and rotor nut in ethanol then distilled water. Use a swab to reach narrow areas. Wipe surfaces dry with a lint-free wipe.
- Apply a few drops of mineral oil (Anti-Corrosion Oil (rotor), cat. no. 9018543) on a soft, lint-free wipe, and wipe the bucket mount and rotor claw. A thin, invisible oil film should cover the bucket mount and rotor claw, but no droplets or smear should be apparent.
    - Important: Before applying oil to the rotor buckets on the rotor, make sure that the rotor and all buckets are completely dry.
- Clean the inside of the centrifuge, centrifuge gasket, and centrifuge lid with di water followed by ethanol on a lint-free wipe. Wipe dry.
- Check the centrifuge gasket for damage.
- Reinstall rotor and buckets.
    - The rotor can be mounted in only one orientation. The pin on the rotor shaft fits into a notch on the underside of the rotor directly underneath rotor position
    - Line up position 1 of the rotor with the pin on the rotor shaft and carefully lower the rotor onto the shaft. Install the rotor nut on top of the rotor and tighten using the rotor key supplied with the QIAcube. Make sure that the rotor is securely seated.
    - When replacing the rotor buckets, the side of the rotor bucket that must face toward the rotor shaft is marked with a gray line. Hold the bucket at an angle with the gray line facing the center of the rotor and hang the bucket on the rotor. Check that all buckets are properly suspended and can swing freely.
    - Important: All centrifuge buckets must be mounted before starting a run.

Tightness Test: The tightness test is performed to check whether the tightness of the pipetting system, including the attached pipetting tip, is sufficient.

- Load an empty 2 ml microcentrifuge tube in position 1 of the shaker.
- Fill a reagent bottle with ethanol and place in position 1 of the reagent bottle rack.
- Load a tip rack of 1000µl wide-bore filter tips onto the QIAcube.
- Start Tightness Test → Tools → Maintenance → Tightness Test → Select the appropriate type of filter-tips (1000ul wide-bore tips) → Start
- Follow the instructions displayed in the touchscreen, and press “Start” to start.

- After the load check, the robotic arm will pick up a tip, aspirate ethanol, and move to the tube. The tip will remain in place above the tube for 2 minutes. The tip will be detached.
- After the protocol is completed, open the QIAcube door and check if the tube contains liquid.
- If the tube is still empty and dry, the tightness of the pipetting system is adequate, and the test result is passing. If liquid is present in the tube at the end of the test, this indicates a failure of the test. Notify the Technical Leader or Section Supervisor. The O-ring may need to be replaced. The instrument will be taken out of service until the tightness test is passed.

b) Performance Check: The QIAcube will be checked annually and after any repair or service with a QC sample and a reagent blank. The performance check will consist of one known sample (including both sperm and epithelial cells), and one reagent blank sample. Performance check samples will be taken through the casework protocol for differential extraction with automated wash protocol. A passing performance check consists of correct and complete profiles for both the sperm and epithelial fractions of the positive control sample, plus amplified reagent blank profiles without extraneous DNA.

c) Preventative maintenance will be provided by a contract vendor annually and within 9-15 months of the previous preventative maintenance.

8.4.4 QIAgility:

a) Maintenance: Once every month, the blocks and tip ejector will be removed from the QIAgility deck to be cleaned and the deck will be cleaned. Rinse the blocks with deionized water followed by ethanol. Wash the tip ejector in bleach solution, rinse thoroughly with hot water followed by deionized water and ethanol. Allow the blocks and tip ejector to dry completely before returning to the instrument, then run the UV light for 15 minutes. Wipe the deck and door panel with deionized water on a lint-free wipe. Do not clean the clear door panel with ethanol. While the computer is off, wipe the keyboard area and mouse with a computer wipe.
b) Maintenance (called “Calibration” in the QIAgility software): Once every 6 months or when a method, deck layout, or tube type has been changed, the settings of the QIAgility will be checked and possibly adjusted. Step 1 must be performed prior to Step 2 to ensure that the robotic pipetting head is aligned properly over the expected tube or plate before the tip is lowered. Lowering the tip without first ensuring that the robotic pipetting head is properly aligned along the X and Y axis may result in significant damage to the QIAgility.

- Step 1 – Calibrate Plate Positions (allows the user to calibrate the X and Y axis) – Open the instrument lid and place plates/tubes onto the worktable → Close lid → Open software (this check should be done separately for all validated protocols) → Under Options → Robot Setup click Calibrate Plate Positions → Select a deck position from the list on the left starting at the top → If there is not a tip in the location you are testing Get New Tip (if there is a tip skip this step and use the pipettor head) → Check Pos (open lid to see the positioning as you verify and/or adjust) → Lower Tip to check X and Y positioning (you are just evaluating that the tip location is centered on the location – the depth will be checked in Step 2) → Adjust to center the tip → Save if any adjustments are made → Home Z Axis → Eject tip → Repeat steps to check each deck position → When all position calibrations are complete click Close.

  Changes will likely not be made, but minor adjustments may be made if needed.

- Step 2 – Calibrate Plate Heights – (allows the user to calibrate the Z axis) - Open the instrument lid and place plates/tubes onto the worktable → Close lid → Open software (this check should be done separately for all validated protocols) → Under Options → Robot Setup click Calibrate Plate Heights →A Configure Plate Heights dialog box will appear → Check the applicable boxes by protocol →

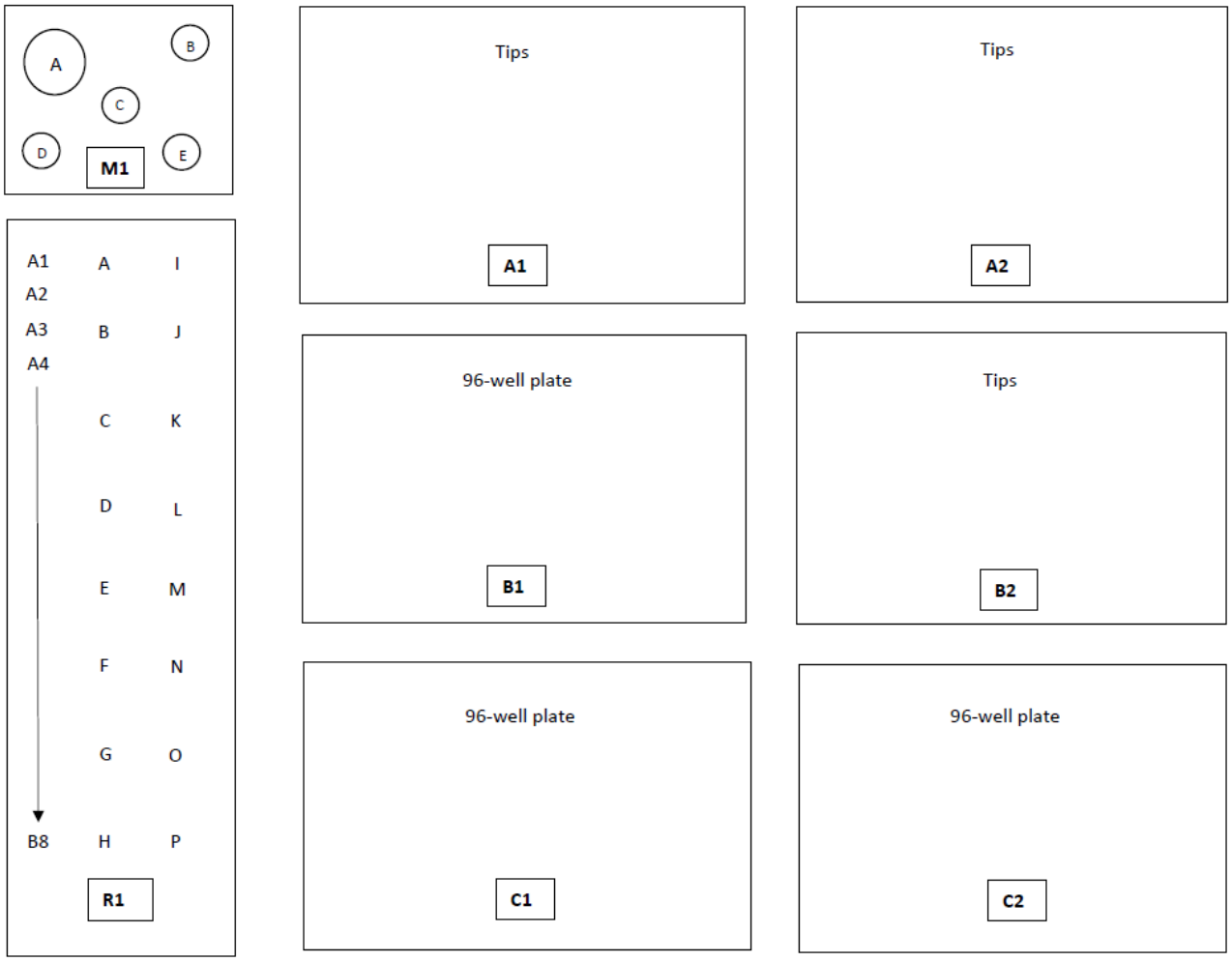
  <u>Trio VSC</u>

  96-well plate 200ul PCR tube @ C1
  Reagent block 200ul PCR tube @ R1
  Reagent block 2.0mL self-standing screw cap tube @ R1
  Mix plate 1.5ml tapered screw cap tube @ M1 (AUTOMATED only)
  <u>GlobalFiler</u>

  96-well plate 200ul PCR tube @ B1
  96-well plate 200ul PCR tube @ C1
  Mix plate 5.0ml tapered screw cap tube @ M1
  Reagent block 2.0mL self-standing screw cap tube @ R1
  Reagent block 500ul self-standing screw cap tube @ R1

Place empty calibration tubes/plates in appropriate deck positions:

- 96 well plates in position B1 and C1
- 0.2ml tubes in positions A1, A2, A3, and A4 of the R1 block
- 2.0ml flip cap tubes in positions A, B, C and D of the R1 block
- 500ul screw cap tubes in positions E, F, G, and H of the R1 block
- 5.0ml tube in position A of the M1 block
- 1.5ml flip cap tubes in positions B, C, D, E of the M1 block



Click Autodetect [checked items] → the instrument will begin to run with the lid open → after completing the selected calibration Select Yes to accept the values (if the averages are not within 10 units of each other, select No and re-run after checking that tubes and plates are sitting correctly → Each selected calibration will run in turn → When the autocalibration is finished select OK → Close

Open each QIAgility protocol separately. The empty calibration tubes/plates can remain on the deck as you run each protocol. Protocols only need to be calibrated to the tubes/plates required, but by positioning all the available tubes/plates each calibration can be run in sequence. No performance check is required after calibration maintenance is performed.

c) Performance Check:

After service prior to the performance check, you may need to update the P-axis values using the Volume Calibration Wizard. If you receive an error or indicator on your pre-run report, follow the next steps.

Select Options → Robot Setup → Calibrate Volume → Volume Calibration Wizard Screen will appear → Select Option 1 from the numbered list → Replace the P-axis values in the table with those provided from the volume calibration of the new pipettor head (paperwork supplied by the service technician) → When complete select "Next" → Answer "Yes" to the Save dialog → Check all the values are correct in the updated list and click "Finish".

Additionally, the calibrations (Step 1 and Step 2 above) should be checked prior to the Performance Check.

Annually and after any repair or service, a NIST or NIST-traceable standard, and a blank will be set up for quantitation and amplification using the QIAgility. The resulting plates will be quantitated, amplified, and run on the 3500. After any repair or service, perform the monthly and biannual maintenance prior to the performance check. To pass QC, the known DNA sample and the kit positive control must provide the correct DNA profile, and there must not be any contamination in the blank.

d) Preventative maintenance will be provided by a contract vendor annually and within 9-15 months of the previous preventative maintenance.

8.4.5 Thermal cyclers (7500):

Preventative maintenance will be provided by a contract vendor annually and within 9-15 months of the previous preventative maintenance. In addition, a background check will be performed monthly.

Performance Check: The two calibrators (1/10 and 1/50) and a negative control will be quantitated annually after preventative maintenance and after any repair or service as a check of the thermal cycler activity.

8.4.5.1 ABI Prism 7500 Monthly Diagnostic

Turn on the 7500 and then start the HID software. From the Home screen, select Instrument > Lamp Status/Replacement.

•If the “Condition” is ‘Good’, the lamp does not need to be replaced. Proceed to “Perform a Background Calibration”
•If the “Condition” is ‘Change Soon’, the lamp may be changed, but it is not necessary.

•If the “Condition” is ‘Failed’, the lamp bulb must be replaced. Proceed to “Replace the Halogen Lamp” (page 63 in the 7500 System Maintenance manual)

Perform the Background Diagnostic

1. Obtain the prepared background plate from the freezer. To prepare a plate if there isn’t one in the freezer:

a) pipette 50ul of deionized nuclease free water into each well of a 96-Well Optical Reaction Plate

b) seal with optical adhesive cover

c) plates may be used up to three times before being remade

2. If using a previously prepared plate, allow the background plate to completely thaw and warm to room temperature (at least 30 min).

3. Remove the background plate from its packaging.

4. Centrifuge the plate for 2 minutes at less than 1500 rpm.

5. Verify that the liquid in each well of the background plate is at the bottom of the well. If not, centrifuge the plate again at a higher rpm and for a longer period of time.

6. Place the tray in its correct orientation in the instrument.

7. From the Home Screen, select Instrument > Instrument Maintenance Manager. Select Background on the left menu.

Select Start Calibration. In the pop-up windows, select Next, Next, Next, Next, and then Start Run.

8. If the run passes; however, there is a warning flag as to possible contamination, turn the plate 180 degrees, and perform the test a second time. If the run passes but the same well(s) are affected, then those well(s) need to be cleaned and the run repeated after cleaning. If the run passes and new well(s) are affected, the run is acceptable. If the run passes after cleaning, but the warning flag appears, the run is acceptable. Document the steps taken and record the well(s) cleaned on the 7500 Monthly Verification Form.

9. If the run fails, record the well(s) out of specification, turn the plate 180 degrees, and perform the test a second time. If the run fails again and the same well(s) are affected, then those well(s) need to be cleaned and the run repeated after cleaning. If the run fails but a new well is affected and that new well is from the same position on the plate as in the first run, then the plate needs to be replaced and the calibration re-run. Document the steps taken and record the well(s) cleaned on the 7500 Monthly Verification Form. If the run still fails, notify the Section Supervisor or the DNA Technical Leader.

10. To clean well(s) on the 7500:

- Identify the contaminated wells of the sample block by first identifying the column and then the well by selecting progressively smaller areas of the plate.
- Remove the plate and the tray holder from the 7500/7500 Fast instrument:
    1. Push the tray door to open it.
    2. Remove the plate and the tray holder.
    3. Close the tray door.
    4. Power off, then unplug the 7500. Allow it to cool for 15 min.

- Open the access door to the 7500.
    1. Insert a thin screwdriver into the keyhole on the edge of the access door, then push to unlatch the door.
    2. Open the access door.
    3. Lift the latch, then push the heated cover door to the back of the instrument.

- Clean the contaminated wells of the sample block using a small volume (50ul) of deionized water:
    1. Pipette a small volume of deionized water into each contaminated well.
    2. Pipette the water up and down several times to rinse the well.
    3. Pipette the water to a waste beaker.
    4. Using a cotton swab, scrub inside of each contaminated well.
    5. Using a lint-free cloth, absorb the excess deionized water.

- Pull the heated cover door to the front of the 7500 instrument. Lift the latch, then secure the heated cover door to the cross bar.

11. After the 7500 background has passed and the monthly diagnostic is complete, close the software, and restart the computer

8.4.5.2 ABI Prism 7500 Biannual Diagnostic

Twice annually – every six months the ROI Calibration, the Optical Calibration, and the Dye Calibration will be performed along with a

defragmenting of the computer. The annual preventative maintenance performed by Life Technologies covers one of the biannual diagnostic calibrations required. The monthly diagnostic should be coordinated to be performed at the same time. The sequence of diagnostic tests should be the ROI, background (monthly), optical, and dye calibration. If dye plates are stored in the original packaging in the freezer, they may be used up to three times (each instrument counts as one use). The plates may store for use for up for six months after opening. If unopened, the plates may be used for up to one year from date of receipt or up to the manufacturer's expiration date. A performance check is not required after the new dye plates are run unless the dye plates are run in conjunction with the annual preventative maintenance.

Defragmenting the Drives (close 7500 software first):

1. Click on the Windows icon in the bottom left corner.

2. Select the Auslogics Disk Defrag software (you may have to switch users to INSTR-ADMIN to perform this task).

3. Make sure the C, D, and S drives are selected.

4. In the “Defrag” drop-down menu select “Defrag & Optimize”. This takes approximately 2 minutes.

5. In the dialog box, the status will change to “Defragmentation Finished” when the defragmenting is complete.

6. Click “x” to close the dialog box.

Performing the ROI Calibration:

1. Obtain the ROI calibration plate from the spectral calibration kit in the freezer.

2. Allow the ROI calibration plate to warm to room temperature (approximately 5 min).

3. Centrifuge the plate for 2 min at less than 1500 rpm.

4. Verify that the liquid in each well of the background plate is at the bottom of the well. If not, centrifuge the plate again at a higher rpm and for a longer period of time.

5. Place the tray in its correct orientation in the instrument.

6. In the 7500 software, select Instrument> Instrument Maintenance Manager.

7. In the ROI screen of the Instrument Maintenance Manager, click Start Calibration.

8. Complete the calibration as instructed by the wizard.

- Clicking Next prompts opens the Run tab.
- Clicking Start Run starts the calibration process and displays the processing messages. Clicking Next opens the Analysis tab.
- Analysis tab indicates the calibration status (Passed/Failed)

9. If you cannot obtain a passing calibration notify the DNA Technical Lead or the Section Administrator.

Performing the Optical Calibration:

If the ROI calibration is at room temperature from performing the ROI calibration, skip to step 3 and spin down any condensation that may have formed.

1. Obtain the ROI calibration plate from the spectral calibration kit in the freezer.

2. Allow the ROI calibration plate to warm to room temperature (approximately 5 min).

3. Centrifuge the plate for 2 min at less than 1500 rpm.

4. Verify that the liquid in each well of the background plate is at the bottom of the well. If not, centrifuge the plate again at a higher rpm and for a longer period of time.

5. Place the tray in its correct orientation in the instrument.

6. In the 7500 software, select Instrument> Instrument Maintenance Manager.

7. In the Optical screen of the Instrument Maintenance Manager, click Start Calibration.

8. Complete the calibration as instructed by the wizard.

- Clicking Next prompts opens the Run tab.
- Clicking Start Run starts the calibration process and displays the processing messages. Clicking Next opens the Analysis tab.
- Analysis tab indicates the calibration status (Passed/Failed)

9. If you cannot obtain a passing calibration notify the DNA Technical Lead or a DNA Team Leader.

Performing the Dye Calibration:

1. Obtain the dye calibration plates from the freezer. System dyes (FAM, NED, ROX, TAMRA, VIC) are part of the spectral calibration kit. Custom dyes (ABY, JUN, MUSTANG PURPLE) are separate.

2. Allow the dye plates to warm to room temperature (approximately 5 min). Do not remove a dye plate from the packaging until it is ready to be run.

3. Centrifuge the plate for 2 min at less than 1500 rpm (when you are ready to run).

4. Verify that the liquid in each well of the background plate is at the bottom of the well. If not, centrifuge the plate again at a higher rpm and for a longer period of time.

5. Place the tray in its correct orientation in the instrument.

6. In the 7500 software, select Instrument> Instrument Maintenance Manager.

7. In the Dye screen of the Instrument Maintenance Manager, click Start Calibration. Each calibration plate takes approximately 8 minutes to run.

8. Complete the calibration as instructed by the wizard.

- FAM, NED, ROX, TAMRA, and VIC dyes → System Dye Calibration
- ABY, JUN, and MUSTANG PURPLE dyes → Custom Dye Calibration
- Overview displays information describing the calibration. Select the dyes that you want to calibrate.
- Clicking Next prompts opens the Run tab. When the software prompts you to load each dye, prepare and load the plates.
- Clicking Start Run starts the calibration process and displays the processing messages. Clicking Next opens the Analysis tab.
- Analysis tab indicates the calibration status (Passed/Failed). When software prompts you to analyze the spectra collected from each dye plate, verify the status of the calibration.

9. If you cannot obtain a passing calibration notify the DNA Technical Lead or designee.

8.4.5.3 RNase P Experiment

It is only recommended to perform an RNase P experiment when initially installing the 7500 system, after moving the instrument to another location, and as needed to verify the function of the 7500 instrument. Refer to the Applied Biosystems 7500 Maintenance Guide Chapter 5 for more information.

8.4.6 Thermal cyclers (Veriti):

Veriti thermal cyclers will be performance checked semiannually or after any repair or service for block temperature non-uniformity, temperature calibration verification, rate test and cycle test utilizing the Driftcon temperature verification system.

8.4.6.1 Veriti Performance Check

Supplies:

- Laptop and power cord with Driftcon software v 2.2.0.0
- Model Driftcon-II Hardware box S/N 4001
- Model 96v-15 Probe Fixture – 15 temperature probes for 96 x 0.2ml block format – serial number 130826-01
- Data cord labeled “A” and “B” at each of the ends respectively
- USB power cord
- 70% Ethanol
- Laboratory Wipes

Thermal Cycler Initial Set-up:

- Turn on the thermal cycler – Tap the touch screen and press the power button in the bottom left corner – select the “warm up [cmpd]” protocol – press Run in the bottom left hand corner to Start – Press start run now to verify Start
- Allow the cover to get up to temperature so that the program will start. It will take a few minutes for the cover to get up to temperature so allow for this extra time. Running a protocol prior to data acquisition ensures that the data is reproducible and reliable.
- Allow the “warm up” program to run completely as you get everything else connected.

Computer Set-up:

- Plug in the laptop to a power source and turn on (the laptop must be plugged in since the hardware box uses the computer to get the power).
- Connect the hardware box to the computer via the black USB power cord.
- Connect the data cord to the temperature probe (“A” end) and to the front of the hardware box (“B” end).

Software Set-up:

- Log in to Driftcon Laptop.
- Double click on Driftcon icon on the desktop.
- Log in to Driftcon software: password for Mr. A Admin – driftcon
- Select Start button – a window will appear for hardware detection – you can click 'Yes' or just let the detection complete on its own.
- Select type of measurement – click (q)PCR then click Next
- Select a Device to be tested (Veriti-Bonnie or Veriti-Clyde from menu) then click Next
- The next screen is for information purposes – verify that the probe calibration date is valid – it would say "Expired" in red next to the serial number if it is expired. Click Next.
- Select the Driftcon protocol from the drop down menu. Click Next.
- The next screen is for information purposes – verify that the probe selected -96v-15. Click Next.
- The next screen will prompt you for environmental conditions – leave these blank – the thermal cyclers are in a temperature sensitive room that is monitored and regulated through the building maintenance. If there is an extreme temperature situation in this room – noticeably hot or very cold, then stop this test and notify the Biology Section Supervisor or DNA Team Leader as this would have a detrimental impact on all the equipment and tests. Click Next.
- The next screen is for information purposes – verify the Control Mode is Default mode, the Reaction volume is 20ul, and the heated lid setting is Off. Click Next.
- The next screen will be left blank. Click Next.
- The next screen is for information purposes. Click Finish.

Thermal Cycler Final Set-up:

- Place the 96v-15 Probe Fixture in the thermal cycler block and close the cover.
- Once the warm up protocol has ended, press the "x" to exit and press the home button in the top left corner to return to the home screen.
- Select the Driftcon program "driftcon [cmpd]" on the thermal cycler. – Run to Start – Press Start Run Now to verify Start
- Verify on the laptop that all 15 sensors are collecting data and that Step 1 of 8 has started.
- The Driftcon will now go through the protocol with no remaining prompts. The protocol consists of 8 temperatures and takes approximately 21-24 minutes to run through to its entirety.

Data Analysis:

- Upon completion of the run the “Analysis Results” screen will pop up indicating that the testing is complete. A log file of the run is automatically saved in the Driftcon software.
- If any of the Analysis results are flagged to be failing (will be represented by red font), contact the Section Supervisor or DNA Team Leader before proceeding).
- If nothing is flagged, from this screen, click “Preview” and the report packet will be generated. Right click on this report and select Print→ Black Ice ColorPlus → Print → this will save a PDF to the C:\LabSave\SCANNERMONITOR folder → change the name of this file to “NAME_DATE_INITIALS” (e.g. Bonnie_102317_AGM)
- Move PDF to R:\Department\Crimelab\Sensitive\Micro\Equipment Maintenance\The corresponding Veriti folder
- This report does not need to be printed, but it must be retained.
- Fill out the Veriti Thermal Cycler Verification Worksheet with the necessary items from the report.
- On the Driftcon Result Report:
  - Page 1 – Thermal Cycler Name, Thermal Cycler S/N, Driftcon Hardware Box S/N, Driftcon Probe S/N
  - Page 3 – Total Cycle Time (Protocol run time)
  - Page 4 – Heat Rate
  - Page 5 – Cool Rate
  - Pages 4, 5, 6, 7, 8, 9 – Accuracy and Uniformity – verify that all result specifications at the times and temperatures collected show a “✓ ” for passing.
- If any of the specifications are out of range contact the Section Supervisor or DNA Team Leader before proceeding.

Clean-up and Storage:

- Open the lid and slide the cover back upon completion (allowing the top of the probe fixture to cool) and continue to leave the thermal cycler running.
  - Be careful when opening the heated lid after the measurement. The inner surface of the lid and the probe fixture can be very hot.
- Disconnect the data cord and USB cord.
- Remove the probe fixture.
  IMPORTANT: the probe fixture can feel "stuck" at the end of the run. When the block is 'hot' (>80 ^{0}C), removing the probe fixture is much easier.
  - Always remove fixture with minimum force and with two hands in a straight upwards vertical movement out of the cycler block. Do not pull or twist excessively as this might damage the internal electronic components of the probe.
  - If removing the fixture from the cycler block is difficult, assure that the block temperature is ambient or higher. Take the Fixture with two hands; clamp the fixture with both hands between index finger

and thumb. Slightly push the left hand side towards you while at the same time the right hand side in the opposite direction and vice versa (clock-wise and counter clock wise). Repeat this a number of times and while making this slight movement lift the fixture with absolute minimum force to investigate if the probes do release from the block.

  - If they do not release your reaction block may be too cold and slightly shrunk which disables easy removal of the fixture from the block. If this occurs start running a PCR program on your cycler and abort the cycler when it reaches 90 degrees on the display. Remove the fixture from the warm cycler block with minimum force and two hands in a straight upward vertical movement.

- Press home button to Exit back to main screen on thermal cycler.
- Turn off the thermal cycler.
- After usage the probes should be cleaned and stored carefully. The probes are the most sensitive parts of the system.
- Clean the sensor tips with a laboratory wipe moistened with 70 % ethanol. Do not apply any force or use other cleaning methods and/or fluids.
- After cleaning the sensor tips, store all the components of the Driftcon hardware in the dedicated case.
- Exit the software and shutdown the laptop.

8.4.7 Genetic Analyzer (3500):

When a spatial and spectral are required, the bi-weekly maintenance must be completed first so that these are performed on non-expired reagents.

After the bi-annual maintenance, PM/repair, change of capillary, or any situation where the capillary has been removed/replaced, the order of operations should be:

1. All reagents and the capillary placed on the 3500 using the appropriate procedure described below
2. Spatial
3. Spectral
4. Performance check

Maintenance Wizards:

- Remove Bubbles Wizard
- Replenish Polymer Wizard
- Fill Polymer Wizard
- Wash Pump and Channels Wizard
- Install Capillary Array Wizard

8.4.7.1 Daily (when instrument is being used):

Click Refresh, then check consumables on the Dashboard—View the gauges on the Dashboard to see the status for anode buffer container, cathode buffer container, and polymer. Visually inspect the level of fluid inside the anode buffer container and the cathode buffer container. The fluid must line up with the fill line. Check for bubbles in the pump block and channels. Use the Remove Bubble wizard to remove bubbles.

8.4.7.2 Bi-weekly:

Clean the instrument:

1. Remove polymer, conditioning reagent, anode buffer, and cathode buffer from the refrigerator to allow to equilibrate to room temperature (15–30°C) before use.
2. Ensure the oven is closed.
3. Press the Tray button on the front of the instrument to move the autosampler to the forward position.
4. Wipe off any liquid on or around the autosampler using a lint-free tissue.
5. Clean off any polymer build-up crystals on the instrument, including the capillary tips, with deionized water and lint-free tissue.
6. Clean the array plug with deionized water and lint-free tissue.
7. Clean out the drip trays with deionized water, or ethanol, and lint-free tissue.

   Note: The drip tray can be removed

8. Run the Wash Pump and Channels Wizard and follow the prompts in the Wash Wizard (the wizard takes approximately 40 minutes to complete). This Wizard will prompt you to change the polymer.

Install buffers (anode buffer container):

1. Check the expiration date on the label to ensure it is not expired and will not expire during use.
2. Allow the refrigerated ABC to equilibrate to room temperature prior to first use. Do not remove the seal until you have completed step 5.
3. Verify that the seal is intact. Do not use if buffer level is too low or seal has been compromised. A fill tolerance of ±1 mm is acceptable.
4. Invert the ABC, then tilt it slightly to move most of the buffer to the larger side of the container. The smaller side of the container should contain <1 mL of the buffer.
5. Verify that the buffer is at the fill line.
6. Peel off the seal at the top of the ABC.
7. With the RFID label toward instrument, place the ABC into the anode-end of the instrument, below the pump. Position the anode in the large chamber of the ABC, then push the ABC up and back to install.

Install buffers (cathode buffer container):

1. Check the expiration date on the label to ensure it is not expired and will not expire during use.
2. Allow refrigerated CBC to equilibrate to ambient temperature.
3. Wipe away condensation on the CBC exterior with a lint-free tissue. Condensation can cause arcing and termination of the run.
4. Check that the seal is intact. Do not use if the buffer level is too low or the seal has been compromised. A fill tolerance of ±0.5 mm is acceptable.
5. Tilt the CBC back and forth gently and carefully to ensure that the buffer is evenly distributed. If you do not tilt the CBC back and forth, the buffer may stick to the sides due to surface tension.
6. Verify that the buffer is at or above the fill line.
7. When ready to install the CBC, place the container on a flat surface and peel off the seal.
8. Wipe off any buffer on top of the CBC with a lint-free tissue. Ensure that the top of the container is dry. Moisture can cause arcing and termination of a run.
9. Place the appropriate septum on each side of the CBC:
    a. Align the buffer septum (the part that is symmetrical) over the 24 holes of the CBC.
    b. Push the septum lightly into the holes to start, then push firmly to seat it.
    c. Align the capillary washing septum over the other chamber of the CBC.
    d. Push the septum lightly into the holes to start, then push firmly to seat it.
10. Click the Tray button on the front panel to move the autosampler to the front position.
11. With the tab facing you and the RFID tag to the right, install the CBC on the autosampler. When properly installed, the CBC tabs will click as you snap them into place on the autosampler.
12. Click the Tray button to retract the autosampler, then close the instrument Door to initialize.
13. In the Dashboard, click Refresh, then check the Quick View section for Updated status.

<u>Change polymer – (as part of Replenish Polymer – not biweekly maintenance)</u>

1. Check the expiration date on the label to ensure that the polymer is not expired and will not expire during intended use.
2. Allow the refrigerated polymer to equilibrate to room temperature (15–30°C) before use.
3. In the Dashboard, click Wizards, then click Replenish Polymer (requires 10 to 20 minutes)
4. Follow the prompts in the Wizard window.

5. When instructed to install the polymer, peel off the seal at the top of the Pouch fitment. Note: You may notice a tiny droplet of polymer inside the fitment (residual from the pouch filling process). This is not expected to cause any performance issues.
6. With the RFID label facing the instrument, slide the pouch fitment onto the slot of the lever assembly. Push the lever up to snap the pouch into the connector end of the instrument pump. Note: The RFID label must face the instrument (away from you) to ensure that the RFID information is read accurately by the instrument.
7. In the Dashboard, click Refresh, then check the Quick View section for the updated status after changing the polymer.

8.4.7.3 Monthly:

Flushing the water trap:

The polymer can back-flow into the pump motor, which can cause damage to the pistons. Flushing the water trap keeps the pistons clean. Before you start this maintenance, make sure the pump is not in action. Performing this procedure while the pump is in action can cause additional damage.

1. Fill a syringe with nuclease free water. Be sure to get all the bubbles out of the syringe before you start the next step. It is recommended to use at least a 20mL syringe.
2. Turn the top-front fitting counter-clockwise to loosen it. Don't remove the fitting, just loosen it enough to attach the syringe to the fitting.
3. Attach the syringe to the fitting. Slowly start injecting the water into the pump.
4. The wastewater will be dispensed into the waste bottle. You may notice some bubbles in the channel as you're completing this step, but this is normal and won't affect the function of the pump.
5. After all the water has been dispensed into the waste bottle, remove the syringe and re-tighten the fitting by turning it clockwise. Don't over-tighten the fitting or it could be damaged. It only needs to be tight enough to prevent water leaks.
6. Remove the waste bottle from the instrument and clean it. Your water trap should be completely flushed and clear of any dried or degraded polymer.

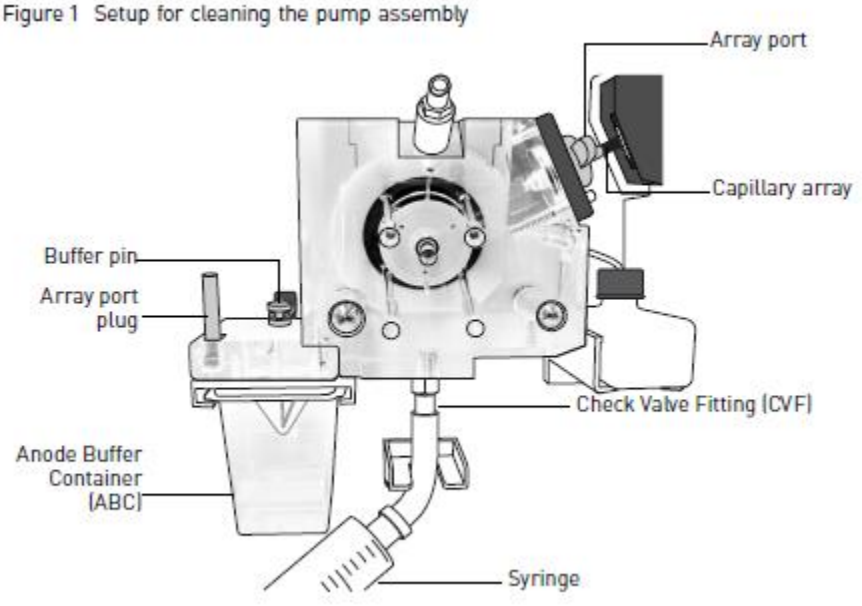
8.4.7.4 Quarterly:

After the start of a new quarter, the computer hard drive will be defragmented and the raw data files on the 3500 desktop will be verified to have been transferred to the GMID-X folder on the R drive. Once the verification of data transfer has been performed, the data may be removed from the instrument computers.

8.4.7.5 Biannual:

Twice a year the pump assembly will be cleaned. This cleaning helps to eliminate polymer that has dried in the channels of the lower block or in the pump assembly. It may also remove some contaminants in the pump assembly that cause premature array failure.

Figure 1 Setup for cleaning the pump assembly



To clean the pump assembly:
1. Power off the instrument.
2. Remove the capillary array.
3. Install the array port plug (where the array was installed) into the array port of the pump assembly and turn the array port lever clockwise (¼ turn) to lock the plug into place.
4. Install an empty Anode Buffer Container (ABC).
5. Remove the polymer pouch.
6. Fill the 20-mL silicone-free plastic syringe (provided) with deionized water (40 °C or colder – water that is warmer may cause damage).
7. Fit the plastic tubing onto the CVF.
8. Dispense at least 5 syringe volumes of deionized water through the pump channel.
9. If there is dried polymer visible, continue rinsing until all polymer is removed.
10. Remove the syringe assembly from the CVF.
11. Remove the array port plug and insert the array port cleaning tool into the array port of the pump assembly and turn the array port lever clockwise (¼ turn) to lock the tool into place.
12. Fill the 20-mL silicone-free plastic syringe (provided) with deionized water (40 °C or colder – water that is warmer may cause damage).
13. Fit the plastic tubing onto the array port cleaning tool.

14. Dispense at least 5 syringe volumes of deionized water through the pump channel.
15. If there is dried polymer visible, continue rinsing until all polymer is removed.
16. Once rinsing is complete, remove the syringe and array port cleaning tool from the array port.
17. Use deionized water and the supplied lint-free swabs to clean out any dried residue around the buffer pin and array port.
18. Wipe the CVF and exterior surfaces of the pump assembly with lint-free lab wipes.
19. Power the instrument on and open the software.
20. Reinstall the capillary array or replace with new one if necessary, using the Install Capillary Array Wizard.
21. Install the polymer pouch.
22. Run the Bubble Remove Wizard before proceeding.
23. Replace the cathode and anode buffers
24. Run a Spatial and Spectral followed by a performance check.

A. A new capillary array will be installed when poor sizing precision, poor allele calling, poor resolution, and/or decreased signal intensity is observed in a run. A significant number of failed injections in repeated runs may also be an indication that the capillary array needs to be changed. Capillary arrays should be good for at least 160 injections but should not be used over 1000 injections.

Note: Capillary arrays may be used beyond the manufacturer's expiration date if the performance is still within quality control measures.

B. A new Spatial will be run at least once annually. The spatial calibration establishes a relationship between the signal emitted by each capillary and the position where that signal falls on and is detected by the CCD camera. A new 3500 spatial will also be run after a capillary array is removed or replaced, the detector door is opened, the detection cell is moved, or the instrument is moved.

1. Access the Spatial Calibration screen. Select Maintenance, then select Spatial Calibration in the navigation pane.

2. Select No Fill if you have previously filled the capillary array with polymer during other instrument maintenance or Fill if you haven't. Typically the first spatial attempted will use the No Fill option since a capillary array replacement will require the capillary to be filled with polymer, but if the spatial doesn't pass, you may use the Fill option for the next attempt.

3. Click Start Calibration.

4. When the run is complete evaluate the spatial calibration to ensure that there is one sharp peak for each capillary (small shoulders are acceptable), one marker (+) at the apex of every peak (no off-apex markers), and all peaks are about the same height. The peaks should be above 6400 RFU and the capillary spacing should be 15 or 16 for capillaries 1-7 and 0 for capillary 8.

5. If the results meet the criteria above, click Accept Results.

If the results do not meet the criteria above, click Reject Results, and attempt a second spatial calibration using the Fill option.

C. A new 3500 Spectral will be run at least once annually. A new 3500 spectral will also be run after an array installation, a new dye set being used on the instrument, the capillary length or polymer type is changed, after the laser or CCD camera has been realigned, or when a decrease in spectral separation is observed.

1. Remove and thaw formamide aliquot from freezer.

2. Select the appropriate Matrix Kit - DS-36 Dye Set J6. Vortex tube thoroughly and spin briefly in centrifuge.

3. Prepare the matrix standard by combining the appropriate volumes: 294 µL of formamide and 6 µL of DS-36 matrix standard. Vortex tube thoroughly and spin briefly in centrifuge.

4. Pipet 10 µL of matrix standard / formamide mixture into wells A1-H1 (briefly centrifuge the 96-well plate if needed).

5. Cover the plate and denature at 95ºC for 3 minutes. Immediately place on ice for at least 3 minutes.

6. Snap the plate retainer (cover) onto the plate, septa, and plate base.

7. Place the plate in the autosampler with the labels facing you (or the instrument door) and the notched corner of the plate in the notched corner of the autosampler. Close the instrument door to re-initialize the instrument.

8. Access the Spectral Calibration screen: Select Maintenance, then select Spectral Calibration in the navigation pane.

9. Select the number of wells (96) in the spectral calibration plate and specify the plate location in the instrument (A).

Note: You do not create a plate for the calibration. The software uses predetermined positions for the calibration.

10. Select the chemistry standard (Matrix Standard) and the dye set (J6) that you are running the calibration for.

11. Make sure Allow Borrowing box and Perform Run 2\Run 3 if Run 1 fails boxes are both checked.

12. Click Start Run.

13. For a passing spectral, the Q value should be >0.95, the maximum Condition Number should be no greater than 8, and no more than one of the eight capillaries uses the matrix from another capillary.

"Condition Number" is a measure of how much the dye spectra overlap. Larger C-Numbers = More Overlap. If there was no overlap in a dye set, the c-value would be 1.0.

The "Q- Value" is a measure of how frequently pull-up and pull-down peaks appear. An ideal matrix, without pull-ups and pull-downs has a Q-value of 1.0.

Complete the Genetic Analyzer AB 3500 Spectral form and attach the Spectral Report from the 3500. This paperwork must be reviewed and approved by the Chief Criminalist/DNA Team Leader before the instrument may be used for casework.

D. Performance Check: After each preventative maintenance, service visit, new spectral, or array installation, a ladder, positive and negative amplification control will be injected and provide the expected results.

   Complete the Genetic Analyzer AB 3500 Performance Check form. This paperwork must be reviewed and approved by the Chief Criminalist/DNA Team Leader before the instrument may be used for casework.

E. Preventative maintenance will be provided by Life Technologies annually and within 9-15 months of the previous preventative maintenance as a part of the BioAssurance Maintenance Plan. This plan also provides for on-site repair of any broken or malfunctioning components in the instrument.

8.4.8 Test Thermometers:

All thermometers used in the laboratory will be handled with care using gloved hands, employed only for the purpose of measuring temperature, and gently cleaned prior to storage (laboratory wipe moistened with deionized water). NIST-traceable thermometers will be stored contained in a dedicated protective box or a hard-plastic sleeve.

Performance Check: Test thermometers are not critical equipment but are used to monitor the performance of critical equipment including refrigerators, freezers,

incubator, heat-block, and thermal mixers by annually checking their expected working temperatures. Test thermometers will be compared to a NIST-traceable thermometer at their working temperature once per year and must pass to be retained in service. Any newly purchased test thermometer will be compared to a NIST-traceable thermometer when put into service and must pass to be retained in service. If the test thermometer does not pass the performance check it and/or the associated critical equipment will be taken out of service. This monitoring will be recorded and checked by the DNA Technical Leader or Section Administrator.

8.4.8.1. Monitoring a Test Thermometer using NIST-traceable Thermometer

1. Place the test thermometer and the NIST-traceable thermometer in the same medium (e.g., water bath).

2. Adjust the temperature until the NIST-traceable thermometer is at the working temperature

3. When the temperature equilibrates, record the temperature of the test thermometer. This record will be checked by the DNA Technical Leader, Biology Section Supervisor, or designee.

4. Notify the DNA Technical Leader or the Section Administrator if the temperature is more than +/- 1° C from the NIST standard.

8.4.8.2. Monitoring a Test Thermometer using the Driftcon as a Thermometer

Software Set-up:

1. Plug in the laptop to a power source and turn on (the laptop must be plugged in since the hardware box uses the computer to get the power).

2. Connect the hardware box to the computer via the black USB power cord.

3. Connect the data cord to the temperature probe (“A” end) and to the front of the hardware box (“B” end).

4. Log in to Driftcon Laptop.

5. Double click on Driftcon icon on the desktop.

6. Log in to Driftcon software: password for Mr. A Admin – driftcon

7. Select Start button – a window will appear for hardware detection – you can click ‘Yes’ or just let the detection complete on its own.

8. Select type of measurement – click thermometer then click Next

9. The next screen is for information purposes –click Next.

10. The next screen will be left blank. Click Next.

11. The next screen is for information purposes. Click Finish

Data Analysis:

- Verify on the laptop that all 15 sensors are collecting data.
- Once the thermometer has reached the desired temperature, the temperature should not rise more than one degree over a 30 second time interval.
- The uniformity should be no larger than 1.00.
- The temperature that should be recorded is the accuracy value.

8.4.9 Thermal mixers/heat-block/incubator:

Thermal mixers, heat-blocks, and incubators will be compared to a NIST-traceable thermometer at their working temperature once per year and will follow the procedure for monitoring of thermometers. If the digital temp doesn't match the NIST thermometer, a note will be added that the user should adjust the digital temperature by adding or subtracting X degrees.

If the thermal mixer, heat-block, or incubator is taken out of service, it will not be put back into service until the repairs have been performed, the unit has returned to the set temperature, the test thermometer has been compared to the NIST-traceable thermometer and that temperature is within +/- 1^{o} C from the NIST standard. This test will be recorded and checked by the DNA Technical Leader or Section Administrator.

8.4.10 Refrigerators and Freezers:

Temperatures will be checked weekly. The acceptable temperatures are:

- Refrigerators: 5°C +/-3°C (acceptable range is 2°C to 8°C)
- Freezers: -20ºC +/-5°C (acceptable range is -25°C to -15°C)

If the equipment temperature lies outside the accepted range:

- Check the temperature with another NIST-traceable thermometer. If the equipment temperature is determined to be within the acceptable range, the old thermometer will be replaced with a new, verified thermometer.
- If the equipment temperature is determined to be outside the acceptable range, the equipment will be adjusted to the proper temperature. If the equipment cannot be adjusted to the proper temperature, it will be taken out of service until repair or replacement. The DNA Technical Leader or the Section Administrator will be notified.

The annual performance check of refrigerators and freezers is performed through the annual comparison of the test thermometer on the unit to the NIST-traceable thermometer following the procedure in Biology QA 8.4.8.1.

If the refrigerator or freezer is taken out of service, the unit will be emptied of all contents and will not be put back into service until the repairs have been performed, the unit has returned to the set temperature, the test thermometer has been compared to the NIST-traceable thermometer and that temperature is within +/- 1° C from the NIST standard. This test will be recorded and checked by the DNA Technical Leader or Section Administrator.

8.4.11 Pipettes:

Pipettes will be performance checked to a NIST traceable standard and certified annually by a contract vendor. Newly purchased pipettes may be put into use if NIST traceable calibration paperwork accompanies the pipette and will then be included in the next annual performance check.

During the annual check to a NIST traceable standard the contract vendor will first test the pipette to assess if it was received in or out of tolerance for both precision and accuracy. If the pipette is received out of tolerance, it will be adjusted and retested. All pipettes will have a record of the “as found” and “as left” data. The “as left” values must be within tolerance for the pipette to be kept in use.

Any pipette with an “as found” value out of tolerance will be reviewed by the laboratory to assess the location (hood or storage), typical use, and potential impact.

Pipettes requiring service and repair will be performance checked to a NIST traceable standard by a contract vendor prior to returning to use.

8.5 Maintenance Instructions for Other Monitored Equipment

8.5.1 DI Water System:

Semiannually at approximately 6-month intervals, a contract vendor will inspect and service the unit. In addition, the monitoring device should be checked at each use. If this device indicates a problem, then the vendor is called to correct it.

8.5.2 Balances:

The electronic top loading and analytical balances are cleaned, calibrated, and serviced at least yearly by a commercial firm.

8.5.3 Chemical Fume Hoods and BioSafety Hoods:

Hoods will be inspected and have their face velocity checked annually by a commercial firm. Hoods may be used as clean workspaces without the fan but cannot be used without proper ventilation when handling and using fume inducing or dangerous chemicals.

8.5.4 M-vac:

Every four years the M-vac will be shipped to the manufacturer for a preventative maintenance check. All repairs or service require shipping the M-vac to the manufacturer.

8.5.5 Alternate light source (ALS)

Annually the ALS will be tested to ensure that expected results are obtained from a designed test sample of known body fluids.

8.5.6 UV Crosslinkers

Quarterly each UV crosslinker will be monitored and tested to ensure sufficient UV radiation for decontamination. Adjustments to the total time will be performed if needed.

8.6 Quarterly Data Backup

- On a quarterly basis electronic files from the QIAgility, the 7500s, and the 3500s will be backed-up on the R drive in designated folders. For the QIAgility, the run files, pre-run reports, and post-run reports will be backed-up. The raw data files for the 7500s (.eds) will be backed-up. The raw data files (.hid) from the 3500s are routinely copied from the instrument and saved in the GMID-X folder on the R drive to create the project and analyze the data. Quarterly, the data on the instrument is verified to have been transferred to the GMID-X folder on the R drive.
- Once all quarterly back-up has been performed, the data may be removed from the instrument computers.

8.7 Monthly GMID-X Database Backup

- On a monthly basis, the GMID-X Database will be backed-up on a USB storage device. The USB storage device shall be stored in a safe outside of the laboratory.
- Prior to completing the backup, ensure all users are logged out of the database. If a user's client connection must be remotely shutdown, log in to the **Administrator** user account.

To perform backup:

1. Start the Database Dashboard and select the **Administration** tab

2. Select **Administration→Export Database**

3. In the Full Database Backup settings, click **Browse**, navigate to the desired location, type a name for the exported file, then click **Open**

4. Click **Export** and wait for the software to complete the operation.

To restore the Database:

1. Start the Database Dashboard and select the **Administration** tab.

2. Select **Administration→Import Database**

3. In the Full Database Restore settings, click **Browse**, navigate to the desired location, select the file, then click **Open**.

4. Click **Import** and wait for the software to complete the operation.

9. Competency Testing and Proficiency Testing

9.1 Competency Testing

Prior to competency testing, technical skills and knowledge will be taught and assessed through lectures, demonstrations, and practical applications for a procedure.

Competency testing is a training measure used to evaluate an individual's technical skills and knowledge to ensure the individual can perform the procedure on casework samples.

Upon completion of training in a particular procedure, the individual must successfully complete a competency test in that procedure to use it in casework.

The competency test will generally be prepared in-house and the key will be supplied to the relevant trainer, supervisor, and/or DNA Technical Leader.

Casework observation is not considered a competency test of the procedure.

If retraining is necessary, individuals shall successfully complete competency testing prior to resumption of casework analyses. This competency test shall include a practical component.

9.1.1 Competency Testing of Serologists and Technicians

- All serologists and technicians, regardless of previous experience, shall successfully complete a competency test before the use of a new or additional procedure on forensic samples or casework reference samples to the extent of their participation in casework analyses.

- Competency testing shall include a practical component and written and/or oral components.

9.1.2 Competency Testing of DNA Analysts and Forensic Biologists

- All DNA analysts and Forensic Biologists, regardless of previous experience, shall successfully complete competency testing covering the routine DNA methods, interpretation, and/or statistical procedures that the analyst will perform prior to participating in independent casework.

- Competency testing shall include a practical component and written and/or oral components.

- Before the use of a new or additional technology, typing test kit, platform or interpretation software on forensic samples or casework reference samples, the analyst shall successfully complete competency testing using the additional

technology, typing test kit, platform or interpretation software to the extent of his/her participation in casework analyses. The competency testing shall include a practical component.

9.2 Proficiency Testing

Proficiency testing is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed.

General proficiency testing requirements are available in QM 5.9.3. Specific requirements in adherence to the FBI Quality Assurance document are covered below and augment QM 5.9.3. The proficiency tests administered are open (known to the analyst as being a test) and include submission of the test results to the provider in order to be included in the published external summary report.

All analysts will perform independent work and must not confer on any part of the test process or the results.

9.2.1 Body Fluid Identification (BFI) only

An external proficiency test (PT) will be administered annually to analysts that are qualified to perform serology in casework but are not qualified DNA analysts.

Each PT shall be assigned to and completed by one analyst.

Typically, the PT has two parts. The first part consists of blind swabs. The blind swabs will have presumptive tests performed for blood, semen, and saliva. Confirmatory tests will be performed **ONLY** on those samples with positive blood (Hematrace) or semen (microscopic exam and p30) presumptive results.

The second part consists of casework type samples with a scenario. These samples will be tested according to the case scenario following laboratory procedures (ex. if AP neg, no confirmatory test needed).

In this second part, given the limited information available in the provided case scenario, some variation between analysts may occur regarding the types of tests performed.

9.2.2 DNA Technical Personnel

An external proficiency test (PT) will be administered semiannually to all DNA analysts, Forensic Biologists, and technical reviewers. One test must be performed in the first six months of the calendar year and the second in the last six months of the calendar year. The interval between the PT will be no fewer than four months and no more than eight

months. For newly qualified DNA personnel, the first external PT must be within eight months of the completion of the qualifying date. The manufacturer's due date will be used for tracking purposes. All PT's require the use of STRmix; however, one test annually is specifically designed with complex mixtures.

9.2.2.1 Routine Forensic Biology PT

Complete serology and DNA testing as normal for proficiency tests.

Guidance will be provided if Y-STR testing is required for qualified analysts.

- This test will be done using STRmix and AX – follow the STRmix SOP for all applicable samples.
- Include in your case file a RMP stat from AX for one single source profile(s) developed from a questioned sample. Highlight the "reported" stat. No additional AX paperwork is required in the case file.
- Perform STRmix deconvolution on everything, like casework, and LR when applicable. The RMP is in addition to the STRmix not replacing it.
- The PT data should be evaluated in the context of the SOPs using STRmix with the ability to condition if applicable.
- Pick a single source questioned profile and run it through it COSTaR and add relevant paperwork to the case file. Do not enter it into CODIS.

9.2.2.2 PG Specific Biology PT (Probabilistic Genotyping)

Complete serology and DNA testing as normal for proficiency tests.

Guidance will be provided if Y-STR testing is required for qualified analysts.

- Fill in Parts I, II, and III the same as usual.
    - Remember that Human Origin and Y-Screening = Not tested
    - Check the STRmix box for all samples including knowns since we will be doing the LR – in the box next to STRmix put "v2.9.1"

- <u>Part IV: Mixture Sample Analysis:</u> – We will be reporting the DNA Proportion (%) per contributor (from STRmix) but we will not be reporting the concentration data at this time**.**
    - Fill in the Estimated number of contributors, and then if the contributor is either "Victim, Suspect, or Unknown"
    - Fill in the DNA Proportion (%) from STRmix mixture proportions
    - If you do a differential – do this for both fractions – in order for both fractions to show up here, you will have to select an answer to differential extraction question in previous Part III

- Part V: DNA Statistical Analysis: Only report any inclusionary stat for the appropriate samples in the following format (The exclusionary conclusions are recorded in the first part of the test by filling in the correct bubbles for inclusion/exclusion of the suspect and victim):

    - Check the Likelihood Ratio (LR) box for each item of evidence
    - In the first box put for each:

      H1: The evidence originated from…
      H2: The evidence originated from…
      The DNA profile obtained from X is approximately X times more likely if it originated from…

    - In the second box for each:

      NIST revised: African American, Asian, Caucasian, Hispanic

  Technical reviewers should be checking this information as part of TR.

- Part VI is not required

- Do not do AX stats or COSTaR. This will be done on one proficiency per year and does not need to be included here.

Analysts will conduct all presumptive serological tests (KM or LMG, AP, and Phadebas) on DNA proficiency tests, regardless of if the case details warrant a particular test. Microscopic confirmatory tests will be performed for AP positive items.

A human origin and Y-screening process is not conducted in the CMPD Biology lab; therefore, these tests are to be reported as “not tested” on the DNA proficiency test.

Group processing (as a non-operator) may be used for one PT for all or part of DNA processing; however, the assigned analyst must perform the interpretation and reporting. Across both proficiency tests, analysts are required to conduct at least one method for each methodology (extraction, quantitation, amplification, and CE) at least once per calendar year.

The method may be conducted manually or robotically ensuring it is validated and the analyst has previously passed a competency test.

The analyst is not required to alternate between manual and robotic.

For analysts qualified in GlobalFiler and Yfiler Plus, a PT must be completed in each of these technologies at least once per calendar year. GlobalFiler will be used in

both semiannual PTs. Typing of all CODIS core loci shall be attempted for each technology at least once per calendar year.

At least one likelihood calculation must be performed on each test. No LRs on exclusionary single source samples are required unless there are no other LRs calculated.

For YFP, statistics shall be calculated for each questioned sample regardless of a visual exclusion or a consistency with an expected contributor.

9.2.3 Technical Review of PT

All PT's will be technically reviewed by an analyst currently qualified and authorized in the scope of testing performed including the method, technology, typing test kit, platform, and interpretation software. An analyst proficiency tested in the specific technology (STRs, Y-STRs) is qualified to serve as a technical reviewer without needing to take an additional proficiency test as a technical reviewer.

After completion of both the administrative and technical review, the PT will be submitted to the Lab Director for final review. After final review, the laboratory shall submit the results for each analyst to the PT provider.

9.2.4 Laboratory Evaluation of PT Results

Upon receipt of the report from the PT provider, the analyst's results will be reviewed by the DNA Technical Leader or designee.

The laboratory shall review and approve all proficiency test results. The tests will be evaluated as satisfactory or unsatisfactory based on the correct results being obtained and the SOPs being followed. Any variation between participant's results will be reviewed by the laboratory. The results of the test will be communicated to the test participant by the DNA Technical Leader and a memo included in the proficiency case file.

Additionally, the review of the DNA proficiency tests includes the following criteria:

- All reported genotypes are correct according to consensus results or are compliant with the laboratory's interpretation guidelines.
- All conclusions are correct or incorrect.
- Any uninterpretable results and/or inconclusive conclusions are compliant with written laboratory guidelines and have been reviewed by the DNA Technical Leader.

- Administrative errors shall be documented, and corrective actions taken to minimize the error in the future.

- All discrepancies or errors and subsequent corrective actions must be documented.

For Probabilistic Genotyping specific tests the additional following criteria will be reviewed upon the return of the results.

- Number of contributors is n+/- 1 of the consensus results and the analyst NOC is supported by the SOP
- Inclusionary/Exclusionary conclusions are correct
- Propositions listed make sense based on the scenario and the DNA results
- Conditioning, if performed, is applicable and conforms to SOP

The review of the DNA Technical Leader's PT will follow the above requirements and be performed by a qualified analyst.

If an error or discrepancy is detected by the PT provider, the internal review process should attempt to determine if the problem should have been detected during the technical review. If this is determined to have occurred, then the technical reviewer or the review policies should be corrected to minimize the possibility of a reoccurrence.

Major discrepancies or errors will be handled according to QM 4.11. The CODIS administrator will be notified of the results of the PT if non-administrative discrepancies affect the typing results and/or conclusions.

10. Corrective Action

10.1 Nonconformities

Nonconformities detected in casework analysis, proficiency tests, testimony, and audits will be addressed by the DNA Technical Leader or designee. Levels of nonconformity generally fall into one of three categories (Class I, II, or III as described in the Laboratory QM 4.11.2.3) and are resolved accordingly.

Minor deviations from SOP and exceptions requiring approval will be noted in the case file and initialed by the DNA Technical Leader or designee.

Class III nonconformities are resolved primarily through documentation in the Biology case file and approved by the DNA Technical Leader or designee. Some Class III nonconformities may be elevated to a memo being included in the case file written by the DNA Technical Leader or designee. Memos are required for all possible contamination events.

Class II nonconformities require the inclusion of a memo in the case file and may be elevated to a Corrective Action involving reporting to the Lab Director and/or the Quality Manager.

Class I nonconformities require the inclusion of a memo in the case file and will be elevated to a Corrective Action involving reporting to the Lab Director and/or the Quality Manager.

The DNA Technical Leader in conjunction with the Biology Section Supervisor and at times the Quality Assurance Manager will determine the severity and classification of the nonconformity. The casework CODIS administrator shall be notified when the nonconformity impacts DNA records entered into CODIS.

Electronic logs of any nonconformities requiring a memo in the case file including all possible contamination events is maintained by the DNA Technical Leader or designee.

10.2 Corrective Action Plan

If a Corrective Action plan is initiated due to the classification level of the nonconformity, it will be documented and tracked by the Laboratory Quality Assurance Manager using the Corrective/Preventative Action Report. Corrective Actions should be completed and implemented as soon as is practicable.

All corrective action plans in the Biology section must be approved by the Technical Leader prior to implementation. The Technical Leader will notify the Biology Section Supervisor of the corrective action plan prior to implementation.

Tracking of the approval will be documented on the Corrective Preventative Action Plan Tracking Form.

The final Corrective Preventative Action Report will include a description of the nonconformity, an identification of the root cause, the impact on casework, and the selection of the corrective/preventative actions implemented (with monitoring duration where applicable) to minimize reoccurrence.

11. Reports

11.1 Case Notes

Notes must be taken for each test performed in accordance with Laboratory QM 4.13.2. The laboratory shall maintain all analytical documentation generated by technicians and/or analysts related to case analyses. The laboratory shall retain, in written, printed, or electronic format, sufficient documentation for each technical analysis to support the report conclusions such that another qualified individual can evaluate what was done and interpret the data.

11.2 Information Contained in Biology Reports

All notes and reports for a case file from the Biology section will be maintained in one folder, and each report will be numbered sequentially. Case type must be a criminal offense except for as described in Biology QA 18 and 20.

The report will include sufficient description of the evidence and any sample collected from an item of evidence, when applicable, must be included in the report to allow for the unambiguous identification of the samples tested. Any stain, sample, or item on which an attempt is made to isolate DNA, regardless of the outcome or result, must be addressed in the final report. A report is required if any part of the DNA testing has been started, even if it was not completed.

The report is not required to address the results from each separate extraction through typing attempt performed on the same sample/item/stain. Reporting may occur of the more comprehensive data obtained from two separate extractions. When replicate amplifications are used in a single interpretation, the reporting will be based on the composite profile.

All Biology casework reports must contain:

1. Case identifier and type of case
2. Description of evidence examined, and identification of samples tested
3. Date of report
4. Results and/or conclusions
5. Laboratory activity date range (except CODIS match reports)
6. Disposition of evidence (except CODIS match reports)
7. A signature and title of the person accepting responsibility for the content of the report
8. Appendix (except CODIS match reports)

Additionally, all DNA reports must contain:

9. Technology used
10. Loci tested or amplification system

11. A quantitative or qualitative interpretive statement to support all inclusions
12. Disposition of the remainder of the evidence used for DNA analysis

The Biology Appendix includes additional relevant background information, including definitions and template wording.

Laboratory Activity:

- Laboratory activity occurs between the start date and the date of the report. The activity start date is the first day of notes taken on an evidence item. In the absence of a notes date (outsourcing, comparison only), the assignment date will be used as the lab activity start date.

- For SAK cutting and inventory cases or swabbing cases going directly to DNA testing without a screening report, there may be two laboratory activity date ranges reported. The first activity range will be from the first day of cutting/inventory notes to the day the evidence is transferred to storage. The second activity date range will be the date that the cuttings are extracted by the DNA analyst to the date of the report. If the storage date of the cuttings is the same date as the DNA extraction, the activity date range may be reported together as one range. If additional evidence is being examined by a DNA analyst in the case, then the date range will reflect the earliest date of notes in the case.

- For guidance regarding laboratory activity reported in amended reports see below in 11.5.

11.3 Release of Case Information

No laboratory employee shall release any information to the public, news media, or any other person unless appropriate as outlined in Laboratory QM 4.13.1.3 and QM 5.10.1. At times it may be necessary to request additional information from the case investigator in order to determine the best evidence to examine or the appropriate tests to perform. In these circumstances, the analyst may orally communicate information to the case investigator prior to issuance of a report. This communication should be documented in the case file. Final conclusions will only be released as an official report and not in any other form.

11.4 Report Writing

1. The report wording guidelines in the Biology SOP are designed to establish consistency in reporting results and to accurately reflect the scientific weight given to the various situations encountered when interpreting and calculating statistics. These guidelines will provide uniformity in reporting and will assist lay persons in understanding the reports. Every possible situation cannot be anticipated. If modifications are necessary to accurately reflect the true meaning of the results in a

report, they must be approved by at least one other qualified analyst during the technical review.

2. The signature on the report indicates the person primarily responsible for the opinions and data generated. The reporting analyst must take ownership of all case related data, perform the interpretation, and check all worksheets for completeness even if they were not the person who performed the laboratory work.

3. The format within the report will be structured to have separate results and conclusions for serology, quantitation, and STR analysis.

11.5 Amended Reports

1. At times it may be required to issue an amended report. To initiate this process, the reset button in PLIMS will be used to open up the original report to modify. The Section Supervisor or DNA Team Leaders are the only ones that have the authority to use the reset button. Unless the case involves the DNA Technical Leader, all technical reviews of amended reports will be performed by the DNA Technical Leader or designee. Per Laboratory QM 5.10.9, all administrative reviews of the amended report will be performed by the Section Supervisor or the Lab Director.

2. In PLIMS the report type is changed to Amended and the assignments tab comments field must show the reason why the amended report is being issued.

3. New applicable review worksheet(s), a printout of the assignment tab showing the comments field, the old report with the invalidated note, and any other supporting documentation will be scanned and attached to the amended report assignment. The applicable review worksheet(s) will be completed based on the content of the amended report, but will at a minimum check:

   - Complaint #, case type, and report number
   - Technology used and loci/amplification system included
   - All items taken into custody listed
   - Results/conclusions for each sample tested
   - Laboratory activity dates and evidence disposition checked
   - Name and title of person responsible for the content of report
   - Spelling and grammar, including names spelled correctly
   - All required pages have case number and initials
   - The content of the report unrelated to the reason it is being amended is consistent with original report

4. The reason why the amended report is being issued should appear in three places.

   1) Assignment comments - added by person making assignment

2) In report above Items received "This report amends the report dated MM/DD/YY to correct... "
3) Old report (print if not already printed) – “Invalid due to ...”

If it was not previously reported, the laboratory activity must be reported in amended reports. If the laboratory activity was previously reported, no changes are made.

If added to an amended report, the laboratory activity date range is between the original start date and the original date of the report being amended. The activity start date is the first day of notes taken on an evidence item. The date range does not reflect the activity of amending the report.

The instructions for amending a report are as follows:

1. Send to Word the report as Open “As Is”. This allows the content of the report to be copied to another word document.

2. Once the original report is copied to another Word document, go back to PLIMS and Send to Word as Recreate Report. This is so the “Amended Report” will show up in the Remarks on the amended report.

3. Now that the report has been recreated, paste back in the original report contents. Ensure the the original signature fields are retained from the recreate report. Paste the body of the report above the signature and paste the appendix below the signature.

4. Add the reason for the amended report to the new report above the Items Received. This should be in the same font size as the body of the report. Phrasing such as "This report amends the report dated XX/XX/XX to correct/ update/include (choose from these verbs or another applicable one) the results/ comparison/conclusion (pick one or choose your own) for Item X." may be used.

5. Make the fix in the report.

6. Print the amended report.

7. Fill out a TR/AR worksheet. In the Notes section put “amended report”.

8. Print the assignment tab from PLIMS which has the reason for the amended report and acts as the “service request” for this assignment.

9. At the top of the original report handwrite an explanation such as “This report invalidated due to issuing of an amended report to correct X”. Date and initial this note.

10. Initial all the administrative pages including the assignment page and all of the original report pages. The original report pages are now administrative pages for the amended report.

11. If there are any corrections to the case file (other than the report), make the required fixes and then date and initial. This page and the original TR and/or worksheet will also be included in the scanned pages for the amended report.

12. Return the case file back to the DNA Technical Leader or designee for TR.

13. Once the TR/AR of the amended report is complete, scan and attach the new paperwork (TR/AR worksheets, assignment page, and original report pages) as a different file name than the original notes packet. Do not rescan any of the original pages.

14. Click the “Ready For Rev.” Ensure that both attachments (the original case notes and the case notes for the amended report) are checked.

15. Route the file in PLIMS and give file to the tech reviewer.

12. Review

General laboratory guidelines for the review processes are addressed in Laboratory QM 5.9.4 and 5.9.5. Some issues specific to the DNA section are addressed here. Reviews will be completed in a timely manner. Three types of casework review are required of all reports and associated case records prior to the publication of the final report. These reviews are self-review, technical review (may include batch review), and administrative review.

12.1 Case File Contents

During the testing process analysts will create records that are printed and included in the permanent paper case file submitted for review and records that are viewed/stored electronically.

Paper case files that include worksheets associated with more than one case will have the relevant DNA #s highlighted on each page. Complaint #s may also be highlighted to reference the applicable case. No highlighting is required for cases that are worked singularly.

The technical documents printed for the case file will be chronologically ordered and numbered from the earliest date to the latest date.

Case files requesting comparison to a previously obtained reference profile from a different Complaint number will have the following documentation added:

If reference profile was obtained:	Documentation to be added
Prior to use of ArmedXpert	• Reference chain of custody • Copies of electropherograms from the reference and associated controls
With ArmedXpert	• Reference chain of custody • Copy of originally reviewed Control Table • Copy of allele table containing reference profile
After use of ArmedXpert	• Reference chain of custody • Copy of allele table containing reference profile • Copy of file's applicable review forms (Batch, TR/AR)

The following lists the printed documents to include in the permanent case file in the expected order (if applicable):

Administrative Documents

- Case technical/administrative review form
- Batch review form
- Service request or assignment page
- Service request history
- Communication sheets or emails
- Medical forms from sexual assault kit
- KBCOPS information
- Chain of custody
- CODIS specimen detail report(s)
- Staff search (if LR>1000)

Technical Documents (numbered pages)

- Handwritten notes/Lab info sheets/General notes
- Extraction
- Sample loading worksheet (QIAgility only)
- 7500 set up sheet
- Standard curve
- 7500 results worksheet
- Amplification information worksheet
- 3500 set up worksheet
- Data evaluation worksheet – STRmix suitability
- Artifacts edits worksheet
- Interpretation worksheet(s) (as applicable)
- Allele tables
- LR from previous report(s)/Statistics – support for inclusion and compound
- CODIS entry worksheet

If rework is required the case file order will be as follows:

- Handwritten notes/Lab info sheets/General notes
- Extraction
- Sample loading worksheet (QIAgility only)
- 7500 set up sheet
- Standard curve
- 7500 results worksheet
- Amplification information worksheet
- 3500 set up worksheet
- Data evaluation worksheet – STRmix suitability
- Artifacts edits worksheet
- Rework worksheets in sequential order through Artifacts edits
- Interpretation worksheet(s) (as applicable) - all

- Allele tables - all
- LR from previous report(s)/Statistics – support for inclusion and compound
- CODIS entry worksheet – all

Case files with GF and Yfiler Plus testing performed concurrently, the case file order will be as follows:

- Handwritten notes/Lab info sheets/General notes
- Extraction
- Sample loading worksheet (QIAgility only)
- 7500 set up sheet
- Standard curve
- 7500 results worksheet
- Amplification information worksheet- GF
- Amplification information worksheet - YFP
- 3500 set up worksheet
- Data evaluation worksheet – STRmix suitability, manual interpretation
- Artifacts edits worksheet
- STRmix interpretation worksheet(s)
- Y-STR manual interpretation worksheet(s)- reference standards not required to be included
- GF allele summary sheets
- Y-STR allele summary sheets
- LR from previous report(s)/Statistics – support for inclusion and compound
- Y-STR statistics
- CODIS entry- all

  NOTE: If not performed concurrently, place all technical worksheets in date order up to and including the artifacts edits worksheet then add the remainder listed.

Deviations from case file order may occur on a case-by-case basis and should be considered by the analyst and resolved during Self-review prior to putting the completed case file into Case Technical Review.

The following lists documents that are viewed/stored electronically (if applicable):

<u>Technical Documents</u>

- Raw Data (.hid file)/Project file (SER file)
- STRmix Results Folder(s)
- COSTaR supporting workbook(s)
- LR from previous report(s)/Statistics – support for exclusion, inconclusive, and exclusion

12.2 Case File Review – Self, Technical, and Administrative

A hardcopy record of the review worksheets will be found in each case file. This review worksheet details the specific elements of each of the reviews, the individuals who performed the reviews, and the date the reviews were completed. The hardcopy included as part of the case file is the official record of the review process. All applicable paper and electronic documents are considered part of the case review process.

Self-review is conducted by the reporting analyst after completion of the report and case file, but prior to entry into technical and administrative review. This initial review is to ensure all case file documentation is complete and accurate. The reporting analyst must review each page of the case file to verify technical and administrative completeness and accuracy.

The reporting analyst is responsible for the case file contents, the data interpretation, and the results and conclusions. Completing the self-review and putting the file into technical and administrative review is acknowledgement from the reporting analyst that the case is complete.

A technical review is a thorough evaluation of information in reports, notes, data, PLIMS fields, and other documents to ensure an appropriate and sufficient basis for the scientific conclusions and must be completed by an individual that is qualified and authorized in the scope of testing performed. For DNA testing, the technical review will be split into a batch review and a case review. Batch technical review will be completed prior to the case technical review.

Biology section casework is often processed in batches where samples from unrelated cases may be extracted, quantified, amplified, and/or analyzed on the 3500 together. A batch technical review may be performed on common elements of the extraction, quantitation, amplification, and 3500 Set Up Worksheets. These reviews are applicable to the worksheets and not necessarily tied to a specific case.

A batch technical review will consist of the following elements:

- All required reagents and expiration dates are present and have been properly recorded
- Testing conforms to protocol specific requirements (may include but not limited to verifying thermal mixer temperatures, incubation times, Qiagility information updated)
- Ensuring that all parameters for passing detailed in quantitation protocol are met
- For batches with plate names, ensure the plate has been named properly
- Ensure date matches appropriate control samples
- All applicable worksheet fields are filled out and are accurate

A case technical review is a thorough evaluation of case specific information in reports, notes, data, PLIMS fields, and other documents to ensure testing conforms to relevant Department and technical procedures and the reported results and conclusions are

accurate and supported by the technical records. It is not expected that the case technical review includes the information reviewed during the batch technical review.

The technical review of DNA case files must be performed by a qualified and proficiency tested DNA analyst in the method, technology, typing test kit, platform, and interpretation software being reviewed and who has not performed analytical testing within that case. An analyst can perform both the batch technical review and case technical review of the same case. If an analyst is performing a case technical review, they must ensure a batch technical review is also completed if applicable.

An analyst that has performed any step of the laboratory work may not perform the technical review on any of the associated cases. This includes but is not limited to Group Processing.

An administrative review is an evaluation of the report and supporting documentation for consistency with laboratory policies, for editorial correctness, and compliance with QAS 11.2 to include verification (if applicable) of:

- Complaint #, case type, and report number checked
- All items taken into custody listed
- Technology used and loci/amplification system included
- Laboratory activity dates and evidence disposition checked
- Name and title of person responsible for the content of report
- Spelling and grammar, including names spelled correctly
- Dispositions for all evidence, extracts, and remaining materials
- Appendix present
- Chain of custody sheets complete-all items taken into custody listed
- All required pages have case number and initials
- Page numbers for technical portion of file
- PLIMS- Verify item descriptions and quantity of sub items created
- Photo upload checked
- STIMS information complete
- Suspect database entry made with correct date of birth
- Verify technical reviewer has removed second copy of CODIS Specimen Detail Report(s)

The self, technical, and administrative reviews will be conducted by different individuals. The relevant Biology Case Review forms outline the requirements for each of the self, technical, and administrative reviews. See Laboratory QA Manual 5.9.4.1 and 5.9.5 for additional information.

12.3 Discrepancies Between Analysts

If an analyst and technical reviewer are unable to resolve a technical issue on which they disagree, they will go to the Technical Leader (TL) who will arbitrate the issue. For further information, please refer to Laboratory QM 5.9.4.1. If the TL is the assigned technical reviewer of the case file and an unresolvable discrepancy arises, a DNA team leader or designee will arbitrate.

12.4 Errors Detected During Review

Minor errors may be corrected by suggestions from the reviewer to the analyst and will be documented in the case file. More serious errors may require further action. This section will follow the policies set in Laboratory QM 4.11.

12.5 Errors Detected After Review

All errors detected after the completion of the case file and the issuing of the report must be brought to the attention of the DNA Technical Leader or designee.

Minor errors may be corrected by making the correction in the case file, noting the correction on the applicable review form, having the technical leader or original reviewer initial and date the addition to the applicable review form, and then scanning the updated document(s) into PLIMS under the Case Info tab. Generally, the workflow is:

1. Required correction is identified (in all impacted case files – if applicable)
2. Case file (or files if it is in all related case files) is given to the reporting analyst to correct
3. Corrections are made by the reporting analyst – remember to date and initial
4. Case file is given to Technical Leader or designee
5. Case file will be checked by DNA Technical Leader to ensure fixes were made
6. A note will be added to the original TR/AR worksheet by DNA Technical Leader referencing the pages with changes along with a date and initial
7. Case file is given back to reporting analyst
8. The updated TR/AR worksheet and all the relevant pages are scanned and attached in PLIMS under the Case Info tab – just the updated pages – not the entire case file – remember this attachment must be part of any discovery in addition to the original case file

** If the corrections also require an amended report, then the updated pages may be scanned in and attached to the assignment for the amended report instead of the Case Info

** If the reporting analyst is no longer an employee, then the workflow will be slightly different – The DNA Technical Leader or designee will make and document the corrections and have a second person (either the original technical reviewer or another qualified analyst) check the corrections and date and initial the TR/AR

worksheet.

Errors of a greater nature may require further action. This section will follow the policies set in Laboratory QM 4.11.

12.6 Case File Review for Testimony

As part of court testimony preparation, analysts should review their complete case file and all standard operating procedures that were in effect at the time of testing.

13. Safety

(for detailed information see the CMPD Laboratory Safety Manual)

A safety and chemical hygiene officer is appointed for the Crime Laboratory. This individual oversees the safety aspects of the Biology section as a part of his/her safety duties with regular inspections. All analysts are required to have Blood Borne Pathogen training annually in accordance with CMPD Directives.

13.1 Policy

The Section will operate in strict concordance with the regulations of the pertinent federal, state, and local health and safety authorities, and the CMPD Safety Manual.

13.2 Written Manuals

General Laboratory Safety guidelines are covered in the Safety Manual. The laboratory safety manual is made available electronically to every Section.

13.3 Disposal of Laboratory Waste

Disposal procedures for biological waste, chemical waste, glass and sharps are to be performed using the appropriate container and in accordance with laboratory policy in the Safety Manual.

13.4 Reagent Notebook

The chemicals used to prepare in-house solutions will be outlined in the “Reagent Logbook” located in the reagent prep area of the laboratory. The associated MSDS sheet will be readily available.

13.5 MSDS

Material safety data sheets will be maintained on all chemicals and reagents used in the Lab. MSDS are available to all laboratory personnel on the R: drive and through the CMPD intranet portal.

14. Audits

Audits are designed to evaluate, confirm, and/or determine the extent to which the Biology Section is meeting defined quality requirements.

All audit documents will be maintained by the laboratory for discovery purposes for the lifetime of the laboratory.

14.1 FBI Quality Assurance Standards (QAS) Audit

- The DNA section must be audited annually utilizing the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories Audit Document. The FBI QAS audit must be conducted once per calendar year, with the interval between audits not less than six months and not greater than eighteen months. At least once every two years, an external FBI QAS audit shall be conducted. Members of an audit team must have successfully completed the FBI's DNA auditor training course.

- Internal and external audits shall be conducted utilizing the FBI DNA Quality Assurance Standards Audit Document in effect at the time of the audit.

- Audit documentation and, if applicable, corrective action(s) shall be reviewed by the Technical Leader to ensure that findings, if any, were appropriately addressed and this review shall be documented. The laboratory will maintain the completed Audit Document and/or the audit report along with the section's written response and documentation of steps taken to resolve any problems detected.

- The audit team will report their findings to the Technical Leader and the Biology Section Supervisor.

- Audit documentation, and if applicable, corrective action(s) shall be provided to the casework CODIS administrator.

- Prior audit reports and prior auditor qualifications will be maintained and will be made available to the audit team.

14.1.1 External FBI QAS Audit

- An external audit shall be conducted by one or more auditor(s) from a second agency(ies). At least one auditor shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.

- Each DNA analyst, technical reviewer, casework CODIS administrator, and DNA Technical Leader will have their education, experience, and training qualifications evaluated and approved during one external audit.

- Prior qualifications may be accepted at the discretion of the DNA Technical Leader without additional audit reviews. If evaluation and approval of minimum educational requirements from a previous employer are accepted by the DNA Technical Leader, this shall be documented through prior external audit documentation and shall be retained by the laboratory.

- A DNA analyst or technical reviewer who receives qualification in an additional technology(ies), typing test kit(s), or platform(s) shall have the additional training qualifications evaluated and approved during one external audit.

- Each validation study shall be evaluated and approved during one external audit.

- The evaluation of technical personnel and the approved validation studies are memorialized in Appendix D and E of the FBI QAS Audit Document.

- All external audit documentation and laboratory responses shall be provided to the FBI within 30 days of laboratory receipt of the FBI QAS Audit Document and/or report. If necessary, an extension may be requested from the NDIS custodian.

14.1.2 Internal FBI QAS Audit

- An internal FBI QAS audit will be conducted in the same manner as an external FBI QAS audit.

- For years in which an internal FBI QAS audit is performed, the audit team must include, at a minimum two qualified DNA analysts. At least one of the analysts must be qualified in the laboratory's current DNA technologies and platforms. The lead auditor must have successfully completed the current FBI’s DNA auditor training course. This may be accomplished by having a single analyst who meets all the specified qualifications or through a combination of the various members of the audit team.

14.2 Annual Laboratory Monitoring Activities

14.2.1 Quality Assurance Audit

An annual internal laboratory quality assurance audit planned and organized by the Quality Assurance Manager with representatives from each laboratory section will be conducted according to the requirements of QM 4.14. The audit verifies compliance with the laboratory’s own requirements for its management system, including the laboratory activities; the ANAB

accreditation program; ISO/IEC 17025:2017 and the effectiveness of the laboratory quality system as implemented.

14.2.2 DNA Annual Case File Review

An annual review of a representative sample of the DNA analyst's case files will be performed and documented by the Technical Leader or their designee. The scope of the review and minimum number of case files shall be defined by the Technical Leader prior to each annual review. This review of case files shall be independent of the annual FBI QAS audit and will be approved by the Technical Leader.

14.3 CODIS Audits

As a functioning CODIS Local site, the lab may be subject to a Federal audit of the CODIS program by the Office of the Inspector General. This is an audit to assess the overall effectiveness of the program and reports are sent to the FBI, not the CMPD Lab. The auditors will establish their own criteria for the audit. Additionally, CODIS auditors from the FBI Laboratory periodically may perform an assessment of the CMPD CODIS program. Findings will be reported directly to the CMPD Lab.

14.4 Laboratory Surveillance Activities and Accreditation Audits

Surveillance and reassessment activities are conducted annually by the accrediting body (ANAB) as part of a four-year accreditation cycle. Year one is a surveillance assessment without witnessing (off-site), year two is a surveillance assessment with witnessing (on-site), year three is a surveillance assessment without witnessing (off-site), and year four is the reassessment or a full laboratory accreditation audit to the most recent version of the accrediting board's manual. Although the laboratory has a complete reassessment audit every four years, the surveillance assessments, which cover a portion of the audit document must be successfully completed to retain accreditation status. The laboratory is expected to continue to meet the requirements under which it was accredited during the entire duration of the accreditation cycle.

15. Contamination

15.1 Decontamination

1. Laboratory benches and hoods will be cleaned with bleach or commercial DNA decontaminant before and after each use and during monthly cleaning. Monthly cleaning records are reviewed and maintained by the Biology Section Supervisor.

2. Cleaning of specific laboratory areas following posted instructions occurs weekly. Weekly cleaning records are posted in the laboratory at designated areas and are reviewed periodically by the DNA Technical Leader or designee.

3. Cleaning of hoods, extraction robots, and liquid handling instruments is documented on the relevant DNA worksheets at time of use.

4. Reusable lab-ware will be cross-linked or autoclaved after washing before being placed back in their respective areas.

5. To sterilize lab-ware (if applicable), the autoclave should be set to at least 20 minutes.

6. Aerosol-resistant pipette tips must be used at all times when handling samples for serological analysis, DNA extraction, quantitation, amplification, and electrophoresis. Pipettes will be wiped down with a commercial DNA decontaminant and exposed to UV light for at least 15 minutes. All tweezers or other metal instruments must be cleaned between each sample handling.

7. All tubes not previously sterilized by manufacturer will be sterilized before use if the tube will be used to hold DNA material.

8. A clean workspace will be maintained at all laboratory benches and hoods by the utilization of bench paper. Bench paper used during the examination of evidence and collection of samples for DNA analysis should be changed at a minimum between each evidence item.

9. Laboratory equipment should be cleaned after each use or as necessary.

15.2 Contamination Contingency Plan

The CMPD laboratory and DNA testing facility is designed to minimize the risk of contamination to an extremely low level by the utilization of many precautions including a separate PCR work area, One-Tube specimen handling, and the separation in time or space of the extraction of questioned and known samples. If the analyst takes the proper precautions outlined in this manual and the procedure manuals, this risk will be kept to a minimum. All interpreted questioned samples will be searched against the local Staff Database.

If a Staff match is made to an employee outside of the Biology Section, the Section Supervisor, the DNA Technical Leader or designee and the CODIS Administrator will be notified. The individual and the Detective in the case will be contacted by the Section Supervisor or the DNA Technical Leader, first by phone and then by email. Any possible matches to visitor/non-CMPD employees will be addressed on a case-by-case basis.

In the unlikely event that contamination should occur in the DNA laboratory, the possible contamination should be assessed to determine if it is isolated or systemic.

First, determine if contamination is occurring in all or most of the samples in a run. If the contamination is present in most of the run samples, proceed to the Systemic Contamination Contingency Plan. If the contamination is present in only one sample, proceed to the Isolated Contamination Contingency Plan.

Any time an Isolated Contamination Contingency Plan is initiated, the DNA Technical Leader or designee or the Biology Section Supervisor must be notified. The procedure used to identify the problem and the conclusions must be clearly identified in each relevant case file. A memo is generated by the DNA Technical Leader or designee and is placed in all the impacted case files. Additionally, the Contamination Log is updated with a brief notation as to the analyst, date of incident, impacted cases, resolution, and TL approval. If the problem is determined to be systemic in nature, the Biology Section Supervisor, Laboratory Quality Assurance Manager and the Laboratory Director will also be notified.

15.2.1 Isolated Contamination Contingency Plan

If possible contamination is observed, the analyst must inform the DNA Technical Leader or designee, Section Supervisor or Laboratory Director if the former is unavailable. This notification will initiate the Isolated Contamination Contingency Plan generally following the steps below. All steps performed will be documented in the memo included in the case file that will be generated by the DNA Technical Leader or designee..

Most instances of possible contamination are observed in the negative controls (negative control/reagent blank). The negative controls are not expected to contain allelic peaks, so the observation of peaks ≥50 RFU in these controls may indicate contamination or drop-in.

Drop-in is generally defined as the observation of one or a few unexplained, non-reproducible low-level peaks within a DNA profile. Drop-in may be observed in negative controls and samples. If one peak ≥50 RFU is detected in a negative control, drop-in may be considered as a potential explanation. Generally, a single peak in a negative control is not considered a pattern of contamination and does not require the notification of the DNA Technical Leader or designee. Associated data should be examined to determine that it is an isolated and random event.

After reviewing the data and observing no additional issues, all data associated with the negative control(s) may be used for comparison.

Contamination in a negative control has occurred when two or more peaks are detected ≥50 RFU. When contamination is detected, the procedures used should be carefully re-examined to determine the source of the contaminating DNA. Contamination is sometimes observed in samples other than the negative controls. Notification to the DNA Technical Leader or designee and initiation of the Isolated Contamination Contingency Plan applies to those instances as well.

Any incident of contamination should be captured in the case file memo including what additional analytical steps were taken to resolve the problem or if the data is suitable for reporting.

Prior to commencing any re-work of the negative control or associated samples, an assessment of case impact should be performed by the DNA Technical Leader or designee. This assessment will attempt to identify the source of the contamination, the step of DNA testing that it occurred, if it is systemic or isolated, and whether the evidentiary profile is affected by the types in the negative control. Not all incidents of contamination will require rework. If the level of contamination sufficiently impacts the associated samples and rework has been exhausted without remedy, then the associated profiles may be deemed not suitable for comparison and reported as not meeting quality control measures.

Rework may or may not be performed based on the initial assessment and the requisite steps may be adjusted by the DNA Technical Leader or designee according to the scenario. Depending on the outcome of the rework, the Systemic Contamination Contingency Plan may be initiated.

General rework steps may include:

a. Preparing a new sample or control for re-injection using a fresh aliquot of amplified product. If this resolves the contamination, the re-injection may be utilized.

b. If the sample or control is contaminated with a known source such as a CMPD employee and re-injection did not resolve the contamination, the sample(s) may be re-extracted if applicable. If none of the original stain material remains, if the contamination persists in the re-extraction, or if the re-extracted profile gives uninterpretable results, the original profile may be utilized at the discretion of the Technical Leader.

c. If the sample or control was contaminated by another sample in that particular run and re-injection did not resolve the contamination, the affected sample (or the batched extraction set, if necessary) may be re-

amplified. Should the contamination persist, the affected sample (or the batched extraction set, if necessary) may be re-extracted from the original material. If none of the original stain material remains, if the contamination persists in the re-extraction, or if the re-extracted profile gives uninterpretable results, the original profile may be utilized at the discretion of the DNA Technical Leader or designee.

15.2.2 Systemic Contamination Contingency Plan

Upon observing possible systemic contamination the analyst must inform the DNA Technical Leader, Section Supervisor or Laboratory Director if the former is unavailable. This notification will initiate the Systemic Contamination Contingency Plan generally following the steps below. All analysts must immediately cease all casework until the source of the contamination is identified or is cleared. Once it is determined the step at which the contamination has been introduced, some non-impacted casework may resume with approval of the DNA Technical Leader.

a. Determine if the contamination is isolated to a particular run or is also evident in previous or subsequent runs. From this information, attempt to determine if the source is likely from the in-house solutions or the manufacturer supplied components. To determine this, prepare new in-house solutions, all of them if necessary, to attempt to determine the faulty solution. If the contamination persists and it is determined to be from a faulty purchased product, return the item to the manufacturer immediately and inform them in writing of the problem.

b. If the problem is not solved after the above steps, the entire laboratory will be thoroughly cleaned and decontaminated. All new solutions will be prepared, if not already done. After this thorough decontamination, several non-evidence samples will be analyzed before casework will be resumed.

16. External Laboratory Testing

CMPD may request the services of an external laboratory to perform testing.

16.1 Outsourcing

Outsourcing is the utilization of a vendor laboratory to provide DNA services in which the NDIS participating laboratory (CMPD) takes or retains ownership of the DNA data.

16.1.1 Requirements of Outsourcing

a) The vendor laboratory must be compliant with the current FBI Quality Assurance Standards for Forensic DNA Testing Laboratories and accreditation requirements of federal law. The vendor laboratory must provide documentation of compliance with QAS and its accreditation.

   - The Technical Leader shall review the vendor laboratory's compliance with these standards and the accreditation requirements of federal law.

b) Before the contract is awarded, the approval of the technical specifications in the contract is at the direction of the DNA TL through documented communication. Final review of the specifications in the contract may be documented by the TL initialing and dating the technical specifications page(s) in the contract or through other documented communication.

c) Prior to the vendor laboratory beginning casework analysis, an on-site visit must be performed by the TL or designee, who is a qualified or previously qualified analyst in the technology, platform and typing test kit used to generate the DNA data. The on-site visit will assess the vendor laboratory's ability to perform analysis on outsourced casework.

   Alternatively, on-site visit assessment and approval may be satisfied by evaluating documentation provided as part of the FBI On-site vendor laboratory Visit Program (OVP). To accept an on-site visit, the visit must be performed by an NDIS participating laboratory using the same technology, platform, and typing test kit. Alternatively, the TL may accept an on-site visit coordinated by a designated FBI employee.

   If accepting an on-site visit from another NDIS participating laboratory or the FBI, CMPD shall have documentation demonstrating the review and approval of the on-site visit by the TL. The TL must approve all on-site visits.

d) At a minimum, the following will be reviewed during an on-site visit:
   - Accreditation documentation

- QAS audit documents, findings, and responses
- Qualifications and proficiencies of laboratory staff
- Facilities and evidence
- Relevant validations
- Manuals and standard operating procedures
- Corrective actions

e) If the outsourcing agreement extends beyond one year, an annual on-site visit shall be required. Each annual on-site visit shall occur every calendar year and shall be at least six months and no more than 18 months apart.

A profile generated by another NDIS participating laboratory from a casework reference sample that the NDIS participating laboratory will only use for comparison is not considered ownership. The laboratory should ensure it is clear that the results from casework reference sample used for comparison were generated by another laboratory.

16.1.2 Ownership of Data

a) All data that CMPD ultimately takes ownership of must have an initial technical review performed at CMPD by a qualified analyst.

    - The ownership review shall be completed by an analyst who is qualified in the technology, platform, typing test kit, and interpretation software used to generate the data and participates in the laboratory's proficiency testing program.

b) Ownership review of data from a vendor laboratory occurs in a series of documented steps. Not all steps may be performed for each case returned from a vendor laboratory; however, each step and the individual performing the step will be recorded, except for step 2 if applicable. The level of review depends on the results obtained by the vendor lab. Requirements are detailed on the CMPD Crime Lab Outsourcing Batch and Ownership TR/AR worksheet.
    1. Batch Review
    2. Data Review Check
    3. CODIS eligibility
    4. Case Review of Vendor Lab Data and Report
    5. Technical Review of CMPD Case File and Report
    6. Administrative Review of CMPD Case File and Report

    <u>Batch Review:</u> Will be completed by a qualified CMPD analyst or a qualified contracted technical reviewer on behalf of CMPD.

    <u>Data Review Check:</u> If the initial batch review was completed by a contract technical reviewer and STR data was generated by the vendor

laboratory, a qualified CMPD analyst will review the vendor lab's report and determine if the data obtained may be eligible for CODIS entry and CMPD reporting.

CODIS eligibility: If there is potential for CODIS entry, the CODIS Administrator (or Back-up) will review and determine if any samples may meet the eligibility requirements for CODIS entry. An eligibility memo will be written and added to the case file.

For cases that are determined to be CODIS eligible, the Biology Section Supervisor or designee will create a service request and assign the case to a qualified analyst for case review.

Case Review of Vendor Lab Data and Report: For cases determined to have CODIS eligible samples, a qualified CMPD analyst will perform a technical review of the vendor case file and data, enter an eligible profile (if applicable) into CODIS and write a report following Biology QA 11. Required documentation is found on the CMPD Crime Lab Outsourcing Batch and Ownership TR/AR worksheet.

For cases that do not contain probative profiles, a CMPD qualified analyst will perform a technical review of the vendor lab results and report. No report will be issued and all documentation will be kept electronically by attaching the documentation in PLIMS.

Administrative/Technical Reviews of CMPD Case File and Report: If a report is written by CMPD, the case file and report will be technically and administratively reviewed according to Biology QA 12.

c) Once the integrity of the DNA data is verified, the CMPD Biology section may take ownership of the data.

d) Ownership is the process by which the responsibility for the products of forensic DNA analyses provided by a vendor laboratory may pass to CMPD. Ownership occurs when any of the following are applicable:

- CMPD Biology section uses samples, extracts, or materials from the vendor laboratory for the purposes of forensic DNA testing
- CMPD Biology section interprets the DNA data generated by the vendor laboratory
- CMPD Biology section issues a report drawing conclusions on a forensic sample analyzed by the vendor laboratory

- CMPD Biology section enters or searches a DNA profile in CODIS from data generated by the vendor laboratory

e) The completion of this analysis, technical review, and upload to CODIS should be performed within 90 calendar days from the upload of the data by the vendor laboratory.

f) Timeline requirements associated with data review are not applicable if upon initial review, cases are found to require additional laboratory work or amended reports need to be issued. Any other justifiable deviations from timeline requirements should be addressed and approved in a timely fashion by the DNA Technical Leader or Biology Section Supervisor. Effort should be made to adhere to timeline requirements and if not possible should be documented as to the reason and remedied as soon as practicable.

g) If CMPD is requested to take ownership and no outsourcing agreement exists with the vendor laboratory, the Technical Leader shall document all of the following prior to acceptance of ownership of resultant data:

- Approval of the casework CODIS administrator and written permission from the NDIS Custodian for any scenario that involves CODIS entry or searching

- Approval of the technical specifications of testing

- Review the documentation of or conduct an on-site visit of the vendor laboratory that has occurred within the 18 months prior

16.2 Non-Outsourcing External Laboratory Testing

The DNA laboratory is not subject to the outsourcing requirements if:

1. An analyst is selecting an appropriate external laboratory and assisting investigators in preparing samples for analysis for genealogical, familial searching, mtDNA, animal, paternity, or other non-STR testing.

2. The sample is sent to the FBI, North Carolina State Crime Lab, or other agency who will upload the results to CODIS as a part of their own analysis. Since the external agency “takes ownership” of the evidence, the CMPD laboratory is under no obligation as a subcontractor.

16.3 Evidence Sent to an External Laboratory

1. Evidence that is maintained in the laboratory in either General Biology Storage (GBS) or in Biology Freezer locations may be requested by the

investigator to be sent either to an outside agency (namely the North Carolina State Crime Laboratory) or a vendor laboratory for additional testing.

2. Documentation from the investigator initiating and requesting the items of evidence to be sent and prior approval by either the outside agency or vendor laboratory must be provided before the evidence is released from the Biology Section.

3. The Chain of Custody for each item will be tracked electronically in PLIMS. All evidence packaged by Biology personnel to be shipped will require the Item to be first transferred to that individual. Relevant notes as to evidence description should be documented either on a Laboratory Information Worksheet or on the submission paperwork.

4. Evidence that is maintained in the laboratory in either GBS or in Biology Freezer locations will require Biology personnel to either release the evidence to the assigned investigator or to a designated Property Control Evidence Technician for shipment or to package the evidence for shipment and then release it to “Released to outside vendor” or “Out to NC State Crime Lab” in the PLIMS system. Evidence items may also be packaged by Biology personnel to be shipped to the North Carolina State Crime Laboratory via courier. Evidence shipped via courier will be transferred to a secure courier location by a Property Control Evidence Technician and recorded in PLIMS as “Out to NC SBI.”

5. Evidence that is packaged for shipment will be packaged in a manner to prevent loss, alteration, contamination or mixing and in a condition to minimize degradation.

17. Records

Retention of proficiency tests, competencies, work authorizations, corrective actions, audits, training records, continuing education, and court testimony monitoring are maintained by the Laboratory Quality Assurance Manager according to QM 4.13.1.2.3 as documents related to the quality assurance program.

17.1 Current Technical Manuals

A copy of the current Biology Standard Operating Procedures for DNA typing of biological material and/or the identification of body fluids, the Biology Quality Assurance Manual and the Biology Training Manuals are accessible and available to analysts on a secured and shared drive location.

17.2 Past Analytical Testing Methods, Procedures and Guidelines

A file will be maintained by the Quality Manager containing all previous analytical testing methods, procedures, operating guidelines, and quality assurance standards.

17.3 Laboratory Supply Records

Lot numbers of critical reagents, reagent preparation records, and ordering records for laboratory supplies will be retained for a period of at least five years. These records may be retained electronically. Batch or lot numbers of materials considered critical to DNA typing will also be recorded on the appropriate worksheets and maintained in the case file.

17.4 Quality Assurance and Audit Reports

Copies of external audit reports will be maintained electronically. Internal audit information will be retained according to QM 4.14.3.

17.5 Licenses and Certificates

Copies of all pertinent licenses and certificates required for the operation of the Biology section are maintained electronically.

17.6 Population Frequency Data

Population frequency data used for statistical calculations in the report will be maintained electronically.

17.7 Case Record

Biology section case records are retained and will be available if the court requests. The entirety of the case record are those materials on which the analyst relies upon to draw conclusions. The case record consists of both paper and electronic case files. Worksheets and forms contained in the paper case file are controlled documents. The analysts and reviewers must decide if the information is properly contained within the case folder so that a competent analyst can determine what tests were performed and if the results justify the conclusions.

All case file notes will be scanned into PLIMS.

Case File (Paper):
All case files are scanned into PLIMS and attached as part of the Notes Packet in the corresponding Biology assignment. The original paper case file is kept in the file room. Case files may not leave the Crime Laboratory unless being temporarily removed for court testimony. Case files will be filed upon completion of the review process and the publishing of the final report. All case files that are removed from the file room are signed out according to QM 4.13.1.2.1.

Case File (Electronic):
The portion of the case file which is generated and stored electronically. Primarily this includes the raw data files (.hid) from the e-grams generated by the 3500, the STRmix run folder, and COSTaR workbooks. These files are stored and available on a secured and shared drive location. If necessary for court testimony, digital or paper copies may be prepared and brought to court.

Additional technical records created for court testimony should be reviewed and that review should be documented prior to trial to ensure that the version created is the version that was technically verified. This includes charts, tables, or presentations created by the analyst or by an attorney.

17.8 Contamination Records

An electronic record is retained in the lab pertaining to any contamination that occurred. The contamination log is maintained by the DNA Technical Leader and records contamination events in the Biology section. Memos detailing the nature, impact, and resolution of the contamination event are contained in all impacted case files.

17.9 Non-conformance Records

An electronic record is retained in the lab pertaining to non-conformance incidents that occurred. The non-conformance log is maintained by the DNA Technical Leader and records substantive non-conformance events in the Biology section. Memos detailing the nature, impact, and resolution of the event are contained in the impacted case files

or applicable quality assurance records. Case file notes documenting minor deviations and exceptions are not part of the non-conformance log and do not require a memo.

17.10 Standard Reference Material Records

All results of calibration or QC testing using NIST or other standard reference materials will be documented and retained electronically.

17.11 Case Communication

All laboratory personnel shall document verbal (in-person or telephonic), written, or email case-related communications in the case file through the Crime Laboratory Communication Log worksheet or through an email chain. These communications shall be included in the administrative portion of the file and/or attached in PLIMS.

All communication shall be neutral, professional, and directly related to the case investigation.

17.12 Validation Records

Validation summaries and the underlying data supporting the summary will be documented and retained electronically.

17.13 Critical Reagent/Equipment Records

Required quality assurance testing, maintenance and/or calibration records of all critical reagents and instruments will be documented and retained.

18. Case Acceptance Policy

Evidence must be submitted in compliance with the case acceptance guidelines of the Charlotte-Mecklenburg Police Department Crime Laboratory. A service request is required for all testing performed in the Biology section, and this request contains a brief case scenario of the context of the evidence submitted for testing.

Service requests will only be accepted if the charge associated is listed as a criminal offense. Non-criminal and unfounded cases will not be accepted except for internal investigation cases that may be worked by the laboratory as non-criminal cases. Non-criminal cases may also be accepted for sexual assault cases. Crimes reported prior to the implementation of KBCOPS in 2001 will be designated as Cold Case Investigations and classified as non-criminal due to those crimes having been previously reported.

The type and number of items accepted per submission is based on case type. For all case types, known standards from victim(s) or subject(s) do not count towards the number of items that may be submitted. An item is expected to be comprised of one piece of evidence (e.g. one piece of clothing, swabbing of blood from a single area, or one weapon). If items are received packaged together, the number of items in the package will be considered to be the number of items submitted (e.g. pants, shirt and shoes packaged together will be considered three items). Typically, the flow of evidence starts with the Biology Section. DNA will be processed for CODIS entry only on those cases where a crime was committed, and the evidence can be linked solely to that event.

Other than a buccal standard, a subsequent service request will not be accepted by the Biology section until a report has been completed on the previous submission. If a buccal standard is added to an existing assignment, the investigating officer should submit an additional service request.

Buccal standards from suspects must include the subject's full name and date of birth in the description for that item in PLIMS. Buccal standards submitted for victims require only the full name in the PLIMS item description.

Buccal standards submitted as victim or elimination standards or collected from juveniles as part of a non-testimonial order will only be compared to evidence profiles in the case under which they were submitted and will not be used for comparison to evidence profiles generated in other cases. Exceptions may occur; however, this will be at the discretion of the Biology Section Supervisor or a DNA Team Leader and will be documented in the case file.

An alternate standard may be accepted for DNA analysis with documentation contained in the case file describing why it can be presumed to have DNA solely contributed by the individual of interest. A sample of this type may be used when a known standard cannot be obtained. The Item Description in PLIMS may reflect the collection of the item for this intended use; however, if the original collection was done without this prior

knowledge, then the original description will be retained and only the case report will reflect the intent of being an alternate standard.

Swab collections from the sexual assault kit may be used as an alternate reference in the absence of a buccal standard. This approval will be based on the data and requires approval from the TL or designee.

18.1 Prioritization

The order of analysis of cases will depend on several factors including the needs of the public, courts, and the police department. However, in general, cases for violent crimes which contain all the components necessary for a proper examination will be given priority. Requests for expedited or priority testing will be accepted in active, open violent crimes investigations with the review and approval of the submitting officer's division Captain (or their designee). Approval by the officer's chain of command should be forwarded to the Lab Director with justification for the priority request.

18.2 Examination of Biological Evidence

18.2.1 Sexual Assault Evidence or Direct to DNA cases

a) All sexual assault evidence collection kits (SAK), except anonymously collected kits, are required to be submitted for DNA testing. Additional evidence may be submitted for testing but only if associated with a criminal case.

b) The first submission is limited to a sexual assault evidence collection kit (SAK). All SAKs will be tested utilizing a Direct to DNA approach with serology performed only upon specific request.

c) Both routine and priority processing of SAKs will consist of the complete inventory of the SAK. Routine processing consists of the selection of one or two sets of swabs for DNA testing and priority processing consists of testing all included swabs.

d) Y-STR's may be performed on any evidence associated with a sexual assault. A meeting with a DNA Team Leader or designee and Detective is required before a service request for Y-STR's can be submitted. Consideration for conducting Y-STR testing should include:

- Any probative autosomal results
- Quantitation data
- The submission of a suspect buccal(s) and elimination standards for comparison.
- Sufficient extract volume (including corresponding reagent blank(s) or substrate material remains

e) Y-STR testing may be recommended in the case report on items that qualify but have no submitted suspect buccal standard. If a suspect is developed and a buccal standard collected, the investigating officer must submit and have approved a service request for Y-STR testing to be performed.

f) If the kit produces a DNA profile foreign to the victim, no additional items will be accepted for DNA testing unless case circumstances (such as multiple suspects or the DNA detected is attributable to a consensual partner) dictate the need for additional processing.

g) If the kit is negative, additional items such as underwear, condom, clothing, or bedding may be submitted in a separate request.

h) Depending on case circumstances, additional evidence items may be submitted as part of the initial request after consultation with the Section Administrator (or designee) or a Team Leader.

i) After a report has been issued on the first set, the next tier of probative items, (maximum of five items) may be submitted upon consultation with the Section Administrator (or designee) a Team Leader.

18.2.2 Homicides

a) A meeting with the Section Administrator or a DNA Team Leader (or designee) is required for all Homicide cases before a service request can be submitted for priority cases or DNA processing of fired evidence. If possible, meeting with a Team Leader or the Section Administrator is advisable for all Homicide cases before a service request has been submitted. Documentation of the meeting will be included in the case file.

b) Biology evidence is limited to ten items per submission. Exceptions may be made with documented approval by the Section Administrator or a DNA Team Leader (or designee).

c) After a report has been issued on the first set, the next tier of probative items, (maximum of ten items) may be submitted upon consultation with the Section Administrator or a Team Leader.

18.2.3 Burglary/Property Crimes

a) The first submission is limited to one item for Biology - typically blood sample(s) from the scene, or items left at the crime scene by the perpetrator (cigarette butt, item of clothing, tool), unless case circumstances (such as multiple suspects) dictate the need for additional analysis.

- If more than one item is listed on the request, the analyst may use their discretion to choose which one to process for DNA. Presumptive testing for the presence of blood is determined by swab description and observation of staining. Selection for DNA testing will be based on swab collection location, positivity of presumptive blood testing, and amount of staining available for testing. Depending on the case scenario and presumptive testing results, only one evidence item is required to be DNA tested.

b) Trace DNA items will not be processed in Burglary or Larceny cases.

c) If a profile is developed, additional items will not be examined, without consultation with the Section Administrator or a Team Leader unless the request is made by an Assistant District Attorney (ADA).

18.2.4 Robbery and Assaults

a) Biology evidence is limited to five items per submission.

b) After a report has been issued on the first set, the next tier of probative items, (maximum of five items) may be submitted upon consultation with the Section Administrator or a Team Leader.

18.2.5 Trace DNA Items

a) Trace DNA, as applied to the CMPD lab's case acceptance policy, is defined as potential DNA left on an object after being casually touched. This differs from handled DNA which is DNA left on an item that was brought to the crime scene by the perpetrator.

b) Trace DNA evidence will be processed only in violent crime cases. Exceptions may be made with prior approval for cases of significant interest to the department and cases that are part of a series or suspected of being related (same suspect(s), MO, date/time, location, or other factors). Evidence other than trace DNA items will be considered for testing prior to accepting trace DNA samples if available.

c) Trace DNA evidence will be processed by the Biology section only if it has not been previously processed by another discipline.

d) Items submitted for trace DNA evidence processing will comply with existing policy relating to the number of items of evidence that may be submitted based upon case type.

e) Elimination standards or suspect standards must be submitted with trace DNA evidence where appropriate (e.g. owner of stolen vehicle used in a violent crime such as carjacking).

f) Drug packaging, credit cards, money, or community areas such as countertops from a hotel/bank for DNA will not be processed due to the number of individuals that have access to these items.

g) The gun and magazine found in the gun are the only items that will be processed in constructive possession cases; however, if the magazine found in the gun is not labeled, it will not be processed. These cases are only processed when a request comes from the Sgt. of the Firearms Enforcement Division or an ADA. In addition, guns that have been taken off an individual will not be processed.

h) Fired evidence will not be processed for DNA, except for investigative purposes only in homicides when there is no other evidence to identify a suspect, link an individual to the scene, or make an arrest. Testing of fired evidence for types of cases other than homicides may be considered at the request of the Investigations chain of command.

- A meeting with the Section Administrator or a Team Leader is required to discuss fired evidence and relevance to the case. Coordination of processing with the Firearms section may be required.

- The request for fired evidence must be reviewed and approved by the Section Administrator or a Team Leader.

18.2.6 Cold Cases

A meeting with the Section Administrator or a Team Leader is required for all cold cases before a service request can be submitted. Testing exceptions may be made, and documentation of the meeting and any exceptions will be included in the case file.

All cases must be classified as a criminal case. Crimes reported prior to the implementation of KBCOPS in 2001 will be classified as non-criminal due to those crimes having been previously reported.

After a report has been issued on the first set, the next tier of probative items, may be submitted upon consultation with the Section Administrator or a Team Leader.

<u>Homicides</u>

Biology Evidence is limited to five items per submission.

<u>Sexual Assaults</u>

Biology Evidence is limited to three items per submission and typically includes the sexual assault evidence collection kit.

18.2.7 Re-examination

a) The Biology Section does not accept requests for the same evidence to be re-analyzed with the same analytical procedure. Evidence will not be accepted for trace DNA analysis if the evidence is open, or the evidence has already been processed in another section of the laboratory.

b) The CMPD lab policy is available in QAM 4.4.7.

18.2.8 Exceptions

a) There may be instances when non-sexual assault evidence items are pre-approved to be recommended for Y-STR testing. Case type, evidence type, autosomal results, and quantitation results will be evaluated to make these decisions.

b) Y-STR testing may be performed on additional case types after the case report has been published. This will be on a case-by-case basis and require consultation by the investigating officer with the Section Administrator or a Team Leader prior to submission of the service request.

c) There may be instances when previously interpreted data will be approved for reinterpretation using STRmix. Case type, evidence type, autosomal results, quantitation results, sample volume and reagent blank volume will be evaluated to make these decisions. These exceptions will be considered after the case report has been published. This will be on a case-by-case basis and require consultation by the investigating officer with the Section Administrator or a Team Leader prior to submission of the service request.

d) Case submissions related to evidence to be processed using the M-Vac will be performed in accordance with the CMPD Standard Operating Procedure.

e) The Section Administrator or a Team Leader may approve an exception to this Case Acceptance Policy, but it should be performed sparingly. If a particular exception is employed routinely, this manual should be amended to reflect the new policy.

f) If a case has been accepted in PLIMS, then the exception has been approved. The exception will be documented in PLIMS.

g) Familial searching requires both autosomal and Y-STR testing results. Y-STR testing may be performed on intimate and/or non-intimate items that qualify but

have no submitted suspect buccal standard. A meeting with the CODIS Administrator or back-up Administrator is required before a service request for Y-STR's can be submitted.

h) Additional testing may be required before a sample can be sent to an outside laboratory for forensic investigative genetic genealogy (FIGG). A service request indicating that the testing is for potential FIGG analysis must be submitted before testing will be conducted.

18.2.9 Outsourcing

a) To be considered for CODIS entry, all evidence sent to a vendor lab as part of an outsourcing agreement must comply with all relevant case acceptance and packaging requirements.

18.2.10 Rapid DNA

a) No forensic evidence processed by automated Rapid DNA Technology may be searched in or uploaded to CODIS at this time.
b) The laboratory will not accept reference or evidence DNA profiles generated by Rapid DNA instruments.
c) Regardless of the results obtained from Rapid DNA analysis, the laboratory will only accept items of evidence which meet the current Case Acceptance policy
d) The laboratory cannot provide a copy of DNA data in CODIS to law enforcement for searching and comparison to DNA profiles generated on a Rapid DNA instrument.
e) CMPD DNA Analysts cannot testify to any DNA analysis performed using a Rapid DNA instrument.
f) Samples must be collected in duplicate, simultaneously (i.e., two swabs). While one swab is processed on the Rapid DNA Instrument, the second must be available for testing through traditional DNA testing.
g) Samples processed in a Rapid DNA instrument will not be accepted by the Laboratory for re-processing.
h) Elimination samples should be collected from law enforcement employees that handle evidence, including samples run on Rapid DNA instruments.

19. Guidelines for Response to DNA Discovery Motions

General guidelines for the release of laboratory information are provided in Laboratory QM 4.13.1.3. Below is a clarification of these policies as they relate to the Biology section.

19.1 Case File Records

The Crime Lab provides a copy of the report and the paper case file as the initial discovery request. The original documents must remain with the case file in the laboratory file room or with a laboratory analyst. The electropherograms for the case file, the raw data files (.fsa or .hid), the STRmix run folders, and any additional electronic case file contents may be provided upon request, but do not require a court order.

19.2 Supporting Documentation

Non case specific supporting documentation requested for discovery may be outlined in a request from a prosecutor or court order. Voluminous supporting documentation will not be copied but will be made appropriately available. Examples of such supporting documentation include but are not limited equipment maintenance logs and reagent quality assurance records. A copy of validation summaries, analysts' proficiency testing summaries, and SOPs/QA Manuals may be provided electronically. These records will not be removed from the laboratory for any reason unless accompanied by a laboratory employee. An external party may view any of the above documentation at the CMPD headquarters building if access has been granted. A departmental official must be present during the review of the data by an external party.

19.3 Digital Records

Any computer records directly related to the case in question may be copied electronically for distribution to the court. CMPD will not provide access to computers, instrumentation, or software which is licensed to the Charlotte Mecklenburg Police Department.

19.4 Outsourcing Records

Copies of the report, case file and all raw data, and corresponding technical and administrative review documentation may be provided upon request. Additional materials will be requested through the applicable vendor laboratory.

20. CODIS Eligibility and General Guidance

CODIS (COmbined DNA Index System) is a collection of databases from forensic laboratories across the United States. The CODIS software is designed by and provided to CMPD by the FBI. Updates to the software may periodically be provided by the FBI and/or its contractors. DNA profiles of convicted offenders and forensic evidence are collected and maintained in files and compared to profiles collected from criminal evidence. CODIS consists of three levels: Local (LDIS), State (SDIS), and National (NDIS). Profiles collected at the local level that meet criteria for state searches are uploaded to SDIS. Profiles that also meet criteria for national searches are then uploaded to NDIS. Forensic autosomal profiles and suspect profiles will be entered into CODIS using the COSTaR workbook. Refer to Biology SOP 10 for guidance.

20.1 CODIS Administrator

One employee will be designated as the local CODIS Administrator and at least one employee will be designated as the back-up Administrator. The CODIS Administrator and back-up Administrator(s) must successfully complete CODIS software training within six months of assuming the position and FBI QAS auditor training within one year of assuming the position. The CODIS Administrator and back-up Administrator will maintain the FBI security clearance required to become a CODIS user and successfully complete the annual NDIS training. The CODIS Administrator will be responsible for management of the local database and will have all administrative rights, including, but not limited to: compliance with CODIS security requirements, compliance with QAS 17, ensuring CODIS users successfully complete the required Annual Review of DNA Data Accepted at NDIS training, upload of profiles to SDIS and review of CODIS generated reports, review and make best efforts to Disposition Matches in accordance with the NDIS Operational Procedures Manual, review and implementation of all CODIS materials and changes to NDIS Operational Procedures, backup of CODIS data, processing of incoming and outgoing search requests, and communication with other laboratories and law enforcement agencies regarding candidate matches. The CODIS Administrator will be responsible for ensuring the Biology section is in compliance with NDIS sample acceptance policy and for the completion of all paperwork required for participation in NDIS. The CODIS Administrator is also responsible for the review and/or approval, as appropriate, of procedures for the entry, searching, match resolution, and retention of DNA records in LDIS/SDIS, including those categories of DNA records that are not uploaded to NDIS. The CODIS Administrator also has the authority to terminate an analyst's, laboratory's, or when applicable, a Rapid DNA partner agency's participation in CODIS until the reliability and security of the computer data can be assured if an issue with the data is identified. Additionally, it is also the CODIS Administrator's responsibility to provide CODIS training to analysts and to inform analysts of any new NDIS procedures and software upgrades.

20.2 Definitions

This list only includes a sampling of definitions in use by the CMPD laboratory. The complete list of NDIS definitions can be found in the NDIS Operational Procedures Manual.

Arrestee: The known sample from a person who has been arrested and in accordance with the law of the applicable jurisdiction is required to provide a DNA sample for analysis and entry into a state DNA database. The term “arrestee” includes persons who have been charged in a formal criminal instrument such as an indictment.

Convicted offender: The known sample from a person who was been convicted of a Federal, Military, or State qualifying offense in a jurisdiction that requires that persons convicted of enumerated crimes or qualifying offenses provide a DNA sample for analysis and entry into a Federal, Military, or State database.

Core Loci: The twenty loci identified by the FBI for use in CODIS. The core loci are CSF1PO, FGA, TH01, TPOX, vWA, D3S1358, D5S818, D7S820, D8S1179, D13S317, D16S539, D18S51, D21S11, D1S1656, D2S441, D2S1338, D10S1248, D12S391, D19S433 and D22S1045.

The 13 original core loci consist of CSF1PO, FGA, TH01, TPOX, vWA, D3S1358, D5S818, D7S820, D8S1179, D13S317, D16S539, D18S51, and D21S11.

Note: Due to the large number of DNA records maintained at NDIS that have the 13 original core loci, NDIS searches will be based upon the original CODIS core loci. The following loci will be used as additional filters for searching: D2S1338, D19S433, D10S1248, D2S441, D12S391, and D1S1656. D22S1045 and SE33 are not included in the NDIS searches.

DNA record: A database record that includes the DNA profile as well as data required to manage and operate NDIS, i.e., the Originating Agency Identifier which serves to identify the submitting agency; the Specimen Identification Number; and DNA personnel associated with the DNA profile analyses.

Elimination (expected donor): A specimen that is voluntarily contributed by an individual for purposes of eliminating their alleles from a Forensic sample and consideration as the putative perpetrator(s). An expected donor sample includes a DNA sample voluntarily contributed by the victim(s) of the crime.

Forensic Mixture: A specimen category that originates from a forensic sample (biological sample found at the scene of a crime) that contains DNA contributed from more than one source attributable to a putative perpetrator(s).

A forensic mixture DNA record shall not have more than 4 alleles at any locus. Forensic Mixtures will consist of ambiguous alleles and/or alleles that are attributable to known suspect(s) and originate from non-suspect sources (vaginal swabs, victim's clothing, etc.). Alleles that can be unambiguously attributed to victims or to expected donor samples will not be entered. Any loci in which ambiguity exists in the assignment of alleles to the putative perpetrator (i.e., potential masking, alleles of similar peak height, STRmix genotypes which include conditioned contributor alleles, etc) may be entered at the analyst's discretion.

Forensic Partial: A profile originating from a single source (or a fully deduced profile originating from a mixture) forensic sample attributable to the putative perpetrator with either locus or allelic dropout at any of the 13 original core CODIS loci. There cannot be more than 3 alleles at one locus while the remaining loci can have up to 2 alleles (this allows for one true tri-allelic pattern.

Forensic Targeted: A forensic partial or a forensic mixture that does not meet the NDIS moderate match estimate threshold of 1 in 10 million but does meet the match rarity estimate threshold of 1 in 10 million if searched at a specified stringency by locus (high or moderate).

Forensic Unknown: A profile originating from a single source (or a fully deduced profile originating from a mixture) forensic sample attributable to the putative perpetrator and contains results for 13 original core CODIS loci. There cannot be more than 3 alleles at one locus while the remaining loci can have up to 2 alleles (this allows for one true tri-allelic pattern).

Unidentified Human: The DNA profile from the recovered deceased (including body parts and tissue) or an individual who is unidentified (e.g., children who can't and others who can't or refuse to identify themselves).

20.3 General guidance

20.3.1 Acceptable Samples for Entry

1. Buccal standards submitted either as expected donor standards or packaged in elimination envelopes will not be used for CODIS entry. Additionally, expected donor standards, as well as victim standards, will only be compared to evidence profiles in the case under which they were submitted and will not be used for comparison to evidence profiles generated in other cases. Exceptions may occur; however, this will be at the discretion of the Biology Section Supervisor or a DNA Team Leader and will be documented in the case file. A consultation with the CODIS Administrator or back-up CODIS Administrator may be needed to determine CODIS eligibility. Instances may occur where a profile is initially entered as a Forensic sample with Source ID = no and is later determined to be consistent with a submitted expected donor sample; the Forensic profile will be removed from CODIS. If a buccal standard has been submitted and it is not

known whether it should be classified as an expected donor sample, the investigator must be contacted and the supporting documentation placed into the case file. In certain situations, it may be reasonable to expect an individual is present in a forensic DNA profile and their reference profile may be used to condition the forensic profile during STRmix analysis. Therefore, it is important to ascertain how each person being submitted for testing is involved in a crime and if there is reasonable expectation for their DNA to be on an item.

2. Missing persons and unidentified human remains cases will generally be sent to an FBI-approved external laboratory for analysis. Since data may consist of various DNA technologies, data entry will be conducted in coordination with the external laboratory. Data entry may be done exclusively by the external laboratory. Refer to Biology SOP 10 for additional information regarding unidentified human remains cases.

3. Samples from biological relatives will be stored in the Relatives of Missing Person Index. These profiles are not able to be uploaded to SDIS; therefore, coordination of STR data entry is necessary with other external laboratories (i.e. mitochondrial DNA testing is being conducted on the sample for NDIS upload). Once the individual has been identified for which this biological relative sample is in the index, the biological relative profile must be removed.

4. DNA records submitted to the Forensic, Forensic Mixture, or Forensic Partial Indexes at NDIS shall only offer those alleles that are attributed to the putative perpetrator(s). Alleles derived from forensic DNA records that are unambiguously attributed to a victim or individuals other than the perpetrator(s), such as an elimination (expected donor) sample, shall not be offered to NDIS.

5. Known reference samples from individuals identified as a suspect in an investigation will be entered as Suspect Knowns. In addition, samples that originate from a source attributable to the suspect (such as the suspect's profile on the suspect's own clothing, cigarette butts, chewing gum, etc.) will also be classified as suspect knowns as opposed to forensic unknowns. For purposes of NDIS eligibility, an item taken directly from a suspect or the suspect's possession shall not be considered a forensic sample.

    a) Mass screening samples (those collected from known individuals that have been obtained through DNA dragnets in an effort to solve a crime) will not be entered.

    b) No samples will be entered into the Suspect Known index without proper documentation. This documentation will normally consist of a CMPD laboratory Service Request with the subject's name listed in the Suspect Information box. Written documentation, such as a memo or email from the investigator or the KBCOPS suspect report, will suffice so long as the subject's name is listed in the document and is confirmed to be a suspect.

In the absence of acceptable documentation, the known sample will be treated as an expected donor standard and any matching evidentiary profiles will be treated in a corresponding manner. An alternate standard submitted as a suspect reference sample will not be entered into CODIS or the Suspect with DNA Profiles at CMPD database. An alternate standard DNA profile will only be compared in the case under which it was submitted.

6. The CMPD laboratory requires data present above analytical threshold in at least seven autosomal loci to be an interpretable profile; therefore, profiles with any less than seven loci will generally not be entered into CODIS. Documentation of CODIS entry exceptions will be noted in the case file by the CODIS Administrator or back-up Administrator.

7. No forensic samples will be entered into the Forensic Unknown, Mixture, or Partial Indexes without proper eligibility documentation. Sufficient eligibility documentation must consist of the following: a crime must have occurred, the profile must be generated from evidence items collected from a law enforcement agency, documentation exists showing how the evidence item is linked to the suspect of the crime, and the item must not have been collected from the suspect's person or in the possession of the suspect when collected. This may entail a review of the item description in PLIMS, the crime scene report, and the investigator's report. It may be necessary to consult with the case investigator if the crime scene report or investigator's report cannot be accessed through the online KBCOPS reporting system. Supporting eligibility documentation will be placed in the case file if not already present. Although the CODIS Administrator or back-up CODIS Administrator approves CODIS entries prior to a case file being turned in for technical review, casework analysts will also be responsible during technical review for verifying a profile is allowable for upload to NDIS. If the profile is determined to be unallowable at NDIS (for example, the profile was obtained from evidence that could not be linked to the crime scene), then it will not be entered into CODIS and will be considered suitable for comparison purposes only. If a profile is entered into CODIS and then later found to be unallowable at NDIS, the profile will be removed from CODIS. The CODIS Administrator will provide NDIS-acceptable data training to analysts as needed. Documentation that training was completed will be maintained by the CODIS Administrator.

8. Individuals that are at least 18 years old are considered adults as it relates to CODIS entry; however, there are instances where individuals that are between 16-18 years old can be entered into CODIS. In general, juvenile suspects less than 18 years of age cannot be entered into CODIS and the CODIS Administrator or back-up Administrator should be consulted prior to entry. The initials of the Administrative reviewer on the DNA case review checklist will also serve as an indication that the date of birth of the suspect has been reviewed for eligibility into CODIS.

If there is documentation that a juvenile suspect has been charged as an adult, any forensic profile (meeting all other eligibility requirements) that matches the juvenile suspect can be entered into CODIS. If there is no documentation that the juvenile has been charged as an adult, any forensic profile that matches the juvenile suspect cannot be entered into CODIS. Instances may occur where a juvenile suspect is initially charged as a juvenile and is later transferred to adult court for trial; forensic profiles not originally entered into CODIS due to the initial juvenile charge may later be considered for entry into CODIS.

The exception to this is for forensic profiles obtained from sexual assault kit samples that are consistent with a juvenile suspect. In this instance, the forensic profile(s) will be entered into CODIS with source ID = yes. All other CODIS entry eligibility requirements must be met. This applies only to profiles derived from items submitted in the SAK (including underwear collected during the SANE exam) and not profiles submitted from non-intimate items collected as part of the case. Unless the juvenile suspect has been transferred to adult court the DNA profile derived from a juvenile suspect buccal cannot be entered into CODIS.

9. For forensic profiles developed from “touch” items, standards from expected donors must be submitted as applicable before the profile can be entered into CODIS (for example, a car owner(s) whose car was stolen). A profile developed from a “touch” item left at the crime scene by a suspect may not require expected donor standards to be submitted.

10. If a profile developed from forensic evidence is not initially entered into CODIS and then it is entered at a later time, a laboratory report will be issued to notify the investigator that the profile has been entered into CODIS and is being searched on a routine basis.

11. As defined by NDIS, a composite DNA profile is one that is generated by combining typing results from different loci obtained from multiple injections of the same amplified evidentiary sample and/or multiple amplification of the same DNA extract from an evidentiary sample. Composite profiles are allowed to be uploaded to NDIS. Any STRmix interpretation performed using replicate amplification is considered a composite profile. These profiles may be entered into CODIS provided all other CODIS eligibility criteria are met. Multiple injections of the same amplified product or amplified product from re-extractions are not considered replicates and should not be combined within STRmix. Composite profiles will not be created from multiple injections and the analyst should select the most informative profile for interpretation and CODIS entry.

12. Data generated on the 3500 Genetic Analyzer instruments using GlobalFiler that was previously reported as not suitable for comparison in whole or part may be reinterpreted using STRmix on a case-by-case basis with approval by the DNA

Technical Leader or designee. Additionally, samples analyzed with legacy data (data generated prior to GlobalFiler amplification on the 3500 Genetic Analyzer) with lab work completed prior to approximately October 1, 2019 may potentially be re-amplified in GlobalFiler for interpretation using STRmix with DNA Technical Leader or designee approval. In conjunction with making the decision to re-analyze and/or re-interpret samples for CODIS entry purposes, CODIS eligibility must be verified by the CODIS Administrator or back-up Administrator prior to testing. The CODIS Administrator or back-up Administrator will document in the case file if a sample is eligible for entry.

13. Evidence analysis may periodically be outsourced to a vendor laboratory. The use of the vendor laboratory must comply with Standard 17 of the FBI QAS Standards. In general, CODIS entry eligibility will be reviewed prior to a case being sent for outsourcing; however, in some circumstances CODIS entry eligibility may instead be conducted upon return of the data from the outsourcing laboratory. Upon data review by a qualified analyst in the CMPD Biology section and prior to entering a profile(s) into CODIS, a staff database search will automatically be done in STRmix for all deconvoluted profiles. This search will include profiles that are ultimately deemed uninterpretable. The DNA profile will be considered the property and responsibility of the CMPD Biology section.

14. Forensic profiles obtained from sexual assault cases where the victim has had consensual intercourse < 120 hours before the alleged incident may be entered into CODIS provided a standard from the consensual partner has either been submitted or requested and all other current NDIS entry eligibility requirements are met. A DNA analyst must evaluate the need for a consensual partner standard. Requests for consensual partner standards from juvenile victims (less than age 16) do not need to be made unless the sexual assault kit forms indicate the juvenile victim had a consensual partner within 120 hours of the alleged assault occurring.

    The following can serve as a guide for when to request a consensual partner standard:

    - Consensual intercourse has occurred within 120 hours of the alleged incident and neither suspect or consensual partner standards were submitted.
    - It is unknown if previous consensual intercourse occurred within the previous 120 hours.
    - A profile does not match the submitted suspect standard, no consensual partner standards were submitted, and the kit forms support the last consensual intercourse being < 120 hours.
    - The sexual assault evidence collection kit has been collected from the victim of a homicide.

    If it is determined a consensual partner standard may be needed, an email to the case detective requesting that standard must be sent prior to turning a case

file in for a sexual assault kit check and/or CODIS eligibility verification. The email will be placed in the Administrative portion of the case file. The email will suffice as to the request being made and the consensual partner standard does not need to be requested in the report.

The email request to the detective should be modeled after the following:

If consensual intercourse has occurred within 120 hours:

The medical history/sexual assault paperwork for the case(s) below indicate the alleged victim had a consensual partner within 120 hours of the alleged incident.

If it is unknown if consensual intercourse occurred within 120 hours:

In the following case(s), "unknown", "unsure", or no information was indicated in the case paperwork; therefore, we were unable to determine if a consensual partner may be involved. If this information is available, please contact the Biology section.

For both situations, the following statement will also be included in the email to the detective:

The listed case(s) is currently undergoing testing and if a CODIS eligible profile is obtained, the profile will be uploaded to CODIS. Please submit available consensual partner standards to the Biology section for analysis. DNA profiles uploaded to CODIS will be removed if subsequent analysis determines the DNA profile is consistent with a consensual partner.

All sexual assault case files will be reviewed by the CODIS Administrator or back-up Administrator (or designee, if necessary) prior to being turned in for technical review to ensure all necessary paperwork (including consensual partner requests) is present in the file. The review will be documented on the DNA Case Review Checklist and will be done regardless of whether a profile is being entered into CODIS or not. If the suspect in a sexual assault case is female and a sexual assault kit has been collected from her then a review of the paperwork by the CODIS Administrator or back-up is not necessary. Case file paperwork review applies only to alleged victims of sexual assaults and not suspects.

If a submitted suspect profile is not consistent with the forensic profile, the case scenario should be used to determine if the forensic profile is eligible for CODIS entry.

15. If evidence has been sent to an outside lab for DNA testing after having previously been examined by the Biology, Firearms, or Latent Prints sections any profiles obtained from touch DNA will be suitable for comparison only and not

eligible for CODIS entry. Profiles obtained from a body fluid may be considered for CODIS entry.

20.3.2 Sample Entry and Upload

1. Called alleles that have been generated through amplification with the GlobalFiler kit will be entered as designated by the GeneMapper software. All CODIS entries will be based on the standardized NDIS allelic ladders. Those loci that are ignored in STRmix due to having alleles that are outside of the standardized NDIS ladder range will not be entered into CODIS. Refer to SOP 10 for additional guidance.

2. Any modifications to previously marked and uploaded profiles will be documented and noted in the appropriate case file by the CODIS Administrator or back-up Administrator.

3. Incremental uploads will be performed as scheduled in coordination with the State CODIS Administrator. A full upload will be performed yearly in coordination with the State CODIS Administrator.

4. With approval of the CODIS Administrator or back-up Administrator, an analyst may use a profile or a contributor to condition a forensic profile for CODIS entry purposes only. The CODIS Administrator or back-up CODIS Administrator must document that the assumption of a profile or contributor is approved for CODIS entry purposes only.

5. All CODIS eligible profiles will be entered into the Non-reviewed profiles specimen category prior to turning a case file in for technical review. All CODIS entries will be unmarked by default and will not be marked and uploaded until technical review is complete.

6. When specimen categories are updated and profiles are marked for upload the CODIS Administrator or back-up CODIS Administrator will run a query in the CODIS software to verify that all profiles that should be marked and uploaded have not been inadvertently left in the unmarked status.

7. Approximately once per quarter the CODIS Administrator or back-up Administrator will run a query of profiles in the non-reviewed profiles category. This will be done as a quality check to ensure that no profiles are inadvertently being maintained in this category when they should have previously been marked and uploaded.

20.3.3 Cold Case Profile Entry

1. It is recognized that with cold cases the acquisition of any and/or all expected donor standards may not be possible. However, requests for expected donor standards in cold cases must be made to the assigned investigator and that request must be documented.

2. No forensic samples will be entered into the Forensic Unknown, Mixture, or Partial Indexes without proper eligibility documentation. Sufficient eligibility documentation must consist of the following: a crime must have occurred, the profile must be generated from evidence items collected from a law enforcement agency, documentation exists showing how the evidence item is linked to the suspect of the crime, and the item must not have been collected from the suspect's person or in the possession of the suspect when collected. This may entail a review of the item description in PLIMS, the crime scene report, and the investigator's report. It may be necessary to consult with the case investigator if the crime scene report or investigator's report cannot be accessed through the online KBCOPS reporting system. Supporting eligibility documentation will be placed in the case file if not already present. If sufficient eligibility documentation is lacking the CODIS Administrator or back-up Administrator will determine if a profile may be entered into CODIS and that decision will be documented.

3. Forensic profiles must meet all other current NDIS entry eligibility criteria in place at the time of sample entry.

4. If a forensic profile is entered into CODIS and then later found to be unallowable at NDIS (i.e. a forensic sample was found to be consistent with a submitted expected donor sample), the profile will be removed from CODIS.

5. Requests by investigators to re-evaluate DNA profiles previously generated but not entered into CODIS (i.e. the case has become classified as a cold case) will be reviewed and eligibility determined by the CODIS Administrator or back-up Administrator.

6. Report data entered into KBCOPS for crimes that were reported prior to the implementation of KBCOPS in 2001 will be designated as Cold Case Investigations and classified as non-criminal due to these crimes having previously been reported. A search of PMNI will show the criminal offense associated with the case number. However, PLIMS must reflect a criminal classification prior to a report being issued and may not be reported as non-criminal.

20.4 Searches

1. Autosearches of profiles in the casework LDIS Indexes will be performed by the CODIS Administrator or back-up Administrator when profiles are marked for upload. Autosearches at the State level will be performed in coordination with

the State lab. Autosearches at the Federal level will be coordinated by the Federal laboratory.

a) Additional searches

1. A one-locus mismatch search in the LDIS Indexes will be conducted twice per year.
2. Local keyboard searches of casework profiles may be performed by the CODIS Administrator or back-up Administrator if necessary (i.e. priority cases). Keyboard searches will only be performed after technical review of the case file has been completed. NDIS procedural guidelines will be followed for any keyboard search request at the State or National level.
3. The Emergency Upload and Search request feature of CODIS allows the immediate search of a profile at NDIS when public safety cannot wait for the routine upload to search at NDIS.
4. Approximately once per quarter the CODIS Administrator or back-up Administrator will run a query in the CODIS software for matches with a pending disposition; this will be done as a quality check to ensure all matches have been reviewed and resolved.

2. It is recognized that profiles may be obtained from evidence that do not meet NDIS entry eligibility criteria by having too few loci or not meeting the match estimator threshold; however, the profile may be considered critical to the case. These will be handled on a case-by-case basis by the CODIS Administrator or back-up Administrator to determine if the profile could potentially be entered or if a one-time search could be conducted at LDIS only. A one-time search will not be conducted if an association cannot be made linking the evidence to the crime. Documentation of CODIS entry exceptions will be noted in the case file by the CODIS Administrator or back-up Administrator. The one-time search at LDIS will be done by the CODIS Administrator or back-up Administrator at the completion of Administrative review. One-time searches at SDIS or NDIS will only be requested if a forensic profile does not meet the minimum number of original core loci for uploading to NDIS but does contain at least 7 of the original core loci and has a match rarity of one in ten million. Necessary paperwork in the case file to show the one-time search was done may consist of the Match Detail Report, the DNA search request form (as found on the CODIS website), email confirmation that the request was received by the State lab, and any associated paperwork should a match occur.

   If a one-time search is conducted, the following wording will be used in the case report: *The DNA profile obtained from [Item] is not eligible for entry into the* [State/ National] *Combined DNA Index System (CODIS) at this time; however, a one-time search will be conducted. Any associations will be the subject of a separate report.*

3. If there is potential for a suspect in an unsolved case to have international connections, the CODIS Administrator or back-up Administrator may submit the profile(s) for Interpol searching following NDIS guidelines.

4. Profiles generated from Officer Involved Shooting (OIS) cases will be reviewed on a case-by-case basis by the CODIS Administrator or back-up Administrator to determine if any profiles are eligible for CODIS entry and/or searching.

5. Any profiles entered into CODIS will be reported in the analyst's case report. It will also be reported that any associations resulting from searches will be the subject of an additional report.

6. Y-STR profiles are not independently searched in CODIS; therefore, searches will be based only on the core autosomal loci.

20.5 Maintenance of an Employee (Staff) DNA Index

The laboratory will maintain a DNA index of employees for use in comparison to unknown alleles/profiles generated from evidence to determine if any evidentiary profiles originated from a CMPD employee. This database will consist primarily of employees of Crime Scene Search, Crime Scene Officers, Detectives, and the Crime Laboratory, although others (i.e. lab visitors) may be added if appropriate.

Employee profiles will only be used for quality control measures or for CMPD forensic protocol development purposes (i.e. validation studies). These profiles will be maintained in a local Staff Index and will not be uploaded to SDIS. Upon entry of an employee's profile into the Staff Index, it will be marked with an anonymous personal identifier code which has been assigned by the CODIS Administrator or back-up Administrator. The CODIS Administrator, back-up Administrator, and Section Administrator shall maintain the only record which correlates individuals' names with personal identifier codes. Although employee standards may be typed by any qualified Biology section analyst, all Staff profiles will be entered into the Staff Index by the CODIS Administrator or back-up Administrator. A qualified DNA analyst will review profile entry for accuracy. As new Staff profiles are entered into the Index the CODIS Administrator or back-up Administrator will conduct an Autosearch against all previously entered forensic profiles. On a monthly basis, new staff profiles (if applicable) will be exported out of the CODIS database and transferred to the computers with STRmix software; therefore, staff profiles will be housed in multiple locations. Upon import of staff profiles into STRmix, it will be verified that the number of staff profiles in CODIS and STRmix are consistent.

20.5.1 Conducting searches against the Staff Index

1. A staff database search will automatically be done for all profiles that are deconvoluted in STRmix. This search will include profiles that are ultimately

deemed uninterpretable. A keyboard search of the Staff Index database in the CODIS software will be conducted for alternate known standards that do not match any forensic evidence profiles in the case. Alternate known standards are not able to be searched against the STRmix staff database, thereby necessitating the need for a manual search in the CODIS database.

2. If the search returns a likelihood ratio (LR) above the minimum LR value of 1,000 for deconvoluted profiles searched against the STRmix staff database or if any matches are returned for profiles searched against the Staff Index in the CODIS database, the analyst will immediately notify the CODIS Administrator or the back-up Administrator to resolve the match. If a match of a forensic profile to a profile in the STRmix staff database or CODIS Staff Index cannot be resolved the Section Administrator and the Technical Leader will be informed. If the match is to a Biology section employee, a Contamination Contingency Plan will be initiated. If the match is to an employee outside of the CMPD Biology section, that employee and that employee's supervisor will be notified. Documentation of this notification will be maintained in the case file. If no sample remains, lab re-work has been exhausted without remedying the issue, and the employee buccal standard is not submitted as evidence, the profile will be reported as not meeting the quality control measures needed for comparison. The profile may be used for interpretation and direct comparison (provided Technical Leader or designee approval) if the employee to whom the match was made provides a buccal standard to be collected as evidence, submitted to Property Control, and analyzed as a case sample. If requested, the employee's identity will be protected, and the buccal standard may be collected and reported using an anonymous unique identifier. There may be instances when an employee is unable to provide a buccal standard (i.e. retirement, resignation, etc.). This will be addressed on a case-by-case basis. If the employee involved is a laboratory employee, discussions may involve the Laboratory Director. Any possible matches to visitor/non-CMPD employees will be addressed on a case-by-case basis.

3. Staff profiles with personal identifier codes between 1 and 112 were previously entered into CODIS without Amelogenin results. The STRmix software automatically defaults the Amelogenin locus to X,X; therefore, the allele designation at this locus may be incorrect for the named individual.

20.6 Generation of Investigative Leads

Investigative leads may be generated either by LDIS, SDIS, or NDIS matches. A match occurs when CODIS makes an association between two or more DNA profiles and a confirmation process is started. A hit occurs when a confirmed or verified match aids an investigation and one or more of the cases(s) involved in the match is unsolved. All potential hits produced by the LDIS, SDIS, and NDIS searches are printed and reviewed concurrently by the CODIS Administrator or back-up CODIS Administrator. The procedure for confirming the match will differ depending on the location of the match.

All match reports will be reviewed for administrative and/or technical content before being issued to the investigator. At a minimum, the report will be administratively reviewed for clerical errors and to ensure the information being reported is accurate. The reviewer must currently be a qualified DNA analyst and technical reviewer who is proficient in the current technology. Verification that the match report and supporting documentation was reviewed will be captured electronically in PLIMS. The match detail reports from those matches that are awaiting offender or casework confirmation and reporting will be maintained chronologically in a CODIS binder located at the CODIS Administrator's desk. All associated paperwork will then become part of the case file associated with the CODIS match report that is released to the investigator.

20.6.1 LDIS Matches

Should a match or matches be determined between cases analyzed within the CMPD laboratory, the following will occur:

1. The source ID of the samples will be checked and determination of a match will occur within 30 days. The CODIS Administrator or back-up Administrator will be responsible for all match resolutions. Mixture profiles or forensic partial profiles that match in CODIS and are questionably a true match will be assessed by at least two analysts (typically the CODIS Administrator and back-up Administrator). The analyst assigned to a specific profile may be consulted as necessary.

2. The data from the appropriate case files will be examined. A copy of the Match Detail Report will be placed in the appropriate case file(s) if it is determined a hit has occurred.

3. The profile will be checked by the CODIS Administrator or back-up Administrator to ensure that it is allowable at NDIS. Supporting eligibility documentation will be placed in the case file if not already present. If the profile is determined to be unallowable at NDIS (for example, the profile was obtained from evidence that could not be linked to the crime scene), the sample will be deleted from the system and appropriate documentation will be placed in the case file. If the profile is allowable at NDIS, the process will continue.

4. In general, a match report will be issued to the investigator regardless if source ID is "yes" or "no". Instances may occur where a match report may not be issued (i.e. linkage of cases was known to the investigator prior to the search occurring). Matches may be generated prior to completion of administrative review of a file; however, match reports will not be issued until both technical and administrative reviews have been completed in PLIMS. Copies of all relevant data will be placed in the appropriate files.

5. Should it be determined after the hit report has been issued that the source of the sample is one that would normally disqualify the sample from CODIS entry

(for example, the source would be classified as an elimination), the sample will be deleted and the appropriate documentation will be placed in the case file.

6. Matches will initially be given a disposition of “Pending”. Upon match confirmation, the disposition of the match will be changed accordingly. Updates to the match can be viewed in the match audit trail in the CODIS program. The CODIS Administrator or back-up Administrator will change the Source ID field for a specimen from “No” to “Yes” as necessary.

7. If a match occurs to a partial profile obtained from a suspect standard, the match will be reported; however, the partial profile will not be used for comparison purposes. A new buccal standard from the associated individual will be requested in the match report. Exceptions to using the suspect partial profile for comparison may be made on a case-by-case basis and in consultation between the CODIS Administrator, Technical Leader, and Chief Criminalist. Any exceptions will be documented in the case file. Suspect profiles entered into CODIS as “partial = yes” may be used for comparison when the reason for the partial status is due to a locus that has been omitted from entry (example: tri-allele).

8. LDIS match report wording

   Report wording should be modeled after the following:

   “Items Previously Reported” will be used in the report to list evidence items associated with the CODIS match being reported.

   For a Local case-to-case forensic hit: A search of the Local CODIS database generated a match to the DNA profile obtained from [contributor #] from [*item*] (DNA #). The following case information is provided as an investigative lead:

   Complaint #:
   Investigator:
   Sample:

   Any connection between these cases must be determined through further investigation. DNA comparisons can be conducted following the submission of a known DNA standard from a suspect to the Laboratory.

   For a Local hit to the suspect database: A search of the Local CODIS database generated a match to the DNA profile obtained from [contributor #] from [*item*] (DNA #). The following case information is provided as an investigative lead:

   Complaint #:
   Investigator:

Sample: [*Buccal standard*] from [*Name*]

Any connection of this individual to the case must be determined through further investigation. DNA comparisons can be conducted following the submission of a known DNA standard from a suspect to the Laboratory.

If you determine that this individual is not a subject of your investigation (i.e. consensual partner or witness), please contact the Biology section so that this profile can be removed from CODIS.

For a Local suspect buccal to a case hit: A search of the Local CODIS database generated a match to the DNA profile obtained from [item] (DNA #). The following case information is provided as an investigative lead:

Complaint #:
Investigator:
Sample:

Any connection between these cases must be determined through further investigation.

20.6.2 SDIS and NDIS Matches

Should a match be determined between a CMPD case and a sample analyzed outside the laboratory, the following will occur:

1. The source ID of the samples will be checked. If the Source ID = No, the confirmation process will be initiated by the CODIS Administrator or back-up Administrator within 30 days of the match. The CODIS Administrator or back-up Administrator will be responsible for all match resolutions.

    a) Mixture profiles or forensic partial profiles that hit in CODIS and are questionably a true match will be assessed by at least two analysts (typically the CODIS Administrator and back-up CODIS Administrator). The analyst assigned to a specific profile may be consulted as necessary.

    b) The appropriate CMPD match data request form (found in Biology QA 19) will be used for offender and arrestee confirmation requests to NDIS laboratories. An email to the State laboratory will suffice for offender and arrestee confirmation requests for SDIS matches.

    c) An email to the SDIS or NDIS lab will suffice when requesting information for casework matches.

d) The match data request and the accompanying request email will be maintained in the appropriate case file(s).

2. The data from the appropriate case files will be examined. A copy of the Match Details Report will be placed in the appropriate case file(s) if it is determined a hit has occurred.

3. The profile will be checked by the CODIS Administrator or back-up Administrator to ensure that it is allowable at NDIS. Supporting eligibility documentation will be placed in the case file if not already present. If the profile is determined to be unallowable at NDIS (for example, the profile was obtained from evidence that could not be linked to the crime scene), the sample will be deleted from the system and appropriate documentation will be placed in the case file. If the profile is allowable at NDIS, the process will continue.

4. All profiles with source ID = no will be confirmed and reported. Copies of all relevant data will be placed in the appropriate file(s); this information will also be scanned and uploaded to PLIMS.

5. In the event of an offender match, the CODIS Administrator or back-up Administrator will request confirmation of the match from the offender laboratory. The hit will be confirmed by re-analysis of the convicted offender sample by the offender databasing laboratory. The CODIS Administrator will receive a report from the offender laboratory. A match report will be issued to the investigator within 14 days of receipt of personally identifying information. Matches may be generated prior to completion of administrative review of the original file; however, match reports will not be issued until both technical and administrative reviews have been completed in PLIMS. If the investigator chooses to pursue the investigation, he/she will be required to submit a known sample from the matching individual to the laboratory. Analysis will generally be performed by the original casework analyst, if available, and a report will be issued detailing the comparison between all comparable DNA profiles generated in the case and the known sample.

   In instances where Source ID = Yes and the match is to an offender, the name of the individual must be verified with the offender laboratory. If the names of the individuals are the same the match will be given a disposition of “Conviction Match”. The match detail report and the accompanying verification email will be scanned and maintained on the CMPD R drive and electronically by the CODIS Administrator and Section Administrator. Information regarding the confirmation of the offender name will also be maintained on the Conviction Match Verifications spreadsheet on the CMPD R drive.

6. In the event of a casework match (regardless if source ID = “Yes” or “No”), the CODIS Administrator or back-up Administrator will exchange contact information

with the external laboratory. A match report will be issued to the investigator. Matches may be generated prior to completion of administrative review of the original file; however, match reports will not be issued until both technical and administrative reviews have been completed in PLIMS. If an external laboratory requests CMPD case information, the case information will be released using a match data casework response form (found in Biology QA 19). The match data information will be administratively reviewed by a qualified DNA analyst proficient in the current technology prior to the CODIS Administrator or back-up Administrator sending the information to the external laboratory. The review will consist of checking for clerical errors and accuracy of information being released. Upon completion of the review, the reviewer will initial and date the official correspondence. The correspondence may be sent to the external lab by mail, fax, or email with either the original or a copy maintained in the case file.

7. Should it be determined after the hit report has been issued that the source of the sample is one that would normally disqualify the sample from CODIS entry (for example, the source would be classified as an expected donor), the sample will be deleted and the appropriate documentation will be placed in the case file.

8. Matches will initially be given a disposition of “Pending”. Upon receipt of match confirmation from the external laboratory, the disposition of the match will be changed accordingly. Updates to the match can be viewed in the match audit trail in the CODIS program. The CODIS Administrator or back-up Administrator will change the Source ID field for a specimen from “No” to “Yes” as necessary.

9. The CODIS program allows for the entry and search of mitochondrial DNA and Y-STR DNA profiles. If potential hits occur using these technologies, the CODIS Administrator or back-up Administrator will contact the lab where the match occurred for guidance in resolving and dispositioning these matches.

10. If notification is received from the State lab or a NDIS lab that identifying information regarding an offender or arrestee can only be released via court order that information will be provided to the case detective via email notification. The notification email should then be attached in PLIMS.

11. Occasionally, an arrestee match may occur where the arrestee’s sample would have been eligible for expunction at the time that the match occurred. The State lab generally reports the identifying information along with an expunction statement. In these instances, a match report will be issued with the arrestee’s personally identifying information. The expunction statement will be included in the report issued to the investigator. Examples of this statement include the below:

    Per the North Carolina State Crime Laboratory:

a) "The subject's DNA sample and record would have been eligible for expunction under N.C.G.S. § 15A-266.3A as of the time the hit occurred. The hit occurred subsequent to the expiration of the 120-day total statutory period set forth in N.C.G.S. § 15A-266.3A(j), (k). Under North Carolina law, "[a]ny identification, warrant, probable cause to arrest, or arrest" resulting from this hit "shall be invalid and inadmissible in the prosecution of the defendant for any criminal offense." N.C.G.S. § 15A-266.3A(m)."

b) "The subject's DNA sample and record would have been eligible for expunction under N.C.G.S. § 15A-266.3A as of the time the hit occurred. The hit occurred prior to the expiration of the 120-day total statutory period set forth in N.C.G.S. § 15A266.3A(j), (k)."

12. SDIS/NDIS match report wording

Report wording should be modeled after the following:

"Items Previously Reported" will be used in the report to list evidence items associated with the CODIS match being reported.

For a State or National case-to-case forensic hit: A search of the [*State/National*] CODIS database generated a match to the DNA profile obtained from [contributor #] from [*item*] (DNA #). The following case information is provided as an investigative lead:

Investigator:
Agency:
Address:
Email:
Phone:
Agency case #:
Case type:
Date of offense:
Sample:

Any connection between these cases must be determined through further investigation.

For a State or National offender/arrestee hit: A search of the [*State/National*] CODIS database generated a match between the DNA profile obtained from [*item*] (DNA #) and *[State/Federal]* convicted offender/arrestee/detainee specimen # [ ]. The DNA database sample was re-examined and confirmed by the *[state lab agency].* This individual is identified as:

[Name]
A.K.A.'s:
DOB:
SSN:
[State] SID #:
FBI #:
Race:
Gender:

This information is provided as an investigative lead, and any connection of this individual to the case must be determined through further investigation. In order to confirm this match, it will be necessary for you to submit a known DNA standard from *[Name].*

If you determine that this individual is not a subject of your investigation (i.e. consensual partner or witness), please contact the Biology section so that this profile can be removed from CODIS.

For a State hit to the suspect database: A search of the State CODIS database generated a match to the DNA profile obtained from [contributor #] from [*item*] (DNA #). The following case information is provided as an investigative lead:

Investigator:
Agency:
Address:
Email:
Phone:
Agency case #:
Case type:
Date of offense:
Sample: [*Buccal standard*] from *[Name]*

Any connection of this individual to the case must be determined through further investigation. In order to confirm this match, it will be necessary for you to submit a known DNA standard from *[Name].*

If you determine that this individual is not a subject of your investigation (i.e. consensual partner or witness), please contact the Biology section so that this profile can be removed from CODIS.

For a State suspect buccal to a case hit: A search of the [*State/National*] CODIS database generated a match to the DNA profile obtained from [*item*] (DNA #). The following case information is provided as an investigative lead:

Investigator:
Agency:
Address:
Email:
Phone:
Agency case #:
Case type:
Date of offense:
Sample:

Any connection between these cases must be determined through further investigation.

20.6.3 Familial Searches

Familial searching may provide investigative information to law enforcement agencies in unsolved cases where all other investigative leads have been exhausted. A familial search is a deliberate search of the North Carolina State DNA Database for the purpose of identifying close biological relatives of the evidentiary profile. If a DNA profile obtained from crime scene evidence and an offender or arrestee share enough similarities it is possible that the source of the crime scene profile could have originated from a close relative of the offender. Familial searching uses DNA analysis and interpretation to provide additional information as to the likelihood that two individuals may be related. The North Carolina State Crime Laboratory (NCSCL) has implemented procedures to conduct familial searches. Familial searches cannot be conducted at the CMPD laboratory and will only be conducted at the NCSCL. Outside agency cases worked by the CMPD lab will be coordinated with the required individuals associated with the outside agency.

1. Any potential cases to be considered for a familial search will be coordinated with the NCSCL and will follow their familial search request guidelines. The only cases to be considered for familial searching will be those that are unsolved violent crimes against a person, such as homicide, felony sexual assault, other violent felonious crimes that have significant public safety concerns, unidentified human remains, and paternity criminal prosecution (i.e. when parent of a child needs determined). Property crimes will not be considered. Case evaluation (including suitability for Y-STR testing) will be conducted by the CODIS Administrator or back-up Administrator at the request of Investigations. The NCSCL will determine the frequency that familial search requests may be submitted. The criteria to be included in the evaluation of familial searching suitability include:

a) The DNA profile is from a biological male.

b) The DNA profile is from a single source or deduced/major single source profile from a mixture. Profiles may be adjusted to remove obligate alleles or partial loci for familial searching purposes only as long as complete results remain with at least 8 of the original core loci.
c) Partial profiles and minor profiles may be considered if complete results are obtained at 8 or more of the original CODIS core loci.
d) Mixture profiles cannot be considered for familial searching.
e) Y-STR testing has been or can be performed in the case. If no extract remains for Y-STR testing, a request for familial searching will be rejected. Consideration may be given if a sample can be re-extracted.
f) The DNA profile currently resides in the National CODIS database and has been searched against the National and other state databases with no investigative leads returned.

2. The NCSCL requires that all DNA profiles that meet the above criteria will be required to develop a Y-STR profile. Single source profiles must contain results at 6 or more loci. Mixture profiles with a major contributor must contain results at 10 or more loci. Documentation of familial search exceptions will be noted in the case file by the CODIS Administrator or back-up Administrator and the DNA Technical Leader.

    a) Y-STR testing will be conducted by the CMPD lab prior to submission of a familial search request to the NCSCL. A lab request for Y-STR testing will be required to be submitted by the case investigator if testing has not already been done. If the sample originated from a differential extraction, it should be indicated on the service request which fraction is being requested for testing. This note may be added to the case file by the analyst, CODIS Administrator, or back-up Administrator if not indicated on the service request.

    b) For cases that need Y-STR testing, a Y-STR CODIS entry worksheet will be created by the analyst performing the testing and technically reviewed. The analyst will then enter the Y-STR profile into CODIS and the technical reviewer will review the CODIS Specimen Detail Report before the file is turned in for Administrative review. Upon completion of the technical and administrative reviews the case file will be given to the CODIS Administrator or back-up CODIS Administrator to initiate the familial search process. The Y-STR profile must be associated with the profile that will be the subject of the familial search, so it must be entered with either the original forensic profile or the adjusted profile (see #6 below). If it is deemed the adjusted profile will be used for the familial search, the CODIS Administrator or back-up Administrator will then enter the Y-STR profile. This entry will be reviewed by a qualified DNA analyst. It is acceptable to have Y-STR CODIS entries for both the original forensic profile and the adjusted profile. The profiles can then be uploaded for searching at SDIS and NDIS.

3. After Y-STR testing is complete and following NCSCL submission guidance, a case synopsis, a Familial Search Request and Review Form, and a lab-to-lab search request form will be submitted to the NCSCL via email.

a) The Familial Search Request and Review Form requires the signatures of the Chief of Police, the investigating officer, and a prosecuting attorney.

b) The lab-to-lab search request form asks other laboratory agencies to search their profiles that are held only at the LDIS or SDIS level. The profile to be searched will be the original CODIS entry profile.

c) The case synopsis will be provided by modeling the NCSCL's Familial Searching Case Notes document.

4. The NCSCL will notify CMPD via email if the request has been approved or denied. Prior to the NCSCL conducting the familial search, the lab-to-lab search request will be disseminated to the CODIS Administrator Google group. Search results will be sent to the CMPD lab. If no positive associations are obtained after two weeks, CMPD will be notified by the NCSCL that a pedigree tree associated to the profile of interest can be built and uploaded in CODIS.

5. The NCSCL will conduct the search and subsequent database analyses. The results of the search will be reported via Forensic Advantage. A familial search request that results in a negative search cannot be subsequently searched any sooner than 12 months from the date of the familial search notification report. Any requests for a profile to be searched again must have a new lab-to-lab search request form and new Familial Search Request and Review Form submitted to the NCSCL via email.

6. Adjusted profiles

a) There may be instances where only a portion of a profile will be included in the familial search (i.e. a profile has a locus with an obligate allele and therefore, cannot be included in the familial search). In this event, a new CODIS entry will be made that only contains the loci to be included in the search. The specimen ID will be entered as the standard format followed by -FS. A notation of "Familial Search" as well as the final specimen category will be entered into the Comments box. The final specimen category may not be the same as the original entry.

b) Adjusted profiles will be entered into the Non-reviewed profiles specimen category at the same time as the Y-STR profile by the CODIS Administrator or back-up Administrator and will undergo an Administrative review to ensure the profiles have been entered correctly. The MME may need to be re-calculated

and verified that statistical thresholds for upload to NDIS are met. The Administrative review will be conducted by either the CODIS Administrator or back-up Administrator (whoever did not enter the profile). One copy of the STR specimen detail report will be printed. Once review of the profile is complete the Administrative reviewer will initial and date the Specimen Detail Report. The CODIS Administrator or back-up Administrator will then update the specimen category, print the Specimen Details Report, and add their initials. The profile can be uploaded for searching at SDIS and NDIS. This paperwork will become part of the familial searching portion of the case file and will ultimately be scanned and attached in PLIMS once the familial search process is complete.

7. Building a Pedigree Tree

a) A pedigree tree must be created in Pedigree Manager for each specimen that undergoes a familial search.

b) Open Pedigree Manager, select “Add Pedigree” and enter the Pedigree Tree ID. In general, the Pedigree Tree ID will be the same as the Specimen ID.

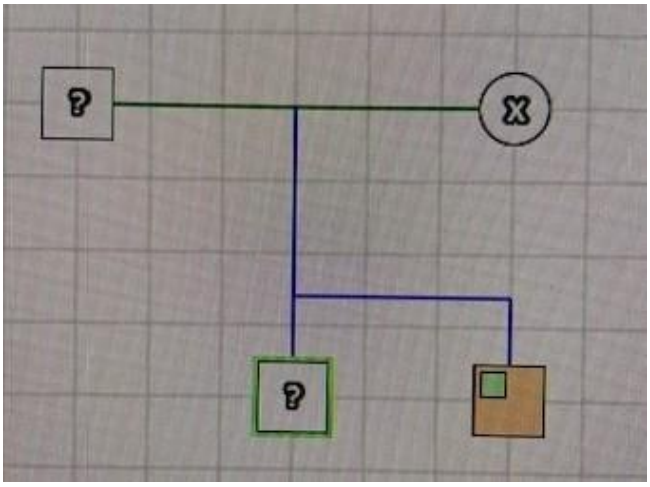
c) Ensure that the Pedigree Category is set to “Familial Search”.

d) Select the box in the pedigree tree and right click to “Add Relationship > Parents”. Repeat again to add “Brother”.

e) Right click on the box representing the Father (square) and select “Set Node to Unknown”. Select “yes” when prompted with “Do you want to mark this node as unknown?”. Confirm that the box representing the Brother is already set to unknown.

f) Select the box representing the target of the search and right click to “Associate the Specimen”. The target of the search is considered a reference sample. This links the DNA Specimen ID with the Pedigree Tree ID. Click “Save”.

g) The pedigree tree in CODIS should resemble:



The top left square marked with “?” represents the Father.
The top right circle marked with “X” represents the Mother.
The lower left square marked with “?” represents the Brother.
The lower right square represents the unknown profile. The green square inside the box represents STR data. A blue square inside the box represents Y-STR data.

The pedigree is designed to return candidate specimens that could be either the parent/child or the sibling of the unknown profile. Although the pedigree indicates a brother, both male and female candidates can be returned.

h) Ensure both the profile and the pedigree tree have been marked for upload.

i) The pedigree tree will be deleted if the search ultimately leads to the identification of a suspect and that suspect’s profile has been confirmed as the source of the evidence autosomal DNA profile. The autosomal profile will remain in CODIS.

8. Potential familial hits during subsequent routine CODIS searches

It is possible that a potential familial hit will occur during subsequent routine CODIS searches by the NCSCL. Convicted offender and arrestee profiles may periodically be updated with Y-STR data. When these updated profiles are searched, they may generate a CODIS match to an evidentiary Y-STR profile. Since this hit does not occur as part of the familial search process, no additional familial search testing will occur at the NCSCL; however, the sample will be confirmed by the NCSCL and a CODIS hit notification letter will be issued as an investigative lead to be reported to the case detective. The hit letter will provide personal identifying information; however, no information regarding the definition of a familial hit will be included. The detective must be made aware that the name being reported is not the actual perpetrator of the crime.

The following statements should be tailored to best fit the associated scenario when issuing a report where the familial hit has occurred during a subsequent routine CODIS search:

This information is provided only as an investigative lead, to which the following information must be understood and applied in the process of further investigation:

- *The named individual(s) is/are NOT the source of the DNA profile obtained from [ITEM].*
- *The DNA results provide an indirect association, based on potential genetic relationships, rather than a direct match between the source of the DNA profile and the named individual.*
- *This search result only indicates the likelihood of a biological relationship; it does not confirm that the named individual is biologically related to the source of the DNA profile.*
- *While the DNA results are best explained by a parent-child or full sibling relationship, other familial relationships could also explain these results.*
- *Other paternally related individuals to a named male individual, and/or of the source of the DNA profile, are expected to have the same Y-STR haplotype.*
- *At this time, female candidate specimens cannot be tested with a secondary technology, such as Y-STRs, to further support the familial relationship between the offender and the specimen of interest.*

Analysis in the case is not considered complete until a known DNA standard has been obtained from a subject developed during the course of your investigation and submitted for comparison purposes.

9. Case file documentation

   Documentation must be included in the case file to show that a case has been reviewed and/or submitted for familial searching. Documentation to be included in the case file and attached in PLIMS should include (as applicable): email or communication log from the investigator requesting a case be reviewed for familial searching, signed familial search request and review form, correspondence between the NCSCL and the CMPD lab, lab-to-lab DNA search request form, LDIS specimen details report showing the addition of Y-STR loci, and the pedigree tree details report. Additional documentation may be added as deemed appropriate.

20.6.4 Rapid DNA

The ThermoFisher RapidINTEL Plus Cartridge has been approved by the NDIS Board for Modified Rapid DNA Analysis on forensic samples. The CMPD laboratory does not currently plan to integrate a Rapid system into the workflow; therefore, the NDIS procedures regarding the use of the cartridge and Modified Rapid DNA Analysis are not applicable.

20.6.5 Forensic Investigative Genetic Genealogy (FIGG)

At the request of an investigator the CMPD laboratory may assist with sample selection and preparation for external agency genealogical testing. The CMPD laboratory does not have the capabilities to conduct the testing and no searches will be conducted. Additional testing by the CMPD lab may be needed before recommending FIGG (i.e. re-quantitation of an extract) and a service request will be required to conduct the testing. If no additional testing for a case is to be performed by the CMPD lab, a service request will not be submitted. Documentation must be included in the case file to show that a case has been reviewed and/or submitted for FIGG. Documentation to be included in the case file and attached in PLIMS should include (as applicable): email or communication log from the investigator requesting a case be reviewed for FIGG, submission paperwork to the FIGG lab, correspondence between the FIGG lab and the CMPD lab, any notes related to sample preparation, and the associated chain of custody for any sample(s) selected for testing. Additional documentation may be added as deemed appropriate.

20.6.6 Hit Counts and Investigations Aided

The CODIS Administrator will be responsible for tracking all hits and investigations aided. The NDIS guidelines for hit counting and number of investigations aided will be followed. Suspect hits are not defined at NDIS; however, any hits between a LDIS unsolved case and the LDIS suspect index will be dispositioned as “Suspect CMPD match”. Hits between an unsolved LDIS case and the SDIS suspect index will be dispositioned as “Suspect hit”. A match between a solved case and the suspect index will be dispositioned as “Investigative Info”. Suspect hit information will be provided to the State CODIS Administrator as a “Forensic hit”. Hit counting data will be forwarded as scheduled in coordination with the State CODIS Administrator.

20.7 Data Backup

Data back-ups on an encrypted thumb drive will be run weekly and monthly. Devices associated with weekly back-ups will be stored in a fire-resistant safe located within a secure room of the laboratory. The CODIS Administrator, back-up Administrator, and Section Administrator will have access to the safe. Devices associated with monthly back-ups will be stored in an off-site, physically separate location. Only the CODIS Administrator, back-up Administrator, Section Administrator, and Laboratory Director will have access to this location. Windows event viewer logs, antivirus/malware/endpoint protection logs, and infrastructure/network device logs will be captured once per week by the CODIS Administrator or back-up Administrator. The logs will be saved to a designated folder on the CODIS server hard drive.

20.8 Annual Review of DNA Records Acceptable at NDIS

1. NDIS requires that each user in a NDIS participating laboratory be reminded annually of the sample types that are acceptable for entry to NDIS. Each user will participate in annual completion of the web-based Annual Review of DNA Data Accepted at NDIS training. A certificate of completion will be issued upon successful completion.

20.9 Deletion of profiles from CODIS

1. The CODIS Administrator and back-up Administrator will be the only people responsible for deletion of profiles from LDIS. A note as to why the profile was deleted will be added to the Comments section of the Specimen Details Report prior to the deletion. The Specimen Delete Report will be maintained in the case file if it is determined during technical review that a profile should not have been entered into CODIS. Profiles deleted prior to a case file being submitted to technical review will generally not be maintained in the case file but the decision is subject to CODIS Administrator or back-up Administrator discretion.

    2. If a case profile is deleted from CODIS after a laboratory report has already been issued stating the profile will be periodically searched, a laboratory report will be issued to notify the investigator that the profile has been removed from CODIS and is no longer being searched. If a profile is deleted from CODIS, the following wording will be used in the report: *The [major] [foreign] [male] profile previously obtained from [contributor #] from the [Item] (DNA #) has been removed from the Combined DNA Index System (CODIS).*

    3. If a file or record supporting the analysis of a sample is destroyed, lost, or no longer available, the DNA record must be administratively removed by the NDIS participating laboratory.

    4. Current NC DNA Database laws only pertain to the expunction of arrestee and convicted offender profiles (15A-266.3A). If charges against a suspect have been dismissed, the DA's office must notify CMPD before any profiles in the Local CODIS database will be removed.

20.10 CODIS Security

1. The CODIS Server shall be located in the 3rd floor server room located at CMPD Headquarters. The server room has secure access and only a designated CMPD IT employee has physical access to the CODIS server. In addition to the designated CMPD IT employee, the CODIS Administrator and back-up Administrator are the only employees to have remote log-on access to the CODIS server. The CODIS workstations will be housed in a secure room within the Biology section. Individuals that have key access to the Biology section on an emergency basis only include the Crime Laboratory Directory, the Lab and Evidence Bureau Major, the Deputy Chief

of Support Services, the Chief of Police, and the Facilities Planning Manager. Any individuals that are not Biology section employees (i.e. maintenance and equipment service representatives) that need access to the room containing the CODIS workstations during workday hours will be monitored by Biology section employees.

2. All CODIS users are responsible for CODIS software security. This includes logging out of the CODIS network upon completion of a CODIS session.

3. The CODIS Administrator and back-up Administrator will be the only individuals with Administrator rights to the CODIS server. If deemed necessary, the Section Administrator may be given Administrator rights. A shared password will be utilized by the CODIS Administrator and back-up Administrator to remotely log on to the CODIS server and to perform shared Administrative tasks only.

4. The antivirus software definitions will be automatically updated by the City of Charlotte.

5. Employees of the CMPD and City of Charlotte IT division may be given usernames and passwords in order to only perform computer maintenance on the CODIS server and workstation. They will undergo clearance by the FBI and will have no access to CODIS software or functions.

Appendix 1 - Abbreviations

Below is a list of abbreviations commonly used in the Biology section. This list is not comprehensive. Non-listed abbreviations may be used if they are easily decipherable to the technical reviewer or if they are first defined in the case file.

Abbreviations may be capitalized, or not capitalized, depending on examiner preference.

Brand names of commercially available products, DNA loci, and most other universally recognized terminology are not included.

Abbreviation	Term	Comments
-, (-), ⊖, Ⓝ , or neg	negative	
+,(+), ⊕, or pos	positive	
+ or *	obligate allele	
^	allele, any	
Δ	change	
ABC	anode buffer container	
als	alternate light source	
amy	amylase	
ap	acid phosphatase	
AR	administrative review	
ART	artifact	
AX	ArmedXpert	
bld	blood	
bpb	brown paper bag	
C	Celsius	
c̄	contains/containing	

Abbreviation	Term	Comments
CBC	cathode buffer container	
Cdbd	cardboard	
COQC	certificate of quality control	
cts	cotton tip swab	
cl t	clear tape	
ctrl	control	
d/i	date/initial	
DCC	discharged cartridge case	
e-gram	electropherogram	
env	envelope	
GBC	General Biology Cage	
GBS	General Biology Storage	
GF	GlobalFiler	
Ⓗ	hospital	
inc	inconclusive	
inj	inject/injection	
K	known standard sample	
KM	Kastle-Meyer (PHT)	
LMG	Leucomalachite green	
m:	marked	
micro	microscopic examination	
n/a	not applicable	

Abbreviation	Term	Comments
ND	no data	
neg cont/ctrl	negative control	
NOC	number of contributors	
NOE	not opened or examined	
NSF or NS	non-sperm cell fraction	
NP	n+4 stutter	
NUFI	not used for interpretation	
obs	observed	
oftc	opened and found to contain	
p30 or PSA	Prostate specific antigen	
pb	presumptive blood	
PF or PFE	Prepfiler/Prepfiler Express	
phr	peak height ratio	
PHT	Phenolphthalein	
pl	plastic	
PLIMS	Property and Laboratory Information Management System	
plshdr	plastic slide holder	
pos cont/ctrl	positive control	
prop or PC	Property Control	
PT	proficiency test	
ptt	purple-top tube	
PU	pull-up	

Abbreviation	Term	Comments
RB	reagent blank	
rbc	red blood cells	
rbs	reddish-brown stain	
rec'd ( )	received (date)	
ret'd ( )	returned (date)	
RFU	relative fluorescence units	
RI	re-inject/re-injection	
rxn	reaction	
SAK	sexual assault (evidence collection) kit	
s or Ⓢ	Suspect	
sbpb or SBPBG	sealed brown paper bag	
sclpl	sealed clear plastic	
sep. fab. obs.	separation of fabric observed	
slhldr	slide holder	
sm	small	
sme	sealed manila envelope	
sol'n	solution	
SF or SP	sperm cell fraction	
spl	sealed plastic	
splb	sealed plastic bag	
ss	single source	

Abbreviation	Term	Comments
ST	stutter	
stc	said to contain	
std	standard	
sw	swab	
s/w	sealed with	
swb or swbx	sealed white box	
swe	sealed white envelope	
TNTC	too numerous to count	
TR	technical review	
und or uw	underwear	
unk	unknown sample	
v or Ⓥ	Victim	
vag	vaginal	
wb	white bag	
wbc	white blood cells	
wh	white	
x:y	dilution of x in y	i.e. 1:5 dilution
YFP	Yfiler Plus	
zpb	zip plastic bag	

Appendix 2 - Definitions

This list of definitions is not comprehensive; however, it lists technical and specialized terms as they are used in the Biology section Quality Assurance Manual and the Biology section Standard Operation Procedures. The following terms shall have the meanings specified:

Accreditation: The formal recognition that a laboratory meets or exceeds a list of standards, including the FBI Director's Quality Assurance Standards, to perform specific tests. Accreditation is administered by a nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic science community in accordance with the provisions of the Federal DNA Identification Act (34 U.S.C. §12592) or subsequent laws.

Accuracy: The ability of a measurement to give results close to a true value.

Administrative review: An evaluation of the report and supporting documentation for consistency with laboratory policies and for editorial correctness.

Allele: Any of several alternative forms of a gene or STR locus found at the same point on a pair of chromosomes.

Allele, any: An allele that is interpreted as including the possibility of drop-out.

Allelic Ladder: An artificial mixture of the common alleles in the human population for a STR marker that provides a reference DNA size for each allele included. Allelic ladders are important for obtaining accurate genotype determinations.

Alternate Reference Sample/Alternate Standard: An item of evidence collected as a known standard and presumed to have DNA solely contributed by the individual of interest. A sample of this type may be used when a known standard cannot be obtained. When collected and submitted as a known reference, it can be extracted as a known reference and if a suitable profile is obtained may be used for comparison and conditioning. Mixture profiles and partial profiles are typically not suitable for use as an alternate reference; however, may be considered with TL or designee approval.

Amplification: The process of producing multiple copies of the DNA (PCR) in order to characterize it.

Analyst: An employee or contract employee, who has 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 these standards. This individual can conduct and/or direct the analysis of forensic samples, interpret data, reach conclusions, and generate reports.

Analytical threshold: The minimum RFU at which detectable peaks can be reliably distinguished from non-allelic peaks for evidentiary samples.

Apparent Hair: A term assigned to a possible hair once it has been microscopically examined and characteristics of a hair have been observed (such as root, medulla, cortex, and cuticle).

Audit: An on-site inspection used to evaluate, confirm, and/or determine the extent to which specified requirements are fulfilled.

Audit team: One or more individuals, including at least one auditor, that performs an inspection of a laboratory. At least one audit team member shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.

Auditor: An individual who has successfully completed the FBI's DNA auditor training course.

Case file: The documentation of procedural notes, controls, and instruments used; observations made; results of tests performed; and charts, graphs, photos, and other documentation generated which are used to support the analyst's conclusions.

Casework CODIS Administrator: An employee of the laboratory responsible for administration and security of the laboratory's CODIS at a laboratory performing DNA analysis on forensic and casework reference samples. An alternate Casework CODIS Administrator must be designated by the laboratory as required by the NDIS operational procedures.

Certified reference material: A material for which values are obtained by a technically valid procedure and accompanied by, or traceable to, a certificate or other documentation which is issued by a certifying body (e.g., NIST).

Code Number: Unique identification number issued to a police department employee. This number must be included on every evidence tape seal in addition to the individual's initials and date of seal.

CODIS: The Combined DNA Index System administered by the FBI. – Refer to QA 20 for additional definitions.

Competency testing: A test or series of tests (practical, written, and/or oral) designed to establish that an individual has demonstrated achievement of technical skills and met minimum standards of knowledge necessary to perform forensic DNA analysis.

Complex: DNA results that are deemed unsuitable for comparison due to four or more contributors.

Composite: A DNA profile generated by combining typing results from different loci obtained from multiple injections of the same amplified evidentiary sample and/or multiple amplifications of the same DNA extract from an evidentiary sample. When separate extracts from a given item are combined prior to amplification, the resulting DNA profile is not considered a composite profile. Within the STRmix software, replicate amplifications that are both used for interpretation are considered composite profiles because the software is determining all the possible genotype combinations using all the peak height information across all evidence input files. STRmix is combining replicated PCRs into a single interpretation.

Conditioned interpretation: Genotype combinations based on assuming a known contributor to the mixture profile obtained from an intimate sample.

Consistent: A partial match that occurs when not all autosomal loci are completely deduced (allele/locus drop-out, allele any's, or combos present). Used when making non-probative associations to an expected donor or to the non-probative fraction of a differential extraction. Multiple complete single source profiles with identical results (for example, identical genotypes at all locations with a weight of one) and is associated with a reference, the results statements may be combined in the report with a "consistent with" statement and only one of the samples needs to have LR calculations performed. Reporting of this type does not include the likelihood ratio calculation.

Contamination: The unintentional introduction of exogenous DNA into a sample or analytical control during DNA testing which results in the presence of a pattern of peaks (two or more) above the lower analytical threshold (LAT) of 50 RFU.

Continuing education: An educational activity (such as a class, lecture series, conference, seminar, or short course) that is offered by a recognized organization or individual that brings participants up-to-date in their relevant area of knowledge.

Contract employee: An individual, not in the employ of the government or vendor laboratory, that performs DNA typing and/or analytical support services for a NDIS participating laboratory. The person performing these services must meet the relevant qualifications for the equivalent position in the NDIS participating laboratory. A contract employee cannot serve as a Casework CODIS Administrator, Laboratory Rapid DNA Administrator, or Technical Leader and cannot be counted as a full-time qualified analyst for purposes of satisfying the definition of a laboratory. Employment of a contract employee by multiple NDIS participating laboratories and/or vendor laboratories shall be disclosed to all employing laboratories and shall only be permitted subject to approval by the Technical Leader of the NDIS participating laboratory for which the contract employee is performing DNA typing and/or analytical services.

Corrective action plan: Evaluates and remediates a nonconformity with the goal to identify, correct, and/or prevent reoccurrence of the nonconformity, when possible.

Coursework: An academic class officially recognized through a college or university program in which the participating student successfully completed and received one or more credit hours for the class.

Critical equipment: Equipment whose accurate functionality directly affects the results of the analysis and requires calibration, certification, or performance check prior to use and periodically thereafter.

Critical reagents: Those reagents whose performance is vital to the success of the DNA testing and require testing on known samples before use on forensic or casework reference samples.

Degradation: The breaking down of DNA by chemical or physical means.

Detection: The process of separating amplified DNA product and creating a visual record of DNA fragments utilizing fluorescent tags.

Developmental validation: The acquisition of test data and determination of conditions and limitations of a new or novel DNA method for use on forensic samples.

Differential amplification: The unequal amplification of one target region or locus over another during the polymerase chain reaction.

Direct Transfer: Direct transfer of DNA includes contact, but also includes activities within the vicinity of an item that may result in the transfer of DNA directly from an individual without any contact, such as speaking, coughing, and sneezing.

Disposition of evidence: The documentation of the retention, return, or consumption of the evidence item(s) upon completion of DNA testing.

DNA: Deoxyribonucleic acid is the basic unit of genetic information.

DNA # (number) – Unique identifier created in the PLIMS software that is associated with a specific Complaint #/Item # combination and is utilized in the Biology section to track and record samples used in DNA testing. A DNA number will be generated for each sample extracted. This number will be initially noted on the DNA extraction worksheet and will be continued throughout the case file.

DNA profile: The genetic constitution of an individual at one or more defined locations (also known as loci) in the DNA.

Electropherogram: A record or chart produced when electrophoresis is used in analysis.

Electrophoresis: A method for separation and analysis of DNA fragments based on their size and charge.

Exclusion: The questioned DNA profile and the known standard DNA profile for comparison are determined to be not consistent through careful, objective, qualitative and quantitative evaluation of the entire pattern of alleles produced at the loci tested. There are two alternative bases for an 'exclusion' conclusion: 1) The basis for an 'exclusion' conclusion using visual comparison is an examiner's interpretation that the genetic profile of a known individual is not consistent with the potential genotypes obtained from an evidentiary sample. 2) The basis for an 'exclusion' conclusion using probabilistic genotyping software is an examiner's observation that the likelihood ratio resulting from comparison of the DNA profile of a known individual to the DNA contained in an evidentiary sample is zero.

Extraction: The process of releasing the DNA from the cell.

Evidence: An item submitted for DNA testing and/or a derivative of an item as defined by the laboratory that is subject to a chain of custody.

External proficiency test: A test obtained from a proficiency test provider accredited to the current applicable standard of the International Organization for Standardization and the applicable test is included on the proficiency test provider's scope of accreditation.

Forensic Biologist: An employee who performs analytical procedures on forensic samples or casework reference samples under the direction of a qualified analyst. A Forensic Biologist may perform serological testing and interpretation of quantitation results. These employees do not interpret data to reach conclusions on typing results or prepare final DNA reports. They may write final reports conveying serological testing and preliminary reports regarding drop at quantitation results if authorized. For the purposes of QAS these employees are categorized as technicians.

Forensic DNA analysis: The process of extraction, quantitation, amplification, generation, and interpretation of biological evidence in criminal matters using DNA technologies.

Forensic Rapid DNA Lead Operator: An employee of the Rapid DNA partner agency who is designated by the Rapid DNA partner agency to oversee the operation of a Rapid DNA instrument(s)/System(s) for their agency and is the main point of contact to the laboratory.

Forensic Rapid DNA Operator: An employee of the Rapid DNA partner agency and is designated by the Rapid DNA partner agency as qualified and authorized to operate a Rapid DNA instrument/System with casework reference and/or forensic samples for that agency.

Forensic Rapid DNA Program: The application of a Rapid DNA instrument/System on casework reference and/or forensic samples. Applications can include operation of a Rapid DNA instrument/System in the laboratory, in a Rapid DNA partner agency, or in a temporary/mobile location. All applications utilized by the laboratory must be recognized

under the laboratory's scope of accreditation.

Forensic science: The application of a broad range of sciences to answer questions of interest to the legal system.

Functional testing: A process to confirm that a software performs the tasks as expected.

Genetic analyzer: Platform that allows for the size separation of DNA molecules through a polymer under the influence of an electric field and the subsequent detection of the separated molecules by fluorescence or other means.

Genotype: The genetic makeup of an organism designated by allele symbols.

GlobalFiler: Amplification kit manufactured by ThermoFisher. Consists of 21 autosomal loci, Amelogenin, DYS391, and Y indel.

Group Processing: Terminology used to describe when multiple analysts are running a quantitation, amplification, or capillary electrophoresis set together or when the quantitation, amplification, or capillary electrophoresis step is performed by a robotic operator.

Guidelines: A set of general principles used to provide direction and parameters for decision making.

Inclusion: Language used in the binary interpretation of data to convey that the questioned DNA profile and the known standard DNA profile for comparison are determined to be consistent through careful, objective, qualitative and quantitative evaluation of the entire pattern of alleles produced at the loci tested.

Inconclusive results: Comparisons to known references that can neither be included or excluded.

Indirect Transfer: Indirect transfer of DNA is when DNA from an individual comes to be on an item via an intermediary surface. Secondary transfer is a type of indirect transfer.

Internal Lane Standard: Known sized DNA fragments that are spectrally distinguished from the DNA fragments of unknown size which enables automated data analysis and assists in achieving high run to run precision in sizing DNA fragments by electrophoresis. The LIZ size standard is evaluated during Data Evaluation to ensure that the fragments ranging in size from 60 to 460 base pairs are properly labeled.

Internal proficiency test: An in-house test produced by the agency undergoing the test.

Internal validation: An accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

Interpretation Software (e.g. Armed Xpert, STRmix): A tool to assist the analyst in assessing the analyzed data by applying quality assurance rules, performing mixture deconvolution, and/or evaluating comparisons.

Known standard: A biological material (e.g., buccal standard or blood card) obtained directly from a known individual and used for purposes of comparison to forensic samples.

Legacy Data: Data generated by a typing test kit, platform, or technology that is no longer in use by the laboratory that is used for the interpretation of DNA types. Data generated on the 3500 with the GlobalFiler kit is not considered legacy and may be reinterpreted using STRmix.

Likelihood ratio: A statistic for the comparison of the probability of the evidence (E), given two competing propositions. The inclusionary proposition (H1), includes the person of interest and, for mixed samples, known and/or unknown, unrelated individuals. The total count of individuals included in the proposition is equal to the number of contributors interpreted to be in the sample. The exclusionary proposition (H2) generally consists of unknown, unrelated individuals, equaling the total number of contributors interpreted to be in the sample.

Locus - (Loci, plural): The specific physical location on a chromosome.

Lower analytical threshold: The RFU value where allelic peaks can be reliably distinguished from non-allelic peaks for reagent blanks and/or negative amplification controls.

Match: All autosomal loci in a questioned sample are completely deduced (no allele / locus dropout, allele any's, or combos) and are the same genotypes as the compared known standard. Used when comparing a known reference profile to legacy data when all loci are completely consistent with no allele/locus dropout, allele any's, or combos.

Method: A combination of procedural steps used to perform a specific technical process. The method includes the validated steps, reagents, and critical instruments needed to perform the process or portion of a process. The same method may be conducted using different equipment (automated vs manual) when appropriately validated.

Methodology: Refers to the categories of methods used to perform a stage of a DNA typing technology or technologies. For example, methodologies for STR technology can include extraction, quantification, amplification, and detection.

Minimal: Limited DNA results that are deemed uninterpretable.

Mixture profile: A DNA profile interpreted as being associated to more than one individual.

Modified interpretation: A genotype combination that accounts for an undetected allele where appropriate (allele, any).

Negative Control: An amplification blank control present in each amplification set and serves as a check for sample contamination introduced during amplification set-up.

NIST: National Institute of Standards and Technology.

Nonconformity: Not meeting, implementing, maintaining, or complying with one or more of the requirements of the Biology section Quality Assurance Manual and the Biology section Standard Operation Procedures.

Obligate allele: An allele that is included in the genotype combinations for a profile.

On-site visit: A scheduled or unscheduled visit to the vendor laboratory work site by one or more representatives of an NDIS participating laboratory.

Outsourcing: 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: The process by which the responsibility for the products of forensic DNA analyses provided by a vendor laboratory is accepted by an NDIS participating laboratory.

Ownership review: The technical review of outsourced DNA data performed by an employee or contract employee who is qualified in the technology, typing test kit, and platform used to generate the data and participates in the laboratory's proficiency testing program.

Peak height ratio (PHR): Calculated for a given locus by dividing the peak height of an allele with a lower RFU value by the peak height of an allele with a higher RFU value and then multiplying this value by 100 to express the PHR as a percentage.

Performance check: A quality assurance measure to assess the functionality of laboratory critical equipment and instruments.

Persistence: The persistence of DNA refers to the retention or loss of DNA from surfaces after deposition. DNA can persist for many years, but it also can be lost quickly, for example, when the objects are regularly used or washed. Persistence is also influenced by substrate type, body fluid type, environmental conditions, and use or contact after the initial DNA deposition. Microbial activity, cleaning, or significant use of items accelerates DNA loss, whereas a lack of contact, an absence of light or moisture, and certain substrates promote DNA retention.

Platform: The type of analytical system utilized to generate DNA profiles, such as capillary electrophoresis, real-time gel and end-point gel instruments or systems.

Polymerase Chain Reaction (PCR): An enzymatic process by which a specific region of DNA is replicated during repetitive cycles consisting of denaturation of the template, annealing of primers, and extension of the bound primers by a DNA polymerase.

Positive Control: A positive amplification control required for each amplification set and is used to assess the proper performance of amplification and typing procedures.

Possible Hair: A term assigned to a trace item collected by an analyst that appears to have the macroscopic characteristics of a hair but has not been microscopically examined.

Precision: Characterizes the degree of mutual agreement among a series of individual measurements, values, and/or results.

Preferential amplification: The unequal amplification of the two alleles present in a heterozygous locus during the polymerase chain reaction.

Prevalence: Prevalence of DNA denotes DNA from known sources and activities that may be expected from specific individuals. For example, it is expected that DNA collected from the steering wheel of a stolen vehicle will be a mixture from the owner(s)/driver(s) of the vehicle and the unknown person who last drove the car.

Probabilistic genotyping: Probabilistic genotyping refers to the use of biological modeling, statistical theory, computer algorithms, and probability distributions to calculate likelihood ratios and/or infer genotypes for the DNA typing results of forensic samples. Probabilistic genotyping is a tool to assist a DNA examiner in the interpretation of forensic DNA typing results. It is not intended to replace the human evaluation of the forensic DNA typing results or the human review of the output prior to reporting. Probabilistic genotyping results in the report of a likelihood ratio.

Proficiency testing: A quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as either internal or external.

Pull-up: A failure of the analysis software to discriminate between the different dye colors used during the generation of test results.

Qualified Personnel: An individual who meets the requirements for the position, has successfully completed the laboratory’s applicable training requirements, and is authorized to perform a specific task or role.

Qualitative statement: A description of the evidence (e.g., partial profile, mixture profile) or a conclusion of any comparisons that were performed without a statistical significance provided (e.g., source attribution, consistent with an intimate sample).

Quality system: The organizational structure, responsibilities, procedures, policies, and resources for implementing quality management.

Quantitation: The process of determining how much DNA has been recovered during extraction.

Quantitative statement: A conclusion that provides a statistical measure of the DNA profile (e.g., random match probability) or comparison performed (e.g., likelihood ratio).

Questioned sample: A biological sample originating from and associated with evidence from a crime scene. A sample associated with evidence from a crime scene may include a sample that has been carried away from the crime scene.

Random Match Probability (RMP): The probability of randomly selecting an unrelated individual from the population who could be a potential contributor to an evidentiary profile.

Rapid DNA Analysis: The fully automated (hands-free) process of developing a CODIS acceptable STR profile from a casework reference or forensic sample. The “swab in – profile out” process consists of automated extraction, amplification, separation, detection and allele calling without human intervention.

Rapid DNA cartridge: A preassembled set of reagents and other analytical components (such as typing test kit) designed for use in a Rapid DNA instrument/System for the extraction, amplification and/or separation of DNA samples. For forensic samples, the cartridge shall include internal quality controls and the ability to estimate the quantity of DNA in the forensic sample that was amplified.

Rapid DNA data: The electronic files produced by the Rapid DNA instrument/System associated with a sample run. Data includes raw data, sample outputs, and instrument log files.

Rapid DNA instrument: An automated device that carries out Rapid DNA analysis or modified Rapid DNA analysis used to develop a CODIS acceptable STR profile from a casework reference or forensic sample.

Rapid DNA partner agency: A criminal justice agency, such as a law enforcement agency or medical examiner’s office, which operates a Rapid DNA instrument/System in conjunction with a laboratory and under that laboratory’s scope of accreditation and is contributing the Rapid DNA data to the laboratory’s Forensic Rapid DNA Program. This definition also applies to the laboratory’s primary/parent agency when developing a

Forensic Rapid DNA Program for use of Rapid DNA instruments by the parent agency outside of the DNA laboratory.

Rapid DNA System: The collection of components that together performs a Rapid DNA analysis consisting of a Rapid DNA instrument, the PCR STR typing test kit/Rapid DNA cartridge/chip, and an integrated Expert System used to develop a CODIS acceptable STR profile from a casework reference sample or forensic sample.

Reagent: A substance or mixture of substances used in the analysis process to detect, measure, produce, or interact with other substances.

Reagent Blank: An analytical control that serves as a check for possible contamination by adventitious DNA in samples, reagents or supplies during the testing procedure.

Recovery: DNA recovery includes the method of collection and the efficiency of the extraction technologies. Significant differences in DNA recovery have been observed between different types of swabs and different collection methods (e.g., swab versus tape lift). Likewise, DNA extraction methods differ in their extraction efficiency, and the same extraction method may vary in efficiency from different substrates and body fluids.

Reference: A standard profile obtained from an individual to be used for comparison purposes.

Regression testing: The process of testing an updated software program to confirm that modifications or new functionality do not unacceptably alter or terminate a desired functionality that behaved correctly before the change was implemented.

Reinterpretation: The reassessment of legacy data that may change the previously documented results. This may be due to a reevaluation of any of the allele calls or genotype calls [to include potential allelic drop-out], removal of alleles (or entire loci) from statistical estimates, or a change in the assumptions.

Relative fluorescent unit (RFU): The level of fluorescence intensity measured from amplified DNA during electrophoresis. Higher quantities of amplified DNA will have higher corresponding RFU values.

Reliability testing: The process of testing a software program beyond its functional aspects to ensure it works appropriately in the laboratory environment. This may include testing multi-user or multi-site scenarios, direct-access and network/server-access scenarios, and interaction with other software programs.

Replicate: STRmix allows for the interpretation of multiple PCR replicates in one interpretation, even if different amounts of template DNA have been added to the PCRs. Within STRmix, the term replicate refers to repeat amplifications of the same DNA extract. Multiple injections of the same amplified product or amplified product from re-extractions are not considered replicates and should not be combined within STRmix.

The use of replicates has been shown to improve the ability of STRmix to differentiate true donors from non-contributors, typically increasing LRs for true donors and decreasing LRs for non-contributors. Replicates may also help the analyst estimate the number of contributors.

Review: An evaluation of documentation to check for consistency, accuracy, completeness, and compliance.

Semi-annual: Used to describe an event that takes place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year, and where the interval between the two events is at least four months and not more than eight months.

Sensitivity studies: Portion of a validation study that is used to assess the ability to obtain reliable results from a range of DNA quantities and to assess the ability of the system to reliably determine the presence of a contributor's DNA over a broad variety of evidentiary typing results (to include mixtures and low-level DNA quantities).

Service: The performance of adjustments or specified procedures by the user, manufacturer, or other service personnel in order to ensure the intended performance of instruments and equipment.

Single source profile: A DNA profile interpreted as being associated to one individual.

Specificity studies: Portion of a validation study that is used to assess the ability to detect genetic information from non-targeted species (e.g., detection of microbial DNA in a human assay) and to evaluate the ability of the system to provide reliable results over a broad variety of evidentiary typing results (to include mixtures and low-level DNA quantities).

Standard Operating Procedures: Orderly, step-by-step processes designed to ensure operational uniformity and to minimize analytical drift.

Standard Reference Material (SRM): A material for which values are obtained by a technically valid procedure and accompanied by, or traceable to, a certificate or other documentation which is issued by a certifying body (e.g., NIST).

Stochastic threshold: The RFU value determined through validation studies where allelic dropout and severe peak height ratio imbalance may occur making quantitative interpretation more difficult, especially with mixtures.

STR testing (autosomal): Technology which targets short repeated sequences of nuclear DNA found in highly polymorphic regions of autosomal chromosomes.

Stutter: A common artifact of PCR that visualized in the data by small peaks that occur immediately before or after an allele.

Support for Exclusion: An analyst's conclusion that there is a level of evidentiary support for the exclusion of a known individual as a possible contributor to the DNA typing results obtained from an evidentiary sample.

Support for Inclusion: An analyst's conclusion that there is evidentiary support for the inclusion of a known individual as a possible contributor to the DNA typing results obtained from an evidentiary sample.

Technical Leader: An employee who is accountable for the technical operations of the laboratory and who is authorized to initiate, suspend, and resume laboratory operations.

Technician: Laboratory support personnel who perform laboratory support duties exclusive of analytical tests on forensic or casework reference samples.

Technical Review: An evaluation of reports, notes, data, and other documents to ensure there is an appropriate and sufficient basis for the scientific conclusions.

Technology: Used to describe the type of forensic DNA analysis performed in the laboratory, such as RFLP, STR, YSTR, XSTR, SNP, microhaplotypes or mitochondrial DNA.

TPPR: DNA Transfer, Persistence, Prevalence, and Recovery. DNA profiling methods and interpretations are not able to address activity-level propositions and; therefore, cannot answer the question of how or when the DNA was deposited. Analysts should not offer probability or possibility explanations of activity-level explanations. General factors related to TPPR may be discussed.

Trace: This category of evidence includes materials that are often microscopic in nature and are readily exchanged between people, places and objects upon contact. Examples of this type of evidence include hair, fiber, glass, paint and soil.

Trace DNA: A minute amount of DNA at any stage of the analysis, from sample detection through to profile interpretation and typically refers to either the very limited and/or invisible biological samples and/or amounts of DNA less than 100 pg.

Transfer: DNA transfer is the physical movement of DNA from one surface or location to another. Except in ground-truth-known experiments, where an individual is observed to have been in contact with a surface/location, it is not possible to know whether the transfer was direct or indirect.

Uninterpretable Data: Data which cannot be interpreted or used for comparison. Profiles that are not suitable for comparison are considered uninterpretable. Loci with complete dropout/no data are considered uninterpretable.

Unknown Individual: A random, unrelated person whose DNA has not been tested by the laboratory.

Unsuitable (not suitable) for comparison: Data that is either uninterpretable or fails to meet quality assurance requirements as defined by the laboratory.

Upper analytical threshold: The RFU value where allelic peaks are known to produce artifacts in other loci which could impact reliable interpretation for the minor component.

Validation: A process by which a method is evaluated to determine its efficacy and reliability for forensic casework analysis and includes developmental and internal validation.

Vendor laboratory: A laboratory that provides DNA analysis services to another laboratory and does not take ownership of the DNA data for purposes of entry into CODIS.

Work product: The material that is generated as a function of analysis that is not subject to a chain of custody.

Yfiler Plus: Amplification kit manufactured by ThermoFisher. Consists of 27 Y-chromosome loci. For interpretation and reporting purposes the two multi-copy loci are counted together and number of loci is 25.

Y-indel: An insertion/deletion marker associated with the Y-chromosome which due to the small size (~81 or ~86 bp) aids in the interpretation of the profile as a male contributor even with degraded samples. Can be either "1" (deletion) or "2" (insertion). Most samples will be "2" (the ancestral "insertion" form) unless the individual is a Haplogroup O individual (East Asian or Southeast Asian).

Y-STR testing: Technology which targets short repeated sequences of nuclear DNA found on the Y chromosome. Short Tandem Repeats found on the male-specific Y Chromosome.

Provisions for Modification and Update of This Manual

Any updates, modifications, additions, or deletions to this manual prepared after the issue date on the cover sheet will have the following information and an updated issue date located at the bottom of each page.

Summary of Revisions

Date Issued	Summary of Changes Made
3-6-00	Foreword - TOC; All of Sec 2, 4, 5, 7, 9-12, 18, 20-22; and Sec 3 pp 1,3
	Sec 8 pp 2, 3; Sec 14 pg 1; Sec 15 pg 1; Sec 17 pg 1; Sec 19 pp 9-24
	Removed appendices
10-19-00	TOC; All of Sec 5, 11, 12, 14, 19; and Sec 7 pg 2
12-5-00	Sec 11 pg 4
2-23-01	All of Sec 4, 9, 12, 14, 15, 16, ; Sec 3 pg 3; Sec 7 pg 2; Sec 11 pp 4-6;
	Sec 19 Literature Routing Slip added; Sec 20 pp 1, 2, 3, 5-7, 9-11
7/26/01	Sec 19 Sexual Assault form changed, Sec 4 all, Sec 5 pg 1, Sec 20 all
10/17/01	Sec 3 pg 3, Sec 20 pp 10 and 11
11/20/01	Sec 8 pp 2,3 and 9
1/18/02	Sec 15 pg 4, Sec 19 changes to Phadebas form and calibration log
1/22/02	All of Sec 8
4/29/02	Sec 5 pg 3, Sec 11 pg 1-5, Sec 19 form changes
8/26/02	Sec 5 pg 4 and 5, Sec 7, Sec 8, Sec 12 pg 1, sec 15 pg 2 and 3, Sec 19 form changes
11/21/02	Sec 21, Section 19 - Laboratory Information Worksheet
7/10/03	TOC, Secs 4, 5, 7, 8, 11, 15, 19, 20, 21 (all)
1/12/04	Sec 8 pp 13, 16 and Sec 5, pg 4
2/26/04	Sec 5 pg 4, Sec 8 pg 2, Sec 9, Sec 11, Sec 12, Sec 19 extraction form
5/17/04	All of Sec 8,9,12,14,21: Sec 11, pg 2-5: Sec 19 Literature Rtg Slip
1/25/05	Sec 11, 15, 21, Sec 8 pg 17, 18 and 21
3/8/05	Sec 19 and 20
1/13/06	Sec 4,5,7,8,9,12,15,17,18,21,22,TOC all; Sec 19 DNA Ext, DNA Amp, Literature Rtg; Sec 20 remove Bromothymol Blue; change Digest Buffer, Pro K, TE; add DNA IQ, Quantifiler QC certificates
10/25/06	Sec 12 all
5/16/07	Sec 7.6.1
9/28/07	Sec 11.4, 14.1.4
1/30/08	Sec 4.3 (4); Sec 7.2; Sec 8; Sec 12.1; Sec 15.1
10/16/08	All of Sec 21
1/21/09	All of Sec 2, adds positions and removes position
1/21/09	All of Sec 18 case acceptance policy
3/5/09	All of Sec 11, abbreviations added
3/5/09	DNA Case Review form
4/9/09	Section 5, changed Microanalysis to Biology
4/9/09	Section 7, added Maxwell 16 to QC
4/9/09	Section 8, removed calibration of 9600

11/30/09	Section 1, added outsourcing; Section 3 adds positions; Section 4, added section entry; Section 5 clarified evidence maintained in lab
11/30/09	Section 6, added TL review; Section 7 added LEV;
11/30/09	Section 8, added pH meter; Section 9, added TL review and date due
11/30/09	Section 10, added TL review and approval; Section 11 updated
11/30/09	Section 12, added CODIS info; Section 14, added TL approval
11/30/09	Section 15, added Staff Search of Unknown
11/30/09	Section 16, outlined guidelines for outsourcing
11/30/09	Section 21, updated and added to CODIS manual per changes described at annual CODIS meeting
2/11/10	Section 7, added TL approval of all QC; added to COQC Forms of Section 20
3/2/10	Section 8, revised reagent expiration dates
3/11/10	Section 20, revised procedure and updated forms
4/9/10	Section 7, Section 8, and Section 11
8/2/10	Section 7, Section 11 and Section 15, additions for new SOP's
8/3/10	Section 21
1/7/11	Sec 3, added notation about previously qualified analysts; Sec 4 removed 310 reference; Sec 7 added labeling pos and neg controls of amp; Sec 12 added Stats page; Sec 8 ,add the 7500 and the Maxwell; Sec 21, add the CODIS back up administrator
4/1/11	Sec 11, added abbreviations; Sec 21 added arrestees
7/18/11	ALL- Combination of Serology manual information and changes made for ASCLD International
10/12/11	Addition of information required by the 9/2011 QAS: 5, 7, 8, 14, and 20
11/21/11	Addition of QAS Audit class in QA3. QA21 CODIS admin duties
12/13/11	QA 16 addition of site visit elements. QA 3 addition of TL and CODIS Admin duties.
2/7/12	QA 14 change for DNA audit finding
2/22/12	Changed how evidence can be received from the Property and Evidence Management Division.
3/5/12	Changes made to QA 21 CODIS Manual for CODIS 7.0 update.
6/4/12	Updated Chain of custody in QA 5
8/28/12	Added Automate to QA 7 and QA 8; modified QA 21
2/1/13	QA 21 updated to reflect new NDIS rules
4/4/14	Changes made to QA 2-5, 7,8 11, 12 ,5, 17-21 to reflect PLIMS and procedural changes
4/24/14	Changes made to QA 8
8/18/14	QA 15.5 corrected by adding he word "not" to "All unknown samples that do not…"
10/22/14	Changes made to QA 5, 8, 9, 11, 12, and 20
1/9/15	Changes made to QA 8.3.4.10 and 8.3.4.12 for new software
6/22/15	QA 3: added memo for TL qual; 5: added freezer to GBS; 7: added email temp change; 8: changes to PC; 11 added abbrev.; 12:added amp results; 20:clarifications and flow charts
2/24/16	Changes and clarifications made to 3, 5, 8, 9, 11, 12, 16, 18 20 and 21 to

3/11/16	Added internal lane standards and ladders to the Examination Document requirements in QA 11.1.
5/2/16	QA 8 -Changed wells for temperature verification; QA 11 and 20 updated to reflect new procedures from CODIS audit
9/1/16	Highlighted material removed from all QA Manual chapters per change made to lab QM 4.3.3.2 on 8/16/16. QA 2: add reference to laboratory management in lab quality manual; add to Crime Laboratory Technician job description; add references to Technical Leader and Chief Criminalist QA 4: add reference where general lab security can be found in lab quality manual; clarify qualifications of entities wishing to view analyst examinations; clarify which reagents will be shared among lab staff; add reference to Biology QA regarding amplified product control; add biohazard will be taken to the loading dock QA 5: add evidence packing received by an analyst will be initialed and dated; clarify stained and wet evidence drying and packaging techniques; add the use of locked evidence cabinets in the Biology section; add DNA extracts can be stored in the Biology freezer in Property Control; clarify exceptions to the One-Tube method; clarification of photos being saved to DEMS; clarify evidence sampling; add pre-amplification and post-amplification will have dedicated supplies QA 7: added information on comparison of buccals to evidence QA 11: add reference to note taking in laboratory quality manual; remove requirement that e-grams will be printed; add service request history to Administrative documents; add reference to release of case information in laboratory quality manual QA 12: add reference where general review guidelines can be found in laboratory quality manual; update timeframe for review process and owner of report; update guidelines for proper recording of data; add electronic data review of GMID-X projects; clarify procedure for discrepancies between analysts; add directions for use of technical review comments sheet; add reference to proficiency testing in laboratory quality manual; add reference to errors in laboratory quality manual QA 20: add criteria for entry of juvenile suspect profiles; update eligibility requirements for profiles from sexual assault cases; add profiles may be entered when generated from GlobalFiler; reference added for location of NDIS standardized allelic ladders QA 21: update location in the Lab Quality Manual where release of laboratory information can be found; remove electropherograms from being provided in discovery and add that .fsa files will be provided in their place
11/29/16	Added Section Administrator as signing authority on table of contents QA3: clarified 3.7 in adding section administrator to TL contingency plan QA6: added section administrator for approval of validation studies QA8: clarified procedures for 8.3.4.11 A, Section administrator as approver of COQC QA9: clarified which presumptive tests had to be performed on DNA PTs.

	QA10: added Section Administrator as approver. QA12: changed arbitrator of issues to the DNA Technical Leader QA15: Removed Quantifiler from 15.2, added QIAgility, added Section Administrator to 15.5 and 15.5.2. #1 QA16: added Section Administrator to site visit QA18: clarified cases that can go into CODIS, added DNA TL to approve exceptions QA20: changed 20.5 to read CODIS administrator and Section Administrator will maintain copy of Staff Database
2/13/17	QA 5: Defined what DNA Extract is considered evidence v. work product in 5.3.3.2. Added Standard Reference Materials to 5.5 and 5.5.1. QA 8: Added handling, cleaning and storage of thermometers; and notification requirements for Thermometer Verifications to 8.3.4.13. QA 11: Added "Sample Loading Worksheet" to 11.1 Technical Documents. QA 12: Added "Sample Loading Worksheet" to 12.1 Guidelines for the proper recording of data.
3/23/17	QA 4.4- clarified lab coat color and stitching for each are of DNA. QA 5.5 change wording to clarify who can make exceptions, QA 5.5.1 #2 change the storage conditions for DNA SRM, QA 8.2.4- clarified that DNA Team Leader or Section Admin will retest QC reagents that fail, QA 8.3.4.4 Change temperature ranges for refrigerators. QA 12, added that the due date for reviews will be noted in PLIMS, QA 15.1- changed time for cleaning of benches, QA 18- added information for Direct to DNA cases, QA 19 deleted sentence about page numbering. QA 20- clarified difference between core CODIS loci and original core CODIS loci. Clarified stats and eliminations
6/28/17	QA 5.3.3.2 – Added a review of electronic data step and a monthly check of extract tubes in freezers by each analyst. Separated the History from the Foreword and Table of Contents and made History a section at the end of the Biology QA Manual.
11/21/17	QA 8 Added Driftcon temperature monitoring procedure and removed temperature verification of the 9700 and luminol QA 8 forms: Updated 9700 Thermalcycler verification worksheet QA 19 forms: Updated CODIS entry worksheet for GlobalFiler QA 20: Updated changes to CODIS entry and added changes to correlate to new QAS and ANAB procedures
3/20/18	QA 5: added information for sending extracts to the State Lab, and clarified what to do with evidence if not processed. QA 8: changed that QC checks can be done together. Added more information on the maintenance of the QIAgility. QA 20: explained how a onetime search is performed; Added that investigators will be notified of a potential match that can be obtained by court order; added wording to use when a profile has been deleted.
10/15/18	**4 & 7**: small clarifications **5**: Added information about bar codes on SAK; added information about swabs taken from evidence while in other sections.

	8: Added o ring oiling for Automates; clarification on lysis buffer for PrepFiler Express; added how to defrag 3130 computer; added Veriti information for the Driftcon; added restart 7500 computer after background. **11**: Changes to abbreviations and technical documents, added amended reports. **12**: Added documents needed for group processing. Added notes about errors detected after review. **15**: Updated information on the contamination log. **17**: Updated PM to QM. **18:** Added information on case acceptance and added Cold Cases. **20:** Added information on how to evaluate consensual partner before DNA, information about cases prior to KBCops. **21:** Added that egrams are available upon request for discoveries.
5/13/19	**8**: 8.3.4.13 B added thermometer verification using Driftcon **16:** Added information about reviewing data and time frames for reviewing data and writing reports **20**: Added elimination standard guidelines Updated partial and mixture profiles upload requirements Added eligibility verification requirement Updated CODIS entry protocol Updated autosearch frequency Added match resolution protocol Added event logs capture Removed requirement of an internal audit Updated antivirus software definition
10/1/19	**QA 8:** overall added NIST or NIST Traceable standard 8.2.4.1- changed wording, 8.2.4.2 added re-testing information; 8.2.4.3 added dilutions are made in di water; NEW 8.2.4.7 Yfiler Plus and Allelic Ladder; 8.2.5 clarified PrepFiler QC; 8.2.4.4, 8.3.4.1, 8.3.4.7 added information for what to do if quant value is not negative. NEW: 8.3.4.6 QA 8 Forms changed to match new QC information **QA 11:** 11.1 added 3500 worksheets to the technical documents **QA 12**: 12.1 added 3500 worksheets, 12.2 added that STIMS be checked during administrative review **QA 18:** added YSTR requirements; 18.2.8 added MVac and YSTR **QA 20**: clarified Autosomal for CODIS entries; 20.3.1, #23 added requests for consensual partner standards, and added that all SAK files have to be reviewed by the CODIS admins; 20.3.3 #2 added the Y STR CODIS worksheet; NEW 20.3.6 added YSTR CODIS entry; 20.9.2 added clarification on deleting CODIS profiles; add composite profile definition
3/3/20	**QA 8:** Remove AP tests and replace with AP Spot Test: create new QC sheet
7/10/20	**Changes to reflect new 2020 QAS requirements** **QA2:** references QM, added contingency plans; removed functional responsibilities

	QA3: added qualifications and responsibilities for DNA analysts, DNA technical leader and CODIS administrator added professional development **QA4:** added commercial cleaners can be used in post amp **QA5**: clarified definitions of evidence and work product**,** added gloves changes and consultations, added STR data handling and added the sexual assault evidence collection kit tracking system **QA6:** added notes for documentation, internal and external validation, material modifications and performance checks. Included information on Software validation and modifications **QA7:** included information for QC, defined critical reagents, what to do about data not meeting quality control measures and legacy data. **QA8**: defined critical equipment, notes about maintenance records and other equipment **QA9**: added guidelines for BFI, DNA and Technical review proficiency tests **QA10**: updated to only contain nonconformities and corrective action plan **QA11**: added information that should be contained in Biology reports, updated the order of items in the case file **QA12**: changes case file contents and had clarifications for technical and administrative reviews **QA14**: updated to add requirements for Internal and external QAS audits, annual casefile review and CODIS audits **QA15**: added information about decontamination **QA16**: added guidelines for the requirements of outsourcing, ownership of data, non-outsourcing external lab testing. **QA 17** added retention times, laboratory supply records, and storage of case files **QA20:** Updated elimination buccal standard definition, Updated age of juveniles for CODIS entry, Clarified when elimination standards are needed for touch item cases, Added investigator email request requirement for SAK's collected from homicide victims, Clarified ownership of DNA records, Updated major group CODIS entry examples, clarification of CODIS entry allele calls, updated when verification occurs that profiles are marked, added requirement to query non-reviewed profiles quarterly, updated Y-STR CODIS entry protocol, added requirement to query matches with pending dispositions quarterly, added clarification of review process of potential CODIS matches, added requirement of initial review process to be complete before issuing CODIS match reports, added requirement of offender match reports to be issued within 14 days, added Rapid DNA policy, updated log files to be retained **QA21**: added discovery information- when a court order is needed
12/14/20	**Changes due to Audit and Clarifications:** **QA 2:** Add what to do if no one is qualified and the TL and CODIS administrator positions are vacant

	QA 3: Add separate authorizations for technical reviews, addition of a competency test if re training is needed, evaluating the need for re-training **QA 4:** DNA extraction lab coats are navy **QA 5:** Photos are added to the documentation of evidence packaging issues, added clarification for "inventory and cut" DNA extracts, added that legacy SAK will have a white barcode with a "L" prefix; added reference to DNA # and combining extracts **QA 7:** Added that if a kit component is ordered separately, then a new QC needs to be done, remove Maxwell kits and added Buffer MTL to the critical reagents, clarify how working solutions of PHT should be named **QA 8:** Added that a DNA Team Leader can review results of a quality assurance measure, added EZ-1, QIAcube, Driftcon and NIST traceable thermometers to critical equipment, added M-vac, centrifuge, vortex, and UV lights to other monitored equipment, added Maintenance for EZ-1 and QIAcube and QIAgility; added that preventative maintenance for 7500 is done on a 12-18 month interval, added M-Vac annual maintenance; annual preventative maintenance moved from a 12-18 month span to a 9-15 month span for Automate, EZ-1, Qiacube, Qiagility, 7500 and 3500. Clarified the performance of the biannual diagnostic on the 7500. Specifically, the length of use and number of uses of dye plates along was added along with including that there is no requirement for PC after the dye plates run. **QA 9:** added that PT are open tests, submitted to director after both TR and AR, Section Supervisor will review the TL's PT results, added "all inclusions and exclusions are correct or incorrect" to evaluation of PT results, **QA 11:** can release information about a case once the TR is completed **QA 12:** TR cannot be done by an individual that participated in Group processing, same analyst can do second read; however, needs to be done before being placed into TR. **QA 14:** 14.1.1 Removed reference to QM, Internal audit needs to have at least 2 qualified DNA analysts **QA 15:** Removed negative pressure and added separation of time or space. Isolated remove QA manager being notified up front, added if systemic then notify Biology Supervisor, QA manager and Lab Director; 15.2.1- removed must immediately cease casework; added definition of pattern of peaks **QA 16:** added no review needed if CMPD is not taking ownership of data; added exception to timelines for additional work/amended reports needed state of emergency **QA 18:** add criteria for DCC **QA 20:** added can assume known individuals for the purpose of CODIS entry; added that print date is marked for upload date; add procedures for Y STR sample entry if an autosomal profile has already been obtained.
4/28/2021	**QA 3:** Removed qualifications for the CODIS administrator and back up administrator to be that of a DNA analyst instead of the Technical Leader.

	QA 5: added unique prefix for SAK's collected outside of Mecklenburg county. **QA 8:** changed calibration to performance check where appropriate, added that the QIAcube will be wiped down with di water followed by ethanol, added a biannual cleaning of the 3500 pump block and the directions. **QA 11:** changed testing to activity, defined laboratory activity and how will be reported. **QA 18:** added information on DCC and YSTR; overall clean up
7/16/2021	**QA 12:** added a requirement for a documented self-review. Updated review checklists in QA 19 Forms
3/21/2022	The following changes are in response to the 2021 FBI QAS, and new instrumentation validations/performance checks. **QA 3:** 3.1.1-added information about analysts hired after 7/1/2009 and technical reviewer qualifications and retraining; 3.1.3 e. added what DNA TL needs to do within one year of being hired; 3.1.5 added minimal qualifications for CODIS admin; 3.1.6 added "responsibilities" wording; added 3.1.7 & 3.1.8 Support personnel; 3.2 1. clarified; 3.2.2. added literature distribution; 3.2.3 added maintain documents for training/agendas **QA 4:** 4.2 1, added dark blue to lab coats **QA 5:** added clarification for initialing tubes and documentation of internal transfers; added that for that visual verification may be completed on the Sampling Worksheet-Internal evidence; 5.1-points to SOP 1.4C for STIMS instructions, added general workflow chart; added 5.5.2-final disposition **QA 6:** 6.1.2 b) added what type and number of samples needed for validations **QA 7:** 7.2#4 added exp date for DNA reagents; 7.2.4 added designee cand approve QC; added 7.2.4.1 Modified Large Volume Extraction Procedure for EZ1 Reagents QC; added 7.3.1 Serological Controls; 7.5.1 b). clarification on legacy data **QA 8:** 8.4.1d) clarify when PC performed on the Automates; 8.4.4 c). add NIST requirements; (or QIAcube QC sample); added 8.7 GMID database backup and 8.8 notes on adding space to GMID X **QA 9:** added 9.1 competency testing; 9.2.2 clarified when to use manual and robotics; 9.2.4 changed evaluations to line up with QAS 2020 **QA 10:** 10.2 added monitor duration and TL notify supervisor

	QA 11: 11.1 Remove #4 Hierarchy; 11.2- add type of case and criminal case; included in what a Technical Review and Administrative review entails; added 12.6 case file review for testimony **QA 12:** 12.2-added clarification of admin review requirements **QA 14:** 14.1 added second bullet; 14.1.1 added where to find educational requirements and validations; 14.1.2 lead auditor needs most current QAS training **QA 16:** 16.1.1a) added TL review compliance with standards and federal law; c) TL needs to be qualified in tech, platform typing kit, on site visit from NDIS labs have to use the same tech etc.; 16.1.2 a). added clarifications on ownership; 16.2 added genealogical, familial searching **QA 17**: added 17.9 non conformance records and 17.11 case communication **QA 18:** case type cannot be unfounded or non criminal; Victims only have to have full name (no DOB); name spelling can be pulled from PLIMS or med forms; 18.2.3 analyst discretion which to choose; 18.2.5 h) added meeting needs to discuss DCC's **QA 20:** 20.1 added at least one back-up Administrator; 20.3.1 #2- when standards from victim and elimination samples can be used; 20.3.1 12-documents that oral communication of standards is acceptable, 16-clarifies when juvenile can be added to CODIS, 22-update guide for requesting elimination standards; 20.3.3 1-updates documentation of CODIS entry based on NDIS allelic ladder, 2-references additional Y-STR profile entry guidance; 20.3.5 3-adds when Specimen Details Report is added to case file, 5 & 6-updates when analyst can make changes to CODIS entry; 20.3.6 6-updates when analyst can make changes to CODIS entry; 20.4 2-clarifies when one-time searches can be conducted; 20.5 added back-up can assign identifier code; 20.5.1 1-added alternate standard staff searches; 20.6.3 added familial searching guidelines; 20.6.5 genealogy testing guidelines added; 20.6.6 updated LDIS/SDIS disposition
9/16/2022	**QA 7:** 7.2.4 removed QIAamp DNA Investigator kit, added Buffer G2; clarify who can perform QC tests, clarify PrepFiler Express Kit and QIAgen EZ-1 kits are separated, remove that Section Supervisor or DNA Tam Leader have to sign off on COQC; 7.2.4.1 #3 of lysis procedure-change to 1 hour; added information on the QC process **QA 8:** 8.1- 5 and 6 added to clarify thermometers and Driftcon; #8- added heatblocks and incubator; 8.2 added test thermometers to other monitored equipment; 8.4.5 added when to do a performance check to 7500; 8.4.6-added Driftcon to the performance check; 8.4.8 added performance check to test thermometers and added who will check that

	record; 8.4.9-added information on the annual performance check and what to do if taken out of service; 8.4.11 **QA 18:** Add that non-criminal SAK's can be accepted. 18.2.5 h). clarified processing of fired evidence used for investigative purposes. 18.2.8 e & f). Added information about familial and forensic genealogy testing **QA 20:** added CODIS admin responsible for review and approval of procedures for CODIS; 20.2 Definitions- added elimination, clarified forensic unknown. 2.3.1#8 added SDIS needs MME of 15,000, #16 added exception for juvenile suspects in SAK cases, #22 changed 72 to 120, added #23 with information about outside lab testing items of evidence; 20.5.1 #3 & 4 added that both supervisor and TL needs to be informed of a match; 20.6.3 added new familial procedure
4/22/2024	**QA 3:** 3.1.1 g) added what to do for missed PT; 3.1.2 f) added analyst can assist in validations, performance checks and material modifications. **QA 5:** 1st bullet: clarifications on consumption and naming;4th bullet: added communication with the officer if only item requested for testing is rejected; 7th bullet: added DNA extract containers; 5.3.1 2nd bullet remove that requires evidence with multiple section testing to be accepted by first section; 5.4 add need documentation in case file for what swabs are used for testing if more than 4;5.5.4 4th bullet: added or designee; 5th bullet: clarifies how long amplified DNA can be kept refrigerated; 5.5.2 2nd bullet: evidence maintained in the lab are stored frozen; 3rd bullet: added complete consumption; 4th bullet: added storage requirements for vendor/outside agency extracts; 5th bullet: added "of the evidence at the conclusion of testing"; 6th bullet: added secure lockers for evidence transfer may be used; 5.6.1- added upload to Evidence.com and removed requirement for photos to have a PLIMS #; 5.6.2: added where to find instructions (SOP 6.8). **QA 7:** added 7.2.4.2 instructions for making a standard curve; 7.5: clarified what re-interpretation is not; 7.5.1: **QA 8:** 8.4.5 added to performance checks the calibrators; 8.4.11 added what to do with pipettes are found to be as found-"out of tolerance" **QA 9:** 9.2.1 added some variation my occur due to limited information available; 9.2.2: Human origin and Y screening are marked as not tested; both STRMix and ArmedXpert interpretations will be made and what stats will be performed; 9.2.3: clarified who can technically review proficiency tests; 9.2.4: added designee, added that variations will be reviewed and that a qualified analyst will review the DNA Technical Leaders PT. **QA 10:** 10.1 added clarifications of the nonconformities classes; 10.2: added notification of corrective action and how they are tracked. **QA 11:** 11.2: needs sufficient description of evidence in the report. Added 8. Appendix will be added to reports (definition of appendix); added category of Laboratory activity; 11.4 added #3, how report will be formatted; 11.5 #3 new review worksheet for amended reports; when to add activity date and how.

	QA 12: Added batch review; 12.1: New case file contents,12.2: clarified review requirements; 12.3: added if TL is technical reviewer, than a DNA team leader or designee arbitrates the discrepancies; 12.5 added clarification on what to do if errors are detected after review. **QA 15:** 15.1.2 added designee; 15.2: clarified was needs to be searched against staff database; added designee; 15.2.1: identifies what is considered contamination and how to handle. **QA 16:** 16.1.1: clarified ownership of known profiles; 16.1.2 a) added what are responsibilities of the reviewer of vendor data; added d) and e). **QA 17:** added maintained electronically to 17.4, 17.5 and 17.6; 17.7 added; 17.8, 17.9, 17.10 added "electronic" added; 17.11: added verbal as in -person or telephonic. **QA 18:** clarified how to label alternate standards; 18.2.1a) All SAKS except anonymous ones need to be tested; b) 1st submission SAK only; c)inventory all kits but explains Routine and Priority; d) added designee and considerations for Y STR's; e) can be recommended in case report even w/o a standard; g) added underwear and condom to be tested if kit is negative; 18.2 a) documentation of meeting added to case file; b) exceptions to number limit can be made by supervisor, DNA team Lead or designee; 18.2.3 clarified items left at the crime scene, added tool and added "depending on scenario" can only test one item; 18.2.5 a) defined touch vs handler DNA; h) added investigations chain of command has to approve testing of fired evidence; 18.2.6 removed requirement to involve both section supervisor and DNA TL; added that a meeting needs to take place, and any deviations to be documented; a) limited to 3 items one of which is SAK; 18.2.8 added instructions for recommending Y's and STRMix; h) changed FGG to FIGG, I for investigative. **QA 19:** 19.1 documented what is provided for case file records; 19.4 added outsourcing reports. **QA 20:** added use of COStaR workbook; 20.2: added clarification of some definitions; 20.3.1 #1 added expected donor; #2 added see SOP 10 for UHR; #4 added expected donor; #5b added expected donor; #6 need 7 loci over analytical threshold; #9 added expected donor; #11 added composite profiles; #12 added when samples can be reinterpreted with STRMix; #13 after data review a staff database search will be done; #14 a standard needs to be submitted or requested changed elimination to consensual partner; no need to review SAK eligibility if the suspect is a female; 20.3.2 #1 alleles outside NDIS range will not be entered into CODIS; #4 added assumption of a "profile or contributor"; 20.3.3 #1 & #4 added expected donor; 20.4 #1a) #3 added Emergency upload request #6 added that Y's will not searched in CODIS; 20.5 new staff profiles added on a monthly basis; 20.5.1 #1 will also search profiles deemed uninterpretable, #2 if LR over 1,000 then notify admin; if staff match occurs and the individual provides a buccal for the case, then profile can be used; 20.6 reviewer and TR must be qualified in the current technology; 20.6.1#5 added "report has been issued" #8 added match reporting; 20.6.2 #4 add "profiles with source ID=no will be confirmed and

	reported; #5 added analysis will generally be performed by original analyst; #7 added hit report has been issued; #10, notification email is attached in PLIMS; Added #11- information about expungement; #12 added email and date of offense to State/National case to case and to suspect database hit reports; 20.6.3 #1when can submit familial cases to state and how frequently; 1c) added minor profiles that have 8 or more of core loci; #2 added state requirements to test Y's for familial; 2 b) add at time of testing; #3 states what form to fill out; 3b) search will be done on original profile; #4 if no positive associations, then a pedigree tree will be built; #5 any subsequent searches need a new lab to lab form; &i) pedigree tree deleted is suspect identified and confirmed; #8 new potential familial hit during subsequent routine CODIS searches; #9 new case file documentation; 20.6.5 FIGG if more testing is required then a service request will be submitted; 20.6.6 replace suspect hit with suspect CMPD match at LDIS; 20.7: data back ups are done monthly; 20.9 #1 if profile is deleted during technical review, then paperwork stays in file; #3 if the case file is no longer available, the DNA record needs to be deleted; #4 expungement needs to come from the ADA's office. **QA 21: removed**
7/27/2026	**QA 1:** Added additional info about QAS to Scope 1.2 **QA 2:** Clarified when TL memo added to Staff Qualifications folder under 2.2.1 DNA TL Contingency Plan **QA 3:** Changed verbiage of introductory paragraph of Personnel to be compliant to QAS language. Updated 3.1.1 Qualifications of DNA Analysts to updated QAS language in sections a) b) d) e) f) g) and i). Updated 3.1.3 Qualifications of the DNA Technical Leader to updated QAS language in sections a) through e), h), i). Updated 3.1.4 Responsibilities of the DNA Technical Leader to updated QAS language in first paragraph and f) and h). Updated 3.1.5 Qualifications of the CODIS Administrator to updated QAS language adding paragraph referring to prior memorialization of education, experience, and training. Updated 3.1.6 Responsibilities of the CODIS Administrator to updated QAS language in first paragraph referring to prohibition of CODIS upload if position is unoccupied. Added Rapid to d). Changed 3.1.7 to be the Qualifications of Forensic Biologist and 3.1.8 to be Responsibilities of Forensic Biologists. 3.1.9 and 3.1.10 are now the Qualifications and Responsibilities of Support Personnel (Crime Lab Technicians). Added 3.1.11 Technical Reviewer. Added analysts and technical reviewers to 3.2 bullet point 1. Professional Development. Added DNA Technical Leader, CODIS Admin, analysts, and technical reviewers to first sentence of bullet point 3 section 3.2. Added All Biology technical personnel to bullet point 5. of section 3.2. Section 3.3 added technical review to Training and Qualification Records bullet point 1. **QA 4:** Simplified section 4.2 Laboratory Layout to state that separate lab coats will be dedicated to separate lab spaces and activities. **QA 5:** Added the requirements of the tape seal INITIALS/CMPD CODE/DATE to third bullet point on opening page and repackaging

	requirements including proper labeling on outer package in fourth bullet point. Added a fifth bullet point to add PLIMS change of description if evidence is rejected for testing. Bullet point seven added an exception for testing if for comparison only and no CODIS entry. Section 5.2 clarified to open tubes in a manner to prevent cross contamination. Clarified 5.3.1 bullet point two to be another Section of the Crime Laboratory. Updated 5.3.2 to specify the use of the GBC as a temporary location, the locations of GBS and the use of evidence lockers. Additional bullet points were added to include guidance on personal custody of evidence. Evidence should only be in the personal custody of the analyst when the examination is started and should be transferred to a secure location when the examination is complete. Directions for the creation of a Bulk Containers was added to 5.5.1. Custody location for Sample Consumed was updated in 5.5.2. Section 5.6.1 additional information was added to Photographs under 5.6.1 to distinguish from evidence and the retention requirements. Section 5.7 is updated with information for Evidence Sent to Outside Agency or Vendor Lab. **QA 6:** Section 6.1 and 6.1.1 and 6.1.2 updated language from QAS to define Developmental Validation, method evaluations, and additional information about Rapid DNA in section 6.1.2 e). Section 6.1.2.1 changed procedures to methods. Section 6.2 Software description of requirements to updated QAS language included all Internal Validation/Testing of software in section 6.2.1. **QA 7:** Added EZ2 to list of critical reagent description under 7.2.4. and added clarification of verification step to include lot numbers and the pass/fail criteria in last paragraph. Section 7.2.4.1 step 5 added refer to COQC for instructions. Last paragraph of 7.3.1 clarifies verification and photograph requirement. Section 7.3.2 changes the expiration date of NIST-traceable to SRM expiration. **QA 8:** Third paragraph of Equipment includes accessed online via a laboratory computer. 8.1 Driftcon is not required annually as long as valid certificate. Section 8.2 Other Monitored Equipment list now includes ALS and UV crosslinkers. 8.4.4 updated to Trio VSC method. Section 8.4.5 paragraph two adds in a negative control. Section 8.4.5.2 Biannual Diagnostics – Performing the Dye Calibration step 7 and 8 include more details and specify names of dye plates and distinguishes System and Custom plates. Section 8.4.6.1 specifies path to save run file. Section 8.4.7 Genetic Analyzer (3500) has new first paragraph to define order that maintenance should be completed. Updated instruction steps 21, 23, and 24. Section 8.5.3 states use of hoods as a clean space. 8.5.4 changes M-vac PM to every four years per manufacturer. Added 8.5.5 and 8.5.6 for ALS and crosslinkers. **QA 9:** Added Forensic Biologists to title of 9.1.2. Added one test annually specifically for PG to 9.2.2. Added Technical Personnel to title of 9.2.2. Added 9.2.2.1 and 9.2.2.2 with specific guidance on completing the proficiency testing paperwork for each type of DNA PT. Clarified group processing in PT requirement, performing a LR, and YFP statistics.

	Section 9.2.4 includes additional information checked for PG proficiency tests. **QA 10:** Section 10.2 completed and implemented as soon as is practicable. **QA 11:** Updated 11.5 Amended Reports with instructions for amending the report. **QA 12:** Added Batch, TR/AR to table in 12.1. and expected order to case file contents. Added additional information about case file order when rework is performed and when both GF and YFP are performed together. Specified Technical documents included but not printed as LR from previous – support for exclusion, inconclusive, and exclusion. Section 12.5 Errors Detected After Review now includes a workflow for case files. **QA 13:** Section 13.2 Written Manuals now includes made available electronically. Section 13.3 now covers all Laboratory waste – biological, chemical, glass and sharps. Section 13.4 specifies location of reagent notebook. Section 13.5 clarifies R drive location through portal for MSDS. **QA 14:** Section 14.1.1 second bullet point includes technical reviewer and changes language to updated QAS requirement of one external audit. Third bullet point adds prior qualifications from previous employer and prior educational review. Added technical reviewer and technical personnel to bullet points four and six. Section 14.1.2 Internal FBI QAS Audit specifies current FBI auditor training. Section 14.2 changed to Annual Laboratory Monitoring Activities with section 14.2.1 now as Quality Assurance Audit. Section 14.2.2 is DNA Annual Case File Review. Section 14.3 removes previous description and information on periodic CODIS audit by FBI. Section 14.4 newly added as Laboratory Surveillance Activities and Accreditation Audits. **QA 15:** Section 15.2 Added staff match to an employee and date of incident. In 15.2.1 Isolated Contamination Plan last paragraph added depending on outcome of rework Systemic Contamination Plan may be initiated. Rework steps now specify sample or control. **QA 16:** Section 16.1.2 Ownership of Data part b) changed to reflect updated workflow. **QA 17:** First paragraph of Records added competencies and work authorizations. Section 17.1 added technical manuals – SOPs, QA, Training. Section 17.2 added quality assurance standards. Section 17.7 changed to case records in first sentence. Added 17.12 Validation Records and 17.13 Critical Reagent/Equipment Records. **QA 18:** Case Acceptance Policy Clarified added cold cases prior to 2001 second paragraph and in 18.2.6. Sixth paragraph juvenile non-testimonial order added. Section 18.2.1 d) added Detective and submission of suspect buccal and sufficient extract volume to 18.2.8 also. Changed 18.2.3 to one item for Burglary/Property Crimes. Changed 18.2.5 from touch to trace DNA. Added 18.2.9 Outsourcing and 18.2.10 Rapid DNA. **QA 19:** Section 19.1 Case File Records added STRmix run folders. 19.2 Supporting Documentation includes a request from a prosecutor.

	QA 20: Section 20.1 CODIS Administrator added Rapid DNA partner agency. Section 20.3.1 Acceptable Samples for Entry 5 b) added additional information on alternate standards and 14 last paragraph added information when suspect standard is not consistent with forensic profile. Section 20.5 Maintenance of an Employee (Staff) DNA Index second paragraph added reviewed for accuracy. Section 20.5.1 bullet point 2 and 3 now have additional guidance on staff hits to an employee. Section 20.6 Generation of Investigative Leads second paragraph added minimum administratively reviewed for clerical errors. 20.6.1 LDIS Matches bullet point 4 clarifies when a match report may be issued. Bullet point 7 added tri-allele for buccal standard. Bullet point 8 added "Items Previously Reported" and [contributor #] to reporting template. Section 20.6.2 SDIS and NDIS Matches bullet point 11 added expungement statement in report and b) North Carolina statute 15A266.3A(j),(k) added. Bullet point 12 added "Items Previously Reported", [contributor #], and detainee to reporting template. Added template reporting for State suspect buccal to a case hit. Section 20.6.3 Familial Searches bullet point 2 added NCSCL single source requirements for Y-STR of 6 or more loci and major with 10 or more loci. Added b) information about profile adjustment for the familial search and entry by CODIS Admin. c) added the case synopsis using the NCSCL's Familial Case Notes document. Rewrote Rapid DNA 20.6.4 to reflect updated NDIS status. Section 20.9 Deletion of profiles from CODIS bullet point 2 added [contributor #]. Section 20.10 CODIS Security bullet point 4 changed to City of Charlotte. **Appendix 1** – Added d/i (date/initial) **Appendix 2** – Updated and added definitions Analyst, casework CODIS Admin, Certified reference material, Code number, Contract employee, Exclusion, Forensic Biologist, Rapid program and operators, Internal lane standard range, Likelihood ratio, Ownership review, Persistence, Prevalence, Probabilistic genotyping, Recovery, Sensitivity studies, Specificity studies, Support for exclusion, Support for inclusion, Technical leader, Technician, TPPR, and Transfer.

Approved by: _____ Date: 7.27.26
(DNA Technical Leader)

_____ Date: 7.27.26
(Section Administrator)

_____ Date: 7/27/2024
(Laboratory Director)

Aby Moeykens

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