DNA Procedures Introduction

Quality assurance measures ensure that laboratory tests yield results that accurately reflect the physical parameters they seek to characterize. As a part of their quality program, the DNA Units, which include, the DNA Casework Unit (DCU), DNA Support Unit (DSU), Federal DNA Database Unit (FDDU) and Biometrics Analysis Unit DNA Group (BAU), have developed standard operating procedures (SOPs) for the various testing methods used in the examination of evidence and database samples. Each laboratory SOP specifies the pertinent materials needed and the procedural steps to perform the test or methodology. These detailed procedures ensure the uniformity of each technique's performance over time and across scientists. This document provides guidance for the proper preparation of laboratory equipment and space, use of personal protective equipment, and general laboratory techniques; it applies to personnel in the DNA Units that work on forensic evidence samples, casework reference samples, and/or database samples.

1 Equipment

1.1 Supplies and equipment will be dedicated for pre- or post-amplification work areas and will not be moved from post- to pre-amplification work areas unless decontaminated. Post-amplification supplies and equipment will not be stored in rooms used for evidence examination or database sample processing unless decontaminated.

1.2 Pipettes dedicated to pre-amplification work areas must be used when performing pre-amplification activities (i.e., serological examination, sample collection, DNA extraction, qPCR, amplification set-up) and any other pre-amplification methodologies. A different dedicated set of pipettes must be used when performing post-amplification activities (i.e., sequencing, capillary electrophoresis set-up) and transferring liquid that potentially contains amplified DNA.

1.2.1 Pipettes dedicated to pre-amplification activities must be irradiated using the interior ultraviolet (UV) light of the biological hood for at least 5 minutes each workday before use. Also, they must be thoroughly decontaminated with a bleach solution and then disinfected/rinsed with 70% isopropyl alcohol each workday before use, as they become visibly soiled, and after their final use on a given workday. Pipettes dedicated to post-amplification activities must be cleaned weekly and as they become visibly soiled.

1.2.2 Sterile disposable pipette tips or transfer pipettes must be used when transferring liquid reagents or samples. A new pipette tip must be used when removing extract from a sample tube or when introducing reagent into a tube that contains extract. The tip must be discarded in the appropriate waste container after use.

1.2.3 To minimize the potential for pipetting inaccuracies, a pipette with a range larger than and closest to the target volume should be used. The pipette should be set to the desired volume by initially dialing into the range of volumes larger than the target volume and then dialing back to the desired volume.

1.2.4 Robotic workstations that use fixed tips must be appropriately flushed with bleach and/or water between each sample and at the conclusion of a procedure.

1.3 New or clean forceps, scalpel blades, or scissors must be used for every sample. Tools must be appropriately discarded or decontaminated with a 10% bleach solution followed by 70% isopropyl alcohol between consecutive samples. Additionally, tools used for mitochondrial DNA (mtDNA) evidence examinations may be exposed to UV light before use.

1.4 Biological hoods must be irradiated with their interior UV light for at least 5 minutes each workday before first use and after final use. A 15-minute exposure time is recommended for mtDNA processes.

1.5 For equipment that requires performance verification (i.e., performance check) prior to use, the results must be recorded in accordance with the LOM and DNA QA procedures.

2 Personal Protective Equipment

2.1 Disposable gloves must be used at all times during examination of evidence and sample processing. At a minimum, gloves must be changed if they become visibly soiled, torn, or when moving between separately packaged evidence items, with the exception of Sexual Assault Kit (SAK) swabs. Personnel are not required to change gloves between swabs collected from a single individual within a SAK.

2.1.1 To prevent transfer of biological material to laboratory surfaces that are not easily decontaminated (e.g., telephones, computer keyboards), used gloves should be removed prior to handling such laboratory devices. Double gloves may be worn to facilitate the removing and donning of outer gloves during those examination procedures in which notes are taken contemporaneously. Gloves must be changed and/or surfaces should be cleaned if inadvertent contact with a surface that may result in transfer of biological material is suspected (e.g., answering phone, scratching face).

2.1.2 When handling evidence items with potential latent fingerprint value, cloth gloves may be worn under the disposable gloves during processing. Nitrile gloves are preferred when processing items of potential latent fingerprint value.

2.1.3 Prior to leaving the laboratory area, used gloves must be properly discarded and personnel should wash their hands.

2.2 A laboratory coat must be worn during all pre-amplification processes. A separate laboratory coat must be worn when handling samples that potentially contain amplified DNA. Laboratory coats that are used in post-amplification laboratory space must not be worn into pre-amplification laboratory space. Laboratory coats should be placed in a laundry receptacle upon becoming visibly soiled. Laboratory coats must not be worn outside of designated laboratory space unless transporting evidence or samples.

2.3 Disposable face masks must be used at all times when handling evidentiary items or database samples, and when performing pre-amplification processes to minimize the potential for introduction of biological material by Laboratory personnel. Face masks do not need to be worn during post-PCR amplification processes. At a minimum, face masks must be changed if they become visibly soiled or torn. Face masks must also be worn when preparing all reagents.

2.4 Masks, gloves, bench paper, or tubes that are visibly soiled with biological material (e.g., blood, semen) must be placed into biological waste containers for disposal. Disposable items that do not show any visible biological staining may be discarded into regular waste containers.

2.5 Eye protection must be worn when performing laboratory tests and when handling reagents or chemicals.

3 Quality Assurance Safeguards

3.1 Pre-amplification work areas will be separated from post-amplification work areas. Amplified DNA is stored in the post-amplification work areas and must not be moved into the pre-amplification work areas.

3.2 All work surfaces in pre-amplification laboratory space must be decontaminated with a 10% bleach solution each workday before use, as they become visibly soiled, and after their final use on a given workday. All work surfaces within the post-amplification laboratory must be cleaned weekly, generally with detergent and water. Using bleach on the capillary electrophoresis instruments may interfere with fluorescence and should be avoided.

3.3 Disposable paper (e.g., bench paper, weigh paper, tissue paper) must be used when processing evidence items to ensure a clean working surface and to prevent the deposition of biological material on permanent work surfaces.

3.3.1 Disposable paper must be changed and appropriately discarded as it becomes visibly soiled or, at a minimum, before and after the completion of the examination of an individual item of evidence.

3.3.2 Evidence items that are packaged together (e.g., vaginal swabs, clothing items) may be processed on the same disposable paper, provided that the paper does not display visible soiling.

3.4 All evidence items or database samples under active examination must be kept separate from other items of evidence or database samples under examination by any other individual(s) working within a common laboratory space.

3.4.1 Evidence from only one case will be examined by an individual at a time and only one evidence package will be opened and collected for processing at any one time. The portion of the stain identified for analysis will be removed/collected from the item, placed into a

corresponding labeled tube or envelope, and the item returned to the evidence packaging. This process will be sequentially repeated for each item within the case.

3.4.2 Only one database kit or sample will be open for processing (e.g., check in, punch) by an individual at any one time.

3.5 Reagents are stored separately from evidentiary and database samples. If the same storage area is used, at minimum, reagents must be placed on a different shelf and above evidentiary material or database samples.

3.6 Casework reagents will generally be dispensed into small aliquots to minimize the number of times the stock reagent is opened.

3.7 When necessary, reagent tubes should be thawed completely and vortexed briefly before use. As appropriate, the tubes can be quick-spun (approximately 2 seconds) to return all liquid to the bottom of the tube.

3.8 Examination of evidence or sample accessioning, DNA extraction, and amplification setup procedures may be performed in the same pre-amplification laboratory rooms if performed at separate times or at separate work stations.

3.8.1 DNA extraction procedures begin with the addition of the extraction reagents to the sample collected for DNA typing. All manual DNA extraction procedures must be conducted within a hood unless otherwise indicated.

3.8.2 DNA extraction steps in which phenol/chloroform/isoamyl alcohol (PCI) reagent is used must be performed in a chemical fume hood.

3.8.3 Manual DNA extraction and amplification setup procedures must be conducted within separate hoods or at separate times if performed in a common hood.

3.8.4 Automated DNA extraction and amplification setup procedures must be conducted on separate Robotic Workstations or at separate times if performed on a common Robotic Workstation.

3.9 While manually processing samples through a common procedural step, only one sample or reagent tube should be open at a time. Remaining sample tubes should remain closed.

3.10 All sample containing tubes that do not display a visible difference after the completion of a procedural step (e.g., color change, volume change, cutting introduction) must be physically moved or marked in a manner that distinguishes them from those on which that step has yet to be completed. This requirement will help to prevent the misloading or double-loading of samples during any procedural step that does not result in an evident physical change to a handled sample.

3.11 During the examination of an evidence item, notes (e.g., description of item, test

result) must be recorded contemporaneously with conducting a procedure on or sample collection from that item. Such notes must be recorded in their final form (i.e., entered electronically). Multiple swabs from the same collection site and packaged together (e.g., vaginal swabs, oral swabs) may be processed together before being individually described in the final case records.

3.12 Extract tubes may be stored refrigerated or frozen. Upon retrieval from storage for subsequent examinations, samples should be brought to room temperature, vortexed (approximately 2 seconds), and quick spun (approximately 2 seconds).

3.12.1 For plate based samples, before removing an adhered cover (e.g., heat sealed cover) the plate should be centrifuged (approximately 30 seconds) to return all the liquid to the bottom of the wells.

3.12.2 Upon completion of testing, extract tubes may be stored at room temperature if the remaining extract is dried down. Instructions for using the Speed-Vac are contained within the appropriate procedure (i.e., DNA 226) in the *DNA Procedures Manual.*

4 Safety

4.1 Refer to the "Safe Work Practices and Procedures," "Bloodborne Pathogen (BBP) Exposure Control Plan (ECP)," "Personal Protective Equipment Policy," and "Chemical Hygiene Plan" sections of the *FBI Laboratory Safety Manual* for important personal safety information prior to conducting these procedures.

4.2 Refer to the "Hazardous Waste Disposal" section of the *FBI Laboratory Safety Manual* for important information concerning proper disposal of the chemicals used in these procedures as well as the biohazardous wastes generated.

4.3 Appropriate safety precautions and proper personal protective equipment will be used during laboratory procedures. Refer to Safety Data Sheets, *FBI Laboratory Safety Manual* and the applicable DNA Procedures for more detailed information. The following safety warnings are noted:

- Direct UV light can be harmful to eyes. UV-protective eyewear should be worn when observing UV lights during crosslinker QC checks.
- Agilent kit components contain dimethyl sulfoxide (DMSO). This dye binds to nucleic acids and will be treated as a potential mutagen.
- Ethyl alcohol is a hazardous material. Use only in a fume hood. Wear appropriate protective clothing and eyewear when handling; be careful not to expose face or hands to splashes.
- Formamide is a teratogen. Avoid inhalation, skin contact, or ingestion. Use nitrile gloves when handling. Dispose of unused portions in appropriate hazardous waste containers. Pregnant women must not handle Formamide.
- Hydrochloric Acid can be hazardous. Wear appropriate protective clothing and

eyewear; be careful not to expose face or hands to splashes.

- Liquid nitrogen can be hazardous. Use cryogenic gloves, appropriate clothing and protective eyewear when handling liquid nitrogen. Be careful to avoid exposure to liquid nitrogen splashes.
- Phenol/Chloroform/Isoamyl Alcohol (PCIA) is an irritant and is toxic. Its use must be confined to a designated hood.
- Performance Optimized Polymer (i.e., POP-4, POP-6) is a chemical hazard and exposure may cause eye, skin and respiratory tract irritation.
- Solutions of Proteinase K can be irritating to mucous membranes. Use eye protection when handling.
- Sodium Dodecyl Sulfate (SDS) is an inhalation hazard. Wear a mask when working with powdered SDS.
- Sodium Hydroxide can be hazardous. Wear appropriate protective clothing and eyewear; be careful not to expose face or hands to splashes. A rapid release of heat can be produced when dissolving sodium hydroxide pellets.

5 References

FBI Laboratory Quality Assurance Manual

FBI Laboratory Operations Manual

FBI Laboratory Safety Manual

DNA Procedures Manual

Rev. #	Issue Date	History
0	06/05/15	New document incorporating requirements and recommendations from nDNAU 200, mtDNAU Laboratory Procedures, and several FDDU Procedures. Document applies to DCU, DSU, and FDDU.
1	06/01/17	Added BAU. 2.1 Changed to separately packaged and made allowance for SAK swabs 2.1.2 Nitrile gloves are preferred for handling latent items. 2.2 Lab coats may be worn outside lab space when transporting evidence. 3.2 Clarified bleach should not be used on CE equipment 3.7 Changed from centrifuged to vortexed 3.12.2 Extracts can be stored at room temp if dried. 5 Added references

Approval

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DNA Quality Assurance Manual

The DNA Units in the FBI Laboratory conduct routine analysis of biological evidence and reference samples. The DNA Units are comprised of the Biometrics Analysis Section's (BAS) DNA Casework Unit (DCU), Federal DNA Database Unit (FDDU), and DNA Support Unit (DSU) and the Terrorist Explosive Device Analytical Center's (TEDAC) Scientific and Biometrics Analysis Unit DNA group (SBAU) as well as the DNA Technical Leader (TL) assigned to the BAS Front Office.

The DNA Units perform work in the categories of testing within the biology discipline, commonly referred to in the FBI Laboratory as the DNA discipline. The DCU provides serological (sero), mitochondrial DNA (mtDNA), and nuclear DNA (nDNA) examination services in conjunction with criminal, counterterrorism, and missing person investigative matters. The SBAU performs exploitation of improvised explosive devices (IEDs) resulting in scientific information of biometric intelligence value and provides nuclear DNA (nDNA) examination services in conjunction with criminal, counterterrorism, and missing person investigative matters. Personnel in the DCU and the SBAU may also provide expert witness testimony in judicial proceedings on both a national and international level. The FDDU provides testing of biological reference samples obtained from individuals convicted of federal felonies and/or certain District of Columbia offenses, individuals who have been arrested on federal charges, and from non-U.S. citizens who have been detained under the authority of the United States government. Additionally, the FDDU supports federal agencies applicable to the Sexual Offense Registration and Notification Act (SORNA), to include federally recognized tribal agencies and U.S. Territories. The DSU facilitates the Quality Assurance (QA), Validation and Research, and Training Programs in support of the DNA Units' examination efforts.

1 Scope

The DNA Quality Assurance Manual applies to personnel in the DNA Units and the casework and databasing operations over which DNA personnel have control. The DNA Units' level 2 documents (i.e., quality manual documents, technical procedures, training manuals, and their accompanying forms) comprise the *DNA Procedures Manual* and supplement the level 1 documents (i.e., FBI Laboratory *Quality Assurance Manual* [QAM] and FBI *Laboratory Operations Manual* [LOM]), and serve as the cornerstone of DNA Units' operations. Additionally, these documents facilitate meeting the *Quality Assurance Standards for Forensic DNA Testing Laboratories* and *the Quality Assurance Standards for DNA Databasing Laboratories* (collectively referred to as QAS) issued by the FBI Director, as well as applicable accreditation requirements.

If laboratory activities are performed at sites outside of the FBI Laboratory permanent control facilities, these activities will be conducted by authorized DNA Unit personnel, using appropriately validated procedures that are approved by the DNA Technical Leader, using equipment under the permanent control of the DNA Units and/or that have been properly

maintained in accordance with the DNA Procedures for Equipment Calibration and Maintenance (i.e., DNAQA 608), and using reagents that are under the permanent control of the DNA Units and prepared or evaluated in accordance with the DNA Procedures for Reagent Purchasing, Preparation, and Records (i.e., DNAQA 609) and/or the relevant DNA procedure.

2 Goals and Objectives

The DNA Units operate in accordance with the quality practices established by the FBI Laboratory. The DNA Units also follow the FBI and FBI Laboratory's policies and practices regarding administrative matters in addition to those addressed by unit specific procedures. Such administrative matters include, but are not limited to staffing, budget, job descriptions, duty hours and leave time.

The DNA Units provide serological, mtDNA, nDNA, and convicted offender, arrestee, and detainee DNA testing services while striving to be a leading organization in the forensic DNA community through:

- Continuously working to improve the overall quality and management of DNA laboratory operations.
- Routinely reviewing unit procedures, quality control standards, expert witness testimony, proficiency testing, and audits.
- Confirming that the analytical data and interpretation of DNA testing results are scientifically accurate and represented in a manner that is of high quality and consistent with the limits of the technical discipline.
- Establishing and maintaining a system for documenting procedures and practices.
- Providing on-site assistance and support to Evidence Response Teams (ERT) at crime scenes and natural disasters when directed by Executive Management.
- Validating new methodologies and technologies and implementing those methodologies and technologies into forensic casework and DNA databasing operations.
- Encouraging Examiners and Biologists to publish scientific articles regarding DNA analysis.
- Liaising with other governmental, university, and private laboratories regarding DNA analysis through participation in the appropriate subcommittees of the Scientific Working Group on DNA Analysis Methods (SWGDAM), the Organization of Scientific Area Committees for Forensic Science (OSAC), the Missing Persons Program, and the DNA Database Program.
- Educating response personnel and/or contributors about DNA analysis and applicable precautions for collection and submission.

- Educating officers of the court about DNA analysis, its forensic applications, and presenting DNA evidence in court.
- Entering DNA profiles into the appropriate indices of the National DNA Index System (NDIS) using Combined DNA Index System (CODIS) software.
- Maintaining compliance with the quality policies and practices established by the level 1 documents and the QAS.

3 Quality System

DNA personnel will follow the DNA requirements and procedures referenced in this manual in addition to any unit specific or Laboratory-wide procedures, policies, and practices. Dissemination of information related to the Laboratory and the DNA QA Program is accomplished through staff meetings and through written and electronic mail communications. The level 1 documents and the DNA level 2 documents can be found at the FBI Laboratory intranet website. The DNA quality system is reviewed annually under the direction and approval of the DNA TL.

3.1 Records Retention

Records generated to fulfill the requirements in the level 1 documents, the DNA level 2 documents or the QAS will be retained in accordance with those documents, to include:

- Proficiency Tests
- Corrective Actions
- Audits
- Training Records
- Court Testimony Monitoring

3.1.1 All internal and external QAS Audit documents will be permanently retained.

3.1.2 The Forensic Examiner training program records for Examiners will be retained permanently. The qualification and authorization electronic communication (EC) will be maintained in Sentinel.

3.1.3 Continuing education supporting records will be retained for at least the current accreditation cycle.

3.1.4 Case file records will be retained as directed by the FBI Information Management Division.

3.1.5 The following databasing records will be permanently retained:

- Analytical Results
- Sample Receipt and Processing Records

- Match Confirmation Files
- Expungement Records

3.1.6 With the exception of case file records and database sample processing records, quality system records will generally be maintained by the DSU.

3.1.7 Electronic records on Biometrics Analysis Section DNA Network (BASNET), to include those in the Sample Tracking and Control Software (STACS), are maintained and backed up according to the BASNET Information System Contingency Plan.

4 Organization and Management Structure

DNA personnel must comply with the responsibilities and requirements in the level 1 documents, the DNA level 2 documents, and the QAS. The organization of each DNA unit is presented in their organizational chart. DNA personnel may perform duties and responsibilities outside of their assigned unit provided they are trained and/or qualified and authorized to perform those tasks and are appropriately proficiency tested, when applicable.

4.1 Contingency Plans

The QAS requires a contingency plan for if the Technical Leader (TL) position is vacated or in the event the number of qualified analysts (i.e., Examiners) falls below two full-time employees who are qualified analysts (i.e., Examiners) at the laboratory. If the Technical Leader (TL) position is vacated, an acting TL will be designated as described below. If at an FBI Laboratory location the number of full-time employees that are qualified DNA examiners falls below two, an examiner(s) from the other FBI Laboratory location may be assigned a temporary duty (TDY) at the laboratory location without two examiners. Alternately, technical reviews will be performed by qualified and authorized FBI Laboratory personnel at the other laboratory facility until the number of qualified examiners returns to two full-time employees.

If the number of qualified examiners falls below two full-time employees who are qualified examiners or if no one in the FBI Laboratory is qualified to fill the technical leader vacancy, the NDIS Custodian and State CODIS Administrator will be notified as required by the *NDIS Operational Procedures Manual*. The appropriate form in the QAS Audit Document(s) will be used to record the notification and any additional correspondence with the CODIS Unit regarding a contingency plan. If an additional contingency plan needs to be submitted to the CODIS Unit, DNA analytical procedures on new casework or new database analyses will not be initiated until CODIS Unit approval is granted. If the TL positions remains vacant (i.e., there is no FBI Laboratory employee qualified to fill the vacancy), casework or database analyses that were initiated prior to the technical leader's vacancy may be completed.

4.2 Date for QAS Personnel Requirements

As QAS are not to be applied retroactively, DNA examiners will comply with the education and experience requirements contained in the QAS in effect on the date of their initial qualification and authorization to perform DNA analysis for the FBI Laboratory. If a qualified FDDU examiner gets additionally qualified and authorized to perform forensic DNA analysis, they must comply with the education and experience requirements contained in the Forensic QAS in effect on the date of their qualification and authorization to perform DNA analysis on casework. DNA personnel's initial and additional qualifications and authorizations will comply with the requirements for training contained in the QAS in effect at that time.

5 Personnel

DNA personnel must have the education, training, and experience commensurate with the examination, processing, and/or testimony provided. Requirements for Technical Leader, CODIS Administrator, analyst, technical reviewer, technician, and laboratory support personnel are detailed in the QAS. Individuals, however titled, may perform the duties associated with the role of analyst, technical reviewer, technician , and/or laboratory support personnel as defined by the QAS provided they have the applicable education and experience, and are appropriately trained and/or qualified and authorized as required in the QAS and FBI Laboratory level 1 documents. Position descriptions are maintained by the FBI Human Resources Division or the applicable contracting official. The duties and responsibilities of the positions in the DNA Units include, but are not limited to the following:

5.1 Biologist (Technical Leader)

The Biologist (Technical Leader) is referred to as the Technical Leader (TL). The TL serves as a member of technical management and is accountable for all technical operations within the DNA Units. The TL may maintain proficiency as an analyst (i.e., examiner as defined by LOM) or technical reviewer as defined by the QAS. The duties and responsibilities of this position include, but are not limited to:

- Oversees all DNA technical operations and has the authority to initiate, suspend, terminate and/or resume such operations for any DNA unit or individual, as necessary.
- Evaluates and records approval of all validation studies and new or modified analytical methods utilized by the DNA Units and reviews proposals for new or modified analytical procedures, as appropriate.
- Assesses the previous training of an experienced Examiner or Biologist and approves a modified training program, as necessary.
- Reviews the academic transcripts of Forensic Examiner Trainees (FETs).
- Reviews training records for Examiners and Biologists, approves their qualification(s), records this review, and authorizes personnel prior to them performing independent analysis on forensic evidence and/or database

samples. Reviews training records for other DNA personnel and authorizes personnel that influence the results of laboratory activities.

- Approves the technical specifications for outsourcing agreements and records this approval.
- Performs a recorded review of DNA audit documents from internal and external audits of the DNA Units and approves any resulting corrective actions, as applicable.
- Ensures that an annual review of the DNA level 2 documents is conducted under his/her direction and records approval of this review.
- Reviews and approves the training, quality assurance, and proficiency test programs within the DNA Units.
- Reviews potential conflicts of interest when a contract employee is employed by multiple National DNA Index System (NDIS) participating and/or vendor laboratories and approves the employment, as appropriate.
- Serves as an approving official on all DNA level 2 documents and ensures the initial review of applicable DNA level 3 documents is recorded.
- Ensures there is a documented contingency plan to identify an individual(s) that will serve as the TL if the position is vacated.
- Approves continuing education programs based on multimedia or internet delivery.
- Approves the program for the annual review of scientific literature by DNA personnel.
- Reviews any inconclusive conclusion obtained on a proficiency test for compliance with laboratory guidelines.
- Ensures the Combined DNA Indexing System (CODIS) Administrator(s) is informed of all non-administrative discrepancies that affect the typing results and/or conclusions of proficiency tests at the time of their discovery.
- Reviews and records the approval of all corrective actions and DNA Unit deviations prior to implementation.
- Ensures he/she is accessible to all laboratory facilities to provide on-site, telephone, or electronic consultation, as needed, or ensures an acting TL is designated, when necessary.
- Ensures that the quality system within the DNA Units complies with the level 1 documents, as well as the QAS.

5.1.1 Acting TL

If the TL is on temporary leave and is not available via phone or electronic means, then the TL will designate a temporary Acting TL (generally, the DNA QA Program Manager or DNA Unit Chief(s)) as a point of contact with the necessary authority to maintain (or suspend) technical operations (e.g., authorize deviations, evaluate nonconformities). One individual may be selected to serve as temporary Acting TL for all the DNA Units, or one may be selected for each unit. The TL will be informed of any reviews and authorizations performed by the temporary Acting TL(s) and follow-up as necessary.

If the TL is on extended leave, an Acting TL(s) may be designated by the BAS Chief or designee. The named Acting TL(s) will temporarily assume all the duties and responsibilities of the position and must meet the qualification requirements stated in the QAS. The TL will be briefed of approvals and authorizations performed by the Acting TL(s) and follow-up as necessary.

If the TL position becomes vacant, the BAS Chief or designee will immediately appoint an individual (or individuals) to serve as Acting TL(s). The Acting TL(s) must meet the qualification requirements stated in the QAS and will assume all the duties and responsibilities of the position until a new permanent TL can be appointed or hired. A TL appointed or hired to fill a vacancy will record his/her review of the records required by the QAS.

5.2 Supervisory Biologist or Supervisory Physical Scientist (Unit Chief)

The Supervisory Biologist/Physical Scientist (Unit Chief) is referred to as "Unit Chief (UC)". The duties and responsibilities of the UC position include, but are not limited to:

- Functions as the head of a DNA Unit and is responsible for the overall management and coordination of operating programs to include future planning, staffing, scheduling, and budget within the respective unit.
- Determines mission-driven objectives and directs strategies and activities through which those objectives are met.
- Ensures all administrative, budgetary, equipment, and space needs are identified for the unit.
- Serves as the direct supervisor of DNA employees including Supervisory Biologists.
- Manages hiring, certifying time and attendance records, personnel and performance issues, and supervising appropriate unit members.
- Oversees the establishment, implementation, and review of administrative policies and procedures.
- Serves as an approving official on applicable DNA level 2 documents, and delegates the initial review of level 3 documents to the TL.
- Approves unit administrative requirements and other unit specific documents, as necessary.
- Ensures that an appropriate individual is designated to serve as the Acting UC in his/her absence.

5.3 Supervisory Biologist (Forensic Examiner)

A Supervisory Biologist also referred to as "Supervisory Forensic Examiner (SFE)", "Supervisory Examiner", or "Supervisor" is an individual who has been assigned responsibility for the oversight of a group of personnel within his/her DNA unit. A Supervisor may be a qualified or previously qualified Examiner and therefore may be equivalent to an analyst or a technical reviewer as defined by the QAS. Supervisors who participate in the proficiency testing program will fulfill the requirements, duties, and responsibilities of an Examiner. The Supervisory Forensic Examiner duties and responsibilities may include, but are not limited to:

- Ensures compliance with unit and FBI Laboratory policies, practices and procedures.
- Participates in a documented training, continuing education and development program as required by the level 1 documents, accreditation standards, FBI policies, and/or the QAS.
- Serves as the direct supervisor of a group of DNA employees which may include Forensic Examiners, Lead Biologists, Biologists, Technical Specialists, DNA Program Specialists, Management and Program Analysts, and/or Management and Program Assistants.
- Responsible for the management of various operational and/or administrative aspects of the unit, as directed by the UC.

5.4 Biologist (Forensic Examiner)

A Biologist (Forensic Examiner) is also referred to as "Forensic Examiner (FE)" or "Examiner". This position is equivalent to an analyst or technical reviewer as defined by the QAS. An Examiner may also be trained and qualified to perform laboratory activities as a Biologist (see section 5.8) and then will be proficiency tested accordingly. The Examiner duties and responsibilities include, but are not limited to:

- Ensures compliance with unit and FBI Laboratory policies, practices, and procedures.
- Participates in a documented training, continuing education and development program as required by the level 1 documents, accreditation standards, FBI policies, and the QAS.
- Directs and approves the analytical work generated by Biologist(s), reviews and interprets such data, generates *Laboratory Reports* or *Match Confirmation Letters*, testifies to the results in court, as necessary, and/or performs technical reviews of casework or databasing records, as authorized.
- Participates in the training of Biologists and Forensic Examiner Trainees (FETs) and interacts with training mentors, as appropriate.

5.5 Biologist (Program Manager)

A Program Manager is assigned additional responsibilities for a specific program(s) in the DNA Unit(s) and/or serves as project manager over major projects and FBI Initiatives within the Laboratory. A Program Manager may be a qualified or previously qualified Examiner or Biologist and may maintain proficiency as a technician, an analyst, or a technical reviewer as defined by the QAS.

5.6 CODIS Administrator

A CODIS Administrator and an alternate administrator will be designated by DCU and FDDU. The FBI Laboratory in Huntsville does not have CODIS access onsite; therefore, the CODIS Administrator in DCU is also responsible for the CODIS activities of SBAU. Each CODIS Administrator is responsible for the Local DNA Index System (LDIS) operated by his/her unit.

The CODIS Administrator designated by DCU must meet the requirements of Casework CODIS Administrator as defined by the Forensic QAS and the CODIS Administrator designated by FDDU must meet the requirements of CODIS Administrator as defined by the DNA Databasing QAS. A CODIS Administrator is a qualified or previously qualified Examiner and may maintain proficiency as an analyst or technical reviewer as defined by the QAS. The CODIS Administrator duties and responsibilities include, but are not limited to:

- Administers the applicable local CODIS network.
- Schedules and records the CODIS computer training of Examiners.
- Ensures that the security and quality of data stored in CODIS is in accordance with state and/or federal law and the NDIS operational procedures.
- Ensures that matches are dispositioned in accordance with NDIS operational procedures.
- Authorized to terminate an Examiner or a DNA Unit's participation in CODIS until the reliability and security of the computer data can be assured if it is compromised.

5.6.1 State CODIS Administrator

The State CODIS Administrator serves as the point of contact for the NDIS Custodian and is responsible for ensuring that the laboratories participating in the FBI Laboratory's State DNA Index System (SDIS) comply with the terms and conditions for participation in the NDIS. In addition to the above responsibilities, the State CODIS Administrator has authority over the CODIS sites in his/her SDIS jurisdiction to terminate an Examiner's or LDIS laboratory'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. The State CODIS Administrator may be a qualified or previously qualified Examiner and may maintain proficiency as an analyst or a technical reviewer as defined by the QAS.

5.7 Lead Biologist

A Lead Biologist is responsible for overseeing laboratory functions that support the casework and/or databasing operations of the DNA Units. This position is equivalent to a technician as defined by the QAS. The Lead Biologist responsibilities include, but are not limited to:

- Ensures compliance with unit and FBI Laboratory policies, practices, and procedures.
- Participates in a documented training, continuing education and development program as required by the level 1 documents, accreditation standards, FBI policies, and the QAS.
- Participates in the sample preparation stages prior to casework and/or database DNA processing to include collection of casework samples and/or front-end processing of database samples, and offender status requests, as needed.
- Performs specific analytical procedures in the laboratory to support casework and/or databasing activities and interacts with Examiners, as appropriate.

- Provides technical and operational support to Biologists regarding standard operational procedures and good laboratory practices.
- Participates in the training of Biologists and interacts with training mentors, as appropriate.
- Participates in troubleshooting, validation, and/or research projects, as needed.

5.8 Biologist

The Biologist position is equivalent to a technician as defined by the QAS. The Biologist duties and responsibilities include, but are not limited to:

- Ensures compliance with unit and FBI Laboratory policies, practices and procedures.
- Participates in a documented training, continuing education and development program as required by the level 1 documents, accreditation standards, FBI policies, and the QAS.
- Performs specific analytical procedures in the laboratory to support casework and/or databasing activities and interacts with Examiners, as appropriate.
- Serves as a mentor during the training of entry-level Biologists.
- Participates in troubleshooting, validation, and/or research projects as needed.

5.9 Biologist (Technical Specialist)

A Biologist (Technical Specialist) is also referred to as "Technical Specialist (TS)". The TS is responsible for performing laboratory functions that are involved with quality assurance/quality control (QA/QC), validation, research, CODIS, and/or training efforts to support the technical operations of the DNA Units. TSs with QA/QC duties generally function as laboratory support personnel and will receive appropriate training specific to their job function. TSs that perform validation will demonstrate competence and be authorized to perform development, modification, verification, and validation of methods. TSs with CODIS and/or validation duties generally do not perform examinations on forensic samples or processing of database samples and therefore are not subject to the personnel requirements as defined by the QAS. TSs that perform examinations on forensic samples or process database samples will comply with the requirements of a technician as defined by the QAS and be authorized to perform laboratory activities. Responsibilities of a TS may include, but are not limited to:

- Ensures compliance with unit and FBI Laboratory policies, practices, and procedures.
- Participates in a documented training, continuing education and development program as required by the level 1 documents, accreditation standards, FBI policies, and the QAS.
- Performs specific analytical procedures in the laboratory that are involved with QA/QC, validation, and research efforts to support casework and/or databasing activities and interacts with Research Biologists, Program Managers, and Examiners, as appropriate.

- Provides guidance and/or direction to Biologists in support of the QA, training, validation, and/or research programs.
- Participates in the sample preparation stages prior to casework and/or database DNA processing to include collection of casework samples and/or front-end processing of database samples, and offender status requests, as needed.
- Identifies specific areas that require monitoring, including technical and quality control, problem solving, and research and validation, to improve the methods and processes carried out by the DNA Units.
- Assists the unit in administrative and/or CODIS duties, as needed.
- Functions as a CODIS Biologist by entering DNA profiles into CODIS following the prerequisite review and verification by appropriate DNA personnel. The CODIS Biologist uploads DNA profiles, maintains CODIS paperwork, coordinates potential Match evaluations, and operates the CODIS software on a daily basis. All individuals functioning as CODIS Biologists receive documented training in CODIS data entry, CODIS software, and CODIS operations.

5.10 Biologist (DNA Program Specialist)

The DNA Units may refer to Biologist (DNA Program Specialist) as "Program Specialist (PS)". The PS performs various levels of administrative tasks, laboratory support, case management, evidence management, and/or QA/QC duties in support of the DNA Units. PSs may also perform duties as listed above for a TS. PSs are typically equivalent to laboratory support personnel as defined by the QAS; however, PSs that perform examinations on forensic samples or process database samples will comply with the requirements of a technician as defined by the QAS.

5.11 Research Biologist

A Research Biologist is responsible for identifying and/or conducting studies that will aid the DNA Units in using novel or improved analytical procedures, as well as conducting validation studies and transferring the knowledge pertaining to the validation of new methods and technologies to casework and database personnel. Research Biologists will demonstrate competence and be authorized to perform development, modification, verification, and validation of methods. A Research Biologist may be a qualified or previously qualified Examiner or Biologist and may maintain proficiency as a technician, an analyst, or a technical reviewer as defined by the QAS.

5.12 Management and Program Analyst

A Management and Program Analyst is responsible for administrative tasks and the management and assessment of unit(s) program operations and projects. In addition, this position plans, develops, and conducts program analyses, identifies inefficiencies, evaluates performance measures, and provides recommendations to management, when necessary. A Management and Program Analyst manages unit budget and financial matters by developing budget estimates and

justifications and ensures unit funds are used appropriately. The Management and Program Analyst may also assist with time and attendance records.

5.13 Management and Program Assistant

A Management and Program Assistant performs clerical and administrative duties. The Management and Program Assistant may also assist with the time and attendance records.

5.14 Temporary Duty Assignments

In the event that additional personnel are needed to meet the changing operational needs of any of the DNA Units, a DNA UC may request that an individual, who possesses the necessary knowledge and skills, be transferred to the respective DNA Unit on temporary duty status. This request must be made in writing, approved by Executive Management and comply with current Laboratory Division (LD) policies. If the operational needs are technical in nature, the TL will determine and approve any necessary training and authorize personnel, as appropriate, in accordance with the level 1 documents.

5.15 Contractors

All DNA contractors will comply with the applicable requirements of the level 1 documents, accreditation standards, FBI policies, and the QAS. Prior to gaining employment by an additional NDIS participating and/or vendor laboratory, a contractor will obtain TL approval. Contractors will perform duties within the scope of the contract statement of work under the direction of the unit's Contracting Officer's Representative (COR). In addition to contractors with Biologist or Examiner titles, the following include possible contractor positions in the DNA Units.

5.15.1 Contractor Supervisor

The Contractor Supervisor (aka Operations Supervisor) provides on-site supervision to DNA contractors employed by their contracting agency assigned to the FBI Laboratory. The Contractor Supervisor is also responsible for assisting DNA Units in operational and support needs.

5.15.2 Supervisory Records Examiner/Analyst

A Supervisory Records Examiner/Analyst performs specific analytical procedures in the laboratory to support casework and/or database activities and interacts with Examiners, as appropriate. A Supervisory Records Examiner/Analyst must meet the qualifications and appropriate training requirements of a Biologist and is equivalent to a technician as defined by the QAS.

5.15.3 Records Examiner/Analyst

A Records Examiner/Analyst can be responsible for performing laboratory functions that are involved with quality assurance/quality control (QA/QC) or evidence management and sample preparation stages prior to casework and/or database DNA processing, as needed. A Records Examiner/Analyst can conduct QC procedures on the reagents and instruments used in casework and/or databasing. This includes performing the actual QC procedures as well as recording the results and assessing the performance of the reagents and instrumentation. A Records Examiner/Analyst can also function as the team leader for contractors assigned to the accessioning process, providing instruction and technical guidance, as needed. A Records Examiner/Analyst assigned to support the DCU Case Administration Group (CAG) manages items of evidence and is responsible for performing various levels of administrative tasks. A Records Examiner/Analyst may also perform Data Analyst tasks or act in support of other DNA Unit programs, as needed. Records Examiners/Analysts are equivalent to laboratory support personnel as defined by the QAS.

5.15.4 Data Analyst

A Data Analyst conducts various functions involving administrative and laboratory support. A Data Analyst may be responsible for retrieving database samples from storage and performing the plate preparation and plate creation process. This includes punching the samples into plates using automated punch workstations and returning samples to storage after analysis. Additional responsibilities include the receipt, check-in, and storage of the samples. A Data Analyst may also assist FDDU Examiners in the resolution of samples which contain missing information, are potential duplicates, and/or potential rejects. A Data Analyst may assist with sample status requests, and expedite requests. A Data Analyst in CAG will assist with the management of items of evidence. A Data Analyst may also conduct QC procedures on the reagents and instruments used in casework and/or databasing or perform validation studies. Data Analysts are generally equivalent to laboratory support personnel as defined by the QAS. Data Analysts may also provide administrative support such as Sentinel tasks and casefile management assistance or act in support of other DNA Unit programs, as needed.

5.15.5 Clerical II

A Clerical II will assist with the receipt and check-in of collection kits, sample storage, and/or provide administrative support to the DNA Units.

5.15.6 IT Support

IT Support personnel provide computer technical support and maintain the BASNET.

6 Training, Qualification, and Authorization

6.1 All personnel that could influence the laboratory activities will act impartially, be competent, and work in accordance with the laboratory quality system.

6.2 The TL will approve any modifications to required training based on the documented assessment of the individual's previous training and experience.

6.3 Training Programs for Proficiency Tested Personnel

6.3.1 The DNA Units will administer and maintain documented training programs for new Examiners and Biologists which identify the requirements necessary for achieving qualification and authorization in each respective position. The training programs will be outlined in the respective training manual and comply with the level 1 documents.

6.3.1.1 All Examiners and Biologists must satisfactorily complete competency testing prior to assuming independent casework or databasing responsibilities. The competency test intended results must be achieved prior to performing the task(s) on casework items or databasing samples.

6.3.2 For Biologists training in an additional module, the training will be administered in accordance with the Biologist Training Manual.

6.3.3 Examiners training in an additional DNA technology or interpretation (e.g., kinship) will not reenter the Forensic Examiner Training Program. A modified training plan will be developed establishing the criteria for successful completion of training in the new technology or interpretation. The modified training plan will be approved by the TL and the trainee's UC.

6.4 Additional Training

6.4.1 Prior to implementation of a new method in the laboratory for forensic examinations or DNA databasing, Biologists will be taught the technical skills and knowledge required to perform the method and Examiners will review the examination records generated using the method in order to authorize and report results.

6.4.1.1 Before the use of the new method on evidence, reference, or database samples, the Biologists must successfully complete competency testing, including a practical component, to the extent of his/her participation in casework or databasing analyses.

6.4.2 Prior to the implementation of a new technology, typing test kit, platform, or interpretation software, Examiners will be taught the technical skills and knowledge required to interpret data, reach conclusions, and generate reports.

6.4.2.1 Before the use of a new technology, typing test kit, platform or interpretation software on evidence, reference, or database samples, Examiners must successfully complete

competency testing, including a practical component, to the extent of his/her participation in casework or databasing analyses.

6.4.3 For an Examiner to be qualified in reinterpretation of legacy data, for which they were not previously qualified within the laboratory, the Examiner must demonstrate the technical skills and knowledge required to interpret data, reach conclusions, and generate reports in the legacy technology, typing test kit, and/or platform.

6.4.3.1 The Examiner must successfully complete competency testing, including a practical component, in the legacy technology, typing test kit, and/or platform to the extent of his/her participation in casework analyses. The competency testing will include practical components of reinterpretation.

6.5 For an Examiner to be qualified to perform technical reviews for any method, technology, typing test kit, platform, or interpretation software or a legacy technology, typing test kit, platform and/or interpretation software on which they were not previously or are not currently qualified as an analyst in the laboratory, training will include the case notes, data analysis, interpretation, and reporting criteria, as applicable, required to perform a technical review.

6.5.1 The Examiner must have successfully complete competency testing before completing a technical review of data and/or reports using the new or additional method, technology, typing test kit, platform or interpretation software used in casework analyses.

6.6 Qualification and Authorization

6.6.1 The TL will review training records for Examiners and Biologists and approve an individual's successful completion of a training program.

6.6.2 Individuals who perform laboratory activities, analyze, review, authorize, verify, or report results, express opinion or interpretation, or perform technical review will be authorized. Qualification and authorization will be recorded in an EC in accordance with the level 1 documents and, if applicable, the appropriate training manual.

6.6.2.1 Prior to use of a newly validated procedure (e.g., method, technology, typing test kit, platform, interpretation software), qualification and authorization is recorded in an EC for all individuals who successfully completed the additional training.

6.6.3 When external proficiency testing does not include a legacy technology, typing test kit, or platform, an Examiner must maintain or reestablish the technical skills and knowledge necessary to perform reinterpretation of the legacy data, as necessary, every two years. This is accomplished through a review of validation records, review of SOPs, and/or review of previous training records applicable to the legacy technology, typing test kit, or platform. The reviews will be recorded and provided to the TL to ensure authorization prior to reporting results requiring the reinterpretation of legacy data.

6.6.3.1 The TL will review the Examiner's records of review and authorize the Examiner to reinterpret legacy data for no more than a two year period.

6.6.4 When retraining of personnel is necessary, the technical leader will be responsible for evaluating the need for and assessing the extent of retraining. The retraining plan will be approved by the technical leader. The individual must successfully complete competency testing, including a practical component, prior to return to participation in forensic examinations or DNA databasing.

6.7 Training of Non-Proficiency Tested Personnel

6.7.1 The DNA Units' training program will also address training for DNA personnel that receive and breakdown evidence.

6.7.2 Individuals that will perform laboratory duties exclusive of analytical procedures on forensic and/or database samples (e.g., sample accessioning, reagent preparation, instrument maintenance) will be appropriately trained for their specific job functions. Training records will be maintained.

6.7.3 Individuals that will perform development, modification, verification, and validation of methods must have the competence to independently or under direction perform experiments, analyze or review data, maintain records, and/or develop conclusions based on validation data. An individual's education, qualification, training, technical knowledge, skills, and experience will be assessed to determine competence to perform the anticipated tasks. Once competence has been demonstrated to the satisfaction of the TL, the individual will be authorized.

7 Facilities and Evidence/Sample Control

7.1 Facilities

7.1.1 DNA laboratory areas in permanent control facilities are located separately from unit offices. Access to the laboratory area is obtained through a bio-vestibule.

7.1.1.1 If laboratory activities are performed at sites outside of the FBI Laboratory permanent control facilities, DNA personnel will ensure requirements for facilities and environmental conditions of the applicable accreditation standards are met, to include verifying that the site is appropriate to ensure the integrity of the analyses and the evidence.

7.1.2 DNA personnel will comply with all health and safety practices established in the FBI *Laboratory Safety Manual*.

7.1.2.1 DNA personnel will use appropriate protective equipment when performing sample check-in, laboratory examinations of evidence, or processing of samples that may contain potentially infectious biological substances.

7.1.2.2 Food and/or drinks are not to be handled or consumed in any DNA laboratory space.

7.1.3 DNA laboratory areas are arranged in a manner that ensures the physical separation of those used for evidence examination, sample accessioning, DNA extraction, amplification set-up and/or other pre-amplification processing from those used for DNA amplification and post-amplification processing.

7.1.3.1 Evidence examination or sample accessioning, DNA extraction, and PCR setup are conducted at separate times or in separate spaces.

7.1.3.2 There are no specific environmental conditions necessary for the performance of DNA laboratory activities; however, extreme temperature fluctuations may impact the performance of capillary electrophoresis instruments.

7.1.4 Amplified DNA product will be generated, processed, and maintained in rooms separate from evidence examination, sample accessioning, DNA extraction and amplification set-up. The doors to the amplification rooms will be kept closed except for passage.

7.1.4.1 Equipment and materials used in laboratory spaces where DNA is amplified or amplified DNA is stored or processed are not to be transferred to, used in, or stored in laboratory spaces where evidence is examined, database samples are processed, and/or unamplified DNA is extracted or stored unless decontaminated before transfer. These items include, but are not limited to:

- Laboratory coats
- Pipettes
- PCR related supplies
- Micro Amp Support Base (Amplification set-up racks)
- General laboratory supplies and materials

7.1.5 Rapid DNA instruments will be maintained in rooms outside of evidence examination or sample accessioning areas or those containing amplified DNA.

7.1.6 Additional housekeeping procedures needed to ensure the quality of the examination or testing procedures are contained in the DNA procedures introduction (i.e., DNAQA 600).

7.2 Security

7.2.1 The DNA Units will follow the level 1 documents and the security practices in the FBI Security Division Policy Directives and Policy Guides.

7.2.1.1 DNA personnel will ensure that individuals without unescorted access to the FBI Laboratory are escorted at all times while under his/her care and in the FBI Laboratory building.

7.2.2 The FBI Laboratory buildings are secured areas. Laboratory space is accessed by the Security Access Control System (SACS) badge and/or a laboratory access key.

7.2.2.1 The LD Security Group is responsible for the control of access keys. Key lists will be reviewed at least annually. A UC, supervisor, or DSU personnel will ensure the LD Security Group and/or the individual are notified when an individual needs to be issued or is expected to relinquish a laboratory access key.

7.2.2.2 The LD Security Group is responsible for making the appropriate changes to the access lists. Access lists will be reviewed annually. A UC, supervisor, or DSU personnel will ensure changes to the SACS badge access lists are requested, as needed.

7.2.3 If laboratory activities are performed at sites outside of the FBI Laboratory permanent control facilities, DNA personnel are responsible for ensuring the security of the testing area. DNA personnel will remain present in the testing area or will record in the case notes the security measures taken to prevent access to the testing area by unauthorized personnel.

7.3 Sample Control

7.3.1 The FDDU does not handle forensic DNA evidence. The FDDU receives, stores, and processes DNA database samples (i.e., known blood and buccal samples) in accordance with FDDU procedures.

7.3.1.1 DNA database samples are stored in designated laboratory space and sample storage areas with restricted access. Database sample storage areas will be locked when unoccupied.

7.3.1.2 The FDDU Chief will authorize the appropriate DNA personnel, and a limited number of other FBI Laboratory personnel and facilities maintenance employees, with unescorted access to database sample storage areas. Individuals not authorized by the FDDU Chief will be escorted.

7.3.1.3 The FDDU will retain all DNA database samples (e.g., FTA cards) indefinitely unless otherwise directed by a legal expungement, as a result of an administrative removal or quantity not sufficient (QNS) removal, or for purposes of research, validation, and/or population databases.

7.4 Evidence Management

7.4.1 DNA personnel will follow the relevant level 1 documents and the DNA evidence management procedures (i.e., DNA 501), when receiving, transferring, examining, storing, or returning evidence. When not under active examination, evidence will be stored, secured, and/or sealed in a manner to prevent loss, cross-transfer, contamination, or deleterious change.

7.4.1.1 In general, evidence is stored at room temperature, refrigerated, or frozen. Evidence such as tissue, bones, and teeth are generally stored refrigerated, but may be stored frozen, if deemed necessary. DNA extracts and amplified DNA products may be stored refrigerated or frozen. For long term storage, DNA extracts may be dried and stored at room temperature.

7.4.1.2 If a sample(s) is collected from evidence that is in the custody of another laboratory unit or a partner laboratory and therefore not in the custody of the DNA Units, the case record and/or chain of custody will appropriately reflect items or samples that are collected or created and preserved for future testing. Virtual transfers may be necessary to enter items and/or samples into STACS when an item of evidence is not received by the DCU or SBAU.

7.4.2 The DCU and SBAU will maintain the security of Evidence Storage Rooms (ESR) in accordance with the appropriate level 1 documents.

7.4.2.1 As appropriate, the DCU and SBAU Chief will authorize DNA personnel, and a limited number of other FBI Laboratory personnel and facilities maintenance employees to enter the applicable ESR unescorted. Individuals not authorized by the applicable UC will be escorted and complete the appropriate log upon entry into the ESR.

7.4.2.2 The applicable UC will ensure the security group access lists are reviewed annually and necessary adjustments are requested.

7.4.3 The DCU CAG centralizes DCU evidence management functions not related to examinations. An appropriately trained individual performs these functions for the SBAU.

7.4.3.1 Appropriately trained individuals accept evidence into the DCU or SBAU and ensure appropriate entries are in STACS. The DNA Units use STACS for both Legacy and Forensic Advantage (FA) cases.

7.4.3.1.1 In general, CAG does not open evidence containers received as part of a Multiple Unit Submission (MUS). If necessary to separate evidence into different storage conditions (e.g., freezer, room temperature), the Chain-of-Custody will reflect this separation to include confirmation of the listed contents within the container upon opening.

7.4.4 For evidence received as a Single Unit Submission (SUS), an appropriately trained individual will open evidence containers as necessary for evidence breakdown and inventory purposes in accordance with the appropriate practices and/or procedures.

7.4.5 An appropriately trained individual will also ensure all items examined by the DNA Units are prepared (i.e., properly packaged) for forwarding to another Laboratory unit or returning to the contributor.

7.5 Evidence and Work Product

7.5.1 Databasing

7.5.1.1 DNA database samples are not evidence. FDDU samples are considered work product at any stage of the analytical process commencing with punch. The FDDU utilizes STACS software for tracking the movement of samples through processing.

7.5.1.1.1 STACS assigns a unique identifier (i.e., FDDU Sample Number) to each DNA database sample upon receipt/check-in, and that unique identifier is maintained through the analytical processes within the FDDU. Additionally, FDDU samples are RFID tagged for use in tracking the samples when moved within the laboratory and when placed in storage.

7.5.1.1.2 Amplified FDDU samples will be stored refrigerated in the post-amplification laboratory. FDDU DNA extracts (if applicable) and amplified product may be disposed of once the data analysis is complete for the FDDU sample plate(s).

7.5.1.1.3 Unless a DNA database sample is expunged according to the FDDU procedure, once DNA databasing is complete, the remaining sample is retained for quality purposes (e.g., match confirmation) and may be used for training, validation, or other DNA unit needs.

7.5.2 Casework

7.5.2.1 DNA extract tubes, DNA dilution tubes, and unprocessed collections (e.g., swabbings, bone powder) retained from items of evidence in the DCU and SBAU are considered secondary evidence.

7.5.2.1.1 Secondary evidence may be retained by the DCU for future testing in support of the National Missing Person DNA Database (NMPDD) program. Once retained in the NMPDD repository storage, physical transfers will not be recorded until the sample is removed for subsequent testing.

7.5.2.1.2 Secondary evidence in the SBAU will generally be transferred to the Evidence Management Unit (EMU) for retention with the evidence.

7.5.2.2 Work product in the DCU and SBAU is material that is generated as a function of analysis of evidence or secondary evidence. Work product includes cuttings that have been processed for extraction, plates containing diluted DNA, amplification product, and material generated from serological analyses (e.g., slides prepared for Takayama hemochromogen testing). Work product is generally not retained or returned.

7.5.2.2.1 Amplified DNA will be stored in a refrigerator/freezer in the post-amplification laboratory areas and physically separated from areas used for evidence examinations, DNA extractions, and PCR set-up. DCU or SBAU amplified DNA may be disposed of after the *Laboratory Report* has been issued for the case or at regular intervals as approved by the TL.

7.6 Examination of Evidence

7.6 The Biologist, or an appropriately trained individual, that opens an evidence container or package will ensure the custody transfer was properly recorded. The item(s) transferred will be verified to the extent possible without unnecessarily opening packaging layers. Any necessary corrections will be made to the Chain of Custody. Any packaging discrepancy (e.g., torn bag, broken seal) will be noted.

7.6.1 The contents of evidence containers or packages not opened by the DNA Units will not be verified.

7.6.2 If a primary evidence package (i.e., packaging in contact with evidence) is opened but no examinations are conducted, a note will be made in the case file.

7.7 The movement and location of all evidence and secondary evidence over which DNA personnel have custody will be tracked. STACS is used to track evidence and secondary evidence within the DCU and SBAU.

7.8 Evidence may be considered under active examination from the time the first sample in a submission (or a group of submissions in a case) is examined for serology or cut for DNA extraction until the time the Examiner determines that all laboratory analysis is complete for that submission or group of submissions. Active examinations are generally not expected to exceed 30 days; however, evidence may be under active examination for up to 6 months. Evidence not under active examination will be stored according to the applicable level 1 documents.

7.8.1 Secondary evidence and evidence under active examination may be stored unsealed in a lockable laboratory space (e.g., ESR, examination suite). Personnel will ensure the laboratory rooms or areas containing evidence are locked at the end of the day.

7.8.2 Access to laboratory space is limited to FBI Laboratory employees, contractors, and limited maintenance and service personnel with SACS badge access; therefore, rooms containing only work product (i.e., post amplification labs) do not need to be individually locked.

7.8.3 If laboratory activities are performed at sites outside of the FBI Laboratory permanent control facilities, DNA personnel are responsible for ensuring the security of the evidence and work product in progress. DNA personnel will remain present in the testing area or will record in the case notes the security measures taken to secure unattended items in order to preserve the integrity of the evidence and work product.

7.8.3.1 If secondary evidence must temporarily remain at a site outside of the FBI Laboratory permanent control facilities, DNA personnel will properly seal and ensure the items are stored in an appropriately secure, controlled access storage location. The storage location and a verification of the integrity of the items upon retrieval from the storage location will be recorded in the case notes and/or chain of custody.

7.9 DNA personnel should use the amount of evidence considered necessary to provide DNA typing results. It is noted that while every attempt is made not to consume the entirety of any particular item of evidence to allow for possible reexamination of that evidence at a later date by another laboratory, the primary goal is to use the amount of evidence necessary to provide DNA typing results. When sample consumption is necessary, a concerted effort to obtain authorization from the prosecutor or contributor to consume evidentiary materials will be made prior to the initiation of DNA examinations (i.e., extraction) on the affected item(s). A record of these communications will be retained with the case records.

7.9.1 For TEDAC cases, samples will be consumed at the discretion of the DNA Units.

7.9.2 Evidence material retained or used for non-casework procedures (e.g., for troubleshooting, validation) is considered work product. Collections made for this purpose will be limited to items with sufficient material for future testing and must be approved by the contributor (for non-TEDAC cases) and recorded in the case notes and report.

8 Validation

8.1 All new technical procedures intended for DNA and/or serological analysis on casework and/or database samples will be validated in accordance with the level 1 documents and the QAS.

8.1.1 Internal validation data may be shared by all locations. Each laboratory location will complete the applicable site-specific studies required by the QAS.

8.1.2 Newly validated DNA methods (from amplification through characterization), typing test kit, or platform instrument model will 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 examinations or DNA databasing.

8.2 Procedural modification(s) (aka material modifications) made to a previously validated and approved technical procedure will be evaluated by comparison to the original procedure using similar samples. Such testing will be completed and approved prior to the issuance of the revised procedure.

8.3 A Rapid DNA instrument used for modified Rapid DNA analysis will be validated in accordance with the level 1 documents and the QAS. An NDIS approved Rapid DNA System requires only a performance check prior to use on casework reference, known, or database samples.

8.4 New software or modifications to software will be evaluated and appropriately validated or tested in accordance with the QAS and the applicable DNA procedures for equipment (i.e., DNAQA 608).

8.5 Validation studies will be technically reviewed by an individual with the appropriate expertise in the subject matter. All developmental validation, internal validation, procedural modifications and software testing records will be reviewed and approved by the TL prior to implementation. Validation records will reflect the date of the review(s) and TL approval.

8.5.1 The TL will ensure the applicable UC(s) are provided the results of an internal validation study and the validation summary before use in the laboratory. When a newly validated procedure will be implemented in a DNA Unit(s), the UC(s) of the applicable unit(s) will record agreement with the validation results and summary.

8.6 Records associated with developmental validation, internal validation, procedural modifications and software testing will be maintained by DSU, typically via electronic records or in validation binders that are scanned into Laserfiche for retention. The summary of the shared validation data will be available at each site.

9 Analytical Procedures

9.1 Standard Operating Procedures

9.1.1 DNA personnel will follow the appropriate level 1 documents when preparing, reviewing, issuing, distributing, and controlling DNA level 2 documents. All technical procedures prepared by DNA personnel will be approved by the appropriate UC(s) and the TL prior to issuance.

9.1.2 DNA level 3 documents (e.g., externally produced quality documents, equipment manuals, user guides) necessary to perform examinations or DNA databasing will be controlled in accordance with the appropriate level 1 document. The TL is designated to ensure the initial review of applicable DNA level 3 documents and any appropriate level 3 document modifications are recorded. Typically, the DNA Units use externally produced quality documents for reference, maintenance, and/or troubleshooting purposes and, therefore, these will not be controlled. Electronic copies of equipment manuals may be retained in STACS or are generally available online.

9.1.3 DNA personnel may request revisions to DNA level 2 documents or request to replace a controlled level 3 document. The DSU, in collaboration with DCU, SBAU, FDDU, and the TL, will coordinate the revision and subsequent issuance of the DNA Unit's controlled documents, as appropriate.

9.1.4 If it is necessary to deviate from an FBI Laboratory quality system document (level 1, level 2, or level 3), the DNA Units will follow the appropriate level 1 document. The TL will evaluate all technical deviation requests prior to approval.

9.1.4.1 Approved minor deviation records will be tracked, generally through the QA ticketing system, and will be compiled for at least an annual review.

9.2 Quality Control of Reagents and Supplies

The DNA Units will follow the relevant level 1 and DNA level 2 documents and the QAS regarding the quality control of reagents and supplies. The use of analytical controls and standards to monitor analytical procedures used for examinations and DNA databasing are described in the applicable procedure(s). Reagents deemed critical are listed in the DNA procedures for reagents (i.e., DNAQA 609).

9.3 Sampling

9.3.1 The types of forensic examinations performed by DNA personnel do not require a sampling plan. Sample collection guidance and sample preparation procedures are described in the appropriate DNA level 2 documents (e.g., DNA 201, FDDU 301, DNA 401).

9.3.1.1 A reasonable assumption of homogeneity can be made for database samples, casework reference samples (e.g., blood tubes, buccal samples), and various types of evidence (e.g., bones, teeth, hair and swabs) examined by the DNA Units.

9.3.1.2 When a reasonable assumption of homogeneity cannot be assumed, the selection of samples or sites is based on an Examiner's knowledge, training, and experience to select the appropriate samples and/or stains to test. In addition, an Examiner may rely on the results of the serological testing and/or the Biologist observations, training, and experience regarding the selection of an appropriate stain/sample. If this information does not allow two stains/samples to be distinguished from one another, a stain/sample may be selected at random.

9.3.1.3 In instances where a portion of an item of evidence may be selected for testing (e.g., one of multiple bloodstains on an item of evidence), the *Laboratory Report* will reflect the tested portion of the item of evidence, making no inference about the whole.

9.3.2 Relevant sampling records are generally recorded in STACS.

9.4 Measurement Uncertainty

Measurement uncertainty does not apply to the examinations or DNA databasing conducted in the DNA Units.

10 Equipment Calibration and Maintenance

All equipment having an effect on the accuracy and validity of DNA examinations or DNA databasing will be properly maintained and calibrated in compliance with the appropriate level 1 and DNA level 2 documents, and the QAS. Reagents deemed critical are listed in the DNA procedures for equipment (i.e., DNAQA 608).

11 Laboratory Reports and Match Confirmation Letters

11.1 DNA personnel will prepare a *Laboratory Report* in accordance with the appropriate level 1 and DNA level 2 documents.

11.2 The FDDU does not issue *Laboratory Reports*; however, it does provide *Match Confirmation Letters* in accordance with the appropriate DNA level 2 document (i.e., FDDU 311).

11.3 The resolution, verification and reporting/notification of database matches, including the release of personally identifiable information, is done in accordance with the NDIS procedures and the appropriate DNA level 2 document.

11.4 Examination/Databasing Records

11.4.1 Case-related and database records will be generated and/or prepared by DNA personnel in accordance with the appropriate level 1 and DNA level 2 documents. Generally, examination records are generated and/or maintained in STACS.

11.4.2 Abbreviations and notations may be used in records provided they are clearly documented and readily comprehensible to the reviewer. A list of commonly used abbreviations/symbols employed in case file and database records is available in Appendix A.

11.4.3 DNA Units maintain the confidentiality of case records and personally identifiable information (PII) according to the level 1 documents. DNA records or case files may be released upon request from an authorized entity (e.g., contributor, discovery request, another NDIS laboratory). DNA examination records (e.g., exam notes, DNA profiles) will be, at a minimum, technically reviewed, if applicable, prior to release.

11.4.3.1 DNA databasing records (e.g., DNA profile, data required to manage and operate NDIS) are only released upon receipt of a written legal request for discovery or other legal request (e.g., Freedom of Information Act [FOIA]). With the FDDU Chief's approval, DNA records and associated metadata may be released to other FBI Laboratory units (e.g., DCU) in the absence of a written legal request.

11.4.3.2 The Federal DNA Identification Act ('Federal DNA Act'; 34 U.S.C. §12592(b) (3)) provides for limited access to the DNA analyses and DNA samples to the following:

(A) to criminal justice agencies for law enforcement identification purposes;
(B) in judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules;
(C) for criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged; or
(D) if personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes.

12 Review

12.1 *Laboratory Reports* (DCU and SBAU) and *Match Confirmation Letters* (FDDU), as well as case or database related administrative and examination records generated by the DNA Units will be reviewed in accordance with the appropriate level 1 and DNA level 2 documents and the QAS.

12.2 Unresolved discrepant interpretations or conclusions between the reporting Examiner and the reviewer(s) will be resolved by the Technical Leader unless elevation to Section Chief or above, as described in the level 1 documents, becomes necessary.

12.3 The release of personally identifiable information associated with a database hit requires at a minimum an administrative review of the *Match Confirmation Letter* or the CODIS *Laboratory Report*.

12.4 STACS is typically used to assign CODIS specimen categories. For database samples, this is based on the sample contributor type. For casework samples, the specimen category is selected by the examiner within STACS. Specimen categories may be edited as necessary and appropriate upon entry of the sample into CODIS.

13 Proficiency Testing

13.1 DNA Units will use external, open proficiency tests to monitor the performance of Examiners and Biologists according to the appropriate level 1 and DNA level 2 documents, and the QAS.

13.1.1 Biologists that are qualified to perform laboratory methods on casework and/or databasing samples will be proficiency tested in each methodology in accordance with the QAS.

13.1.2 Examiners will be tested on the interpretation and/or technical review of serological and/or DNA data in each technology and on each typing test kit in which they participate in casework and/or databasing in accordance with the QAS.

13.1.3 Proficiency testing requirements do not apply to the use of a Rapid DNA System; however, Examiners qualified to perform modified Rapid DNA analysis must be proficiency tested in accordance with the QAS.

13.2 If an Examiner or Biologist is on leave or otherwise assigned for a period that takes them out of the proficiency test cycle, the Examiner or Biologist will complete any necessary training or retraining and will complete a competency test (aka a requalification test) in accordance with the retraining procedures above and the appropriate training manual prior to resuming casework or databasing and then return to the proficiency testing cycle within eight months.

14 Nonconformities

14.1 DNA Units will follow the appropriate level 1 documents when a potential nonconformity is identified.

14.2 DNA Personnel will notify the TL and/or the QA/QC Group, of all situations and conditions for which a correction, concession, or corrective action is necessary. The requirement, the situation or condition, and any action taken should be included in the notification, typically via a QA ticket.

14.2.1 Biologists and Examiners are qualified to determine appropriate action to address a correction or concession.

14.2.2 The TL is responsible for determining if reported nonconformities potentially require corrective action and/or preventive action. Corrective actions and preventive actions in the DNA Units will be implemented in accordance with the appropriate level 1 documents. *Corrective Action Requests* (7-254) will be approved by the TL prior to implementation.

14.2.3 The appropriate CODIS administrator(s) will be notified when the nonconformity impacts DNA records entered into CODIS.

14.3 When applicable, a copy of the nonconformity record (e.g., CAR), a communication log referencing the CAR and/or a note describing the action taken to address a nonconformity involving casework examinations or DNA databasing will be retained in the case file or database records.

14.4 Nonconformity notification records (i.e., QA tickets) will be maintained such that nonconformities addressed by a correction or concession may be monitored for trends. Nonconformity records will be compiled at least quarterly for the TL to review.

15 Audits

15.1 DNA Units are audited annually in accordance with the QAS. The level 1 documents detailing internal audits do not apply to QAS audits.

15.1.1 Audits performed as part of an accreditation assessment (i.e., ISO 17025, accrediting body requirements), will satisfy the external agency audit requirement for a specific year if conducted in accordance with the QAS and within the QAS required time interval.

15.2 Under the direction of the TL, the DSU QA Program Manager will ensure all suggestions, recommendations, findings, and possible nonconformities as a result of the audit process are addressed. The TL is responsible for ensuring that when necessary nonconformities are appropriately addressed and recorded.

15.3 The TL will ensure records of all external QAS audits are provided to the NDIS Custodian as required by the QAS and the NDIS procedures. Internal and external QAS audit documentation, and if applicable, corrective action(s) will be provided to the appropriate CODIS administrator(s).

15.4 In addition, the DNA Units are subject to periodic audits of the quality system conducted in accordance with the FBI Laboratory internal audit program. Records associated with these Forensic Analysis Support Unit (FASU) directed quality assurance audits are maintained according to the appropriate level 1 documents.

16 Professional Development

16.1 Continuing Education

16.1.1 The DNA Units will comply with the continuing education requirements of the level 1 documents.

16.1.2 In addition, the TL, CODIS Administrators, and currently qualified (i.e., proficiency tested) Examiners (i.e., analysts and technical reviewers) must stay abreast of topics relevant to the field of forensic and/or databasing DNA analysis in accordance with the QAS.

16.1.2.1 Continuing education requirements of the QAS are fulfilled by attending seminars, courses, professional meetings, or other sessions/classes in relevant subject areas at least once a calendar year.

16.1.2.2 Appropriate supporting records, as required by the QAS, for at least 8 hours per Examiner will be maintained by DSU.

16.1.3 Supervisors will ensure personnel have the appropriate access to continuing education opportunities.

16.1.4 The FBI's Virtual Academy (VA) is generally used to record continuing education hours.

16.2 Scientific Literature

The TL and currently qualified Examiners are responsible for the on-going review of scientific literature. The TL will ensure scientific journal articles or other relevant publications are distributed for review at least annually. The records of completion will be maintained by DSU. DNA personnel have ample access to scientific journal articles through the FBI Library.

16.3 Testimony Monitoring

16.3.1 All DNA personnel who provide testimony or who review such testimony will follow the appropriate level 1 documents.

16.3.2 A listing of all Forensic Examiners who did not testify over the course of a calendar year will be maintained by the DSU.

17 Outsourcing

The DNA Units do not outsource. If an external provider will be used for examinations or DNA databasing, the DNA Units will follow the requirements in the level 1 documents and/or will ensure compliance with the outsourcing requirements listed in the QAS prior to accepting ownership of any products for DNA testing.

18 References

FBI Laboratory Quality Assurance Manual

FBI Laboratory Operations Manual

FBI Laboratory Safety Manual

DNA Procedures Manual

Biometrics Analysis Section DNA Network, Information System Contingency Plan (ISCP), latest version.

Federal Bureau of Investigation, Quality Assurance Standards for DNA Databasing Laboratories, latest version.

Federal Bureau of Investigation, Quality Assurance Standards for Forensic DNA Testing Laboratories, latest version.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, latest version.

National DNA Index System (NDIS) Operational Procedures Manual, latest version.

Rev. #	Issue Date	History
12	06/15/18	Added DNA Databasing and sample processing throughout as needed because the LOM definition of examination is limited to testing on evidence. 3.1.4 RMD renamed IMD 7.1 Added that DNA DB samples are treated as reference material. 7.9.3.1 Added i.e. FDDU Sample Number
13	02/18/20	Extensive revisions for 17025:2017, AR 3125, and QAS 2020. Relocated, reordered, or renumbered requirements as appropriate.Replaced references to QAM and LOM with level 1 docs and DNA procedures with DNA level 2 documents throughout. Added requirements for work done outside of FBI laboratory permanent facilities.

Redacted - Signatures on File

Approval

DNA Technical Leader Date: 02/14/2020

DCU Chief Date: 02/14/2020

DSU Chief Date: 02/14/2020

FDDU Chief Date: 02/14/2020

SBAU Chief Date: 02/14/2020

QA Approval

Quality Manager Date: 02/14/2020

Appendix A: *Commonly Used DNA Abbreviations*

Abbreviations	Term
↑	Elevated or High
↓	Decreased or Low
-	Deletion, Negative, or Negative Amplification Control
-A, -a	Non-Template Nucleotide Addition (Minus-A)
A	Adenine
AA	African American
ABNA	Analyzable But Not Alignable
AI	Allele Imbalance
ALS	Alternate Light Source
AMP	Amplify or Amplification
AMP BLANK	Amplification Blank
AP	Acid Phosphatase
BC	Barcode or Blood Card
BIS	Blood/Buccal Internal Standard
BKND, BKGND	Background
BL	Blank
BLK	Black
BP	Base Pairs
BT	Bleed-Through
C	Cytosine
CAU	Caucasian
CE	Capillary Electrophoresis or CE Instrument
CM or CMNG	Case Management or Case Management Next Generation
CO	COfiler
CODIS	Combined DNA Index System
CS, CYC SEQ	Cycle Sequence(d)
CT	Cross talk or Cycle Threshold
D, DIL, DIL'N	Dilution
DA	Data Analysis
DB or DBASE	Database
DD	Dissociated Dye
DNA	Deoxyribonucleic Acid
EPP	Electrophoresis Plate Preparation
EXBT	Excessive Bleed through
EXP	Extraction Plate
FB	Differential Female Reagent Blank
FBI	Federal Bureau of Investigation
FC	Female Control
FI	Failed Injection
FNC	Finger Nail Clipping(s)
FT	Faint
G	Guanine

GA	Genetic Analyzer
GF	GlobalFiler
GFE	GlobalFiler Express
GMID, GMIDX	GeneMapper ID or GeneMapper ID-X
GTT	Grey Top Blood Tube
HEMO	Hemochromogen
HETERO	Heteroplasmy
HV1, HVI	Hypervariable Region 1
HV2, HVII	Hypervariable Region 2
HV1A, HVIA	Hypervariable Region 1A
HV1B, HVIB	Hypervariable Region 1B
HV2A, HVIIA	Hypervariable Region 2A
HV2B, HVIIB	Hypervariable Region 2B
HV3	Hypervariable Region 3
I2	Second injection for a particular evidence extract
ID	Identifiler (FDDU), Identifiler Plus (DCU/SBAU), or Identification
ID+	Identifiler Plus
IDD	Identifiler Direct
INC	Inconclusive
INJ	Injection
IP	In Progress
K	Known Sample
KN	Known Negative
KP	Known Positive
LF	Laserfiche
LM	Left Message
LN	Lot Number
LOR	Loss of Resolution
MB	Differential Male Reagent Blank
MINI	MiniFiler
MIX	Mixture
M MIX, MM	Master Mix
MP	Missing Persons or Miniprimer
MPS	Miniprimer Set
MORPH	Morphology
mtDNA	Mitochondrial DNA
NA	Not Analyzable or Not Applicable
NAV	Navajo
NC	Negative control
nDNA	Nuclear DNA
NEG	Negative or Negative Amplification Control
NFC	Not Further Characterized
NMPDD	National Missing Persons DNA Database
NP	Nucleotide Pair or Position
NR	No Results

NSP	Non-Specific Peak
OL	Off Ladder
ON, O/N	Overnight
OS	Off Scale
PC	Positive Control
PCR	Polymerase Chain Reaction
P2	Second amplification for a particular evidence extract
PHENO	Phenolphthalin
PH	Peak Height
PHR	Peak Height Ratio
POS, +, 9947A, 007	Positive or Positive Amplification Control
POST	Post PCR
PPID, PP, PRO+	Profiler Plus ID
PTT, PT(B)T	Purple Top Blood Tube
PU, PU (B, G, Y, R, or P)	Pull Up (in Blue, Green, Yellow, Red, or Purple channel(s))
PUN	Punch
Q	Questioned Sample
QCP	Quality Control Plate
QNS	Quantity Not Sufficient
QUANT, QNT	Quantify or Quantification
RB	Raised Baseline or Reagent Blank
rCRS	Revised Cambridge Reference Sequence
REC'D	Received
RE-INJ	Re-injection
RE-PREP	Re-prepared
REF	Reference
RES	Resolution
RFU	Relative Fluorescent Units
RGT, RGNT	Reagent
R/S	Resuspended
RT	Real-Time
RTT, RT, RT(B)T	Red Top Blood Tube
RTW	Ready To Work
RW	Rework
S2	Second cycle sequencing reaction for a particular evidence extract
SAK	Sexual Assault Kit
SEH	Southeastern Hispanic
SEQ	Sequence or Sequenced
SEI	Secondary Evidence Inventory
SERO	Serology
SP	Spike
SPLIT	Split Peaks
SQ	Size Quality
SS	Single Source
ST, S	Stutter

STD	Standard
STR	Short Tandem Repeat
SUB	Subject
SWH	Southwestern Hispanic
T	Thymine
TC	Thermal Cycler
T/C	Telephone Call
TD	Trial Date
TF	Target Factor
TL	Technical Leader
TRI	Triallele
T/S	Tape Sealed
UD	User Defined
UHR	Unidentified Human Remains
VLD	Validation Plate
VM	Voicemail
UNSUB	Unidentified Subject
WCR	Whole Control Region
WI	Weak Injection
WK	Weak
WK1/2	Weak at only 1 or 2 loci
VWK	Very Weak
X2	Second extraction for a particular item of evidence
Ys	Y-STRs
YF	Yfiler
YTT	Yellow Top Blood Tube

Additional abbreviations, acronyms, and chemical abbreviations are contained in the DNA level 2 documents.

DNA Procedures for Equipment Calibration and Maintenance

1 Purpose

This document establishes the procedures used to maintain the performance of laboratory equipment, including software, to ensure the accuracy and reliability of the data generated for forensic DNA examinations and DNA databasing.

2 Scope

These procedures apply to all DNA personnel in the DNA Support Unit (DSU), DNA Caseworking Unit (DCU), Federal DNA Database Unit (FDDU), and Scientific and Biometric Analysis Unit DNA Group (SBAU) that are responsible for ensuring the reliability of equipment that have an effect on the quality of forensic DNA examinations (i.e., body fluid identification, nuclear DNA, and mitochondrial DNA) and DNA databasing (i.e., individual characteristic databasing).

3 Responsibilities

Personnel with responsibilities related to ensuring the reliability of equipment will follow the responsibilities identified in the appropriate FBI *Laboratory Operations Manual* (LOM) practices and those identified below.

3.1 The DNA Unit Chiefs will ensure that adequate resources (e.g., personnel, funding, materials) are provided for the calibration, performance verification (PV), preventative maintenance (PM), and/or repair of DNA equipment.

3.2 The DNA Quality Assurance/Quality Control (QA/QC) personnel and additional DNA Unit personnel, as appropriate, will:

- Coordinate, manage, perform and/or facilitate the calibration, PV, PM, general maintenance, and/or repair of laboratory equipment.
- Ensure equipment that requires calibration, PM, and/or PV is entered in the appropriate Sample Tracking and Control Software (STACS).
- Ensure that instructions for PV and general maintenance are maintained.
- Maintain calibration, PM, PV, and repair records for laboratory equipment.
- Advise the Technical Leader of current activities or problems related to these procedures.

3.3 DNA personnel are responsible for the day-to-day operation and control of the equipment present in their laboratory work area(s). DNA personnel will perform the following functions as necessary:

- Conduct and record PV and/or general maintenance of equipment as required or as needed.
- Clearly identify equipment as "out of service" when an item cannot be performance verified, successfully calibrated, the calibration due date has been exceeded, and/or essential maintenance is required.
- Notify the QA/QC personnel whenever an instrument or item of equipment is "out of service" and/or requires calibration, PV, maintenance, and/or repair.

4 Procedures

4.1 DNA personnel will comply with the practices set forth in the FBI Laboratory *Quality Assurance Manual* (QAM) and the appropriate LOM Practices for all equipment used for casework and DNA databasing.

4.2 Calibration, PM, and PV intervals are based upon manufacturers' operating guidelines, historical performance experience, and/or the performance check requirements of the *Quality Assurance Standards for Forensic DNA Testing Laboratories* or *Quality Assurance Standards for DNA Databasing Laboratories* (QAS), as applicable. With the exception of equipment maintained at facilities outside of the FBI Laboratory's permanent control (see section 4.2.3), calibration, PM, and PV of equipment will be routinely conducted at the minimum frequency listed in Appendix A.

4.2.1 Calibration, maintenance (i.e., PM, general maintenance), and PV records will be maintained in accordance with the appropriate LOM practices, generally within the appropriate STACS.

4.2.2 PV and general maintenance procedures performed by DNA personnel will be maintained, generally within the relevant DNA procedures or in the appropriate STACS.

4.2.3 Equipment maintained at an offsite location outside of DNA unit permanent control may be used so infrequently that calibration, PM, or PV at the minimum frequency defined in Appendix A is not practicable. In these instances, the performance of critical equipment will be verified to ensure accurate functionality prior to the use of the equipment in forensic examinations or DNA databasing. DNA personnel will ensure appropriate performance check records are retained for each piece of equipment to be used.

4.3 Software having an effect on the accuracy or validity of DNA examinations and/or DNA databasing will be considered equipment and must meet the applicable requirements of the QAM and LOM.

4.3.1 Additional software testing requirements prior to using the software for casework or DNA databasing are listed in section 4.10.

4.4 Critical equipment are those whose accurate functionality directly affects the results of the analysis and requires calibration, certification, or performance check prior to use and periodically thereafter. Equipment that is deemed critical:

- Traceable Thermometer used for PVs
- Balance
- Incubator/Thermal Shaker used in casework or databasing analysis
- Thermal Cycler Temperature Verification System
- Thermal Cyclers
- Rapid DNA Instruments/System
- Real Time PCR Instruments (aka Sequence Detection Systems)
- Robotic Workstations/Robotic Systems
- Capillary Electrophoresis Instruments
- Mechanical Pipettes
- Expert systems software approved for use at NDIS

4.5 An item of equipment will be clearly identified as "out of service" if successful calibration cannot be achieved, the minimum frequency since the last successful calibration, PM, or PV has been exceeded, and/or maintenance or repair is required.

4.5.1 Equipment deemed “out of service” will not be used in casework examinations or DNA databasing until it successfully undergoes calibration, PM, and/or PV, as applicable. The “out of service” status may be indicated by use of a physical sign and/or by placing the equipment in a maintenance status in STACS.

4.6 External Calibration

4.6.1 DNA personnel do not perform calibration services. When required, calibrations will be performed by external vendors.

4.6.1.1 The DNA units do not have measuring equipment whose measurement uncertainty affects the validity of the DNA results or that require metrological traceability of results; therefore, calibration is used as a form of performance check.

4.6.1.2 The DNA units will use calibration laboratories accredited to ISO/IEC 17025, when possible. However, since the measurement equipment is not used to establish or maintain metrological traceability; the calibration report is not required to include the pre and post adjustment/repair data.

4.6.2 The types of equipment that undergo external calibration as the method for ensuring accurate functionality are:

- Balance
- Electronic Temperature Monitoring Component(s)
- Multichannel Verification System (MVS) Calibrator Plate
- Mechanical pipette
- Thermal Cycler Temperature Verification System

4.6.3 Newly acquired or repaired equipment that require calibration but are not accompanied by current calibration records will be calibrated or performance verified prior to being initially placed into service or returning to service for casework or databasing.

4.7 Maintenance

4.7.1 General maintenance (e.g., routine cleaning, greasing O-rings, replacing reagents and consumables) of instruments and equipment is generally performed by QA/QC or appropriately trained personnel. Equipment does not require PV after general maintenance.

4.7.2 PM services will be performed by external vendors according to manufacturer recommendations or specifications.

4.7.3 The types of critical equipment that undergo regular PM are:

- Rapid DNA Instruments/System
- Robotic System (Extraction)
- Robotic Workstation (Quantification /Amplification Set-up)
- Real Time PCR Instruments (aka Sequence Detection Systems)
- Capillary Electrophoresis Instruments

4.7.3.1 Critical equipment require a PV following PM. PV procedures for critical equipment are generally maintained in the relevant technical procedure.

4.7.4 Newly acquired critical equipment will undergo PM during the next full cycle (i.e., calendar year) after the date the equipment is placed into service. Equipment under a service warranty may be exempt from PM requirements during the term of the warranty.

4.7.5 The types of equipment that are not considered critical but may undergo regular PM to ensure proper performance are:

- Biological Cabinet (hood)
- Liquid Nitrogen Generator
- Microscope
- Refrigerator / Freezer
- Punch Instrumentation

4.8 Performance Verification

4.8.1 PV may be performed by DNA personnel or an external vendor.

4.8.2 PV refers to those methods used to assess the functionality of laboratory instruments, equipment, or reagents that affect the accuracy and/or validity of forensic sample analysis and may be accomplished in several ways which include but are not limited to:

- Running a known control or reference sample through the equipment/process as detailed in the applicable technical procedure

- Performing a diagnostic check on the equipment
- Performing a self-test
- Temperature verification or temperature monitoring

4.8.3 The types of instruments and equipment that will undergo PV prior to being initially placed into use for forensic casework examinations or DNA databasing, following annual PM (if applicable), repair, or service and prior to returning to use in forensic casework examinations or DNA databasing are:

- Incubator/Thermal Shaker used in an analytical procedure
- Rapid DNA Instruments/System
- Robotic System (Extraction)
- Robotic Workstation (Quantification / Amplification Set-up)
- Robotic Workstation (Capillary Electrophoresis Set-up)
- Real Time PCR Instruments (aka Sequence Detection Systems)
- Thermal Cycler
- Capillary Electrophoresis Instruments

4.8.3.1 The method of PV following maintenance or repair should be commensurate with the repair conducted.

4.8.3.2 Transport of critical equipment will be done in accordance with manufacturer recommendations. If transported, DNA personnel will ensure proper functioning of the critical equipment, which may include a PV, prior to use in forensic examinations or DNA databasing.

4.8.4 If the PV indicates that the item is not performing as expected, the instrument or piece of equipment will be clearly identified as "out of service" and not used in forensic examinations or DNA databasing until it can be demonstrated that it is performing as expected.

4.8.5 Equipment that is not in regular use may be put into storage in accordance with any manufacturer recommendations. If equipment in storage misses a required calibration, PM, or PV, the performance of critical equipment will be verified to ensure accurate functionality prior to the use of the equipment in forensic examinations or DNA databasing.

4.9 Temperature Monitoring

4.9.1 The types of equipment that undergo regular temperature monitoring as a method of PV are:

- Refrigerator / Freezer
- Incubator (including Thermal Shaker)

4.9.2 Temperature monitoring will be performed by an electronic temperature monitoring system or by DNA personnel utilizing digital thermometers. Thermometers used for temperature monitoring will be traceable and therefore appropriately calibrated and/or undergo PV at the required intervals.

4.9.3 The temperature ranges for incubators (including thermal shakers), refrigerators, and freezers are as follows:

- Incubators (as indicated in the applicable SOP or +/-3ºC)
- Refrigerators (4ºC +/-3ºC)
- Freezers (-20ºC or -80ºC +/-10ºC)

4.9.4 When temperature monitoring is performed by an electronic temperature monitoring system, the temperature will be recorded at least once per day by the system. The electronic temperature monitoring system will collect and maintain this information.

4.9.4.1 If the temperature of the equipment goes outside of the acceptable range, DNA personnel will be notified (typically via email by the ViewLinc software system).

4.9.4.1.1 During normal business hours, the QA/QC personnel will check the piece of equipment and determine what action, if any, is necessary.

4.9.4.1.2 Additional notifications may occur outside of normal business hours. When practicable, notified DNA personnel will take action necessary to mitigate any potential detrimental impact to evidence, samples, or reagents.

4.9.5 If a temperature reading is outside the acceptable range the settings may be adjusted as needed.

4.9.5.1 If an appropriate temperature can be reestablished, the records will reflect at least the final temperature observed.

4.9.5.2 If the appropriate temperature cannot be established or maintained, the records will reflect at least the final temperature observed and QA/QC personnel will be notified.

4.10 Software

4.10.1 Software having a direct effect on the quality of DNA examinations and DNA databasing will be checked to ensure it meets the specifications (i.e., Biometrics Analysis Section DNA Network [BASNet] baseline configuration document(s) and applicable SOP requirements) prior to being placed into or returning to service. Checking the baseline configuration documents(s) is typically done by or in conjunction with a unit's information technology (IT) technical point of contact (TPOC) or the DNA IT support contractors (i.e., Robotech Science, Inc.).

4.10.2 Robotech Science, Inc. (RTS) ensures the BASNet is protected from unauthorized access, safeguarded against tampering and loss, operated in an environment that complies with laboratory specifications, and maintained in a manner that ensures the integrity of the data and information. A System Security Plan is maintained by RTS.

4.10.2.1 System failures are recorded to include the appropriate immediate and corrective actions. Generally, the IT helpdesk software (i.e., Ivanti) is used to record system failures and the actions and resolution to address the failures.

4.10.3 Where practicable, software permissions will be restricted to prevent unintended adjustments from invalidating test results.

4.10.4 New software or new modules of existing software and modifications to software that will be used for forensic examinations or DNA databasing will be evaluated to assess the suitability of the software for its intended use in the laboratory and to determine the necessity of validation studies or software testing. This evaluation will include the determination of which studies will and will not be conducted and will be documented.

4.10.4.1 New software or new modules of existing software that are used as a component of instrumentation, used for the analysis and/or interpretation of DNA data, or used for statistical calculations will be appropriately validated in accordance with the QAS.

4.10.4.2 New software used for forensic examinations or DNA databasing but that do not impact the analytical process, interpretation, or statistical calculations will be tested for functionality.

4.10.4.3 Modifications to software will be evaluated to determine if the modifications result in a major or minor revision to the software and; therefore, what testing is necessary prior to use for forensic examinations or DNA databasing.

4.10.4.3.1 Modifications to STACS or other information management systems used for the collection, processing, recording, reporting, storage, or retrieval of data will be authorized, recorded, and validated/tested before implementation.

4.10.4.3.2 A major revision to software used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations requires validation in accordance with the QAS prior to implementation.

4.10.4.3.3 A minor revision to software that does not impact the analytical process, interpretation, or statistical calculations requires at a minimum, a functional test.

4.10.5 Software validation studies and software testing may be shared by all laboratory locations. The summary of the applicable shared validation data will be accessible at each location. Site-specific reliability testing will be conducted at each laboratory location.

4.10.6 Expert system software approved for use at NDIS will be subject to recertification in accordance with the NDIS Operational Procedures and the frequency requirements in Appendix A.

4.10.7 Software testing and validation studies will be recorded and the records reviewed and approved by the Technical Leader prior to implementation.

5 Records

DNA personnel will comply with the record keeping requirements of the appropriate LOM Practices.

6 References

FBI Laboratory Quality Assurance Manual (QAM).

FBI Laboratory Operations Manual (LOM).

DNA Procedures Manual

National DNA Index System (NDIS) Operational Procedures Manual

Federal Bureau of Investigation, Quality Assurance Standards for DNA Databasing Laboratories, latest revision.

Federal Bureau of Investigation, Quality Assurance Standards Audit for DNA Databasing Laboratories, latest revision.

Federal Bureau of Investigation, Quality Assurance Standards for Forensic DNA Testing Laboratories, latest revision.

Federal Bureau of Investigation, Quality Assurance Standards Audit for Forensic DNA Testing Laboratories, latest revision.

Rev. #	Issue Date	History
11	12/30/16	Added BAU as needed throughout. Defined Quarterly and Annually and added 3500 to Appendix A.
12	02/18/20	Made additions for ISO 17025: 2017, ANAB AR 3125, and QAS 2020 including additional equipment defined as critical, addressing equipment maintained outside of the laboratory's permanent control, and requirements for software Revised BAU to SBAU Revised DSU QA/QC Group to QA/QC personnel Added other DNA personnel to QA/QC responsibilities Deleted Autoclave Moved Expert System from 4.7.3 to 4.9.6 Added temperature monitoring notifications outside business hours

Redacted - Signatures on File

Approval

DNA Technical Leader Date: 02/14/2020

DCU Chief Date: 02/14/2020

DSU Chief Date: 02/14/2020

FDDU Chief Date: 02/14/2020

SBAU Chief Date: 02/14/2020

QA Approval

Quality Manager Date: 02/14/2020

Appendix A: ***Calibration, PM, and PV Frequency Requirements***

Type of Instrument / Equipment	Required Action	Minimum Frequency
Balance	Calibration	Annually
Capillary Electrophoresis (CE) Instrument [i.e. 3130 XL Genetic Analyzer, 3500xL Genetic Analyzer, 3730 DNA Analyzer]	PV	3130/3500: Annually 3730: Quarterly
	PM	Annually
Electronic Temperature Monitoring Component	Calibration	Annually
Electrophoresis Detection Instrument [i.e., Agilent 2100 Bioanalyzer]	PV	Annually
Expert System Software approved for use at NDIS	PV	Quarterly
Incubator / Thermal Shaker	PV	Quarterly
Liquid Nitrogen Generator	PM	Every 2 years
Microscope	PM	Annually
Multichannel Verification System (MVS) Calibrator Plate	Calibration	Annually
Pipette	Calibration	Annually
Punch Instrument	PM	Annually
Rapid DNA Instrument	PM	Annually
	PV	Quarterly
Real Time PCR Instruments (aka Sequence Detection System)	PV	Annually
	PM	Annually
Refrigerator / Freezer	PV	Daily (work days)
Robotic System (Extraction) [i.e., QIAcube, EZ1, QIAsymphony]	PV	Annually
	PM	Annually
Robotic Workstation (Quant Amp Set-up) [i.e., Tecan]	PV	Quarterly
	PM	Annually
Robotic Workstation (CE Set-up) [i.e., Agilent Bravo]	PV	Annually
Thermal Cycler	PV	Annually
Thermal Cycler Temperature Verification System	Calibration	Annually
Thermometer	PV	Annually
UV Crosslinker	PV	Annually

PM = Preventative Maintenance PV = Performance Verification
Quarterly will occur 4 times per year, generally every 3 months.
Annually will occur within a calendar year.

DNA
Procedures for Reagent Purchasing, Preparation, and Records

1 Scope

This document applies to DNA personnel responsible for the purchasing and receipt, preparation, and labeling of laboratory reagents and consumables used for the serological and/or DNA analysis of forensic evidence and/or databasing samples in the DNA Casework Unit (DCU), the DNA Support Unit (DSU), the Federal DNA Database Unit (FDDU), and the Scientific and Biometric Analysis Unit (SBAU).

2 Responsibilities

DNA personnel will:

- Know the location in the laboratory of the Safety Data Sheets (SDSs)
- Be aware of the health and safety hazards for the chemicals used.
- Ensure that all laboratory reagents are prepared correctly and properly labeled.
- Properly store reagents in a manner to minimize degradation.
- Inspect the reagents to ensure that they have not become visually contaminated or degraded.
- Not use deteriorated or outdated reagents and solutions.

3 Procedures

The DNA units comply with the FBI Laboratory *Quality Assurance Manual* (QAM) and *Laboratory Operations Manual* (LOM) and the *Quality Assurance Standards* (QAS) *for Forensic DNA Testing Laboratories* and *for DNA Databasing Laboratories* with regard to the quality control (QC) of reagents. Reagent records will be maintained, generally via the DNA units' Sample Tracking and Control Software (STACS).

3.1 Commercial Reagent Records

3.1.1 Purchase requests will be prepared by appropriate personnel for all commercial reagents and consumables. These requests will describe the types of supplies and/or services requested and may be maintained in a written or electronic format. The appropriate Unit Chief (UC) will approve purchase requests prior to ordering.

3.1.2 Various companies may supply one or more chemicals, reagents, or DNA analysis kits used in the analysis of forensic evidence and/or database samples. Final selection of

suppliers will be in accordance with Federal Procurement Regulations - Simplified Acquisition Procedures.

3.1.2.1 Suppliers of critical reagents are typically evaluated during validation but the evaluation may be based on previous purchasing history and/or the results of QC testing.

3.1.2.2 When a vendor, reagent specification (e.g., concentration), or consumable specification (e.g., Vivicon filter molecular weight cut-off) affects the laboratory activities, the pertinent information will be listed in the appropriate DNA procedure.

3.1.2.3 Current supplier and purchasing information for reagents and consumables is generally maintained in STACS.

3.1.3 DNA personnel will ensure that quality affecting supplies, reagents, and consumables comply with specifications defined in the appropriate technical procedure and/or the purchase request. Any discrepancies will be brought to the attention of the personnel responsible for ordering DNA supplies, reagents, and consumables. Quality affecting supplies, reagents, and consumables that conform to the expected specifications will be received into STACS.

3.1.4 The following information will be recorded for the receipt of commercial reagents and kits:

- Name of material
- Manufacturer lot number
- Date received
- Expiration date, when provided

3.1.5 Commercial reagents must be labeled with the identity of the reagent and will be directly labeled and/or use a barcode system to electronically track the expiration date.

3.1.5.1 Commercial reagents are generally prepared and stored as recommended by the manufacturer. Additional guidance may be found in STACS or the appropriate DNA SOP.

3.1.5.2 The expiration date of commercial reagents is determined by the manufacturer or utilizing the respective SDS.

3.1.5.2.1 If no expiration date is provided by the manufacturer, generally a 10 year expiration date will be assigned.

3.1.5.2.2 If the expiration date provided by the manufacturer only specifies a month and year, the recorded expiration date will be the last day of the month specified. The commercial reagent container will then be labeled with the newly established expiration date.

3.1.5.2.3 If an expiration date beyond that provided by the manufacturer is assigned, records to establish the extension of the expiration date will be maintained.

3.1.5.2.4 If an expiration date is exceeded, the QC procedure or use of the reagent on a known sample may be used to demonstrate continued efficacy beyond the assigned expiration date. Records demonstrating the continued efficacy of the reagent will be maintained.

3.1.6 If a non-reagent consumable (e.g., swabs, tubes, microcons, centristrips) has an expiration date assigned by the manufacturer, that expiration date is not applicable to DNA units' operations and may be extended as deemed appropriate by the Technical Leader (TL). The new expiration date will be recorded in STACS.

3.2 Laboratory Prepared Reagent Records

3.2.1 All laboratory prepared reagents will be prepared in accordance with the information contained within STACS and/or the relevant DNA procedure. A list of reagent recipes and control preparation guidelines generally used in the DNA units are listed in Appendix A for reference.

3.2.2 Reagent preparation will be recorded, generally within STACS, to include:

- Name of reagent
- Date prepared
- Lot number (e.g., barcode, batch identifier) assigned to the reagent
- Lot number (e.g., barcode, batch identifier) of each component
- Initials of the preparer
- Initials of the individual performing the QC check (if applicable)
- Lot/batch # of the QC controls (if applicable)
- QC results (pass/fail) (if applicable)

3.2.2.1 The information recorded for reagent preparation and use must be sufficient to provide a documented audit trail.

3.2.2.2 Unless otherwise specified, reagents that are made internally will expire one year from the date prepared. If an expiration date is extended, records demonstrating the continued efficacy of the reagent will be maintained.

3.2.2.2.1 If an expiration date is exceeded, the use of the reagent on a known sample may be used to demonstrate continued efficacy beyond the assigned expiration date. Records demonstrating the continued efficacy of the reagent will be maintained.

3.2.3 Laboratory prepared reagents will be labeled with the identity of the reagent and will be directly labeled and/or use a barcode system to electronically track the following:

- Preparer's initials
- Date prepared
- Expiration date
- Lot number (e.g., barcode, batch identifier)

3.2.3.1 Reagents stored in limited use quantities (i.e., single use aliquots) may be in a storage container (e.g., bag, box) labeled with the identity of the reagent with the associated barcode(s) readily available.

3.2.3.2 Once dispensed for use (e.g., on a robotic workstation, on another instrument), the trough or tube will be labeled with the identity of the contained reagent with the necessary barcode available for scanning.

3.2.4 Laboratory prepared reagents will be stored at an appropriate temperature to prevent degradation or deactivation of the active ingredients. Recommended storage conditions may be listed in STACS and/or Appendix A.

3.2.5 Laboratory prepared reagents will be tested for reliability prior to or concurrent with use in casework examinations or DNA databasing. QC procedures for reliability testing may be contained in the appropriate DNA procedure or in STACS or reliability testing may be accomplished by testing appropriate positive and/or negative controls. Dilutions of a stock commercial reagent (e.g., 1X CE buffer) will not require reliability testing. Multiple reagents may be simultaneously tested for reliability.

3.3 Critical Reagents

The QAS defines critical reagents as reagents whose performance is vital to the success of the DNA testing and require testing on known samples before use on forensic or database samples. The reliability of the following critical reagents is evaluated prior to their use on evidence or databasing samples.

3.3.1 The following are identified as QAS critical reagents:

- Nuclear DNA Quantification Kits (i.e., Quantifiler DUO, Quantifiler TRIO)
- Mitochondrial DNA Quantitative PCR (qPCR) system:
  - Double stranded synthetic standard (dsT8sig)
  - TaqMan® Fast Advanced Master Mix
  - Amplification primers (Qfor8, Qrev8, L, M, G, B)
  - Probes (QRL8 [FAM], C [VIC], and U [NED])
  - Double stranded Internal Positive Control DNA (C/E)
- STR Amplification Kits (i.e., Globalfiler)
- Y-STR Amplification Kits (i.e.,Yfiler)
- Mitochondrial DNA amplification and sequencing systems:
  - 10X PCR Buffer
  - BSA
  - Amplitaq Gold
  - Primers for mtDNA amplification and sequencing
  - Deoxyribonucleotide triphosphate mix (dNTPs)
  - Big Dye Sequencing Kits
  - HL60 DNA
- EXOSap-IT

- Amplification and Sequencing components (if not within a test kit or system):
  - Amplitaq Gold
  - Primers
  - Allelic Ladders
- Rapid DNA Cartridge

3.3.2 The QC procedures used to ensure the reliability of critical reagents are contained in the appropriate DNA procedure or in STACS.

3.3.3 The results of the QC testing, as well as the reagent's acceptance or rejection for use, will be recorded. The reagent will be available for use once the necessary acceptance is recorded, generally in STACS.

4 Safety

4.1 Refer to the "Safe Work Practices and Procedures," "Bloodborne Pathogen (BBP) Exposure Control Plan (ECP)," "Personal Protective Equipment Policy," and "Chemical Hygiene Plan" sections of the *FBI Laboratory Safety Manual* for important personal safety information prior to conducting laboratory procedures.

4.2 Refer to the "Hazardous Waste Disposal" section of the *FBI Laboratory Safety Manual* for important information concerning proper disposal of the chemicals used in laboratory procedures as well as the biohazardous waste generated.

4.3 Appropriate safety precautions and proper personal protective equipment will be used during reagent preparation and performance of laboratory procedures. Refer to Safety Data Sheets, *FBI Laboratory Safety Manual*, and relevant DNA procedures for more detailed information.

5 Records

Records pertaining to the receipt, preparation, and/or QC of laboratory reagents will be kept in the STACS or an equivalent log or storage location. These records will be maintained by the DSU QA Group and/or in the applicable DNA Unit. Records verifying the completeness of each commercial order will be maintained by appropriate personnel.

6 References

FBI Laboratory Quality Assurance Manual

FBI Laboratory Operations Manual

FBI Laboratory Safety Manual

DNA Procedures Manual

Federal Bureau of Investigation, Quality Assurance Standards for DNA Databasing Laboratories, latest revision.

Federal Bureau of Investigation, Quality Assurance Standards for Forensic DNA Testing Laboratories, latest revision.

U.S Government Printing Office. Title 48 Code of Federal Regulations Part 13 (48CFR13), Federal Procurement Regulations - Simplified Acquisition Procedures.

Rev. #	Issue Date	History
8	02/15/19	Revised critical reagent list to add new mtDNA qPCR reagents and update kit examples. Removed autoclaving instructions from Appendix A. Adjusted reagent recipes to reflect current default volumes. Added new qPCR reagent recipes. Added SEB+DTT recipe.
9	02/18/20	Updated to BAU to SBAU Added consumables as appropriate 3.1.2.1 Reworded as most evaluations are done through validation 3.1.2.2 Added example of consumable specification 3.1.2.3 Removed separate listing since STACS is generally used to maintain suppliers for reagents and consumables 3.2.5 Added testing appropriate controls 3.3 Updated QAS definition. Changed tested to evaluated 3.3.1 Added Rapid DNA cartridges App A Added Bode Collector as an option for making BIS

Approval Redacted - Signatures on File

DNA Technical Leader Date: 02/14/2020

DCU Chief Date: 02/14/2020

DSU Chief Date: 02/14/2020

FDDU Chief Date: 02/14/2020

SBAU Chief Date: 02/14/2020

QA Approval

Quality Manager Date: 02/14/2020

Appendix A: *Reagent Recipes and Control Preparation*

Reagent Preparation Guidance:

If more or less reagent is needed than what is listed below, the components should be adjusted proportionally to make the volume needed. Graduated cylinders and/or pipettes closest in capacity to the volume of liquid being measured should be used. If the pH meter is used, the performance will be verified prior to use. Any reagent in which microbial growth is observed must be discarded. Store all reagents in sterile containers unless otherwise noted. When available, purchased ready to use reagents of equivalent or higher quality may be substituted for the reagents listed below.

1X Genetic Analyzer Buffer with EDTA

- Combine 100 mL of 10X genetic analyzer buffer with EDTA with 900 mL reagent grade water.
  - For single reservoir on a 3130XL: Combine 3.5 ml 10X Genetic Analyzer buffer with EDTA with 31.5 mL reagent grade water
  - For single set-up on a 3730: Combine 20 mL of 10X Genetic Analyzer buffer with EDTA with 180 mL of reagent grade water
- Store refrigerated for up to 1 month.

Acid Phosphatase Spot Test Solution, 100 mL

- Add 2.6 g Acid Phosphatase Spot Test powder to 100 mL reagent grade water and stir until dissolved.
- Store frozen for up to one month.

3% Bleach Solution, 100 mL (For TECAN only)

- Dilute 3 mL molecular grade bleach (or equivalent) to 100 mL with reagent grade water.
- Store at room temperature.
- Prepare daily.

10% Bleach Solution, 50 mL (for use on evidentiary items)

- Dilute 5 mL household bleach (or equivalent) to 50 mL with reagent grade water.
- Store at room temperature.
- Prepare daily.

10% Bleach Solution, 10 L (for cleaning purposes)

- Dilute 1 L household bleach (or equivalent) to 10 L with reverse osmosis

(RO) purified water.
- Store at room temperature.
- Prepare at least weekly.

Bovine Serum Albumin (BSA), 1.6 mg/mL, 80 mL

- Add less than 80 mL of reagent grade water to a container.
- Add 128 mg of bovine serum albumin.
- Bring final volume to 80 mL with reagent grade water.
- Store frozen.

Demineralization/Extraction Buffer, 1L

- Add 900 mL of 0.5M EDTA solution to a container and stir on medium.
- While stirring, add 10g of N-Lauroylsarcosine sodium salt.
- Allow mixture to go into solution.
- Adjust to pH 8.0 with hydrochloric acid (HCl) or Sodium Hydroxide (NaOH).
- Bring final volume to 1 L with 0.5M EDTA solution.
- Store at room temperature.

1M DTT (Dithiothreitol), 10 mL

- Dissolve 1.54 g of DTT in 10 mL of reagent grade water.
- Store frozen.

5M DTT (Dithiothreitol), 2 mL

- Dissolve 1.54 g of DTT in 2 mL of reagent grade water.
- Store frozen.

70% Ethyl Alcohol (EtOH), 100 mL

- Dilute 74 mL 95% ethyl alcohol to 100 mL with reagent grade water.
- Store at room temperature.

HEPES-Buffered Saline (HBS), 1 L (10mM HEPES / 144 mM NaCl / pH 7.2)

- Dissolve 8.42 g NaCl in 900 mL reagent grade water.
- Add 2.38 g HEPES and stir until dissolved.
- Adjust to pH 7.2 with 2.5 M NaOH.
- Bring final volume to 1 L with reagent grade water.
- Store refrigerated.

3% Hydrogen Peroxide Solution, 1 L

- Dilute 100 mL of 30% hydrogen peroxide solution to 1 L with reagent grade water.
- Store refrigerated.

mtDNA Amplification Primers

Amplification primers will be initially hydrated with TE^{-4} to a stock concentration of 100 µM. The stock concentration will be diluted to a working concentration of 30 µM (A1, A2, B1, B2, C1, C2, D1, D2, 617) or 10 µM (miniprimers) as appropriate.

Calculation:

Optical Density (OD) (A260) / Extinction Coefficient (OD units/µmole) = µmole of primer
100 µM = 100 µmole/L = 100 µmole/1000 mL = 0.1 µmole/mL
= 0.1 µmole/1000 µl = 0.0001 µmole/µl
µmole of primer / 0.0001 µmole/µl = µl TE^{-4} for 100 µM solution

(The OD and Extinction Coefficient can be found on the certificate for each primer.)

Prepare a 100 µM stock solution from lyophilized primer

- Add 1 to 2 mL of TE^{-4} to vendor tube with lyophilized primer (depending on tube size) and vortex.
- Let sit for ~5 min at room temperature and vortex again.
- Transfer liquid from vendor tube to a 50 mL conical tube.
- Add an additional 1 to 2 mL of TE^{-4} to vendor tube, vortex, and transfer to same 50 mL conical tube.
- Add remaining amount of TE^{-4} to bring solution to volume determined by calculation. (Remember to subtract the initial 2-4 mL used)
- This will be the 100 µM stock primer solution (vortex before transferring to other tubes) used to prepare the 30 µM, 10 µM and 1 µM primer solutions as needed.

Prepare a 30 µM solution for primers A1, A2, B1, B2, C1, C2, D1, D2, 617 from the 100 µM stock solution and store frozen.

A1 primer:

- Transfer 4.5mL of 100 µM stock solution to a new 50 mL conical tube.
- Add 10.5 mL of TE^{-4}.

All other primers:

- Transfer 3.15 mL of 100 µM stock solution to a new 50 mL conical tube.

- Add 7.35 mL of TE^{-4}.

Prepare a 10 µM primer solution for all miniprimers from the 100 µM stock solution.

- Transfer 300 µl of 100 µM stock solution to a new 50 mL conical tube.
- Add 2700 µL of TE^{-4}.

mtDNA Quantitative PCR IPC - Double Stranded Internal Positive Control DNA (C/E)

- Reconstitute forward (C) and reverse (E) oligonucleotides in TE^{-4} buffer.
- Prepare 100 µM solutions of the forward and reverse oligonucleotides using information from vendor certificate of analysis.
- Combine these in equal volumes and tightly cap, mix, and quick spin the tube.
- This generates the **primary (1°) stock** of the double-stranded IPC DNA at 50 µM (3×10^{13} copies/µl). Store frozen.
- Prepare a dilution series using TE^{-4} as follows:
  - 2º stock: Transfer 10 µl of primary stock into 1,542 µl TE^{-4} (1.94×10^{11} copies/µl).
  - 3º stock: Transfer 10 µl of 2º stock into 1,542 µl TE^{-4} (1.25×10^{9} copies/µl).
  - 4º stock: Transfer 10 µl of 3º stock into 990 µl TE^{-4} (1.25×10^{7} copies/µl).
  - 5º stock: Transfer 10 µl of 4º stock into 990 µl TE^{-4} (1.25×10^{5} copies/µl).
  - 6º stock (working dilution): Transfer 10 µl of 5º stock into 990 µl TE^{-4} (1.25×10^{3} copies/µl).
- Store frozen.

mtDNA Quantitative PCR Primers (Forward [Qfor8, L, G] and Reverse [Qrev8, M, B])

- Reconstitute all primers in TE^{-4} buffer.
- Prepare 100 µM stock solutions of each primer using information from vendor certificate of analysis.
- Store frozen.
- Prepare working dilutions of each primer in TE^{-4} buffer as follows:
  - For Qfor8 and G (1.25 µM) transfer 12.5 µl of 100 µM stock solution to a new tube and add 987.5 µL of TE^{-4}.
  - For Qrev8 and M (22.5 µM) transfer 225 µl of 100 µM stock solution to a new tube and add 775 µL of TE^{-4}.
  - For L and B (7.5 µM) transfer 75 µl of 100 µM stock solution to a new tube and add 925 µL of TE^{-4}.
- Store frozen.

mtDNA Quantitative PCR Probes (QRL8 [FAM], C [VIC], U [NED])

- Prepare a 6.25 µM working dilution from each 100 µM probe stock.
  - Transfer 62.5 µl of 100 µM stock solution to a new tube and add 937.5 µl of TE^{-4}.

- Store frozen and protected from light as much as possible.

mtDNA Quantitative PCR Primer/Probe/IPC Mix (PPI Mix)

- Prepare working dilutions of all primers, probes, and IPC DNA.
- Add 80 µL of all primers, probes, and IPC DNA into each tube. Vortex, pulse spin.
- Store frozen.

mtDNA Quantitative PCR Standard - Double Stranded Synthetic Standard (dsT8sig)

- Reconstitute Tfor8sig and Trev8sig oligonucleotides in TE^{-4} buffer.
- Prepare 2 µM solutions of the forward and reverse oligonucleotides based on their respective molecular weights of 34,960.7 g/mol and 35,969.3 g/mol.
- Combine these in equal volumes and tightly cap, mix, and quick spin the tube.
- This generates the **primary (1°) stock** of the double-stranded **dsT8sig** standard at 1 µM (6.023×10^{11} copies/µL). Store frozen.
- Prepare the **secondary (2°) stock** of **dsT8sig** from the **1° stock** using TE^{-4} buffer. The **2° stock of dsT8sig** should be at a final concentration of 5×10^{9} copies/µL.
- Add 1194.6 µL TE^{-4} buffer to 10 µL aliquot of **primary (1°) stock.** Tightly cap, mix, and quick spin the tube.
- Store frozen.

mtDNA Sequencing Primers (1 µM)

New lots of primers used in cycle sequencing will be diluted from the 100 µM primer stocks.

Prepare a 1 µM solution from the 100 µM stock solution and store frozen:

A1 primer:

- Transfer 240 µl of 100 µM stock solution to a new 50 mL conical tube.
- Add 23,760 µL of TE^{-4}.

All other primers:

- Transfer 150 µl of 100 µM stock solution to a new 50 mL conical tube.
- Add 14,850 µL of TE^{-4}.

Miniprimers:

- Transfer 50 µl of 100 µM stock solution to a new 50 mL conical tube.
- Add 4950 µL of TE^{-4}.

Phenolphthalin Solution, 1 L

- Combine 4 g phenolphthalin, 40 g NaOH, and 200 mL reagent grade water.
- Add 800 mL of ethanol and mix.
- Store refrigerated in an amber bottle over zinc (generally enough to cover the bottom of the bottle).
- This solution may be used for up to 3 months.

Saturated D-Glucose Solution

- Dissolve 10 g of dextrose in 10 mL reagent grade water with mild heating.
- Store at room temperature for up to 1 month.

2.5 M (10% w/v) Sodium Hydroxide (NaOH), 100 mL

- Add 10 g of NaOH to 80 mL reagent grade water.
- Store at room temperature.

Sperm Wash Buffer, 1 L (10 mM Tris-HCl / 10 mM EDTA / 50 mM NaCl / 2% SDS, pH 8.0)

- Add 10 mL 1 M Tris-HCl, 20 mL 0.5 M EDTA, 10 mL 5 M NaCl, and 100 mL 20% SDS to approximately 800 mL reagent grade water.
- Adjust to pH 8.0 with HCl or NaOH.
- Adjust the final volume to 1 L with reagent grade water.
- Store at room temperature.

Stain Extraction Buffer (SEB), 1 L (10 mM Tris-HCl / 100 mM NaCl / 10 mM EDTA / 2% SDS, pH 8.0)

- Dissolve 5.84 g NaCl in approximately 500 ml reagent grade water.
- Add 10 mL 1M Tris-HCl.
- 20 ml 0.5M EDTA.
- Add 100 mL 20% SDS.
- Adjust to pH 8.0 with HCl.
- Adjust the final volume to 1 L with reagent grade water.
- Store at room temperature.

SEB with Dithiothrietol (SEB w/DTT), 5 mL (10 mM Tris-HCl / 100 mM NaCl / 10 mM EDTA / 2% SDS / 39mM DTT)

- Add 30 mg of DTT to 5 mL of SEB and stir until dissolved.
- Store at room temperature for up to 1 month.

Takayama Hemochromogen Reagent

In a chemical fume hood, combine:

- Add 1 mL saturated D-glucose solution
- Add 1 mL 2.5 M NaOH
- Add 1 mL pyridine with 2 mL reagent grade water.
- Mix thoroughly.
- Store in an amber bottle at room temperature for up to 1 week.

TNE, 1 L (10 mM Tris-HCl / 100 mM NaCl / 1 mM EDTA, pH 8.0)

- Add 10 mL 1 M Tris-HCl
- Add 5.84 g of NaCl
- Add 2 mL 0.5 M EDTA to 750 mL reagent grade water.
- Adjust to pH 8.0 with HCl or NaOH as necessary.
- Adjust the final volume to 1 L with reagent grade water.
- Store refrigerated.

Control Preparation Guidance:

Blood/Buccal Internal Standard (BIS)

An individual providing the BIS control must have a previously characterized and documented STR profile in the FDDU.

- A blood BIS control is an FTA bloodstain card prepared with liquid blood or blood collected via a finger stick.
- A buccal BIS control is the FTA card from a Whatman EasiCollect™ device which is used to collect and transfer a buccal sample to the card, the collector from a Bode Collector device used for a buccal collection, or an equivalent card collected using an approved collection device.

Blood Known Positive Swab

- Prepare a 1:250 dilution of whole blood.
- Add approximately 100 µL of diluted blood to each clean swab.
- Allow the swabs to dry completely.
- Store refrigerated or at room temperature.

mtDNA NIST Standard Reference Material - NIST SRM 2392-I (HL60)

Prepare a 140 pg/µl dilution from 1.4 ng/uL stock:

- Transfer 10 µL of stock to a new 1.5 mL tube.
- Add 90 µL of TE^{-4}.

mtDNA Positive Control (HL60)

Calculation:

Concentration of HL60 (stock) x V1 = 10 ng/µL x 200 µL
V1 = amount of stock needed to make a 10 ng/µL solution
200 µL – V1 = amount of TE^{-4} needed to make a 10 ng/µL solution

Prepare a 10 ng/µL stock solution from the vendor stock of the HL60 DNA.

- Add amount of stock and TE^{-4} determined by above calculation.
- Store frozen.

Prepare a 20 pg/µL solution from the 10 ng/µL stock.

- Add 19,960 µL of TE^{-4} to 40 µL of the 10 ng/µL solution.
- Store frozen.

Prepare a 100 pg/µL solution from the 10 ng/µL stock.

- Add 14,850 µl of TE^{-4} to 150 µL of the 10 ng/µL solution.
- Store frozen.

Semen Known Positive Slide

- Prepare a 1:10 dilution of neat human semen with reagent grade water.
- Pipette 4µL of diluted semen to center of microscope slide.
- Allow slide to air dry (generally for 10 minutes).
- Store at room temperature.

Semen Known Positive Swab Preparation

- Add 1.5 mL of human semen to 3.0 mL of reagent grade water.
- Add approximately 100 µL of diluted semen to each swab.
- Allow the swabs to dry completely.
- Store frozen.

DNA
Procedures for Case File Assembly and Reviews

1 Purpose

These procedures address the preparation and review of DNA Casework Unit (DCU) and Scientific and Biometrics Analysis Unit (SBAU) DNA case files and *Laboratory Reports* (7-1, 7-1 LIMS, 7-273, or 7-273 LIMS).

2 Scope

This document applies to DNA personnel in the DCU and the SBAU and establishes procedures for the preparation and review of DNA discipline case file records and *Laboratory Reports* and supplements the relevant practices in the FBI *Laboratory Operations Manual* (LOM).

3 Procedures

DNA personnel with responsibilities related to the assembly of case files will follow the responsibilities identified in the FBI *Quality Assurance Manual* (QAM) and LOM.

3.1 Case Records

3.1.1 All case-related records will be retained as physical supporting records or electronic supporting records in accordance with the appropriate LOM Practices.

3.1.1.1 The DCU and SBAU use Sample Tracking and Control Software (STACS) in lieu of Forensic Advantage (FA) to record and/or generate many of the case-related administrative and examination records.

3.1.1.2 Electropherograms retained as supporting records (i.e., printouts or PDFs) should be of sufficient resolution to demonstrate that all DNA types are supported by the analytical data during technical review.

3.1.1.3 When a single lab number has multiple Case Records for examination in the DNA units, the supporting records retained for each Case Record may be truncated to the pages of examination and administrative records that support the examinations reported under the specific Case Record.

3.1.1.4 When supporting records are retained electronically, the Examiner will ensure they have reviewed the records. If the Examiner's initials (or secure electronic equivalent) are not on each page of the examination records, the Examiner will record their review typically by using available electronic tools (e.g., Adobe Acrobat Pro) to mark at least the first page of a PDF, by approving the record when uploaded to the Case Record Object Repository in FA, or by

recording their review in a communication log.

3.1.1.5 Copies of examination or administrative records generated by other Laboratory units or outside entities that are not used by the examiner in the evaluation of the evidence or to support the results or conclusions do not need to be retained in the DNA *Supporting Documentation Envelope* (7-251), commonly referred to as a 1A, or the electronic supporting records.

3.1.2 If amendments to technical records are made, DNA personnel ensure the change can be tracked to the previous versions or the original observation. Amendments include the date of the alteration, an indication of the altered aspects, and the personnel responsible for the alteration. Nothing in the administrative and/or examination records may be obliterated or erased.

3.1.2.1 Contemporaneous revisions are not considered amendments. Changes are considered contemporaneous if made before reaching a decision point. Decision points may include transferring samples to the next stage of processing, uploading completed examination records to STACS or FA, or submitting the file for technical review.

3.1.2.2 If an identifier or similar addition is made to the case records (e.g., laboratory number, the "SECRET" or "copy" designation) manually or through the use of a stamp or other electronic means (e.g., page counter), this addition is not considered an amendment and does not require the date or initials of the person making the addition.

3.1.2.3 The following methods may be used to track changes made to completed records.

- Changes to hard copy and/or handwritten records may be tracked using a single strike-out, dating and initialing the change or by retaining any pages that are replaced in the 1A.
- Changes to electronic records in STACS are tracked within STACS.
- Electronic record pages may be annotated, added, or amended when the revised or additional pages are clear. If a page is replaced, the original page will be retained but marked to indicate it was replaced.
- A new file may revise a portion of, or the entirety of, the original file, as appropriate through a version history for the file or by an addition to the file name (e.g., 2016-00123_caseworkbook followed by 2016-00123_caseworkbook revised) and retention of the original electronic file. Additional revisions will be subsequently tracked.
- Changes to electronic records not otherwise tracked may be summarized in a communication log.

3.1.3 Sufficient information (i.e., barcode or other unique identifier) regarding the instruments and reagents used in the examination will be recorded as prompted by STACS or the templates used to record case notes (e.g., the mtDNA Workbook).

3.1.4 A list of commonly used abbreviations/symbols in DNA records is available within the DNA QA Manual (i.e., DNAQA 601).

3.1.5 Administrative Records

The following are examples of administrative records in the DNA Units:

- Record of the Technical and Administrative Review
- Case Record Report, for FA cases
- *Laboratory Work Sheet* (7-2), for Legacy cases
- Copy of incoming communication(s)
- Communication Logs and records
- Chain-of-Custody Log(s)
- Copy of *Examination Plan* (7-262), for Legacy cases
- Deviation Requests
- Records of the Combined DNA Index System (CODIS) or other appropriate database(s) eligible profile/sequence(s)

3.1.6 Examination Records

Examination records consist of all work notes generated by a biologist and/or examiner that support the results and/or conclusions in the case. The following are examples of examination records in the DNA Units:

- Copy of the issued *Laboratory Report*
- Serology Notes
- Collection Notes
- Extraction Notes
- Quantification Notes
- Sample Dilution/Combination Notes
- Amplification/Cycle Sequencing/CE Notes
- Electropherograms
- Sequencher™ sheets
- Allele Tables/Sequence Summary Sheets
- Statistical Calculations (e.g., STRMix, EMPOP, YHRD, KinCAlc)
- Moderate Match Estimate (MME) Calculator results
- Match Rarity Estimate (MRE) Calculator results
- Compact disc(s) containing Genetic Analyzer 3130xl or 3500xL analysis files and/or Sequencher™ files (when applicable)

3.1.7 For cases with CODIS eligible profiles, the following information must be recorded and verified prior to upload to SDIS. The information may be recorded and verified as case file records or via STACS, as applicable. Refer to the appropriate DNA procedure for CODIS entry and eligibility requirements (i.e., DNA 209).

- DNA profile and Amelogenin (if applicable) results being entered
- Specimen category (e.g., Forensic Unknown, Missing Person)
- Relevant eligibility information
- MME and/or MRE Calculator results, if applicable
- Pedigree and metadata for missing person, if applicable (Missing Persons cases only)
- Consent forms (Missing Persons cases only)

3.1.8 Case-Related Records from Non-FBI Laboratories

Relevant examination and administrative records generated by a non-FBI laboratory for a case assigned to the DCU or SBAU will be categorized as administrative records and will be retained in a 1A and/or may be uploaded to the Case Object Repository in FA.

3.2 Expedited Results

3.2.1 When results are disseminated prior to the issuance of the *Laboratory Report*, the following results or conclusions require verification/technical review by another qualified Examiner and that verification/technical review recorded in the case notes prior to dissemination:

- Mitochondrial DNA (mtDNA) conclusions of "cannot be excluded" or "inconclusive"
- Comparisons to nuclear DNA (nDNA) mixture profiles evaluated with STRMix
- Statistical results
- Conclusions based on kinship calculation results

3.2.2 The following do not require verification/technical review prior to dissemination of expedited results:

- Comparisons to single source nDNA profiles (if statistical results are not provided)
- Comparisons to nDNA profiles resulting in a manual exclusion
- mtDNA exclusions
- Parent/offspring comparisons to full profiles (if no statistical results provided)
- Other testing results (e.g., serology)

3.2.3 DNA examination records will not be released without a recorded technical review.

3.2.4 Any dissemination of expedited results will be recorded in accordance with the appropriate LOM Practices. The record must include the opinions or interpretations communicated by dialog with the contributor.

3.3 Sequence Confirmation

The mtDNA sequences for all samples and associated controls (HL60, NC, and RB) will be confirmed/verified by a second qualified individual. Sequence confirmation may be completed prior to completion of the *Laboratory Report* or during technical review. Refer to the appropriate SOP in the *DNA Procedures Manual*.

3.4 Formatting and Content of a Laboratory Report

3.4.1 An Examiner will prepare a *Laboratory Report* in accordance with the appropriate LOM Practices. The *Laboratory Report* will contain or reference the following information, as appropriate:

- Case identifier (i.e., laboratory number(s) and/or Case ID number(s)).
- Description of the evidence received or examined by the DNA Units.
- Description of the DNA technology (e.g., STR, YSTR, mtDNA) used for analysis.

- Identification of the loci or amplification system or region(s) for which characterization was attempted.
- Results and/or conclusions.
- Qualitative interpretative statement and/or a quantitative (statistical) statement.
- Issue date.
- Disposition of evidence.
- Name of the Examiner responsible for the content of the *Laboratory Report*.

3.4.2 The Results of Examination section of the *Laboratory Report* will include, as appropriate, sampling descriptions, results and/or conclusions, statistical calculation results, information pertaining to the entry of sample(s) profiles into the CODIS or other appropriate databases, and a Methods/Limitations section. Evidence listed in the *Laboratory Report* as received but not examined may be addressed in the Listing and Description of Evidence, Results of Examination, or the Remarks sections, as appropriate.

3.4.2.1 The initial entry of a profile into a DNA database will be included in the *Laboratory Report*.

3.4.2.2 The extent of database searches will be communicated to the contributor and updated as needed.

3.4.3 The Remarks section of a *Laboratory Report* will contain the disposition of evidence and other remarks as required by the appropriate LOM practice. This section may also contain requests for additional samples (e.g., additional bones from an Unidentified Human Remains (UHR), additional relatives of a Missing Person), information pertaining to samples retained for future testing (e.g., for the National Missing Persons DNA Database (NMPDD), population databasing), and potential additional testing that may be suitable (i.e., Y-STRs).

3.4.3.1 Evidence will be dispositioned as consumed when no evidence material remains for future testing (e.g., the entire swab tip is cut from the swab, an entire bone fragment is powderized and used for extraction).

3.5 Reviewing a Laboratory Report

3.5.1 Technical and administrative reviews will be conducted in accordance with the appropriate LOM Practices. The case file records will reflect that the technical and/or administrative review(s) were conducted and who performed those review(s).

3.5.2 Technical and administrative reviewers may be self-assigned in STACS.

3.5.2.1 The technical reviewer(s) must be currently or previously qualified in the methodology being reviewed, be authorized to conduct technical reviews, and be proficiency tested semi-annually as a Forensic Examiner (i.e., conducting interpretation and/or technical review).

3.5.2.2 If a portion of the examination records are technically reviewed by a separate

technical reviewer (e.g., the assigned technical reviewer authored pages of examination records, expedited results), the review of the affected portion of the examination records will be noted in the case file.

3.5.2.3 An administrative reviewer does not need to be currently or previously qualified in the methodology being reviewed or be semi-annually proficiency tested.

3.5.3 Unresolved discrepant conclusions between the reporting Examiner and the reviewer(s) will be resolved by the Technical Leader unless elevation to Section Chief or above, as described by the appropriate LOM practice, becomes necessary.

3.5.4 Technical Review

Completion of the technical review signifies agreement with the examination process and technical information in the case file and *Laboratory Report*.

3.5.4.1 In addition to the requirements in the appropriate LOM Practice, the technical reviewer will review:

- The administrative and examination records and the *Laboratory Report.*
- The *Laboratory Report* to verify that the results/conclusions are supported by the data for each item tested.
- The statistical calculations, if applicable.
- The CODIS eligibility, or eligibility for other appropriate databases, of the DNA profile/sequence(s), including the DNA types and specimen category for eligible samples, if applicable.
    - The specimen category may be reviewed within STACS and not captured in the case file.

3.5.4.1.1 The technical reviewer will ensure that calculations and data transfers subject to human error (i.e., manual calculations or transcriptions) are checked. If the technical records do not indicate a necessary check was performed (e.g., quantitation data transcriptions), the technical reviewer will perform the check.

3.5.4.2 In addition, for nuclear DNA results, except for those generated using an NDIS approved Rapid DNA System on casework reference samples, the technical reviewer will:

- Review all supporting electropherograms to verify that all DNA types and conclusions are supported by the analytical data, if applicable. If electropherogram printouts or PDFs are not of sufficient resolution to verify all DNA types, the technical reviewer must request additional electropherogram printouts or PDFs or review the data electronically and record that the data was electronically reviewed.
- Ensure all controls, internal size standards and allelic ladders meet the interpretation guidelines for reported results, if applicable.

3.5.4.3 For mitochondrial DNA results, the sequence confirmation will fulfill the technical review requirement of the supporting electropherograms, the DNA types (aka sequences), and controls. The technical reviewer, if necessary, will generate the appropriate

sequence confirmation records. If the sequence confirmation is done prior to the technical review, the technical reviewer will review the sequence confirmation records, to include:

- The Sequencher™ project and profile sheets from the Examiner and confirmer to ensure they are included.
- The case summary sheet to ensure it contains all analyzed sequences with the correct sequence ranges and profiles.
- Sequence results to ensure the appropriate sequences were compared to known phylogenetic alignments, if applicable.
- The review of the controls.

3.5.5 Administrative Review

Completion of the administrative review indicates that the *Laboratory Report* has been approved and is authorized for issuance.

3.5.5.1 In addition to the requirements in the appropriate LOM Practice, the administrative reviewer will:

- Review the administrative and examination records and the *Laboratory Report* for clerical errors and ensure the presence and accuracy of the report elements listed above.
- Review the Chain-of-Custody.
- Ensure that a technical review was completed, when applicable, and properly recorded.

3.5.6 The electronic signatures of the technical and administrative reviewer are captured in STACS and/or FA.

3.6 Issuing a Laboratory Report

3.6.1 Upon completion of the appropriate reviews, the *Laboratory Report* and supporting records will be serialized in Sentinel in accordance with the appropriate LOM Practice.

3.6.1.1 When a physical 1A is created, a physical attachment will be added in Sentinel. At least the total number of physical pages and/or data discs of administrative and examination records retained within the 1A envelope will be accounted for on the outside of the 1A envelope.

3.6.1.2 When supporting records are compiled electronically, a digital 1A will be created and uploaded to Sentinel as a digital attachment.

3.6.2 The *Laboratory Report* will be considered issued when the *Laboratory Report* is uploaded to Sentinel. The issue date is the date of upload approval and is captured on the official record of the *Laboratory Report* in Sentinel. This record contains the FBI file copy of the *Laboratory Report.* The issue date is not required on the copy of the *Laboratory Report* retained within the 1A.

4 Records

Examination and administrative records will be generated and retained in accordance with this procedure and the appropriate LOM Practices.

5 References

FBI Laboratory Operations Manual (LOM)

FBI Laboratory Quality Assurance Manual (QAM)

DNA Procedures Manual

FBI Laboratory National DNA Index System (NDIS) DNA Data Accepted at NDIS (Operational Procedures), latest version.

Federal Bureau of Investigation, Quality Assurance Standards for Forensic DNA Testing Laboratories, latest version.

Federal Bureau of Investigation, Quality Assurance Standards Audit for Forensic DNA Testing Laboratories, latest version.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
10	06/05/18	4.1.1.2 Added that electropherograms retained as physical supporting records should be of sufficient resolution to demonstrate that all DNA types are supported by the analytical data. 4.5.2.1 Added Technical Reviews (TR) must be authorized by the TL. 4.5.4.2 Added to first bullet if the printed electropherograms are not of sufficient resolution to verify the DNA types during TR. 4.5.6 Signatures of TR and Administrative Reviews may be captured in STACS and/or FA.
11	09/13/19	Updated BAU to SBAU after LD reorganization. Removed responsibilities section and renumbered remaining sections. 3.1.1.3 Added allowance for truncated records. 3.1.1.4 Added requirements for FE review of electronic records. 3.2 Update section to reflect changes to level 1 requirements and provide examples for application by the DNA units. 3.1.5 Deleted ECS search slip. Moved Laboratory Report to 4.1.6. 3.1.6 Added issued Laboratory Report and MME calculation. 3.2.1 and 3.2.2 Added Kinship requirements. 3.2.4 Added requirement to record opinions and interpretations. 3.4.2 Evidence listed in the report but not worked can be addressed in any of the report sections. 3.4.2.1 & .2 Added database entry requirements 3.4.3 Added other LOM required remarks. 3.5.4.1 and 3.5.5.1 Added reference to LOM requirements 3.5.4.2 Added exception for profiles generated using an NDIS approved Rapid DNA system. 3.1.6.2 Revised requirement for digital attachments.

Approval Redacted - Signatures on File

DNA Technical Leader Date: 09/12/2019

SBAU Chief Date: 09/12/2019

DCU Chief Date: 09/12/2019

QA Approval

Quality Manager Date: 09/12/2019

DNA
Procedures for Administering Proficiency Tests

1 Purpose

Proficiency testing is used to monitor the performance of qualified Examiners and Biologists who conduct mitochondrial DNA, nuclear DNA, and/or serology casework examinations, and/or DNA database sample processing for the FBI Laboratory DNA Units. The DNA Units include the DNA Casework Unit (DCU), the DNA Support Unit (DSU), the Federal DNA Database Unit (FDDU), and the Biometrics Analysis Unit (BAU) DNA group. Proficiency testing also demonstrates that the analytical procedures are being performed properly and produce results within established performance criteria.

2 Scope

2.1 These procedures apply to:

- DNA personnel who conduct examinations on evidence and/or database samples, interpret serology and/or DNA results, and/or perform technical reviews of casework and/or database analysis.
- DNA personnel who perform duties relating to the management, records, and tracking of proficiency tests and associated corrective actions.

2.2 DNA personnel are proficiency tested to the full extent in which they participate in casework and/or DNA database analysis in the following biology discipline categories of testing.

- 3.1 Nuclear DNA (twice per calendar year)
- 3.2 Mitochondrial DNA (twice per calendar year)
- 3.3 Body Fluid Identification (once per calendar year)
- 3.4 Individual Characteristic Database (twice per calendar year)

Proficiency testing, as applicable, will occur at the minimum frequency listed. Multiple categories of testing may be conducted on a single proficiency test.

2.3 Only external proficiency tests approved by ASCLD/LAB or from providers accredited to the International Standards for proficiency testing (i.e., ISO/IEC 17043) will be used to fulfill the requirements of the *Quality Assurance Standards for Forensic DNA Testing Laboratories* and *Quality Assurance Standards for DNA Databasing Laboratories* (together referred to as QAS).

2.4 For these procedures, an Examiner will include individuals (however titled) who perform the role of analyst (i.e., interpret data) and/or technical reviewer as defined by the QAS and a Biologist will include individuals (however titled) who perform the role of technician (i.e., perform examinations) as defined by the QAS and FBI *Laboratory Operations Manual* (LOM).

2.5 Laboratory support personnel whose responsibilities are limited to evidence management, sample collection, accessioning, and/or other lab duties exclusive of analytical techniques on forensic or database samples will not be proficiency tested.

3 Responsibilities

DNA personnel will follow the responsibilities identified in the appropriate LOM practices and those identified below.

3.1 The Technical Leader (TL) will:

- Review and approve the proficiency testing program described in this procedure.
- Review and approve the proficiency tests to be used in the DNA Units as required by the appropriate LOM practices.
- Ensure that all qualified Examiners and Biologists participate in proficiency testing to the full extent in which they perform casework analysis or DNA database sample processing.
- Review reported inconclusive or not interpretable results for compliance with DNA procedures.
- Evaluate all discrepancies and errors associated with a proficiency test and address the nonconformity, as necessary.
- Inform the appropriate CODIS Administrator of all non-administrative discrepancies that affect the DNA typing results and/or conclusions.
- Designate personnel other than Examiners and Biologists (i.e., contractors) to be proficiency tested.

3.2 The DNA Support Unit (DSU) Quality Assurance (QA) group will:

- Manage the DNA proficiency testing program to ensure compliance with these procedures.
- Ensure the responsibilities of the Unit Proficiency Test Representative listed in the appropriate LOM practices are fulfilled.
- Notify the TL of any serious problems or atypical results, discrepancies, and/or errors with a proficiency test distribution.
- Ensure that proficiency test results are submitted to the provider by the established due date.
- Ensure all participants are notified of their final test results.
- Ensure the TL is informed of the evaluation results of all participants.

3.3 Examiners will:

- Complete all proficiency tests assigned to them to the full extent in which they participate in casework or DNA database sample processing.
- Notify the TL if problems are encountered with the proficiency test samples which may negatively impact the successful completion of the test.
- Perform technical reviews and/or submit their proficiency test(s) for technical review.
- Perform reviews when not participating in the same distribution or after

completing his/her portion of a test in the same distribution.
- Return the completed proficiency test to the DSU QA Group by the established due date.

3.4 Biologists will:

- Complete all proficiency tests assigned to them to the full extent in which they participate in casework or DNA database sample processing.
- Complete the proficiency test in sufficient time to allow the Examiner to conduct his/her portion of the test.
- Notify the Examiner if problems are encountered with the proficiency test samples which may negatively impact the successful completion of the test.

4 Procedures

DNA personnel will comply with the FBI Laboratory *Quality Assurance Manual* (QAM) and the appropriate LOM practices, as well as the QAS requirements.

4.1 Serology Proficiency Tests

4.1.1 Examiners and Biologists that currently perform, interpret, and/or technically review serological casework examinations will participate in a minimum of one open, external serology proficiency test per calendar year (January through December).

4.1.2 Serology proficiency testing will be conducted in a manner consistent with typical casework and will involve the examination of potential biological materials for the presence or absence of blood and semen. The relevant tests routinely performed should be conducted on the items contained in the proficiency test.

4.1.2.1 The relevant tests will be determined using the case scenario provided by the PT provider for the test. If insufficient information is provided to make an informed decision, samples will be tested for both blood and semen.

4.1.2.2 Presumptive tests and confirmatory tests will be conducted as they would be in casework examinations. All possible serology tests need not be performed on each sample, as appropriate.

4.2 DNA Proficiency Tests

4.2.1 Examiners and Biologists that currently perform, interpret, and/or technically review DNA casework or database examinations will participate in a minimum of two open, external DNA proficiency tests per calendar year (January through December) in each applicable DNA technology (i.e., STR, Y-STR, mtDNA) in which they perform casework or database sample examinations.

4.2.1.1 Multiple technologies/categories of testing may be performed on a single proficiency test.

4.2.1.2 Participation in DNA proficiency testing is required between January 1st and June 30th and July 1st and December 31st of each year. The interval between the issuance of each test must be at least four months and no more than eight months.

4.2.1.3 If an individual is not administered a proficiency test and falls out of the proficiency testing cycle for a specific technology or methodology, that individual will not perform casework or databasing examinations using that technology or methodology until a requalification test is successfully administered. Refer to the section on Requalification Testing.

4.2.2 The methods and typing test kits used on proficiency tests in the calendar year will be in accordance with the QAS and in a manner consistent with typical casework or databasing applications.

4.3 The distribution date will be used to track the proficiency testing cycles. The DSU QA Group will maintain the proficiency testing schedule for DNA personnel.

4.4 DNA personnel will follow the reporting procedures established by the specific test provider. The comments section(s) of the test provider's results forms will be used to address any results or conclusions that fall outside the reporting restrictions of the test provider's results forms.

4.5 All proficiency tests will undergo the appropriate technical and administrative reviews in accordance with the appropriate LOM practices and DNA procedures prior to submission of the test results. Record of the technical and administrative reviews will be retained with the proficiency test records.

4.5.1 Data quality reviews (e.g., review of capillary electrophoresis (CE) data for determining need for reinjections) are not considered a confirmation of identification or a technical review of the proficiency test and therefore may be conducted by an individual participating in the same distribution.

4.5.2 Data confirmations conducted for technical review purposes (i.e., mtDNA sequence confirmations, FDDU secondary analysis review) will be conducted by an individual not participating in the same distribution or a participant who has completed his/her portion of the test.

4.5.3 Technical and administrative reviews of casework tests will be performed in accordance with the applicable DNA procedures for case file reviews.

4.5.4 Technical and administrative reviews of DNA databasing tests will be conducted as described below.

4.5.4.1 A secondary review (technical review) of the data will be performed and recorded in

Sample Tracking and Control Software (STACS). The secondary review may include the use of a National DNA Indexing System (NDIS) approved expert system. A secondary review of the data will include the following:

- A review of all DNA types to verify that they are supported by the raw or analyzed data
- A review of all controls, internal lane standards, and allelic ladders to verify that the expected results were obtained.
- A review to confirm that the reworked samples have appropriate controls

4.5.4.2 A technical review of all notes, worksheets, and electronic data supporting the results will be conducted and recorded in the proficiency test records.

4.5.4.3 An administrative review of the proficiency test records will be recorded in the proficiency test records.

4.6 Proficiency test results will be submitted to the proficiency test provider on or before the provider's due date.

4.6.1 The Proficiency Test Program Manager (PTPM) or the DSU QA group will submit test results for the individual test participants, unless a provider requires a participant submit their individual test results.

4.6.2 External tests not accepted by the provider do not satisfy the proficiency test requirement. If this should occur, a new external proficiency test will be ordered as soon as possible and appropriate records will be maintained.

4.7 Any potential inconsistency or error, or any issue with a proficiency test that may have affected the results or evaluation of the test should be proactively communicated to the Biology Proficiency Review Committee (PRC) through the PTPM.

4.8 Evaluation of Proficiency Test Results

4.8.1 All proficiency test results will be evaluated in accordance with the appropriate LOM practices and the QAS requirements. The *Proficiency Test Evaluation Form* (Appendix A) will be used to record the evaluation.

4.8.2 Results reported as inconclusive or not interpretable will be reviewed by the TL for compliance with unit specific procedures. This review may be conducted prior to the evaluation (i.e., as part of the administrative review).

4.8.3 The DSU QA Program Manager or designee will ensure that the completed *Proficiency Test Evaluation Form* (Appendix A) is provided to proficiency test participants in accordance with the appropriate LOM practice.

4.8.4 The TL will be informed of the results of all participants.

4.8.5 Proficiency test records will be maintained by the DSU QA Group.

4.9 Discrepancies and Errors

4.9.1 All discrepancies and potential technical, analytical, and/or administrative errors will be evaluated by the TL and/or the appropriate Unit Chief(s) and handled in accordance with the appropriate LOM practices. The TL will initiate necessary actions in conjunction with the Unit Chief(s).

4.9.2 The TL will inform the appropriate CODIS Administrator of all non-administrative discrepancies that affect the DNA typing results and/or conclusions at the time of discovery.

4.9.3 The DSU QA Group will ensure any corrected data sheets and exam sheets or DNA database notes are maintained with the appropriate proficiency test records.

4.10 Requalification Testing

4.10.1 When an individual is on extended leave (i.e., for a period that takes the individual out of the proficiency testing cycle), the TL will ensure that the individual completes any necessary training and completes a requalification test prior to resuming casework or DNA databasing examinations.

4.10.1.1 Individuals returning from leave of greater than 2 months will be given a reacclimation period prior to requiring an external proficiency test or requalification test be completed.

4.10.1.2 An external proficiency test may be used as a requalification test provided that the results of the external proficiency test are received from the manufacturer and consequently evaluated as successful prior to the individual being requalified to perform independent casework or DNA databasing examinations.

4.10.2 External proficiency tests or test samples that are not consumed during the corresponding test period (e.g., evidence type samples from a database test, semen samples from a mtDNA test) will be retained and may be used for requalification testing, competency testing, or for other internal testing.

4.10.2.1 When an unused external proficiency test is used as a requalification test it will be administered as an internal test according to the appropriate LOM practices.

4.10.3 The *Proficiency Test Evaluation Form* (Appendix A) will be utilized to record the evaluation of an internal test.

4.10.3.1 This form is not required for competency testing administered following the completion of training.

5 Records

5.1 A member of the DSU QA Group will ensure the following information is recorded for all external proficiency tests administered in the DNA Units and that the information is available upon request.

- Name(s) of test participant(s).
- Test type (position type and internal/external).
- Test identification number.
- Distribution date.
- Date returned.
- Due date.
- Evaluation date.
- Name of evaluator.
- Results: satisfactory or unsatisfactory.
- Description of discrepancy, when appropriate.

5.2 A member of the DSU QA Group, or a designee, will ensure the appropriate records as listed in the LOM are retained in a hardcopy or electronic format.

6 References

FBI Laboratory Quality Assurance Manual

FBI Laboratory Operations Manual

DNA Procedures Manual

Federal Bureau of Investigation, Quality Assurance Standards for Forensic DNA Testing Laboratories, latest revision.

Federal Bureau of Investigation, Quality Assurance Standards Audit for Forensic DNA Testing Laboratories, latest revision.

Federal Bureau of Investigation, Quality Assurance Standards for DNA Databasing Laboratories, latest revision.

Federal Bureau of Investigation, Quality Assurance Standards Audit for DNA Databasing Laboratories, latest revision.

Rev. #	Issue Date	History
8	05/25/16	Changed DCU/FDDU to DNA personnel and added BAU. 2.3 Added allowance for accredited provider. 2.5 Added lab support personnel will not be tested. 3.2 Added “or designee” and fulfills responsibilities of unit PT rep. 4.2.1.3 Added reference to Requalification Test section. 4.3 Reworded only. Distribution date still used to track PT cycles. 4.6.1 Added allowance for participant to submit a test. 4.10 Changed to Requalification Tests and reordered requirements. 4.10.1.1 Added reacclimation period. 4.10.1.2 Added that an external PT may be used as a requal test. 5 Added “or designee” Appendix B Changed Report of Exam to Lab Report.
9	06/01/17	Revisions to align with LOM revision on 12/15/16 1 Added qualified and defined DNA Units 2.2 Deleted ASCLD/LAB-International replaced with biology discipline 3.1 Added responsibility to approve tests 3.2 Removed designee 3.3 Added reviewer requirement 4.1.2.1 and .2 Added context to the term relevant tests 4.5.1 moved the FDDU secondary review example to 4.5.2 4.5.3-4.5.4.3 Added review instructions and procedures for FDDU reviews 4.9.3 Added maintaining corrected records 4.10.3 and Appendix B Deleted Proficiency Test Results Form 5.1 Replaced PT database with information that must be maintained Appendix A Revised form to list participants with signatures

Approval

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Appendix A: *DNA Proficiency Test Evaluation Form*

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