



Forensic Biology Section

Forensic Biology Quality Assurance Policy

1. **Scope**

- 1.1. The Forensic Biology section has a quality system that works to ensure the integrity of the DNA testing process. There is also an extensive set of lab wide quality assurance policies, but this policy specifically addresses the analysis of DNA as prescribed by the FBI Quality Assurance Standards (QAS) for forensic DNA and DNA databasing laboratories.
- 1.2. The Forensic Biology section has three major responsibilities:
 - 1.2.1. Providing DNA analysis of biological material from criminal cases submitted to the Crime Lab by any law enforcement agency in the state of Maine.
 - 1.2.2. Maintaining a database of DNA profiles from casework evidence items, missing persons, and convicted offenders according to Maine's DNA Database and Databank Act.
 - 1.2.3. Assisting the Office of the Chief Medical Examiner with identifying decedents by comparing their DNA to close relatives or secondary known references.
- 1.3. DNA profiles from criminal casework, convicted offenders, unidentified human remains, and missing persons or their relatives are maintained in Maine's State DNA Index System (SDIS). This database is regularly uploaded to the National DNA Index System (NDIS) at the Federal Bureau of Investigation (FBI), creating a combined system of state and national databases which is referred to as the Combined DNA Index System (CODIS). These databases compare DNA profiles from casework samples, convicted offender samples and various other groups collected in each state throughout the United States and return match reports for potential hits. Parts of these databases separately search for matches between unidentified persons and family members of missing persons.

2. **FBI Quality Assurance Standards (FBI QAS)**

The Forensic Biology section follows the FBI Quality Assurance Standards (FBI QAS). The FBI QAS standards cover the following areas which are addressed in this policy:

- FBI QA Standard 3 – Quality Assurance Program
- FBI QA Standard 4 – Organization and Management
- FBI QA Standard 5 – Personnel
- FBI QA Standard 6 – Training
- FBI QA Standard 7 – Facilities and Evidence/Sample Control
- FBI QA Standard 8 – Validation
- FBI QA Standard 9 – Analytical Procedures
- FBI QA Standard 10 – Equipment
- FBI QA Standard 11 – Reports and Documentation
- FBI QA Standard 12 – Review
- FBI QA Standard 13 – Proficiency Testing
- FBI QA Standard 14 – Corrective Action
- FBI QA Standard 15 – Audits
- FBI QA Standard 16 – Professional Development
- FBI QA Standard 17 – Outsourcing Ownership



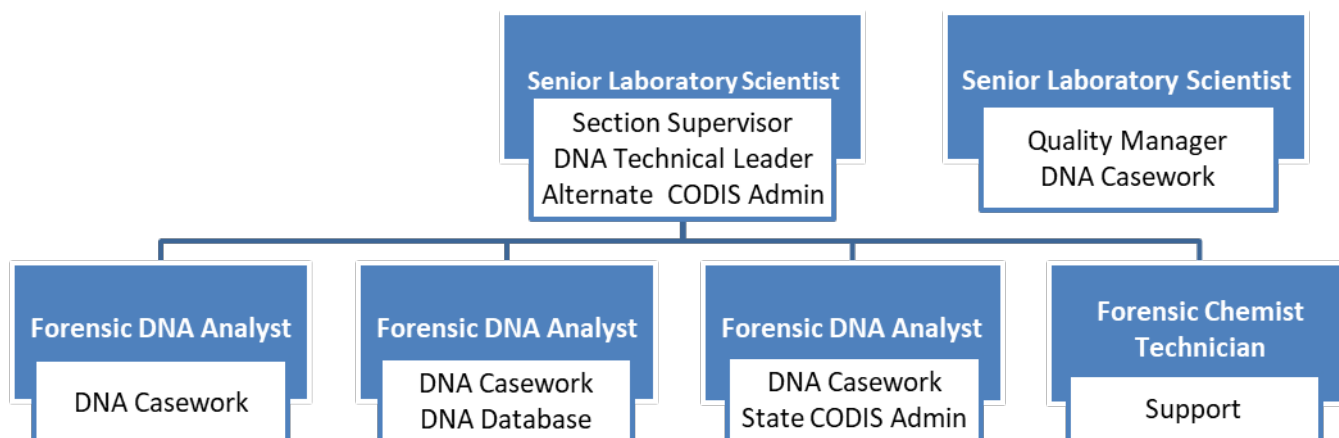
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Quality Assurance Program

- 2.1. The Forensic Biology section is committed to providing the highest quality DNA analysis to the State of Maine and strives to stay on the cutting edge of new technology and innovative DNA analysis techniques to provide faster results and greater discrimination from smaller samples. All actions taken by Crime Lab staff should be done in good faith with the highest ethics, public safety interest, and respect for civil rights possible. Sometimes there may be limited information regarding the origin of evidence or the circumstances surrounding a case. When that occurs, the staff will attempt to obtain clarification from the investigator or prosecutor in the case.
- 2.2. The lab wide policies Document Control (QA-P001) and Archiving (QA-P026) address document retention as defined by the State of Maine Records Management.
- 2.3. An annual review of the quality system is conducted by the DNA technical leader by reading and marking as reviewed the methods, policies, and forms in the lab records management system (Paradigm).
- 2.4. An annual review of case files and database records are conducted concurrently with the annual internal audit performed by the Quality Manager. The scope of review is defined and approved by the DNA technical leader.
 - 2.4.1. The approved scope for casework records includes a variety of cases from several different DNA Analysts covering a range of sample types (blood, epi, and differential if possible). Spot checks of the worksheets, data, report, and chain of custody should be performed on each case.
 - 2.4.2. The approved scope for database records includes a variety of convicted offender batches and CODIS Hits. Spot checks of the worksheets, data, and CODIS Hit reports should be performed.

3. Organization and Management



3.1. Organization Chart

- 3.1.1. There is 1 Supervisor/DNA technical leader position and 5 full-time DNA Analyst positions. The Crime Lab's Quality Manager is also a qualified DNA analyst and performs DNA casework on a part-time basis. Technical Reviewer positions may be contracted on occasion (otherwise the qualified DNA analysts perform all the technical reviews).



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- 3.1.2. There is 1 Forensic Chemist Technician position that serves as support staff (does not perform DNA analysis).
- 3.1.3. The DNA Analysts, Quality Manager, and DNA technical leader all perform DNA casework.
- 3.1.4. Some of the DNA Analysts also perform DNA database lab work.
- 3.1.5. One DNA Analyst is a Senior Laboratory Scientist and serves as the State CODIS Administrator as well as doing casework. Another qualified DNA Analyst serves as the Alternate CODIS Administrator.
- 3.1.6. The staff are predominantly state employees with the occasional temporary contract employees.
- 3.2. Contingency plan for vacancy in the TL position:
 - 3.2.1. Should the TL take a leave of absence from the laboratory for any significant period of time, the Director will appoint an interim TL to fulfill the duties until the return of the TL.
 - 3.2.2. If the TL permanently leaves the service of the laboratory, the Director will immediately appoint an interim TL to fulfill the duties until a permanent replacement is hired.
 - 3.2.3. In either event, the interim TL will be required to meet all the education and experience requirements defined below, and he or she will review the validations and methodologies currently used in the DNA lab, as well as the educational qualifications and training records of currently qualified DNA analysts.
 - 3.2.4. If it is impossible to appoint an interim TL, the Director will **immediately notify the FBI NDIS Custodian and offer a contingency plan within 14 days of the vacancy.**
 - 3.2.5. Without a TL, work on any casework samples or database samples that are in progress on the date the TL leaves the laboratory may be completed, but no new work will begin on casework or database samples, and no technical reviews will be done on data from external sources, until the FBI NDIS Custodian approves the contingency plan.
 - 3.2.6. It should be documented that no new casework or database samples were initiated until the FBI approves the contingency plan.
- 3.3. Contingency plan if only 1 full-time qualified DNA analyst:
 - 3.3.1. If the number of full-time qualified DNA analysts drops below 2, the Crime Lab will contract the services of a second full-time qualified DNA analyst.
 - 3.3.2. Without at least 2 full-time qualified DNA analysts, work on any casework samples or database samples that are in progress on the date the number of full-time qualified DNA analysts drops below 2 may be completed, but no new work will begin on casework or database samples.
 - 3.3.3. Since a single DNA analyst cannot do technical reviews on their own work, their cases and data from external sources cannot undergo technical review until the Crime Lab contracts the services of a second full-time qualified DNA analyst. If a case of another DNA analyst has already been technically reviewed and only needs to be administratively reviewed by the single DNA analyst, that report may go out.
- 3.4. The date of hire (or appointment or promotion if already employed) determines which version of the FBI QAS is applicable to a position's education, experience, and training requirements.



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- 3.5. The position of CODIS Administrator must be occupied in order for the laboratory to upload DNA profiles to NDIS. If the Alternate CODIS Administrator position can assume the CODIS Admin responsibilities, then DNA profiles may be uploaded to NDIS.

4. **Personnel**

4.1. Job Descriptions:

- 4.1.1. Official state job descriptions can be found in Paradigm under each individual's 'Training and Safety' folder (under 'Education and Experience').

4.1.2. Forensic Biology Supervisor:

- 4.1.2.1. The supervisor is the manager of the day-to-day operations and personnel in the Forensic Biology section.
- 4.1.2.2. The supervisor also serves as the DNA Technical Leader (TL) for the Forensic Biology section.
- 4.1.2.3. The supervisor is responsible for technical problem solving, day-to-day management of the DNA laboratory, and resolving technical review issues when DNA analysts cannot agree. The supervisor may perform DNA casework and review cases and must be accessible to laboratory personnel to provide consultation as needed.
- 4.1.2.4. As TL, the supervisor is accountable for the section's technical operations. If he/she delegates these responsibilities, they are still ultimately responsible and will periodically review documentation of such.
- 4.1.2.5. As TL, the supervisor shall perform and document the following items:
- Stop or suspend laboratory operations in the section if deficiencies are detected. The TL must also authorize initiating or resuming technical operations if individuals or techniques have been stopped or suspended.
 - Evaluate and approve validations and methods used in the section (or review within 1 year of appointment).
 - Review the academic transcripts and training records for newly qualified DNA analysts, technicians, and technical reviewers, as well as approve the qualifications of DNA section members before they conduct independent casework analysis (or review within 1 year of appointment).
 - Approve the technical specifications for outsourcing agreements for DNA analysis.
 - Review potential conflicts of interest when contract employees are employed by multiple NDIS participating and/or vendor laboratories.
 - Review internal and external DNA audits.
 - Approve corrective actions in the section.
 - Annually review the section's procedures.
 - Review and approve the training, quality assurance, and proficiency tests in the section.



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4.1.3. State CODIS Administrator:

- 4.1.3.1. The CODIS administrator is a DNA analyst that is also the CODIS Manager and administrator of the laboratory's SDIS database and computer system.
- 4.1.3.2. An Alternate CODIS Admin will perform these same duties in the absence of the regular CODIS Admin.
- 4.1.3.3. The CODIS administrator shall perform and document the following items:
 - Stop or suspend a DNA analyst's or the laboratory's participation in CODIS in the event of a problem.
 - Administer the laboratory's local CODIS network.
 - Schedule and document the CODIS computer training of DNA analysts.
 - Assure that the security and quality of data stored in CODIS is in accordance with state and/or federal law and NDIS procedures.
 - Assure that the dispositions for candidate matches are set in accordance with NDIS procedures.

4.1.4. Forensic DNA Analyst:

- 4.1.4.1. The DNA analysts are responsible for performing DNA analysis and serology testing on casework and convicted offenders, performing technical and administrative reviews of laboratory work, and performing quality assurance or other duties as needed.
- 4.1.4.2. The DNA analyst will have documented mixture interpretation training.

4.1.5. Forensic Chemist Technician:

- 4.1.5.1. The technician is responsible for providing support to staff performing DNA analysis and serology on casework and convicted offenders, performing quality assurance duties including reagent prep and maintaining instruments, as well as other duties when trained and qualified.

4.2. Qualifications

4.2.1. The Supervisor/Technical Leader (or interim TL) must:

- 4.2.1.1. Be a full-time employee.
- 4.2.1.2. Have a graduate degree in biology, chemistry, or a forensic science related area.
- 4.2.1.3. Have a minimum of 12 credit hours from a combination of undergraduate and graduate courses covering the subject areas of biochemistry, genetics, molecular biology, statistics and/or population genetics, or other subjects which provide a basic understanding of forensic DNA analysis.
- 4.2.1.4. Have a minimum of three years of experience as a qualified DNA analyst with human DNA samples in a forensic laboratory.
- 4.2.1.5. Be currently or previously qualified in each technology used in the section (or have documented training within 1 year of being appointed).
- 4.2.1.6. Have successfully completed the FBI's DNA auditor training course (or complete within 1 year of appointment).



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- 4.2.2. The CODIS Administrator (and Alternate CODIS Admin) must:
 - 4.2.2.1. Be a current or previously qualified DNA analyst.
 - 4.2.2.2. Have working knowledge of computers, computer networks, and computer database management.
 - 4.2.2.3. Have successfully completed the FBI-sponsored training in CODIS software within 6 months of being appointed.
 - 4.2.2.4. Have documented DNA mixture interpretation training.
 - 4.2.2.5. Have successfully completed the FBI's DNA Auditor training course within 1 year of being appointed.
 - 4.2.2.6. The Alternate CODIS Admin must meet these same requirements so they can assume the CODIS Admin duties if needed.
- 4.2.3. DNA Analysts must:
 - 4.2.3.1. Have a BA/BS degree in biology, chemistry, or a forensic science related area.
 - 4.2.3.2. Have successfully completed college course work covering the subject areas of biochemistry, genetics, molecular biology, statistics or population genetics, or other subjects which provide a basic understanding of forensic DNA analysis.
 - 4.2.3.3. Have course work or training in statistics and population genetics as it applies to forensic DNA analysis.
 - 4.2.3.4. Have a minimum of six months of forensic DNA laboratory experience including the successful analysis of a range of samples typically encountered in forensic casework prior to independent casework analysis using DNA technology.
 - 4.2.3.5. Have successfully completed a qualifying test before beginning independent casework responsibilities.
- 4.2.4. Technicians must:
 - 4.2.4.1. Have on-the-job training specific to their job functions.
 - 4.2.4.2. Have successfully completed a qualifying test before participating in forensic DNA typing responsibilities.

5. **Training**

- 5.1. Personnel in the section are trained according to the Forensic Biology section Training Manual current at the time of their training relative to the duties that position will perform.
- 5.2. The signoff sheets for completed training of each DNA analyst is documented in Paradigm.
- 5.3. The Technical Lead approves the training, competency testing, and qualifications of DNA analysts prior to them performing independent casework (documented in Paradigm).
- 5.4. The DNA analyst training program will cover:
 - 5.4.1. DNA analysis, DNA profile interpretation and statistical qualification of inclusions.
 - 5.4.2. A wide variety of the types of samples that are encountered in casework and/or databasing.
 - 5.4.3. The technical skills and knowledge required to perform DNA analysis.
 - 5.4.4. The technical skills and knowledge required to perform technical reviews.



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- 5.4.5. The skills and knowledge required to perform testimony in court and a mock court exercise.
- 5.4.6. The training will include practical and written and/or oral competency testing.
- 5.5. The Technician training program will cover:
 - 5.5.1. The duties they will be expected to perform.
 - 5.5.2. The training will include practical competency testing.
- 5.6. The Technical Lead may approve modifications to an individual's training program based on a documented review of that individual's prior knowledge and work experience, but the individual will still be required to take a competency test.
- 5.7. When new or additional methods for DNA analysis are validated and are to be used in the section (be it a technology, profiling kit, platform, or interpretation software), the analysts will pass a practical and written/oral competency test relative to their participation in the use of the new/additional method.
- 5.8. When retraining a qualified analyst as part of a corrective action or extended absence:
 - 5.8.1. The need for retraining will be evaluated and approved by the Technical Lead.
 - 5.8.2. The DNA analyst will undergo a competency test that includes a practical component prior to returning to DNA analysis work.
- 5.9. Qualified DNA analysts do the technical review of DNA casework and database work, but occasionally a temporary contract employee may be hired to assist.
- 5.10. There is no reinterpretation of legacy data (kits are no longer commercially available). The original interpretation of any legacy data shall stand on its own, or remaining samples may be reanalyzed with current technologies for current interpretation.

6. Facilities and Evidence/Sample Control

- 6.1. DNA Laboratory Design
 - 6.1.1. The DNA laboratory is designed to minimize the potential for contamination by separating the areas for DNA extraction, PCR setup and PCR amplification. The CODIS accession/extraction lab, the CODIS PCR Setup lab, the Reagent Preparation area, the upstairs Main, DNA Extraction, and PCR Setup labs are referred to as Pre-PCR labs and measures are taken to keep them free of PCR product.
 - 6.1.2. The upstairs Amplified DNA lab and the downstairs CODIS PCR lab are Post-PCR labs because PCR product is generated, analyzed, and disposed of in those areas.
 - 6.1.3. To keep PCR product out of Pre-PCR labs, scientists should adhere to the following principles:
 - 6.1.3.1. Not working in the Pre-PCR labs after handling open tubes of PCR product.
 - 6.1.3.2. Papers that have been in Post-PCR labs should not be brought into Pre-PCR labs.
 - 6.1.3.3. Equipment such as tube racks and instruments that have been inside Post-PCR labs should not be taken out of that laboratory until their surfaces are cleaned with bleach.



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- 6.1.3.4. Reagents that have been in the Post-PCR labs should never be brought into Pre-PCR labs; they should be disposed of in the waste containers or poured down the sink drain (if allowed by SDS).
- 6.1.3.5. Tubes containing amplified DNA should never be brought into Pre-PCR labs.
- 6.1.3.6. Trash bags from the Post-PCR labs should be tied shut and carried straight outside; they should not be left in the hallways.
- 6.1.4. Guidelines as to where certain procedures and tasks are performed are outlined as follows (exceptions must be noted in case notes):
 - 6.1.4.1. Reagent Preparation: reagents are prepared in the clean environment of the Reagent Preparation area, but some procedures (such as preparing 5% Chelex or dispensing water into conical tubes) may be done in the DNA Extraction or Main Lab areas if it cannot be performed in the Reagent Prep area.
 - 6.1.4.2. Evidence Examinations: examination of evidence items should be carried out in the Main Lab area but can also be performed in the DNA Extraction lab if necessary.
 - 6.1.4.3. DNA Extraction for casework: DNA extractions for casework are carried out in biological safety hoods in the DNA Extraction lab. Steps that cannot be performed in a biosafety hood, such as chiseling skeletal remains, can be performed on the bench in the DNA Extraction area.
 - 6.1.4.4. Semi-automated procedures to extract and purify DNA on the Maxwell RSC48 instrument are manually pre-treated and lysed in biological safety hoods in the DNA Extraction lab and then transferred to the Maxwell instrument.
 - 6.1.4.5. Accessioning and Extracting Convicted Offender Samples: accessioning (i.e. opening, logging in, and repackaging) convicted offender samples as well as the DNA extraction of these samples is carried out in the CODIS PCR Setup lab.
 - 6.1.4.6. PCR Setup for casework: preparing master mixes and aliquoting extracts for quantitative PCR and DNA profiling must be performed in a biosafety hood in the PCR Setup area. PCR Setup for convicted offenders is performed in the downstairs CODIS PCR Setup area.
 - 6.1.4.7. PCR Setup of Convicted Offenders: preparing master mixes and aliquoting convicted offenders for DNA profiling is performed in the downstairs CODIS PCR Setup area.
 - 6.1.4.8. Polymerase Chain Reaction (PCR) Amplification: the production and handling of PCR product from casework (real-time quantitative PCR and DNA profile amplification) is performed in the upstairs Amplified DNA area for casework and performed in the downstairs CODIS PCR lab for convicted offenders.
 - 6.1.4.9. Capillary Electrophoresis (CE): the CE of casework is carried out in the upstairs Amplified DNA area for evidence items. The setup and handling of amplified product from convicted offenders is performed in the downstairs CODIS PCR lab. CE of convicted offenders can be carried out in the upstairs Amplified DNA area or the downstairs CODIS PCR lab.



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- 6.1.4.10. Dedicated Equipment: each laboratory has equipment dedicated to its location and function. An annual inventory takes place to track the movement of equipment.
- 6.1.4.11. Reagent Grade Water: the laboratory purchases water suitable for reagent preparation and DNA extractions. Amplification grade water is included with the DNA profiling kits.
- 6.1.4.12. Lab Coats: disposable lab coats are used in the laboratory testing areas. Lab coats should not leave the Post-PCR labs except as trash.
- 6.1.4.13. Gloves: scientists must discard their disposable gloves and should also wash their hands before leaving the Post-PCR lab. The exception to this rule is when carrying waste from the Post-PCR lab to the dumpster outside of the building: gloves should be worn to do this and then be discarded with the waste.
- 6.1.4.14. Sticky Mats: sticky mats are placed at the thresholds inside the Amplified DNA labs in an effort to remove any PCR product that could be on the soles of shoes. Anyone exiting a Post-PCR lab should step with both feet on the sticky mat before exiting.
- 6.1.4.15. Refrigerator and freezer temperatures should be monitored and recorded on a Temperature log at least once a week, preferably two to three times a week, to ensure equipment is functioning properly.
- 6.1.4.16. Irradiation of Tubes and Reagents: tubes and reagents used for DNA extraction and PCR setup are sterilized in the Reagent Preparation area according to the procedure entitled "Irradiation of Reagents and Supplies in the Ultraviolet Crosslinker".
- 6.1.4.17. PCR Product Waste: tubes and plates containing PCR product are discarded in the waste containers in the Post-PCR labs. This PCR product should only leave the laboratory in closed bags to be carried directly outside of the building. PCR product should never be taken into any other area of the Crime Lab.
- 6.2. The Crime Lab and DNA section have a security system and limited access.
 - 6.2.1. A lab-wide Laboratory Security policy outlines how the integrity of the evidence and security of the laboratories are monitored and maintained.
 - 6.2.2. Access by non-laboratory personnel will be limited and will provide a secure environment for staff and prevent possible loss, tampering, contamination or compromising of evidence.
 - 6.2.3. The restricted areas of the laboratory consist of the entire building except the lobby and the conference room.
 - 6.2.4. Laboratory work areas are always secured and accessed only with keys or proximity cards programmed to allow specific staff members into work areas.
 - 6.2.5. All exterior entrance/exit points are locked, and any visitors requesting access to the restricted areas of the Crime Lab are required to fill out the Logbook, which will record the following: date, name, and address/department of visitor; time in/out; department or person visited.
 - 6.2.6. The Director or a section supervisor may approve the call-out of laboratory personnel to receive evidence after hours.



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- 6.2.7. All laboratory personnel are issued keys and/or security cards to the Crime Lab, evidence storage rooms, laboratories, and offices. A master list of all personnel with keys and/or security cards is maintained by the Director. Master keys to all areas of the laboratory are secured in the Director's office. Lost or stolen keys and/or security cards must be reported to a section supervisor or Security Officer as soon as possible.
- 6.2.8. The building alarm must be armed when there is no one in the building.
- 6.3. Evidence Control
 - 6.3.1. The lab-wide Evidence Storage and Handling policy and the Evidence Receiving and Return policy explain practices and controls to minimize loss, contamination, and deleterious change of the evidence.
 - 6.3.2. Technicians and scientists mark all pieces of evidence and/or evidence containers with a unique case number, item number, and their date and initials. The Crime Lab has a Laboratory Information Management System (LIMS) that can assign and track case and item numbers and maintain a chain of custody for each item or sub-item.
 - 6.3.3. All evidence awaiting analysis is stored in secure evidence lockers, freezers, or refrigerators. If the freezers and refrigerators are not locked (with keys removed), they must be located in a secure area of limited access, such as within the DNA laboratory.
 - 6.3.4. The unique case number and item number should be written on every tube that an evidence item is transferred into. If a portion of an evidence item is taken, a unique identifying suffix is added to the item number to create a sub-item number. The case number and item/sub-item number will distinguish each sample throughout analysis. When setting up samples for real-time quantitative PCR, DNA profile amplification, or CE, the tray or strings of tubes that samples are aliquoted into will have a corresponding worksheet to indicate the contents of the tubes, plate, or rotor.
 - 6.3.5. Sealed evidence items from cases in progress may be temporarily stored in secure freezers or refrigerators, in a scientist's personal work-in-progress (WIP) storage space within the Main Lab, or on benches and shelves within the DNA laboratory.
 - 6.3.6. The packaging and storage conditions should minimize the chance of loss, contamination, and deleterious change.
 - 6.3.7. Bloodstain cards may be dried overnight in the Serology Laboratory or the DNA Extraction Lab (preferably in laminar flow biosafety hoods) because the areas are secure and are protected by the electronic security system.
 - 6.3.8. The length of time evidence may be in an analysts' possession or in short term storage and be considered a 'work in progress' will be based upon a justifiable expectation of frequent examination.
 - 6.3.8.1. Short term storage may be utilized when evidence is in the active process of examination. During this time, evidence may be stored in a DNA analyst's personal storage area within the Forensic Biology Laboratory or in the possession of the examiner. Only items too large for storage inside drawers or cabinets may be stored on or under a workbench.



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- 6.3.8.2. After the established time period, evidence must be returned to the long-term evidence storage area (Incoming Evidence Locker, DNA Freezer, or DNA Refrigerator) and retrieved as needed. Exceptions to these time periods may be granted by the section supervisor upon request from the examiner in the event of technical or other justifiable problems.
- 6.3.9. When a case is completed and reviewed, evidence items (other than DNA extracts) should be transferred to the Evidence Receiving area to be returned to the submitting agency.
- 6.3.10. Any remaining DNA extracts from casework items will be stored indefinitely in the freezers at the Crime Lab.
- 6.4. Consumption of Evidence: Evidentiary samples may be limited. Add the maximum amount of evidentiary sample that can fit in a tube if it is thought very little biological material is present, trying to retain sufficient sample for replicate analysis if practical. Epi/Touch DNA swabs are usually consumed since they are typically low-level samples.
- 6.5. Disposition of Evidence: The comments section of a report will include whether evidence items were consumed, retained, or are ready to be returned to the submitting agency. All convicted offender samples are retained indefinitely.
- 7. **Validation**
 - 7.1. Developmental Validations
 - 7.1.1. The section will only use methods that have been validated through evaluation of a method's efficacy and reliability in forensic casework analysis.
 - 7.1.2. Developmental validations that test a method's conditions and limitations as performed by other laboratories will be maintained in the section's library or validation binders.
 - 7.1.3. Developmental validations must include characterization of the genetic marker, species specificity, sensitivity studies, stability studies, reproducibility, case-type samples, population studies, mixture studies, precision and accuracy studies, and PCR-based studies (to include reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and product detection studies).
 - 7.1.4. New software or new modules of existing software that is a part of an instrument, or used for DNA analysis, interpretation, and statistical calculations must also have undergone developmental validation.
 - 7.2. Internal Validations
 - 7.2.1. Internal validation of methods will take place prior to implementation to demonstrate a method (steps, reagents, and the instruments and software needed to perform a process such as DNA extraction, quantification, amplification, detection, analysis, interpretation, and statistical calculations) performs reliably, effectively, and as expected in the laboratory.
 - 7.2.2. Internal validation studies will be documented and summarized, using both known references and non-probative evidence samples (mock or adjudicated evidence items for casework; convicted offender card samples for database testing) to demonstrate reproducibility and precision, sensitivity and stochastic effect, mixtures studies (for casework testing only), and contamination assessment.



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- 7.2.3. Internal validation of DNA methods (amplification through profiling), DNA profiling kits, and platform instruments will include testing with a certified reference standard (such as a component from a relevant NIST Standard Reference Material set).
- 7.2.4. The data from the internal validation should be used to help define quality assurance parameters and interpretation guidelines (including mixture interpretation for casework testing and statistics if applicable).
- 7.2.5. If a new detection platform or typing kit is introduced after an internal validation, the internal validation studies should be repeated with the new type of instrument or kit.
- 7.2.6. If new software, new modules of existing software, or major revisions/modifications to existing software are introduced, validation studies must be done to test the performance of the software.
- 7.2.7. Validation studies and summaries should be reviewed and approved by the TL before being implemented in casework or databasing.
- 7.2.8. Before a scientist can use a newly validated system in casework or databasing, that scientist must successfully pass a competency test or external proficiency test and be signed off as proficient by the TL and approved by the Director. Scientists intimately involved with a validation project, to the extent they will be utilizing the method in casework or databasing, may be signed off as competent by the TL based on their documented participation in the validation.
- 7.3. Modifications to Standard Operating Procedures
 - 7.3.1. Significant changes to analytical procedures will be documented and subject to evaluation as determined by the TL.
 - 7.3.2. Test results using the modified procedure should be compared to test results using the original procedure with similar DNA samples.
 - 7.3.3. The modifications and their evaluation should be documented, incorporated into a new version of the protocol, reviewed by the TL, and approved by the Director before they are incorporated into casework applications.
- 7.4. Performance Checks
 - 7.4.1. Performance checks are tests using known standards to evaluate the accuracy and/or validity of analysis on a specific instrument (if that instrument is new or undergoes service) as well as upgrades to analytical software packages.
 - 7.4.2. Test results from the performance check should be compared to test results using the original, validated procedure with similar samples; comparable values should be obtained from the original and new instrument or software package.
 - 7.4.3. If a new model of instrument uses the same software package, only a performance check needs to be performed; if both the instrument model and the software change simultaneously, a performance check is inadequate, and an internal validation needs to be performed.
 - 7.4.4. Performance checks should be run and documented on essential detection platforms (i.e. sequencers and real time thermal cyclers) on an annual basis. Similarly, a performance



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check should be run after an instrument is serviced (such as an annual Performance Maintenance service) on an essential detection platform.

7.5. Novel Forensic DNA Methodologies

- 7.5.1. In special situations, methods that have not been internally validated may be used for casework if approved by the TL.
- 7.5.2. When the need occurs, methods will be selected that have been used by reputable technical organizations or published in relevant scientific texts/journals or have been appropriately evaluated for a specific or unique application.
- 7.5.3. Copies of the method along with thorough case notes will be maintained in the case folder as documentation of the procedure used.

7.6. The laboratory does not use Rapid DNA instruments.

7.7. Validation studies (developmental, internal, modifications to SOP's, and software testing) that are approved by the TL should be retained and be available for review.

8. Analytical Procedures

- 8.1. Each analytical technique used in the section has a standard operating procedure that reflects current practices and includes reagents, sample preparation, equipment and controls that are necessary for that procedure. Each procedure also includes guidelines for safety and quality assurance.
- 8.2. These written analytical procedures are readily available to the scientists performing the procedure in the laboratory where the procedures are carried out.
- 8.3. Analytical methods are based on the internal validations originally performed, are approved by the TL and Quality Manager, and will be reviewed by the TL and scientists in the DNA discipline (as it applies to their duties) on an annual basis.
- 8.4. When a significant change is made to a procedure, the version number of the procedure will change, and all scientists who perform that procedure will read and sign that they have read the procedure prior to using it in casework.
- 8.5. Reagents
 - 8.5.1. The following reagents are deemed essential and require QC testing before use:
 - 8.5.1.1. DNA profiling kits (e.g. Fusion or Y23).
 - 8.5.1.2. DNA quantitation kits (e.g. Sybr Green Alu repeat).
 - 8.5.2. The following reagents are deemed important and may be QC tested before use:
 - 8.5.2.1. DNA extraction kits (e.g. QIAamp columns).
 - 8.5.2.2. Chelex resin beads (for DNA extraction).
 - 8.5.3. Written procedures are used for evaluating essential reagents and materials, the acceptable ranges of results, and how to address unacceptable results. Records of all QC'd reagents and kits are maintained in individual QC Folders in the section.
 - 8.5.4. Receipt of reagents and/or chemicals by the section are recorded in the Forensic Biology Chemical Logbook.



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- 8.5.5. Commercial reagents are labeled with the date received at the time of receipt. The scientist who receives the reagent(s) is responsible for making sure that an SDS is on file for that reagent in the section's SDS as well as sending a copy to the Chemical Hygiene Officer for the lab wide SDS.
- 8.5.6. When reagents are opened, they are labeled with a date opened. If there is no expiration date on the container, a date may be assigned (generally one year from the date opened). When a reagent is transferred from a large container to a smaller one, the smaller container is labeled with the identity, expiration date and lot number of the reagent.
- 8.5.7. Recipes for in-house reagents used in the DNA section (e.g. extraction, quantification, amplification and typing) are kept in the Forensic Biology Solutions Logbook. The lot numbers of the components are recorded, and a Lab lot number is assigned. Most reagents are prepared in the Reagent Preparation area to minimize the potential for contamination.
- 8.5.8. When reagents are prepared in-house, they are labeled with the identity of the reagent and an expiration date. The lot number for in-house reagents is composed of the date of preparation and the individual preparing the reagent.
- 8.5.9. Expiration dates for reagents may be extended by retesting or documenting the reagent continues to perform as expected, thereby extending the expiration date. This documentation should be recorded in the original QC folder.
- 8.6. Quantification
 - 8.6.1. DNA extracts generated from evidentiary samples will be quantified using the procedure "Rotor-Gene Real-Time PCR Quantification of DNA Extracts." The quantification results help to determine the amount of DNA extract to add to the PCR reaction.
 - 8.6.2. It is optional to quantify DNA extracts from reference samples.
 - 8.6.3. Samples that have a low concentration (typically 0.05 ng per microliter or less) may be concentrated and amplified without repeating the quantification procedure, at the discretion of the analyst.
 - 8.6.4. If a sample quantifies as "having an insufficient amount of DNA to produce an interpretable DNA profile" (specified in the Amplification and Detection protocols), no further DNA analysis needs to be conducted.
- 8.7. Controls and Standards
 - 8.7.1. Reagent Blank Extraction Controls
 - 8.7.1.1. For each set of samples extracted, a minimum of one reagent blank is concurrently extracted and DNA profiled using the same kit, instrument, and injection conditions as the forensic samples in the batch.
 - 8.7.1.2. At least one reagent blank should be amplified at the same volume of extract as the least concentrated forensic sample in the batch, or the maximum volume of DNA extract possible (i.e. the most sensitive condition used in the samples).
 - 8.7.1.3. If a sample is re-amplified with the same DNA profiling kit, the reagent blank does not need to be re-amplified if the reagent blank's previous amplification volume is equal to or greater than the volume of the forensic samples in the new set of amplifications.



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- 8.7.1.4. If the reagent blank associated with a particular batch of extractions is depleted, the samples in that batch cannot be amplified with a different DNA profiling kit or under different amplification conditions.
- 8.7.1.5. The reagent blank should not give interpretable results in order for the results of that batch of samples to be reported (see "Control Failure" below).
- 8.7.2. Quantification Standards and Controls
 - 8.7.2.1. Quantification standards and controls are prepared in accordance with the Rotor Gene preparation forms.
 - 8.7.2.2. The variation of the standards and controls must be within acceptable ranges.
 - 8.7.2.3. If virtual or external standard curves are used, a calibrator must be run concurrently with the samples.
- 8.7.3. Amplification Controls
 - 8.7.3.1. Positive and negative amplification controls are included with every set of amplification reactions.
 - 8.7.3.2. The negative control has only TE buffer or water instead of DNA extract.
 - 8.7.3.3. Positive controls must give appropriate results and negative controls must give no interpretable results if data is to be reported (see "Control Failure" below).
- 8.7.4. Allelic Ladders / Internal Size Standards
 - 8.7.4.1. An internal size standard is included as a part of every sample analyzed on the 3500 Genetic Analyzer.
 - 8.7.4.2. Allelic Ladders are analyzed as a part of every run on the 3500 Genetic Analyzer.
 - 8.7.4.3. If a ladder in a set of runs fails, a ladder injected on the same instrument may be used as long as the controls still give appropriate results.
 - 8.7.4.4. The Ladder and size standard must give appropriate results if the data is to be reported.
- 8.7.5. Control Failure
 - 8.7.5.1. Positive PCR Control: Ideally, all of the alleles in the positive control will be detected, but the positive control is considered appropriate even if some alleles dropout or fall below the detection threshold, as long as the interpretable loci are consistent with the expected profile. If the positive control does not work or does not type correctly, repeat the injection (re-inject or re-aliquot and re-inject) to ensure it is not simply due to a faulty aliquot or failed injection. If the positive control does not work or types incorrectly repeatedly, the test results for that set of amplifications will be interpreted as "inconclusive" or "uninterpretable" and should be re-amplified with a new positive control. If multiple positive controls are run with a batch of samples, only one of the positive controls must work in order to report the data from that batch.
 - 8.7.5.2. Negative PCR Control – if the negative control gives an interpretable DNA profile, repeat the injection of the negative control (re-inject or re-aliquot and re-inject) to ensure it is not simply due to a faulty injection or contaminated well on



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the plate. If the negative control fails repeatedly, the test results for that set of amplifications will be interpreted as "inconclusive" or "uninterpretable" and should be re-amplified with a new negative control.

- 8.7.5.3. Reagent Blank Extraction Control – if the reagent blank control gives an interpretable DNA profile, repeat the injection of the reagent blank (re-inject or re-aliquot and re-inject) to ensure it is not simply due to a faulty injection or contaminated well on the plate. If the reagent blank repeatedly fails, any DNA profiles obtained from the set amplified with that particular control should be interpreted as "inconclusive" or "uninterpretable" and the reagent blank and corresponding samples should be re-amplified. If the relevant reagent blank continues to fail after re-amplification, any DNA profiles obtained from the set extracted with that particular extraction control should be interpreted as "inconclusive" or "uninterpretable" and the evidence items should be re-extracted and analyzed (if sample size permits) with a new reagent blank extraction control. If there is no further sample to re-extract (especially if the source of the contamination can be identified and explained), the DNA profiles may be reported along with full disclosure of the contamination event in the report.
- 8.7.6. NIST Standard Reference Material (SRM)
 - 8.7.6.1. Procedures will undergo performance checks with the NIST SRM, or against standards that are traceable to NIST, annually or whenever significant changes are made to typing procedures, as determined by the TL.
 - 8.7.6.2. Results of testing against NIST SRM will be maintained in the section. The TL will verify that the proper results have been obtained.
- 8.7.7. Interpretation of Data
 - 8.7.7.1. Written guidelines for interpretation and comparison of DNA profiles are in the relevant 'Analysis and Interpretation' protocols and the "Genetic Analysis" protocol.
- 8.7.8. Preventing Contamination
 - 8.7.8.1. Contamination is the unintentional introduction of exogenous DNA into a sample and must be monitored, detected and controlled.
 - 8.7.8.2. The steps for examining, extracting, and setting up PCR of samples are separated by time or space (or both) as much as possible to minimize the possibility of one sample contaminating another, especially between known and unknown samples.
 - 8.7.8.3. The laminar flow of filtered air inside the biosafety hoods minimizes the chance of an aerosol traveling from one tube to another provided only one tube is open at a time and good aseptic technique is employed. Opening tubes outside of a biosafety hood should be kept to an absolute minimum, especially tubes containing DNA extracts.
 - 8.7.8.4. The following practices are part of good aseptic technique:
 - Wear gloves while performing procedures.
 - Cleaning the workspace, pipettes, and racks with 10% bleach between uses.



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- Cleaning tools such as forceps with 10% bleach and then drying or rinsing with ethanol before use and between each individual specimen.
- Only one evidence item should be examined at a time; only open one tube of DNA extract at a time; use aerosol resistant pipette tips.
- Change pipette tips between each transfer and addition of reagent, unless specifically allowed in a protocol.
- Microcentrifuge tubes and in-house reagents must be irradiated before use, if possible.
- Aliquots of reagents should not be returned to the original stock container, unless specifically allowed in a protocol.

8.7.9. Monitoring for Contamination:

- 8.7.9.1. The Reagent Blank control is an analytical control sample that contains no template DNA and is used to monitor contamination from extraction to final fragment or sequence analysis, whether from the reagents used or through the handling of samples; this control is treated the same as, and parallel to, the forensic samples and known references being analyzed.
- 8.7.9.2. The Negative Control is used to detect DNA contamination in the amplification reagents; this control consists of only amplification reagents without the addition of template DNA.
- 8.7.9.3. Essential reagents are tested for efficacy as well as absence of exogenous DNA by running Reagent Blank Controls and Negative Controls when essential reagents are QC tested before being used in casework or databasing.

8.7.10. Detecting Contamination:

- 8.7.10.1. All reagent blanks, negative controls, and essential reagents undergoing QC testing are analyzed under the same conditions as evidence samples to check for the presence of interpretable DNA profiles.
- 8.7.10.2. If a Reagent Blank Control gives an interpretable STR profile, the Reagent Blank Control should be reinjected.
- 8.7.10.3. If a Reagent Blank gives an interpretable profile repeatedly, the Reagent Blank should be re-amplified (sample permitting). If the profile is not repeated, the data associated with that Reagent Blank can be reported; if an interpretable profile is detected repeatedly, see "Control Failure" above.
- 8.7.10.4. If a Negative Control gives an interpretable profile repeatedly, the test results for that set of amplifications will be rendered inconclusive and need to be reamplified (see "Control Failure" above).

8.7.11. Decontaminating:

- 8.7.11.1. When contamination is detected, the reagents used in the incident should be disposed of unless they can be verified as not being the source of contamination.
- 8.7.11.2. Any surface of a work area or equipment thought to be contaminated should be cleaned with a 10% bleach solution.



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8.7.12. Reporting data potentially affected by contamination:

8.7.12.1. If contamination is repeatedly detected in a casework sample as a mixture of a forensic DNA profile combined with a source of contamination that can be identified (e.g. Forensic Scientist or Law Enforcement agent), the data can be reported as a mixture, and full disclosure of the contamination and its source will be clearly explained in the report.

8.7.12.2. Database samples may be used if the contamination comprises 10% or less of the mixture of DNA profiles.

9. **Equipment**

9.1. The laboratory will use suitable equipment for DNA analysis as determined by the TL.

9.2. "Critical" equipment are those devices used to deliver, weigh, measure or detect a precise quantity in a procedure in which the quantity is required to be specific and reproducible and where a small variation in measurement will impact the laboratory analysis results.

9.3. The following equipment is deemed critical:

- Mechanical pipettes.
- Thermometers (NIST-traceable).
- Heat blocks and incubators used for DNA extraction.
- Thermal cyclers (e.g. ProFlex).
- Extraction robot (e.g. Maxwell).
- Genetic analyzers (e.g. 3500).
- Quantitative-PCR thermal cyclers (e.g. Rotor Gene-Q and QuantStudio 5).
- Temperature-verification system for thermal cycler QC.

9.4. "Important" equipment are those devices used to deliver, weigh, measure or detect a precise quantity in a procedure in which the quantity is required to be specific and reproducible BUT a small variation in measurement will NOT significantly impact the laboratory analysis results.

9.5. The following equipment is deemed important:

- Balances.
- Centrifuges.

9.6. Thermal cyclers, qPCR thermal cyclers, robotic extraction instruments, and genetic analyzers require validation prior to use. New instruments that are the same model as an already validated instrument only require a performance check prior to use.

9.7. All critical equipment requires calibrations or performance checks prior to use and then annually thereafter.

9.8. Calibrations and/or validations will be conducted with standards traceable to national or international standardizing bodies, such as the National Institute of Standards and Technology (NIST).

9.9. Performance checks will be conducted with DNA extracts and consumables of known values or DNA profiles. The schedule for maintenance will be documented on the cleaning charts for each laboratory space.



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- 9.10. NIST Standard Reference Material (SRM) will be analyzed annually to verify the correct DNA profiles are obtained. If established standards do not exist, the laboratory must show evidence of correlation of results. Calibration guidelines are detailed in instrument SOPs and records are maintained in the Instrument Folders or the supervisor's office.
- 9.11. New instruments and equipment, or instruments that have undergone repair or significant maintenance will be calibrated before use in casework analysis. Instruments that have documented proof of calibration by an outside agency do not require in-house calibration before being placed into service.
- 9.12. After repair or significant maintenance, the following instruments will be calibrated, or performance checked before being used in DNA analysis again (unless there is documented proof of calibration by an outside agency):
- Thermal cyclers (e.g. ProFlex).
 - Extraction robot (e.g. Maxwell).
 - Genetic analyzers (e.g. 3500).
 - Quantitative-PCR thermal cyclers (e.g. Rotor Gene-Q and QuantStudio 5).
- 9.13. If an instrument fails a calibration check and cannot be recalibrated immediately, an "OUT OF SERVICE" sign should be placed on the instrument, and the supervisor informed. Appropriate action, such as scheduling a service call, will then be taken.
- 9.14. Thermometers used to monitor temperatures of refrigerators/freezers are NIST traceable; they are to be replaced after the calibration period has expired. Electronic thermometers, such as those used to calibrate instruments, will be calibrated annually by an outside vendor.

10. Reports & Documentation

- 10.1. There are lab-wide policies related to reports and documentation. The following items clarify issues specific to DNA Analysis.
- 10.2. Case Folders
- 10.2.1. Case folders contain all of the documentation associated with a case, including case notes, worksheets, DNA profile summaries, DNA entry, statistics, and the file review sheets.
- 10.2.2. The combination of case notes, worksheets, electropherograms, and DNA profile summary sheets should support the conclusions drawn in the laboratory report.
- 10.2.3. The procedures for taking and maintaining case notes are outlined in the laboratory wide quality assurance policies.
- 10.2.4. There must be sufficient documentation of the technical analysis of samples such that another qualified individual could interpret and evaluate the data.
- 10.3. Reports
- 10.3.1. Copies of final, signed reports should be maintained in the relevant case folder. The Laboratory Information Management System also stores electronic copies of all reports written in the LIMS system.
- 10.3.2. Standard reports should include the case number, date of report, description of the evidence examined, description of the technology (e.g. STR, Y-STR) and kit name used, results/conclusions of the testing and DNA analysis for each forensic sample tested, a



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quantitative or qualitative interpretative statement to support all conclusions (see page 7 of the comparison document), disposition of evidence, and signature and title of the person accepting responsibility for the contents of the report.

10.4. Release of Case Report Information

10.4.1. Written procedures for the release of case report information can be found in the Forensic Biology "Control of DNA Records" protocol and the lab-wide quality assurance policies.

10.5. Quality Assurance logs are kept in their respective areas for the current log period (typically three-months) and are then filed in a binder or scanned into Paradigm.

11. Review

11.1. Technical and administrative reviews of case files and database files are conducted to ensure that conclusions are valid and supported by valid data. There are lab-wide policies on case file review, but the following items clarify issues specific to DNA Analysis.

11.2. A technical reviewer must be a qualified scientist, defined as an individual who is currently or previously qualified in the specific DNA technologies that the review is encompassing (including the methods of DNA extraction and quantification, the DNA typing kit, the electrophoresis platform, and the interpretation software). For DNA profiles, the technical reviewer must agree on the allele calls, interpretations, and conclusions made by the reporting scientist.

11.3. An administrative reviewer is not required to be a current or former DNA analyst unless they are verifying DNA profile data or data entry into SDIS (i.e. alleles and specimen category), in which case they must be a current or former DNA analyst qualified in the specific DNA technologies that the review is encompassing (including the methods of DNA extraction and quantification, the DNA typing kit, and the electrophoresis platform).

11.4. Sequence of review process

11.4.1. When the reporting DNA analyst has completed all analyses, interpretations, and report writing, they should put their name on a Case File Review form, mark the request 'Draft Complete' in LIMS, and forward the case file to another qualified scientist for Technical Review.

11.4.2. When errors or omissions are noted during technical or administrative reviews, the reviewer should initial and date beside the 'Review' signature line on the Case File Review form before returning the case file to the reporting DNA analyst.

11.4.3. If DNA profiles are to be entered or searched in SDIS, the data needs to be technically reviewed first (and marked as such on the Profile Summary or Case File Review sheet). Then the profile can be entered or searched in SDIS. The data entry needs to be printed from SDIS and technically reviewed for accuracy.

11.4.4. Only after all necessary changes have been completed, or if no changes were necessary, should the reviewer sign and date the Technical or Administrative Review signature line. At the same time, the appropriate level of review should be marked in LIMS.

11.4.5. Reports are released electronically and must be marked 'Draft Complete' and 'Administratively Reviewed' in LIMS.

11.5. In the case of discrepancies, the scientists should discuss the problem and come to a resolution that both scientists can agree on. Re-extraction or re-amplification of the samples may be



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necessary to obtain a consensus. If the two analysts cannot reach an agreement, the TL will be asked to help decide.

- 11.6. **Technical review** is the evaluation of reports, notes, data, and other documents in a case file or database file to ensure correct interpretation of DNA profile data and that an appropriate and sufficient basis is documented for the scientific conclusions in the case file and report.
- 11.7. The following information is verified during the technical review of a casework file:
 - 11.7.1. Check all "Examination of Evidence" notes for the following:
 - Description of packaging and seals.
 - Appearance of evidence item.
 - Statement about any sampling (cutting, swabbing) and their sub-item #'s.
 - Location of any remaining sample or empty packaging that will be transferred or returned.
 - 11.7.2. Check all "DNA Extraction" worksheets for correct item numbers, lot numbers, and that all fields are filled in.
 - 11.7.3. Check all "qPCR" worksheets for the following:
 - Correct item numbers, lot numbers, and that all fields are filled in.
 - Whether a sample has insufficient DNA to produce an interpretable DNA profile as specified in the Amplification and Detection protocols.
 - 11.7.4. Check all "qPCR Quantitation Reports" for correct item numbers, appropriate values for standards and controls, and any unusual results are noted.
 - 11.7.5. Check all "Amplification" worksheets for correct item numbers and DNA concentrations, lot numbers, and that all fields are filled in.
 - 11.7.6. Check all genetic analyzer injection list worksheets for correct item numbers and that all fields are filled in.
 - 11.7.7. Check all genetic analyzer DNA data for the following:
 - Correct item numbers.
 - Each page is initialed and dated.
 - Controls gave appropriate results.
 - Ladders and internal lane standards appear appropriate.
 - Unusual peak balances are noted or highlighted.
 - Artifacts, including pull-up and stutter, are noted and/or deleted.
 - 11.7.8. Check all "PopStats" statistical printouts for correct entry of item numbers and alleles.
 - 11.7.9. Check all "DNA Profile Summary" sheets for the following:
 - Correct item numbers.
 - Peak heights or comments on relevant allele balance.
 - Major and or minor donors are noted or highlighted.
 - Whether a locus/profile is inconclusive or produced no results.



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- Notations about profiles matching, not matching, or are included or excluded as potential donors to mixtures when compared to known references and/or other evidence samples.
- Artifacts have been deleted if profile is going to be electronically exported to SDIS.

11.7.10. For DNA profiles being entered or searched in SDIS:

- Profiles should be technically reviewed (and marked as such on the Profile Summary or Case File Review sheet) before being entered or searched.
- Verify there is documentation for the eligibility of the DNA profile to go into CODIS.

11.7.11. Check SDIS entry reports and SDIS keyboard searches for the following:

- Check that the correct alleles were entered, and that the appropriate specimen category was chosen.
- Initial and date the CODIS entry and match detail printouts.

11.8. The following information is verified during a technical review of a database file:

11.8.1. Check all "DNA Extraction" worksheets for correct item numbers, lot numbers, and that all fields are filled in (if not Direct Amp).

11.8.2. Check all "qPCR" worksheets for correct item numbers, lot numbers, and that all fields are filled in (if not Direct Amp).

11.8.3. Check all "qPCR Quantitation Reports" for correct item numbers, appropriate values for standards and controls are noted, and any unusual results (if not Direct Amp).

11.8.4. Check all "Amplification" worksheets for correct item numbers, lot numbers, and that all fields are filled in.

11.8.5. Check all genetic analyzer injection list worksheets for correct item numbers and that all fields are filled in.

11.8.6. Check all genetic analyzer DNA data for the following:

- Correct item numbers.
- Controls gave appropriate results.
- Ladders and internal lane standards appear appropriate.
- Any unusual peak balances are noted or highlighted.
- Artifacts, including pull-up and stutter, are noted and/or deleted.

11.8.7. Check all "DNA Profile Summary" sheets for the following:

- Correct item numbers.
- Correct allele calls by comparing to genetic analyzer DNA data.
- Peak heights or comments on relevant allele balance.
- Artifacts have been deleted if profile is going to be electronically exported to SDIS.

11.9. **Administrative review** is the evaluation of the report and supporting documentation (particularly the DNA Profile Summary sheets) to ensure the scientific conclusions in the report are supported by data and are consistent with laboratory policies and protocols, checking the report for grammatical and typographical errors, and checking the accuracy of any manual data entry (such as entering alleles into SDIS).



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- 11.10. The following information is verified during an administrative review of a case file:
- 11.10.1. Check cover page of report for name of primary investigator, all fields are completed (e.g. city/town, offense), and names of victims, suspects, and any references are listed, including names for any known references that have been submitted.
 - 11.10.2. Check 'Evidence Received' section for inclusion of all items submitted directly to DNA, and for parent items of any sub-items transferred to DNA.
 - 11.10.3. Check 'Evidence Item Inventory' section for any sub-items transferred to DNA or created by DNA analyst during analysis. Item descriptions should be concise but complete, identify the specific sub-item tested and what parent item it relates to, and include "human bloodstain" or "containing sperm cells" if confirmed.
 - 11.10.4. Check "Results" section for the following:
 - 11.10.4.1. A paragraph listing the dates of previous DNA reports at the start of the report if previous DNA Analysis reports have been issued.
 - 11.10.4.2. Description of item (and what was cut or swabbed) if submitted directly to DNA (except for epithelial swabs).
 - 11.10.4.3. Any confirmatory tests performed by the DNA analyst (sperm searches, HemaTrace test).
 - 11.10.4.4. List of items that had insufficient quantity of DNA to attempt further analysis.
 - 11.10.4.5. List of items amplified, and the system (i.e. kit names) in which they were amplified.
 - 11.10.4.6. Results of attempts at DNA profiling (e.g. profile obtained or not; profile is mixture or single source; too complex or of limited genetic info; profile matches or does not match known references submitted including statistics).
 - 11.10.4.7. List of DNA profiles that were entered or searched in SDIS.
 - 11.10.4.8. List of item numbers that were not tested at this time.
 - 11.10.5. Check "Conclusions" section for:
 - 11.10.5.1. Conclusions drawn from all DNA profiles, such as matching a known reference or other evidence items (with identity statement if appropriate), include or exclude a known reference as a potential donor, or if no conclusions can be drawn from the results.
 - 11.10.5.2. If a forensic DNA profile was entered into SDIS, and the results of that search if available.
 - 11.10.5.3. If a known reference from a suspect was searched in the Maine DNA database, and the results of that search if relevant to the case.
 - 11.10.5.4. A list of item numbers being retained at the Crime Lab, returned to the submitting agency, or consumed in analysis.
 - 11.10.6. Check that all examinations identified in the case notes are in the report.
 - 11.10.7. Check that all examinations identified in the report are in the case notes.
 - 11.10.8. Check that conclusions drawn in the report are accurately reflected in the notes and accurately derived from documented test results and interpretations.



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- 11.10.9. Check that significant errors/discrepancies in packaging, labeling, analysis, or anything of significance that would adversely affect the reliability of results are noted in the report.
- 11.10.10. Check the chain of custody for at least one item or sub-item.
- 11.10.11. Check laboratory case file pages (including Communication Logs and other correspondence, police reports, etc.) for laboratory numbers, initials, dates and page numbers as necessary.
- 11.10.12. Ensure strikeouts and interlineations are properly initialed and dated.
- 11.10.13. Check report for proper grammar, sentence structure and clarity.
- 11.10.14. Check report for accurate Crime Lab item numbers and investigator item numbers.
- 11.10.15. Check report for accurate names, dates of birth, firearms serial numbers, vehicle registration numbers, vehicle identification numbers, etc. as necessary.
- 11.10.16. Check for appropriate evidence receipts.
- 11.10.17. Check SDIS entry reports and SDIS keyboard searches, for the following:
 - If DNA profiles have been entered into SDIS/NDIS, verify that the correct alleles were entered and that the appropriate specimen category was chosen.
 - If DNA profiles have been keyboard searched in SDIS, verify that the correct alleles were entered.
 - If DNA profiles are in NDIS-eligible categories, verify that they are marked for upload.
- 11.11. The following information is verified during an administrative review of a database file:
 - 11.11.1. Ensure pages are initialed and dated, strikeouts and interlineations are properly initialed and dated, and specimen numbers and lot numbers are on worksheets.
 - 11.11.2. Check import reconciliation reports for any errors.
 - 11.11.3. Check number of samples in file against number of samples in uploads.
 - 11.11.4. Check specimen numbers said to be batched in the database file against the CMF or printouts of the genetic analyzer injection lists if possible.
 - 11.11.5. Check the amelogenin allele calls for each specimen against a listing of the reported sex of the donors generated from the databank or the individual convicted offender cards. This amelogenin check may be performed at a separate time than the rest of the administrative review.
- 11.12. If an analyst testifies during the calendar year, their testimony should be monitored and documented as directed in the lab-wide policies.

12. **Proficiency Testing**

- 12.1. The lab-wide policy regarding proficiency testing is outlined in the Proficiency Testing policy. The following items clarify issues specific to DNA Analysis.
- 12.2. Each scientist performing DNA analysis (DNA analysts, technicians, and others designated by the section supervisor) will be externally proficiency-tested semiannually in each DNA technology they are qualified to perform to the full extent in which they participate in DNA analysis.
 - 12.2.1. The interval between tests is measured by the due date of each proficiency test.



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- 12.2.2. “DNA Technology” is used to describe the type of forensic DNA analysis performed in the laboratory, such as the different STR or Y-STR kits. All of the technologies a scientist is qualified to perform must be reported at least once per calendar year. Multiple technologies may be reported on a single proficiency test. Typing of all CODIS core loci will be attempted for each technology at least once per calendar year.
- 12.3. When a scientist is trained in a new DNA technology, they must include that form of analysis/technology on their next external proficiency test.
- 12.4. Each scientist must complete an external proficiency test using both manual and automated methods at least once per year if they are qualified in both.
- 12.5. LIMS reports are not required for proficiency tests; the external provider’s data sheet is the report.
- 12.6. Proficiency tests are evaluated using the following criteria:
- All reported inclusions are correct or incorrect.
 - All reported exclusions are correct or incorrect.
 - All reported genotypes are correct or incorrect according to consensus genotypes or within established empirically determined ranges.
 - All results reported as inconclusive or uninterpretable are consistent with written laboratory guidelines.
 - All final proficiency tests are evaluated as unsatisfactory or satisfactory.
- 12.7. The TL will review proficiency test results for compliance with laboratory guidelines and forward results to proficiency test participant and have them document that they have reviewed their reported results.
- 12.8. The CODIS Administrator will be notified of all non-administrative discrepancies that affect the typing results and/or conclusions at the time they are discovered.
- 13. Corrective Action**
- 13.1. The Crime Lab has a lab-wide corrective action policy. Corrective Actions are maintained in Paradigm.
- 13.2. Corrective Actions relevant to DNA analysis or scientists performing work in the section must have the approval of the DNA technical leader prior to implementation.
- 13.3. The CODIS administrator must be notified when a corrective action impacts DNA records entered into the CODIS database.
- 14. Audits**
- 14.1. The section will be audited annually to ensure the FBI DNA Quality Assurance Standards (QAS) current at that time are being followed using the current FBI DNA QAS Audit Document.
- 14.2. The auditor or audit team shall have at least one person who is a qualified auditor and have at least one person that is, or has previously been, a qualified analyst for each specific DNA technology performed in the section.
- 14.3. Audits of the section against the FBI DNA QAS current at that time must be done by an outside agency a minimum of once every two years.



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- 14.4. Each qualified DNA Analyst, DNA technical leader, and CODIS Administrator will have their education, experience, and training qualifications evaluated and approved during 2 successive, separate external audits (documented in the audit document).
- 14.5. Any DNA analyst qualified in a new technology, DNA typing kit, or platform will have the new training qualification evaluated and approved during 1 external audit (documented in the audit document).
- 14.6. Any new validations will be evaluated and approved during 1 external audit (documented in the audit document).
- 14.7. Internal and external audit documentation (including any findings and related corrective actions) will be reviewed and approved by the DNA TL.
- 14.8. Internal and external audit documentation (including any findings and related corrective actions) will be reviewed by the CODIS administrator.
- 14.9. All external audits (regardless of frequency) shall be submitted to the NDIS custodian within 30 days of receiving the completed, official audit document from the auditors. If the 30-day deadline cannot be met, an extension may be requested from the NDIS custodian.

15. Professional Development

- 15.1. The TL, analysts and technicians will stay abreast of developments in the field of Forensics relevant to their duties by reading current literature, such as papers in the Journal of Forensic Sciences (JFS) or the Forensic Science International: Genetics (FSIG). Staff is encouraged to circulate relevant reading materials.
- 15.2. Articles relevant to the section can be retrieved from the Internet or scanned from journals, circulated, signed off, and stored through Paradigm.
- 15.3. All DNA staff must attend or view online a minimum of one relevant seminar, training course, or professional meeting each year (a minimum of eight cumulative hours within a calendar year) or attend formal meetings to review relevant trainings attended by other Forensic Biology staff members.
- 15.4. Scientists are encouraged to obtain and maintain membership in reputable scientific organizations, such as the American Academy of Forensic Sciences or International Society for Forensic Genetics.
- 15.5. Training records, course attendance and educational records are stored in Paradigm.
- 15.6. There is a lab-wide policy on testimony review of qualified scientists.

16. Outsourcing Ownership

- 16.1. A vendor laboratory is a private or government lab that performs DNA analysis on casework samples or convicted offender samples. There does not need to be a contract or exchange of funds for an outside lab to be considered a vendor lab.
- 16.2. The Crime Lab takes “ownership” of casework samples or convicted offender samples sent to a vendor lab under any of the following criteria:
 - 16.2.1. The Crime Lab will use any samples, extracts, or materials from the vendor laboratory for the purposes of forensic testing.
 - 16.2.2. The Crime Lab will interpret the data generated by the vendor laboratory.



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- 16.2.3. The Crime Lab will issue a report on the data from the vendor lab.
- 16.2.4. The Crime Lab will enter or search a DNA profile in SDIS from data generated by the vendor laboratory.
- 16.3. If samples are sent to a vendor lab and the Crime Lab is expected to take ownership, the following criteria must be met:
 - 16.3.1. The vendor lab must follow FBI QAS for Forensic DNA Testing or DNA Databasing, depending on the type of samples sent.
 - 16.3.2. The vendor lab must be an accredited laboratory.
 - 16.3.3. The data and reports are technically reviewed to the same standards as in-house DNA analysis (including a current CODIS user verifying the sample's CODIS eligibility and specimen category).
 - 16.3.4. The DNA technical leader or designated DNA analyst (qualified or previously qualified in the technology, platform, and kit) will perform an on-site visit of the vendor lab before the vendor lab initiates work on the outsourced samples, to include:
 - 16.3.4.1. The name of the person that performed the visit, their qualifications, and the date the on-site visit occurred.
 - 16.3.4.2. An assessment of the vendor laboratory's ability to perform DNA analysis on the samples to be outsourced.
 - 16.3.4.3. A copy of the vendor lab's most recent external audit, including any findings and responses and/or follow-up actions to any findings in the report.
 - 16.3.4.4. A summary of the visit, including a list of other documents reviewed, such as accreditation documents, validations, etc.
 - 16.3.5. If an outsourcing agreement extends beyond 1 year, the following criteria must be met:
 - 16.3.5.1. A new on-site visit performed annually, every calendar year, at least 6 months apart but no more than 18 months apart.
 - 16.3.5.2. The visit should be performed by the DNA technical leader or a designated DNA analyst (qualified or previously qualified in the technology, platform, and kit).
 - 16.3.5.3. Or the Crime Lab may obtain documentation of another NDIS laboratory's on-site visit using the same technology, platform, and kit.
 - 16.3.5.4. In either case, the on-site visit shall be documented in the same manner as the original visit, reviewed, and approved by the DNA technical leader.
- 16.4. If casework samples are sent directly from the Crime Lab to a vendor lab at the Crime Lab's request, and ownership is to be taken:
 - 16.4.1. The DNA technical leader must approve the technical specifications of the outsourcing agreement before it is awarded.
 - 16.4.2. The Crime Lab will review and maintain documentation of the vendor lab's external audit report, the vendor lab's responses, and follow-up actions to any findings.
 - 16.4.3. If the type of DNA analysis requested could have been conducted at the Crime Lab but was not (due to backlog, time constraints, etc.), then all data must be reviewed in such a



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way as to assess the integrity of the vendor lab's data (for example, a review of case notes, or re-analysis of data).

- 16.5. If an outside agency (such as a law enforcement agency) sends or requests the Crime Lab sends casework samples to a vendor lab, and the Crime Lab will be expected to take "ownership" of the samples or data (see above), the following criteria must be met:
 - 16.5.1. The DNA technical leader must approve of the outsourcing agreement and accept ownership of the data before the analysis is initiated.
- 16.6. If Convicted Offender samples are sent out to a vendor lab and ownership is to be taken by the Crime Lab, the above criteria apply as well as the following:
 - 16.6.1. 100% technical review of the vendor lab's data per the Crime Lab's convicted offender DNA analysis policies and procedures prior to uploading DNA profiles to NDIS.
 - 16.6.2. A minimum of 5% of the samples sent to the vendor lab must be part of a quality assurance check, including the following:
 - 16.6.2.1. QC Samples which the Crime Lab knows the genotype of the samples before reviewing the data from the vendor lab. QC Samples should include the first set(s) of data that will be returned from the vendor lab, to verify the concordance of the data at the outset of the contract.
 - 16.6.2.2. Random Reanalysis Samples which the Crime Lab independently repeats the extraction and DNA typing of samples after reviewing data from the vendor lab. Random Reanalysis samples will be selected at the discretion of the DNA analyst but should include samples that had unusual results (e.g. off-ladder-alleles and tri-alleles) or samples that the reviewer has questions or doubts about the vendor lab's results.
 - 16.6.2.3. The comparison of QC Samples and Random Reanalysis Samples to vendor data will be documented and retained in a binder or case file.
- 16.7. If no outsourcing agreement was in place before the vendor lab performed DNA analysis, the following must take place before the Crime Lab can accept ownership:
 - 16.7.1.1. Written approval from the CODIS administrator and the NDIS Custodian for any scenario that includes CODIS entry or searching.
 - 16.7.1.2. Review and approval of the technical specifications of the DNA testing.
 - 16.7.1.3. Perform and on-site visit of the vendor lab, or review documentation of an on-site visit of the vendor lab by another NDIS laboratory.

17. **Definitions**

- 17.1. "Weekly" means the workweek, including the next workday if necessary.
- 17.2. "Monthly" means a calendar month, plus 7-days if necessary.
- 17.3. "Quarterly" means January to March, April to June, July to September, and October to December, plus 7-days if necessary.
- 17.4. "Annually" means once during a calendar year.



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- 17.5. “Semiannually” means two times during a calendar year, with the first test occurring in the first six months of the year and the second test occurring in the second six months of that year, and the interval between tests is at least four months but not more than eight months.