CMPD Crime Laboratory Biology

Quality Assurance Manual

Approved by: _____ Date:_____
(DNA Technical Leader)

_____ Date:_____
(Laboratory Director)

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Provisions for Modification and Update of This Manual

Any updates, modifications, additions, or deletions to this manual prepared after the issue date on the cover sheet will have the following information and an updated issue date located at the bottom of each page.

Summary of Revisions

Date Issued	Summary of Changes Made
3-6-00	Foreword - TOC; All of Sec 2, 4, 5, 7, 9-12, 18, 20-22; and Sec 3 pp 1,3
	Sec 8 pp 2, 3; Sec 14 pg 1; Sec 15 pg 1; Sec 17 pg 1; Sec 19 pp 9-24
	Removed appendices
10-19-00	TOC; All of Sec 5, 11, 12, 14, 19; and Sec 7 pg 2
12-5-00	Sec 11 pg 4
2-23-01	All of Sec 4, 9, 12, 14, 15, 16, ; Sec 3 pg 3; Sec 7 pg 2; Sec 11 pp 4-6;
	Sec 19 Literature Routing Slip added; Sec 20 pp 1, 2, 3, 5-7, 9-11
7/26/01	Sec 19 Sexual Assault form changed, Sec 4 all, Sec 5 pg 1, Sec 20 all
10/17/01	Sec 3 pg 3, Sec 20 pp 10 and 11
11/20/01	Sec 8 pp 2,3 and 9
1/18/02	Sec 15 pg 4, Sec 19 changes to Phadebas form and calibration log
1/22/02	All of Sec 8
4/29/02	Sec 5 pg 3, Sec 11 pg 1-5, Sec 19 form changes
8/26/02	Sec 5 pg 4 and 5, Sec 7, Sec 8, Sec 12 pg 1, sec 15 pg 2 and 3, Sec 19 form changes
11/21/02	Sec 21, Section 19 - Laboratory Information Worksheet
7/10/03	TOC, Secs 4, 5, 7, 8, 11, 15, 19, 20, 21 (all)
1/12/04	Sec 8 pp 13, 16 and Sec 5, pg 4
2/26/04	Sec 5 pg 4, Sec 8 pg 2, Sec 9, Sec 11, Sec 12, Sec 19 extraction form
5/17/04	All of Sec 8,9,12,14,21: Sec 11, pg 2-5: Sec 19 Literature Rtg Slip
1/25/05	Sec 11, 15, 21, Sec 8 pg 17, 18 and 21
3/8/05	Sec 19 and 20
1/13/06	Sec 4,5,7,8,9,12,15,17,18,21,22,TOC all; Sec 19 DNA Ext, DNA Amp, Literature Rtg; Sec 20 remove Bromothymol Blue; change Digest Buffer, Pro K, TE; add DNA IQ, Quantifiler QC certificates
10/25/06	Sec 12 all
5/16/07	Sec 7.6.1

9/28/07	Sec 11.4, 14.1.4
1/30/08	Sec 4.3 (4); Sec 7.2; Sec 8; Sec 12.1; Sec 15.1
10/16/08	All of Sec 21
1/21/2009	All of Sec 2, adds positions and removes position
1/21/2009	All of Sec 18 case acceptance policy
3/5/2009	All of Sec 11, abbreviations added
3/5/2009	DNA Case Review form
4/9/2009	Section 5, changed Microanalysis to Biology
4/9/2009	Section 7, added Maxwell 16 to QC
4/9/2009	Section 8, removed calibration of 9600
11/30/2009	Section 1, added outsourcing; Section 3 adds positions; Section 4, added section entry; Section 5 clarified evidence maintained in lab
11/30/2009	Section 6, added TL review; Section 7 added LEV;
11/30/2009	Section 8, added pH meter; Section 9, added TL review and date due
11/30/2009	Section 10, added TL review and approval; Section 11 updated
11/30/2009	Section 12, added CODIS info; Section 14, added TL approval
11/30/2009	Section 15, added Staff Search of Unknown
11/30/2009	Section 16, outlined guidelines for outsourcing
11/30/2009	Section 21, updated and added to CODIS manual per changes described at annual CODIS meeting
2/11/2010	Section 7, added TL approval of all QC; added to COQC Forms of Section 20
3/2/2010	Section 8, revised reagent expiration dates
3/11/2010	Section 20, revised procedure and updated forms
4/9/2010	Section 7, Section 8, and Section 11
8/2/2010	Section 7, Section 11 and Section 15, additions for new SOP's
8/3/10	Section 21
1/7/2011	Sec 3, added notation about previously qualified analysts; Sec 4 removed 310 reference; Sec 7 added labeling pos and neg controls of amp; Sec 12 added Stats page; Sec 8 ,add the 7500 and the Maxwell; Sec 21, add the CODIS back up administrator
4/1/2011	Sec 11, added abbreviations; Sec 21 added arrestees
7/18/2011	ALL- Combination of Serology manual information and changes made for ASCLD International
10/12/2011	Addition of information required by the 9/2011 QAS: 5, 7, 8, 14, and 20
11/21/2011	Addition of QAS Audit class in QA3. QA21 CODIS admin duties
12/13/2011	QA 16 addition of site visit elements. QA 3 addition of TL

	and CODIS Admin duties.
2/7/2012	QA 14 change for DNA audit finding
2/22/12	Changed how evidence can be received from the Property and Evidence Management Division.
3/5/12	Changes made to QA 21 CODIS Manual for CODIS 7.0 update.
6/4/2012	Updated Chain of custody in QA 5
8/28/2012	Added Automate to QA 7 and QA 8; modified QA 21
2/1/13	QA 21 updated to reflect new NDIS rules
4/4/2014	Changes made to QA 2-5, 7,8 11, 12 ,5, 17-21 to reflect PLIMS and procedural changes
4/24/2014	Changes made to QA 8
10/22/2014	Changes made to QA 5, 8, 9, 11, 12, and 20
1/9/2015	Changes made to QA 8.3.4.10 and 8.3.4.12 for new software
6/22/2015	QA 3: added memo for TL qual; 5: added freezer to GBS; 7: added email temp change; 8: changes to PC; 11 added abbrev.; 12:added amp results; 20:clarifications and flow charts
2/24/2016	Changes and clarifications made to 3, 5, 8, 9, 11, 12, 16, 18 20 and 21 to
3/11/16	Added internal lane standards and ladders to the Examination Document requirements in QA 11.1.
5/2/2016	QA 8 -Changed wells for temperature verification; QA 11 and 20 updated to reflect new procedures from CODIS audit

Foreword

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

The CMPD Biology QA Manual is a compilation primarily of guidelines provided by SWGDAM, the FBI Quality Assurance Audit Document and ASCLD-LAB International.

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

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

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

TABLE OF CONTENTS

1. Goals and Objectives

1.1 Goals

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

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

1.2 Scope

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

1.3 Program Objectives

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

2. Organization and Management

2.1 Laboratory Management

- Laboratory management is described in QM 4.1. The appropriate levels of authority within the department but outside the Crime Lab Bureau are described in the CMPD Administrative Volume 100-003. These documents, along with Section 3 of this document, outline the authority and interrelation of the staff.

2.2 DNA Technical Leader

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

2.3 Functional Responsibilities

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

Crime Laboratory Technician

1. Assist the Chief Criminalist in administrative tasks.
2. Assist in reducing the backlog by reviewing lab requests waiting to be worked.
3. Order supplies for the section.
4. Keep the section stocked and clean.
5. Makes reagents.

Criminalist I – Trainee

1. Train under the established training protocol

Criminalist II - Screener

1. Analyze casework in Biology for screening and body fluid identification.
2. Remain current on techniques in the scientific community.
3. Provide assistance in validations of new screening/body fluid identification test under the direction of Team Leaders and Chief Criminalist.

4. Provide assistance with crime scenes as necessary.
5. Provide training to the Sexual Assault Detectives as needed.
6. Report any issues to their Team Leader.

Criminalist II -DNA

1. Analyze Biology casework evidence in the area of forensic biology and/or DNA testing.
2. Remain current on techniques in the scientific community.
3. Provide assistance with crime scenes as necessary.
4. Assist the DNA technical leader in the implementation of DNA technology.
5. Report any issues to their DNA Team Leader.

Criminalist III – DNA Team Leader

1. Analyze Biology casework evidence in the area of forensic serology and DNA
2. Remain current on techniques in the scientific community
3. Provide assistance with crime scenes as necessary
4. Responsible for assisting in training new employees.
5. Responsible for assisting Officer and Detectives with Biology questions.
6. Perform the administrative duties of the Chief Criminalist in their absence.
7. Responsible for supervisory duties of their team and bringing any issues to the attention of the Chief Criminalist.
8. Perform the local CODIS Administrator duties. (as specified)
9. Maintain QC records for reagents, kits and equipment. (as specified)

DNA Technical Leader (For more detailed information, see Section 3.3 of this manual and OM 3.5)

1. Develop and implement new techniques, policies, and procedures to keep the laboratory current
2. Analyze Biology casework evidence in the area of forensic serology and/or DNA testing
3. Remain current on techniques in the scientific community
4. Provide assistance with crime scenes as necessary
5. Respond to any reports of problems regarding DNA analysis from the laboratory staff

Chief Criminalist (For more information see OM 3.2)

1. Provide leadership for the direction of the Section
2. Assist the laboratory director in personnel related matters
3. Assist in the prioritization of case work
4. Assist in the yearly evaluations of Section employees
5. Assist in providing funding for the Section
6. Maintain organization and professionalism among the employees

7. Analyze casework evidence as necessary in the area of forensic serology and/or DNA testing
8. Monitor analysts for casework analysis and courtroom presentation as needed
9. Manage grants.

3. Personnel Qualifications and Training

- All persons involved in the actual recovery, evaluation, analysis, and interpretation of body fluid identification and/or DNA evidence shall have a background appropriate to their duties.

- A current copy of all job descriptions within the Biology Section will be maintained.

3.1 General Qualification Requirements for All Biology Personnel

- All analysts will have a minimum of a BA/BS degree or its equivalent degree in biology, chemistry, or forensic science related area. In addition all DNA analysts will have the following:

1. Successful completion of college course work (graduate or undergraduate level) covering the subject areas of biochemistry, genetics, and molecular biology (molecular genetics, recombinant DNA technology) or other subjects which provide a basic understanding of the foundation of forensic DNA analysis, as well as course work and/or training in statistics and population genetics as it applies to forensic DNA analysis. (Anyone hired after July 1, 2009 will have 9 or more semester hours of the above courses.)

2. A minimum of six (6) months of forensic DNA laboratory experience, including the successful analysis of a range of samples typically encountered in forensic case work prior to independent case work analysis using DNA technology.

3. Successfully completed a qualifying test before beginning independent casework responsibilities.

4. Successful completion of an in-house training program as outlined in the DNA Training Manual. The analysts responsible for validation of a new technique and establishing a training program for the procedure are exempt from this requirement. For newly hired personnel, depending on the experience of the individual, the training may cover the following:

    - Evidence handling procedures
    - Documentation and reporting procedures
    - Safe lab practices
    - DNA STR methodology
    - Body fluid identification methodology (if applicable)
    - DNA QA and QC systems and methods
    - Equipment operation, monitoring, calibration and maintenance
    - Buffer and solution preparation

- Quantitative and qualitative evaluation of DNA test results
- DNA case acceptance policies
- Interpretation of results
- Statistical evaluation of test results
- Courtroom demeanor and expert testimony training (if applicable)

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

3.2 QA/QC Officer

The Biology Section shall have an appointed QA/QC Officer who will work with the Crime Lab QA manager to ensure the adherence to all DNA and general laboratory QA/QC guidelines. Specific delegated responsibilities of the DNA QA/QC Officer include:

1. Responsibility for functions pertaining to proficiency tests and audits, as well as ensuring that all personnel within the section adhere to QA/QC guidelines.

2. Responsibility for ensuring that the data from the manufacturers and the testing of critical reagents is maintained. While the QA/QC Officer is not required to actually perform all of the quality control checks in the laboratory, he does have the responsibility to ensure that the functions are performed.

3. Rejection of any chemical, solution, supply, reagent, or material that fails to meet specifications.

3.3 DNA Technical Leader

1. In addition to the General Qualification Requirements for all DNA personnel, the DNA technical leader must have a minimum of a Master's degree in biology, chemistry, or forensic science related area and successfully completed a minimum of 12 semester or equivalent credit hours of undergraduate and graduate course work covering the subject areas of biochemistry, genetics, and molecular biology (molecular genetics, recombinant DNA technology) or other subjects which provide a basic understanding of the foundation of forensic DNA analysis, as well as course work and/or training in statistics and population genetics as it applies to forensic DNA analysis. At least one of the graduate level classes will consist of 3 or more semester hours. In addition, the Technical Leader must have completed the FBI DNA auditor training.

2. A technical manager or leader of a laboratory must have a minimum of three years of forensic human DNA laboratory experience.

3. A technical leader must manage the technical operations of the laboratory, and specifically is:

- Responsible for evaluating all methods used by the laboratory and for proposing new or modified analytical procedures to be used by examiners.
- Responsible for technical problem solving of analytical methods and for the oversight of training, quality assurance, safety and proficiency testing in the laboratory.
- Accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.
- Responsible for initiating, suspending, and resuming DNA analytical operations for the laboratory or examiners in the laboratory.
- Responsible for reviewing qualifications of examiners in the laboratory.
- Responsible for reviewing the internal and external DNA audit documents and, if applicable, approve corrective actions.
- Responsible for approving the technical specifications for outsourcing agreements.
- Approve all Corrective Actions in DNA prior to implementation.
- Responsible for annually reviewing the procedures of the Biology section and documenting these reviews.
- Responsible for reviewing requests by contract employees for employment by multiple NDIS participating laboratories and if no potential conflict of interest exists, approving such requests.

3.4 Continuing Education

All DNA personnel performing casework must stay abreast of developments within the field by reading current scientific literature and attending Continuing Education (CE) sessions.

The Biology Section personnel will stay current on developments in the literature by reading documents on the internet, journals, etc. Journals are passed around the laboratory to each analyst; the administrative assistant in the laboratory keeps copies of all sign off sheets for the reading of journals. Electronic articles are sent with read receipt to the analysts by the Chief Criminalist or DNA Team Leaders. By opening the email, the analyst will be indicating that they are responsible for reading the article. A copy of the email and the article can be found in the Micro folder on the R Drive.

Additionally each DNA analyst must attend, at a minimum, one CE session each fiscal year which runs from July through June. It must be directly related to the analysis of DNA evidence. This would include conferences, seminars, workshops, or courses which impart in-depth technical knowledge on forensic DNA testing. Computer courses, even CODIS computer training, is not acceptable for annual training. The FBI online audit training course covering the Quality Assurance Standards, taken through the Learning Management System on the CODIS website or on the FBI Academy website, is approved by the Technical Leader to count for a minimum of 16 hours toward continuing education.

The analyst must fill out a Training Action Report, and if grades or a certificate are given, this should be supplied for the record as well.

3.5 Training Records

Education records will be maintained for each analyst in the Section and/or with the Laboratory QA Manager according to the Crime Laboratory QM.

3.6 Casework CODIS Administrator/Back-up

The Casework CODIS administrator and back-up CODIS administrator will have the same educational requirements as the Technical Leader.

The Casework CODIS administrator and/or back-up will be responsible for:

- Administering the laboratories local CODIS network
- Scheduling and documenting the CODIS computer training of the analysts.
- Assuring the security and quality of the data stored in CODIS is in accordance with state and federal laws and NDIS operational procedures.
- Terminating an analyst or laboratories participation in CODIS, if the data has been compromised.
- Responsible for assuring that matches are dispositioned in accordance with NDIS operational procedures.

3.7 DNA Technical Leader Contingency Plan

- In the event that the DNA Technical Leader leaves the laboratory, the CODIS Administrator or a qualified analyst will resume the responsibilities of the DNA Technical Leader until a replacement can be found. A memo can be found in the Qualifications folder for analysts other than the CODIS administrator/back-up that meet CMPD's qualifications for Technical Leader.

4. Facilities

The CMPD Biology Laboratory was built as a part of the 1996 construction of the headquarters building and designed for DNA analysis.

4.1 Access to the Biology Laboratory

General laboratory security is addressed in QM 5.3.4 and PM 9. Amplified DNA samples may be maintained for temporary storage in the amplification room freezer or refrigerator until technical review is complete. DNA extracts will be stored long term in sealed freezer boxes. Anyone with access to the laboratory, or wishing to tour the laboratory will either give a buccal swab for the local database or wear complete personal protective gear.

4.2 Extraction and PCR Setup

PCR amplifications, evidence examinations, DNA extractions, DNA quantitation, and PCR setup are conducted at separate times or separate spaces. Designated areas in the laboratory for each process are provided and each phase of testing must be performed in the specified area. DNA extraction of standards and unknowns must be performed at separate times or spaces.

Analysts will maintain separate materials used in manual extraction, with the exception of the Qiagen kits. Some items such as quantitation kits, STR kits, and 3130 reagents may be shared among the lab staff.

4.3 Amplified Product Control

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

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

- In general, items needing to be removed from the amp room will be completely decontaminated using 10% bleach or DNA Away. Some exceptions to this rule are:

    1. Small items may be brought into the PCR room for a limited purpose and a brief period of time, and removed immediately provided that the item does not touch any surface in the room. Examples of these types of items may be computer disks, CD writers, and PCR setup transfer racks.

2. Biohazard waste will be taken directly from the biohazard area to the disposal area on the first floor without being transferred to the pre-amplified areas.
3. Lab coats used in the amplified area will be taken directly to the cleaning bin without being transferred to the pre-amplified areas.
4. Any case file documents brought into the amplification room will be restricted to the areas adjacent to the CODIS terminals and the GeneMapper analysis workstations. Case file documents will not be placed in areas used for sample preparation. Notes for use during sample preparation may be placed in sample prep areas but will not be removed from the amplification room.

- Nothing removed from the amplified product work areas will be moved to the serology analysis, DNA extraction, quantitation, or PCR setup areas. Amplified product work areas include the chemical hood, refrigerator, and areas adjacent to the thermal cycler, heat block, centrifuge, and 3130.

- All trays, decappers and scissors/forceps will be cross-linked after washing before being placed back in their perspective areas.

4.4 Laboratory Layout

- The laboratory is located on the fourth floor of the CMPD headquarters building.

- Lab coat color or color in the stitching of the name tag will separate the function of the analyst in the laboratory: white for screening, gray for DNA extraction through PCR set-up and light blue for the post amp room.

5. Evidence Control

5.1 Sample Identification

- Each sample will be labeled with a unique identifier according to CMPD evidence guidelines outlined in the Crime Lab Quality Manual. DNA extracts must be numbered by the DNA Number obtained in PLIMS.

5.2 Guidelines for Collecting Evidence for DNA testing

1. Wear disposable latex or nitrile gloves when handling evidence which may contain biological fluids. Change gloves often, and as soon as they are contaminated by a body fluid.

2. Air dry all stained evidence thoroughly. Never package wet body fluid evidence in plastic bags.

3. Evidence containing body fluid stains on it should be kept in a cool, dry location prior to submission to the laboratory.

4. All biological fluid evidence should be submitted to the laboratory or property as soon as possible after the date of the offense. This includes rape kits prepared from rape/homicide victims.

5. Liquid known blood samples should be kept under refrigeration prior to submission to the laboratory. Never freeze a liquid blood sample.

6. Use sterile swabs for absorbing bloodstains and never make contact with bare skin.

5.3 Chain of Custody

5.3.1 Transfer of Bulk Evidence from Property Control

Evidence will be requested from Property Control using the “Pull List” in PLIMS. Evidence for priority cases may be requested by email or personally picked up from Property Control. Each analyst has an assigned area/cabinet where their evidence is maintained while the case is pending in the laboratory. Upon completion of a case, any evidence that is maintained in the laboratory will be transferred into General Biology Storage (GBS).

5.3.2 Retention of Portions of Bulk Evidence

Routinely, it is important to maintain the integrity of certain evidence by retaining it in the freezers in the Biology section of the laboratory. These cuttings or swabs will

be created as sub items in PLIMS and will be maintained in General Biology Storage (GBS).

5.3.3 Electronic Database Maintenance

5.3.3.1 Biology Chain of Custody

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

5.3.3.2 DNA Number

Due to the size of the tubes and the complicated numbering system at CMPD, a sequential numbering system will be employed for the analysis of DNA samples. Each sample, when initially introduced to DNA testing, will be assigned a unique number which will be assigned by PLIMS and will be carried with that sample throughout the analysis and storage. They will be created as sub items in PLIMS from the swab or cutting.

DNA extracts and extraction material maintained from consumed items will be considered evidence and upon completion of analysis, will be transferred to General Biology Storage (GBS).They will be placed in the analysts' individual boxes in the freezer and labeled with the analysts' initials and the content of DNA #'s. Once the box is full, they will be sealed with evidence tape.

5.4 Evidence Sampling

- For evidentiary samples (unknowns), if there is more than one swab, (up to 4 swabs) a portion of each swab will be used for analysis. If more than 4 swabs the ones chosen will be done at the analyst's discretion.

5.5 Specimen Preservation and Storage

Samples will be handled in a manner to prevent loss, alteration, contamination or mixing. Analysts will wear a mask, lab coat and gloves while handling and screening evidence, both to protect the samples from contamination and for personal protection. A hair net may also be worn when examining hair or collecting trace. A DNA analyst may cut their unknown samples for DNA at the bench area as long as the full PPE as described above is worn. Analysts will also discard disposable pipette tips after each use and will not have more than one DNA containing sample tube open at a time. All microcentrifuge tubes will be opened with decappers or by using the side of the pipette handle. If another employee needs to look at the evidence, a mask will be worn by the observing employee while around the open evidence.

Items will not be accepted for DNA analysis if the evidence has already been processed in another section of the laboratory. An exception can be made by the Chief Criminalist or DNA Team Leader for Cold Cases if the scenario permits. This exception will be noted as a communication in PLIMS.

If a sample is inadvertently rendered unusable, it will be documented in the case file. If no result is able to be reported due to this, the final lab report will indicate the reason why no results were reported for the sample.

All known standards will be analyzed separately from all questioned samples. All samples will be handled using the One-Tube method which states that only one tube will be opened at any time when a tube which contains DNA is in close proximity to another tube which does, or is intended to, contain a DNA sample. The only exceptions to the One-Tube method are the air drying step of the DNA IQ extraction, QIAgility set up, the Quantifiler Trio and post amp setup on 96-well reaction plates. STR pre-amplification and post-amplification areas will have dedicated equipment and supplies.

A notation will be clearly made in the notes of the case file if the sample and/or DNA extract is consumed and there is nothing left to analyze.

5.5.2 Sample Storage

1. All evidence submitted for testing will be stored under the appropriate conditions to minimize degradation of the sample.

2. Questioned and known samples will be stored frozen unless the substrate does not require freezing, such as samples stored on FTA paper. Any case samples not currently in progress will be maintained frozen within the section. Cuttings used in the extraction process are considered work product unless the stain has been completely consumed. If the item is consumed and there is nothing to re-analyze, then the cutting will be considered evidence and will be maintained as DNA# –M. This applies to all touch item swabs collected by someone other than the Biology section.

3. Amplified DNA from STR typing case samples will be stored refrigerated until the analysis is completed and the case file has been reviewed. Amplified DNA is only considered work product, and will be disposed of properly once all technical review of those samples is complete.

4. A statement must be placed in the official report regarding the disposition of the remainder of the evidence used for DNA analysis. Any remaining material including the DNA extracts will be maintained in General Biology Storage.

5.6 Data Handling and Storage

5.6.1 Copies of Originals

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- All case files are scanned into PLIMS and the original is kept in the file room.

Photographs may be taken to further document an item of evidence. All photos will be contained in the case file or attached in PLIMS. Additional copies will be maintained electronically on the R Drive or on a CD submitted as an evidence item to Property Control.

5.6.2 Storage of STR Data

- Refer to Biology SOP 6.3

6. Validation

Validation of new systems must be performed before casework analysis. Since some studies are not practical or possible by CMPD, validation may be a combination of the manufacturer's and CMPD's studies. However, CMPD is responsible to ensure that the results are reliable and reproducible for forensic type samples. Validation studies from other agencies may be used to compare to the results obtained at CMPD, but they may not replace the basic studies which will determine if the system is suitable for casework analysis. All validation studies will be reviewed and approved by the Technical Leader prior to use on casework.

6.1 Documentation

All records, including electronic data, must be retained for as long as the particular methodology is being employed or may be testified to in court. A hard copy of the essential validation record for each DNA system must be retained for and a copy provided for independent review if directed by the court. This record will be comprised of data sheets for each sample which is demonstrative of the results obtained for a particular study. Each study will also contain a summary of the interpretation of the results.

6.2 Characterization of the DNA Loci

Novel forensic DNA methodologies shall undergo developmental validation to ensure the accuracy, precision and reproducibility of the procedure. The developmental validation shall include the following:

1. Documentation which defines and characterizes the locus.
2. Species specificity, sensitivity, stability and mixture studies.
3. Population distribution data are documented and available.
4. The population distribution data would include the allele and genotype distributions for the locus or loci obtained from relevant populations. Where appropriate, databases should be tested for independence expectations.

6.3 Developmental Validation of the DNA Analysis Procedures

Prior to the implementation of a new DNA procedure, each of the following validation studies must have been conducted by the scientific community, manufacturer, or the CMPD Laboratory.

1. Standard Specimens - The typing procedure should be evaluated using fresh body tissues and fluids that have been obtained and stored in a controlled manner.

Determine if DNA isolated from different tissues from the same individual yields the same typing profiles.

2. Consistency - Using specimens obtained from donors of known phenotypes/genotypes, evaluate the reproducibility of the techniques both within the laboratory and, if possible, between different laboratories.

3. Population Studies - Establish population distribution data in different racial groups for amplified fragments.

4. Reproducibility - Prepare dried stains using body fluids from donors of known phenotypes and analyze to ensure that the stain specimens exhibit accurate, interpretable and reproducible DNA typing profiles.

5. Non-probative Evidence - Examine DNA profiles in non-probative evidentiary stain materials. Compare the DNA profiles obtained for the known standard versus questioned samples deposited on typical crime scene evidence.

6. Non-human Studies - Determine if DNA typing methods designed for use with human specimens detect DNA profiles in nonhuman source stains.

7. Publication – It is imperative the results of experimental studies are shared as soon as possible with the scientific community through presentations at scientific/professional meetings. It is imperative that the complete details of the experimental study be afforded the opportunity for peer review through timely publications in scientific journals. If this information is already readily available to the scientific community due to the publications of the manufacturer and other forensic laboratories using similar methodology, the CMPD laboratory is not required to repeat these publications unless the validation reveals significant conflict with previous information.

6.4 Internal Considerations

1. Internal validation shall be performed and documented by the laboratory.
2. The procedure shall be tested using known and non-probative evidence samples. The laboratory shall monitor and document the reproducibility and precision of the procedure using human DNA control(s).
3. The laboratory shall establish and document match criteria based on empirical data.
4. Before the introduction of a procedure into forensic casework, the analyst or examination team shall successfully complete a qualifying test.
5. Material modifications made to analytical procedures shall be documented and subject to validation testing.

6.5 Non-Routine Procedures

Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published by reputable technical organizations or in relevant scientific texts or journals, or have been appropriately evaluated for a specific or unique application.

7. Analytical Procedures

7.1 Standard Operating Protocols (SOPs)

All protocols and procedures must be stored in the laboratory such that all analysts have access. The SOPs and/or the QA manual must contain reagents, sample preparation, extraction, equipment, and controls which are standard for DNA analysis and data interpretation. See QM 5.4 for adjustments to SOP's.

7.2 DNA Standard Reference Material

The DNA laboratory will check its DNA procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available NIST standard reference material or standard traceable to a NIST standard. The results will be documented and available for review

7.3 Data Interpretation

7.3.1 All visual matches must be confirmed by the numerical match criteria inherent in GeneMapper.

7.3.2 All statistical interpretations must follow the 1996 NRC report, "The Evaluation of Forensic DNA Evidence". Exceptions will be made if subsequent recommendations are made by the SWGDAM or any other nationally recognized body.

7.3.3 The database used to derive statistical calculations must be representative of the appropriate populations, namely African American, Caucasian, and Hispanic.

8. Monitoring of Equipment and Consumables

8.1 Monitoring Program

8.1.1 Frequent monitoring of items and events is encouraged and is not limited by mention in the Monitoring Program. This Monitoring Program establishes standards that are necessary for accreditation purposes and that are not described in other quality assurance documents.

8.1.2 Monitoring in this program consists of data describing a procedure or observation (what) recorded (how) on a worksheet or other record (where) by a qualified individual (who) at specified and recorded interval of time (when), as well as an assessment of whether the data is acceptable.

8.1.3 Critical monitoring is monitoring that, if not monitored as scheduled, could negatively affect the quality of casework. Non-critical monitoring (e.g., to extend the service life of an instrument) is expressly allowed to be non-compliant with the Monitoring Schedule.

8.1.4 Analysts are expected to verify that all required monitoring related to the tasks they are performing is in order and acceptable.

8.1.5 Monitoring records will include:

- the common name of the item, information, or event being monitored
- related information as applicable (e.g., manufacturer, model/catalog number, lot number, etc.)
- the location of the monitoring or equipment, or storage location
- specifications to be met (e.g., test results, cleaning procedure, storage conditions)
- the identity of the operator(s) responsible for the record & date(s)
- the data required to demonstrate the specifications were either met or not met, or a note stating that the item is out of service
- expiration date of the item or monitoring interval

8.1.5.1 Records for required consumables & purchased chemicals will also include the date received, and who received, and the quantity/size. As applicable, manufacturer inserts and certificates of analysis will be attached.

8.1.5.2 For prepared reagents, monitoring records will also include the date prepared & who prepared, the quantity/size, the name & lot number of the

components, and additional information as required (e.g., pH, whether autoclaved). Lot numbers for prepared reagents will be in the format "MMDDYY**" where MM is the two-digit month, DD is the two-digit day, YY is the two digit year, and ** is initials of the person making the reagent (2-3 letters), and a letter designation for the reagent as outlined in the reagent logbook.

8.1.5.3 Records are not typically made for dilutions and aliquotting of reagents. Daily QC of PHT, LMG, AP tests, Phadebas tests, ABAcards for p30 or Hematrace is only recorded in the applicable case record. All other monitoring records, including COQC records, will be stored in the applicable binder in the laboratory.

8.1.6 While a monitored item is out of service, monitoring is not required. Any item that is beyond its expiration date or required monitoring interval will be removed from service.

8.2 Required Consumables, Chemicals, and Prepared Reagents

8.2.1 Labeling of chemicals and prepared reagents is specified in PM 5.2. Additionally, they will be labeled with the appropriate storage conditions.

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

8.2.2.1 Expired consumables, chemicals, and prepared reagents are not used in evidence analyses; however, they can be used for research or training purposes, but must be clearly marked 'Not to be used for casework.'

8.2.3 Prepared reagents

8.2.3.1 Recipes for all prepared reagents will be readily available in the solution preparation area. The only allowed deviation to the recipe is that the quantities of a prepared reagent may be adjusted (unless otherwise noted), as long as the ratio of the components remains the same.

8.2.3.2 When using water as a component of a prepared reagent, purified water (i.e., not tap water) will be used.

8.2.3.3 All glassware and plasticware will be cleaned prior to use and rinsed with DI water. If appropriate, glassware will be autoclaved to ensure sterility.

Unsterile disposable plasticware which needs to be sterile will be autoclaved prior to use and disposed of immediately after use.

8.2.4 Critical Reagents

The following critical reagents will be tested prior to use with casework. They may be tested concurrently with casework samples as long as the casework samples and their corresponding blanks are employing different, previously validated critical reagents, or they may be tested alone. They will only be tested with previously checked reagents. If any component of a critical reagent changes, (e.g., the same lot of DNA IQ kits with a different lot of alcohol) then the new reagent must be separately tested. The records related to the results are attached to a Certificate of Quality Control (COQC) unless otherwise noted. The COQC must be approved by the Chief Criminalist, a DNA Team Leader, or a Technical Leader designee before the critical reagents are used in casework. Information from these reagents will be placed in the QC records spreadsheet found on the R Drive. This is used by analysts during technical review.

Failed lots may be retested to confirm that the first test was performed properly. The lot may be accepted for use if the lot passes the retest. If the lot fails the retest, the DNA Technical Leader or acting TL will be notified immediately and the reagent will be retested by the DNA Technical Leader or a DNA Team Leader. Upon failure of the second retest, the reagent will not be accepted for use. Prepared reagents will be discarded and purchased chemicals will be returned to the manufacturer as soon as possible.

8.2.4.1 Luminol must be tested daily prior to use with a known blood stain and a negative control. No COQC is required; the results are recorded in the case record.

8.2.4.2 PHT, LMG, AP:

Presumptive reagents will be tested after the reagent is made and prior to distribution. QC will consist of testing a stain of known body fluid (blood for PHT & LMG, semen for AP) and a blank reagent control. The known body fluid will yield an appropriate color change and the blank reagent control will yield no color change. The tests will be performed under the same conditions as casework samples. The reagent QC is recorded with the COQC. The subsequent daily positive and negative tests are performed by the individual casework analyst prior to use and recorded in case records. Blood standards will be tested at values of 1:10 and 1:100; both must be positive. Reagent blanks must be negative.

8.2.4.3 ABA card p30 and Hematrace:

Each lot must be tested. QC will consist of a reagent blank and dilutions of a known semen or known blood standard. A 1:100 dilution of semen standard must be positive. Each day of use, a positive and negative control will be run by one analyst, and results will be posted on the board with analyst's identity and date. The initial test is recorded with the COQC, but subsequent tests are recorded in case records.

8.2.4.4 Phadebas:

Each lot of Phadebas tablet must be tested. Testing must include a reagent blank and dilutions of a known saliva standard (1:10, 1:100, 1:500 and 1:1,000). All standards, except the 1:1,000 standard, must have a color change. The reagent blank will not yield a color change. The reagent QC is recorded with the COQC. The subsequent daily positive and negative tests are performed by the individual casework analyst prior to use and recorded in case records.

8.2.4.5 QIAamp DNA Investigator kit, DNA IQ kit, DNA IQ Reference Sample Kit, PrepFiler Express Kit, PrepFiler Express BTA Kit, ProK, and DTT:

A known human sample, preferably a NIST or NIST-traceable standard, will be extracted and quantified. To pass QC, at least 0.075ng/µl of DNA must be observed in the sample and no DNA observed in the reagent blank. ProK will be tested using the archived blood QIAgen extraction procedure.

8.2.4.6 Quantifiler Trio kit:

A NIST-traceable standard and a negative reagent control will be quantified. To pass QC, two sets of standards will be run (one set prepared from a previously QC'd kit and one set from the kit being QC'd) and alternately used as the applied standard curve. The standard curves generated must conform to current DNA SOP standards, the known human DNA control must be detected, and the negative reagent control must quantify at zero.

8.2.4.7 Identifiler Kit:

A NIST-traceable standard, will be amplified. To pass QC, the laboratory sample and the kit positive control must provide the correct DNA profile, and there must not be any contamination in the amplification blank.

8.2.4.8 Formamide, LIZ, and POP-4:

A positive control, negative control, and ladder will be injected in a genetic analyzer. To pass QC, the ladder and positive control must be labeled as expected, and no DNA profile observed in the negative control.

8.2.5 Chemicals within a kit will only be used with other chemicals from that same lot of kit. For example, DNA controls, allelic ladders, and primer sets from an STR kit that were validated together must be used together.

8.2.6 Items are not left open and are put away as soon as possible when evidence is in the work area. Whenever possible, use aliquots that will not be re-used.

8.2.7 Disposal of hazardous wastes will be handled as described in the Safety Manual or the MSDS.

8.3 Equipment and Instruments

8.3.1 Operating manuals and warranty information provided by the manufacturer will be maintained in a file in the Section office or in close proximity to the instrument.

8.3.2 Any time service or maintenance is performed on an instrument, it will be recorded.

8.3.3 If applicable, a performance check will be performed on an instrument after preventative maintenance or repair work and prior to its use in casework.

8.3.4 Each instrument which needs to be monitored and/or calibrated will be checked on an appropriate schedule. Calibration will be done using appropriate certified standards and will be documented in the calibration binder. Some instruments will only be calibrated routinely by certified external agencies. Any instrument or equipment that is not monitored by its due date will be removed from service until the appropriate monitoring is performed.

8.3.4.1 Automate DNA Extraction robots:

A. Maintenance: Once every month, the D-Rings will be greased and the instrument will be cleaned.

B. Diagnostic Testing: Once every 4 months, the axis, temperature, version and error tests will be performed. Any changes in the error test will be noted and the DNA Technical Leader or their designee will be notified. If the other tests are not passed, the instrument will be serviced by a qualified technician.

C. Performance Check: The Automates will be checked annually and after any repair or service with a known and a blank sample. Upon QPCR, the known must contain at least 0.075ng/µl of DNA and the blank must not have any DNA

D. Preventative maintenance will be provided by a contract vendor annually and within 12-18 months of the previous preventative maintenance.

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

8.3.4.3 Chemical Fume Hoods and BioSafety Hoods: Hoods will be inspected and have their face velocity checked annually by a commercial firm.

8.3.4.4 Cold Storage (Refrigerators and Freezers): will be checked weekly. The acceptable temperatures are:

- Refrigerators: 5°C +/- 3°C
- Freezers: -20ºC +/- 10°C

If the equipment temperature lies outside the accepted range:

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

8.3.4.5 DI Water System: Every six months, a contract vendor will inspect and service the unit. In addition, the monitoring device should be checked at each use. If this device indicates a problem, then the vendor is called to correct it.

8.3.4.6 Genetic Analyzer (3130):

1. Every 2 weeks, the 3130 will be cleaned and maintained.
2. Every 3 months (quarterly), the injection lists from the 3130 will be removed from the instruments and saved on the R: drive in the GMID-X folder.

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

4. Preventative maintenance will be provided by Life Technologies annually and within 12-18 months of the previous preventative maintenance as a part of the BioAssurance Maintenance Plan. This plan also provides for on-site repair of any broken or malfunctioning components in the instrument.

8.3.4.7 Maxwell DNA Extraction robot: will be performance-checked annually and after any repair or service with a known and blank sample. Upon QPCR, the known must contain at least 0.075 ng/µl of DNA and the blank must not have any DNA.

8.3.4.8 Pipettes: will be calibrated annually by a contract vendor.

8.3.4.9 Qiagility:

A. Cleaning: After the Qiagility has been cleaned, it remains clean until used (the “in-use” date). The expiration date for the cleaning is 7 days after the in-use date.

B. Maintenance (called “Calibration” in the Qiagility software): Once every 4 months, the settings of the Qiagility will be checked.

C. Performance Check: Annually and after any repair or service, a NIST-traceable standard, and a blank will be quantitated and amplified. To pass QC, the laboratory sample and the kit positive control must provide the correct DNA profile, and there must not be any contamination in the blank.

D. Preventative maintenance will be provided by a contract vendor annually and within 12-18 months of the previous preventative maintenance.

8.3.4.10 Thermal cyclers (9700): will be tested semiannually for block temperature uniformity and for temperature verification. The apparatus used to test temperature verification will be calibrated yearly by a vendor and the documentation will be retained with other thermal cycler records.

A. Temperature Non-Uniformity Test

*NOTE: It is recommended that this procedure be performed immediately after turning the instrument on because the sample block cover is not hot at this time.

1. Place the Temperature Verification Frame on the sample block.

2. Coat the following wells with mineral oil using a cotton swab: A1, A2, A11, A12, C4, C5, C8, C9, F4, F5, F8, F9, H1, H2, H11, and H12.

3. Turn on the 9700.

4. Press F4 (Util).

5. Press F1 (Diag).

6. Press F3 (TempVer). The temperature verification screen appears.

7. Press F2 (TNU). This configures the 9700 for the Temperature Non-Uniformity Test. The TNU performance screen appears.

8. Place the temperature and dummy probes in the wells as directed by the on-screen instructions. The wire is attached to the dummy probe.

9. Thread the probe wire through the notch in the frame. Make sure the probe is attached to the digital thermometer. Turn on the digital thermometer to the “200” position.

10. Slide the heated cover forward and pull the lever down.

11. After temperature set points are reached, press F1 to run the test. The sample block will heat to within 1°C of the 37°C set point, while the heated cover will heat to within one 1°C of 35°C.

12. The block temperature will stabilize at the set point and count down. When the time reaches zero, read the digital thermometer and enter the actual block temperature into the 9700. Also, record the block temperature on the verification worksheet.

13. Follow the onscreen prompt and move the temperature and dummy probes to designated wells. Press F1 (Run) to measure the temperature.

14. Repeat these steps to measure and record the temperatures of the remaining wells at the 37°C set point.

15. After checking all wells at the 37°C set point, follow the onscreen steps to measure the temperature at the 95°C set point. Enter the

measured temperature into the 9700 and record on the verification worksheet.

16. After measuring the temperature of all wells, the 9700 will display the results of all wells. Press F1 (Accept).

17. The TNU Performance screen will then appear.

18. If the temperature of the sample block wells is uniform, the instrument will display the message “Pass” after each set point temperature. Record the TNU Performance set point results on the verification worksheet.

19. If the temperature of the sample block wells is not uniform, the instrument will display the message “Fail” after each set point temperature(s) for which the test failed. Repeat the test to determine if errors were made. If the test fails a second time, record the results and contact Life Technologies Technical Support.

20. Press F5 (Cancel) to return to the Temperature Verification screen.

B. Temperature Calibration Verification Test

1. Coat wells A6 and B6 with mineral oil.

2. Place the temperature probe in well A6 and the dummy probe in well B6 and thread the wire through the notch in the frame.

3. Slide the heated cover forward and pull the lever down.

4. Press F1 (Temp). The system configures for the Calibration Verification Test. The Calibration Verification screen appears.

5. Press F1 (Run). The block and heated cover will go to 85°C. When the cover reaches within 1°C of 85°C, the test will commence.

6. The temperature will stabilize at the set point and the Calibration Verification screen counts down. When the clock reaches zero, read the digital thermometer. Enter the value into the 9700 and record on the Temperature Verification worksheet.

7. Press Enter.

8. The block temperature and heated cover will move to 45°C. When the cover is within 30°C of the set point, the system will begin the second reading. Repeat steps 6 and 7 for this set point.

9. A summary screen appears at the conclusion of the test. Press F1 (Accept). The 9700 evaluates the calibration of the sample block temperature.

10. The Calibration Verification screen appears with the results of the test. If the sample block is properly calibrated, the message “Calibration is good,” will appear.

11. If the sample block is improperly calibrated, the message “Instrument may require service,” will appear. If so, repeat the test. If the test fails a second time, record the results on the Temperature Verification worksheet and contact Life Technologies Technical Support.

12. Clean the wells with cotton swabs soaked with 95% EtOH to remove the mineral oil and exit to the Diagnostics screen.

C. Rate Test

1. Press System from the Diagnostics Screen. Press F1 on the System Performance screen to enter the Rate test.

2. Install an empty 96-well sample plate and cover. Close the heated cover.

3. Press F1 (Cont).

4. At the conclusion of the test, the Cool and Heat Test screen appears and displays the test results and whether the test results passed or failed.

5. Record the results on the Temperature Verification worksheet.

6. If the test fails, repeat the test. If the test fails a second time, record the results and contact Life Technologies Technical Support.

D. Cycle Test

1. Press F2 on the System Performance screen to enter the Cycle Test.

2. Make sure that an empty 96-well sample plate and cover are on the sample block.

3. Press F1 (Cont).

4. At the conclusion of the test, the Cycle Performance screen appears and the results will be displayed.

5. Record the results on the Temperature Verification worksheet.

6. If the test fails, repeat the test. If the test fails a second time, record the results and contact Life Technologies Technical Support.

7. After completion of all tests, turn off the instrument.

8.3.4.11 Thermal cyclers (7500): Preventative maintenance will be provided by Life Technologies annually and within 12-18 months of the previous preventative maintenance as a part of the BioAssurance Maintenance Plan. In addition, a background check will be performed on a monthly basis. A sample of known quantity will be quantitated annually as a check of the thermal cycler activity.

A. ABI Prism 7500 Monthly Diagnostic

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

•If the ”Condition” is ‘Good’, the lamp does not need to be replaced. Proceed to “Perform a Background Calibration”

•If the ”Condition” is ‘Change Soon’, the lamp may be changed, but it is not necessary.

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

Perform the Background Diagnostic

1. Obtain the prepared background plate from the spectral calibration kit in the freezer.

2. Allow the background plate to completely thaw and warm to room temperature (at least 30 min).

3. Remove the background plate from its packaging.

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

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

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

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

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

8. If the run does not pass, record the well(s) out of specification, turn the plate 180 degrees, and perform the test a second time. If the same well does not pass, then that well needs to be cleaned. If a new well does not pass and that new well is from the same position on the plate as in the first run, then the plate needs to be replaced but the run is acceptable. If a well does not reproducibly fail, then no wells need to be cleaned.

B. ABI Prism 7500 Biannual Diagnostic

Twice annually – every six months the ROI Calibration, the Optical Calibration, and the Dye Calibration will be performed. The annual preventative maintenance performed by Life Technologies covers one of the biannual diagnostic calibrations required. The monthly diagnostic should be coordinated to be performed at the same time. The sequence of diagnostic tests should be the ROI, background (monthly), optical, and dye calibration. If dye plates are stored in the original packaging in the freezer, they may be used up to three times for six months after opening.

Performing the ROI Calibration:

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

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

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

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

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

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

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

8. Complete the calibration as instructed by the wizard.

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

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

Performing the Optical Calibration:

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

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

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

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

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

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

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

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

8. Complete the calibration as instructed by the wizard.

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

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

Performing the Dye Calibration:

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

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

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

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

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

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

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

8. Complete the calibration as instructed by the wizard.

- Overview displays information describing the calibration. Select the dyes that you want to calibrate.
- Clicking Next prompts opens the Run tab. When the software prompts you to load each dye, prepare and load the plates.
- Clicking Start Run starts the calibration process and displays the processing messages. Clicking Next opens the Analysis tab.

• Analysis tab indicates the calibration status (Passed/Failed). When software prompts you to analyze the spectra collected from each dye plate, verify the status of the calibration.

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

C. RNase P Experiment

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

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

8.3.4.13 Thermometers – will be compared to a NIST-traceable thermometer at their working temperature once per year. The NIST-traceable thermometer will be checked for accuracy by an outside vendor annually. Pre-calibrated digital thermometers are exempt from annual verification during the manufacturer's term of calibration.

A. Thermometer Verification

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

2. Adjust the temperature until the certified thermometer is at the working temperature

3. When the temperature equilibrates, record the temperature of the test thermometer.

9. Proficiency Testing

General proficiency test information is available in QAM 4. Specific issues addressed differently in the Biology section are described here.

9.1 Open Proficiency Testing

1. Each Section analyst conducting DNA testing will be tested at least twice each year with an external proficiency test (PT). One test must be performed in the first six months of the calendar year and the second in the last six months of the calendar year. The interval between the final submissions of the tests to the laboratory director will be no fewer than four months and no more than eight months. For newly qualified analysts, the first external PT must be taken within six months of the completion of the qualifying test. The date due to the manufacturer will be used for documentation purposes.

2. PT tests should involve all members of the "team". Each person who performs technical review during normal casework duties should perform this function during the PT. Major discrepancies or errors will be handled according to QAM 4.11. Manual and robotic extractions and set ups will each be used at least once during the completion of the two tests taken during the proficiency cycle year. The Maxwell, Automate, and QIAgility will each be used on at least one test a year to show continued proficiency in robotic extractions and set ups.

3. Analysts must complete the test analysis in time for the material to be reviewed and arrive at the test provider before the due date. The following sequence will occur:

    - All examiners will perform independent work on their PT. The test takers must not confer on any part of the test process or the results at this stage.
    - The test results are submitted to the analyst assigned as their technical reviewer.
    - One individual may perform both forms of review; however, analysts may not perform the review on their own test material.
    - The analysts will then submit the reviewed material back to the SA containing documentation that the reviews have been completed.
    - The director will then submit the material to the PT provider for review.

4. This will serve to meet the PT requirement for the technical review aspect of the analysis "team". If an error or discrepancy is detected by the PT provider, the internal review process should attempt to determine if the problem should have been detected during the technical review. If this is determined to have occurred, then the technical reviewer or the review policies should be corrected to minimize the possibility of a reoccurrence.

5. Each Section analyst conducting only Body Fluid Identification will be tested at least once a year with an open proficiency test. Due to the fact that DNA analysts do not

take a separate proficiency for Body Fluid Identification, they will conduct all presumptive serological tests on their DNA proficiency.

6. These samples will be furnished as part of an external proficiency testing program from an ASCLD/LAB approved vendor.

7. In addition to criteria for evaluation of proficiency tests listed in the laboratory QAM the following criteria for DNA proficiency tests will be applied also:

   - All reported genotypes and/or phenotypes are correct according to consensus genotypes/phenotypes or within established empirically determined ranges.
   - The basis for inconclusive interpretations in proficiency tests must be documented.
   - All discrepancies/errors and subsequent corrective actions must be documented.
   - Administrative errors shall be documented and corrective actions taken to minimize the error in the future.
   - All tests will be reviewed and approved by the DNA Technical Leader.

10. Corrective Action

10.1 Casework Errors

Corrective action for errors detected in proficiency tests or in casework, after a report has been issued, will be acted upon according to PM 6. Contamination issues are discussed in Section 15 of this manual.

All corrective actions in the Biology section must have documented approval by the Technical Leader prior to implementation.

11. Reports

- All notes and reports from the Biology section will be maintained in one folder, and each report will be numbered sequentially.

11.1 Case Notes

Notes must be taken for each test performed in accordance with QAM 4.13.2.1. A Biology case will contain the following in the order listed below:

Administrative Documents

- Technical/Administrative Review Checklist
- Technical Review Sheet, if necessary
- Service Request or submission form
- Communication sheets or emails
- Med forms from sexual assault kit, if applicable
- KBCOPS information, if applicable
- Chain of Custody
- Staff search, if applicable
- Match Estimation report, if applicable
- CODIS Specimen Detail Report, if applicable

Examination Documents (numbered pages)

- Handwritten notes/Lab info sheets/General notes
- Extraction (questioned sample sheets followed by knowns sample sheets)
- 7500 Set up Sheet
- Standard Curve
- 7500 Results Worksheet
- Amplification Information
- 3130 Set Up Worksheet
- 3130 Injection List Worksheet
- QC check print out
- Allele Table (or Combined table) from Armed Xpert
- GeneMapper printouts of case sample data, including internal lane standard (ILS) (evidence profiles followed by known profiles)
- GeneMapper printouts of control sample data (all positive controls followed by all negative controls followed by reagent blanks, followed by ladders)
- Mixture interpretation printouts, if applicable
- Statistics, if applicable
- CODIS entry worksheet

11.2 Abbreviations

Attached is a list of abbreviations commonly used in the Biology laboratory during taking of notes. Items such as brand names of commercially available products, DNA loci, and other universally recognized terminology are not included.

This is an attempt to capture most of the commonly used abbreviations; however, others may be used if they are not cryptic or indecipherable to the reviewer. Some abbreviations are exclusive to certain testing and might not appear elsewhere. Also, abbreviations may be capitalized, or not capitalized, depending on examiner preference.

Abbreviation	Term	Comments
α human	anti-human	
#	number	
my ID	analyst initials, complaint #	
-, (-) or neg	negative	
+, (+) or pos	positive	
ab	amplification blank	
als	alternate light source	
amy	amylase	
ap	acid phosphatase	
bld	blood	
bl	blue	
blk	black	
C	celsius	
CAU	Caucasian	
Cdbd	cardboard	
CIDI	complaint #. Item #, date and initials	

Abbreviation	Term	Comments
cts	cotton tip swab	
COA	Certificate of Analysis	
c.o.f.	cut out and frozen, or retained	
conf	confirmed	
cl t	clear tape	
ctrl	control	
cys	crusty yellow stain	
ec	epithelial cell	
env	envelope	
epi	epithelial cell fraction	
et	evidence tape	
fxn	fraction	
GBC	General Biology Cage	
GBS	General Biology Storage	
gr	grey	
grn	green	
hds	heads	
inc	inconclusive	
k	known standard sample	
L or L/L or LL	Luma Lite	
L/S or S/S	Long sleeve or short sleeve	
LMG	Leucomalachite green	

Abbreviation	Term	Comments
L/W or S/W UV	Long wave or short wave ultraviolet light	
m:	marked	
meth tape	methanol tape	
micro	microscopic examination	
n/a	not applicable	
ND	no data	
neg cont	negative control	
NOE	not opened or examined	
Ns/nsf	non sperm	
NUFI	not used for interpretation	
obs	observed	
oftc	opened and found to contain	
omni	OmnichromeP	
pb	presumptive blood	
p30 or PSA	Prostate specific antigen	
pc	phase contrast	
PCB	Property Control Bureau	
pf	paper fold	
phr	peak height ratio	
PHT	Phenolphthalein	or KM for Kastle-Meyer
pl	plastic	
plshdr	plastic slide holder	

Abbreviation	Term	Comments
prop	Property Control	
ps	Property Sheet	
ptt	purple top tube of blood	
r	red	
RB	reagent blank	Q=questioned, K=known
rbc	red blood cells	
rbs	reddish-brown stain	
rec'd ( )	received (date)	
ret'd ()	returned (date)	
RET	red evidence tape	
RFU	relative fluorescence units	
rs or (r.s.)	representative sample	
rtn	retained	
rtt	red top tube of blood	
rxn	reaction	
s or su	Suspect	
sbpb or SBPBG	sealed brown paper bag	
sclpl	sealed clear plastic	
sep. fab. obs.	separation of fabric observed	
slhldr	slide holder	
sm	small	
sme	sealed manila envelope	

Abbreviation	Term	Comments
sol'n	solution	
sp/sf	sperm cell fraction	
spl	sealed plastic	
st	stained sperm slide	
stc	said to contain	
std	standard	
sw	swab	
s/w	sealed with	
swb or swbx	sealed white box	
swe	sealed white envelope	
sc	Sperm cell	
sz	size	
t	tape	
TNTC	too numerous to count	
u	microscopic exam	
und or uw	underwear	
unk	unknown sample	
V or Vi	Victim	
vag	vaginal	
vw	very weak	in conjunction with reactions
w or wk	weak	in conjunction with reactions
w/	with	

Abbreviation	Term	Comments
wb	white bag	
wbc	white blood cells	
wh	white	
w/o	without	
XTL	Transfer to external laboratory	
x:y	dilution of x in y	i.e. 1:5 dilution
Δ	change	

11.3 Minimum Information for DNA reports

At a minimum, every report must contain:

1. Case identifier
2. Description of evidence examined
3. A description of the methodology
4. Locus or loci tested, or kit
5. Results and/or conclusions
6. An interpretive statement using quantitative or qualitative methods
7. Date issued
8. Disposition of the evidence
9. A signature and title of the person(s) accepting responsibility for the content of the report.

11.4 Release of Case Information

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

11.5 Report Writing

1. The report wording guidelines in the Biology SOP are designed to establish consistency in reporting results and to accurately reflect the scientific weight given to

the various situations encountered when interpreting and calculating statistics. These guidelines will provide uniformity in reporting and will assist lay persons in understanding the reports. Every possible situation cannot be anticipated. If modifications are necessary to accurately reflect the true meaning of the results in a report, they must be approved by at least one other qualified analyst during the technical review.

2. A list of the actual DNA allele designations need not be listed on the report due to the cumbersome nature.

3. The signature on the report indicates the person primarily responsible for the opinions and data generated.

12. Review

General laboratory guidelines with regard to review processes are addressed in QAM 5.9.4 and 5.9.5. Some issues particular to the DNA section are addressed here.

12.1 Guidelines For The Proper Recording of Data

The following information will be recorded in the permanent file of every case submitted for review.

1. Sample description, including packaging information (if applicable)
2. Notes to document all tests performed on each item and the corresponding test results, notation of amount of sample remaining
3. DNA extraction information
4. Quantitation results
5. Amplification results
6. 3130 worksheet
7. Injection List
8. Computer generated GeneMapper electropherograms of samples and controls (if applicable)
9. Staff searches (if applicable)
10. CODIS data entry (if applicable)
11. Match Estimator (if applicable)
12. Mixture Interpretation print outs, if applicable

12.2 Case Review – Technical and Administrative

A hard copy of the technical and administrative review will be found in each case file, the hardcopy of the review sheet is the official review sheet. An administrative review is an evaluation of the report and supporting documentation of consistency with laboratory policies and for editorial correctness. A technical review is an evaluation of reports, notes, data, and other documents to ensure an appropriate and sufficient basis for the scientific conclusions.

It is not required for the administrative reviewer to be a current or former qualified DNA analyst. The technical reviewer must have two qualifications:

- They must be a qualified examiner in the present technology. Qualified examiner means they have gone through a training program at CMPD or a previous lab and have completed a qualifying test at CMPD.

- They must be continually proficiency tested in accordance with the semiannual rule on the specific aspect of technical review. This generally is accomplished by reviewing the PT of another analyst before submission to the PT provider. (see

Section 9 regarding Proficiency Testing for more information). The Technical Reviewer and the Administrative Reviewer will consist of two different individuals.

12.3 Discrepancies Between Analysts

All data, test results, and reports will undergo a technical review by a second qualified analyst. Both analysts must agree on the interpretation of the data to be reported.

If an analyst and technical reviewer are unable to resolve a technical issue on which they disagree, then the DNA Technical Leader will arbitrate the issue. Issues on how to report complicated profiles which may fall outside section interpretation/reporting guidelines are often resolved by receiving input from all qualified DNA analysts in the Section. After the conference, if a disagreement still exists, the report should be written to reflect the more conservative opinion. For further information, please refer to QAM 5.9.4.

12.4 Errors Detected During Review

Minor errors may be corrected by suggestions from the reviewer to the analyst. More serious errors may require further action. This section will follow the policies set in QAM 4.11.

13. Safety

(for detailed information see the CMPD Laboratory Safety Manual)

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

13.1 Policy

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

13.2 Written Manuals

General Laboratory Safety guidelines are covered in the Safety Manual. Written general laboratory safety manuals will be prepared and issued to every Section.

13.3 Disposal of Biological Waste

Disposal procedures for biological waste are to be followed in accordance with laboratory policy in the Safety Manual.

13.4 Reagent Notebook

The chemicals which are used to compose each solution will be outlined in the Reagent Notebook. A brief hazard summary will be given for each chemical. The associated MSDS sheet will be readily available. The area containing the Reagent Notebook and the MSDS sheets will be labeled for easy recognition.

13.5 MSDS

Material safety data sheets will be maintained on all chemicals and reagents used in the Lab. These sheets will be in a designated place accessible to all personnel.

14. Audits

Audits are designed to evaluate the Section's performance in meeting its quality policies and objectives and are intended to be a learning process.

The DNA section must be audited annually. Audits must be conducted once per calendar year, with the interval between audits not less than six months and not greater than eighteen months.

In addition, the DNA section must undergo an external audit at least every other year. In years in which an external audit is not required, the section has the option of either an external or internal audit. At least one member of the external audit team must be or have been previously qualified in the specific technology in which the section is being audited. For years in which an internal audit is performed, the audit team must include, at a minimum two qualified DNA analysts. At least one member of both the external and internal audit teams must have successfully completed the DNA Auditing Workshop sponsored by the FBI. All audit documents will be maintained by the laboratory for discovery purposes for the lifetime of the laboratory.

There are potentially five types of audits to which the DNA section may be subject:

14.1 External Audit

1. The section will be inspected at least every other year by a team composed of qualified auditors from an outside agency solicited by the Laboratory Director. The audit team will consist of current or previously qualified analysts in the CMPD's current DNA technology and platform.

2. These individuals will use the current FBI DNA Quality Assurance Audit Document and will report their findings, at a minimum, to the Chief Criminalist and DNA Technical Leader.

3. The items addressed in the audit checklist identify essential criteria.

4. The DNA Technical Leader will review all findings with the section and will maintain the audit report along with the section's written response and documentation of steps taken to resolve any problems detected. The external audit report and the section's responses to the audit will be forwarded to the NDIS custodian within 30 days of the laboratory's receipt of the report. If necessary, an extension may be requested from the NDIS custodian. Criteria for assessment of audits are described in the Internal Laboratory Audits section of PM 2.4.

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

14.2 Internal Audits

An annual general laboratory audit will be conducted as a requirement of ASCLD/LAB accreditation and all aspects of it will be complied with as described in PM 2.4

An internal audit of the DNA section will be conducted in the same manner as an external audit, will utilize the current FBI DNA Quality Assurance Audit Document, and all findings, responses, and documentation of corrective actions will be maintained by the laboratory.

14.3 CODIS Audits by the IG Office

As a functioning CODIS Local site, the lab may be subject to a Federal audit of the CODIS program. This is an audit to assess the overall effectiveness of the program and reports are sent to the FBI, not the CMPD Lab. The auditors will establish their own criteria for the audit.

14.4 ASCLD/LAB Audits

This audit will be conducted every five years or as deemed appropriate by the accreditation board. The standards will be described in the most recent version of the Laboratory Accreditation Board manual. An ASCLD/LAB audit will satisfy the section's annual audit requirement.

14.5 Internal CODIS Audits

This audit will be conducted by the CODIS administrator or the back- up CODIS administrator, no less than twice per calendar year. It will be conducted on completed case files from each qualified DNA analyst to ensure compliance with NDIS guidelines for sample entry, as per the Biology QA 21.8.2.

15. Contamination

15.1 Decontamination

Laboratory benches, hoods, and other surfaces should be cleaned at a minimum once per week with 10% chlorine bleach (or commercial DNA decontaminant) or after each handling of liquid bodily fluids. Hoods #1, 2 and 8 will contain a check sheet which will indicate the date and person who performed the decontamination. For DNA hoods and areas, documentation will be made on the worksheets. In addition to the weekly comprehensive cleaning, all surfaces of the immediate work area will be wiped with 10% bleach or a commercial DNA decontaminant after each analysis or the paper changed between each sample. If no work was performed in the area that week, the check sheet will be marked with “Not Used” or other appropriate notification.

15.2 Sterilization

Aerosol-resistant pipette tips must be used at all times when handling samples for serological analysis, DNA extraction, amplification, and electrophoresis. Pipettes will be wiped down with a 10% bleach solution or commercial DNA decontaminant, or exposed to UV light for at least 30 minutes. All tweezers or other metal instruments must be sterilized between each sample handling. Depending on the item, approved methods of sterilization include treatments with 10% bleach solution, UV radiation, or a heat sterilization device. With each daily use, all instruments, DNA trays and decappers will be crosslinked after cleaning.

All tubes or devices will be sterilized before use if the tube or device will be used to hold DNA material or DNA reagents during the process. The preferred method for plastic-type devices is autoclaving for at least 20 minutes. 96-well plates used for Quantifiler or Quantifiler Y analysis are exempt from this requirement.

15.3 Clean Work Surface

Laboratory benches which utilize a paper covering should be decontaminated on a regular basis depending on the amount of use of the area. Paper sheets used during screening or cutting of evidence should be changed between handling of each type of evidence.

15.4 Microscopes and Instrumentation

Microscopes and other instruments which are frequently handled should be cleaned as necessary with a bactericidal wipe or solution.

15.5 Contamination Contingency Plan

The CMPD laboratory and DNA testing facility is designed to minimize the risk of contamination to an extremely low level by the utilization of many precautions including a separate PCR work area, One-Tube specimen handling, negative pressure where appropriate, and the separation of unknown and known samples. If the analyst takes the proper precautions outlined in this manual and the procedure manuals, this risk will be kept to a minimum. All unknown samples that do not match any of the standard profiles in a case will be searched against the local Staff Database. In the unlikely event that contamination should occur in the DNA laboratory, the following steps should be followed to determine the source. Of course, routine forensic casework often includes mixtures of individuals involved in the case and this should be taken into account before this plan is initiated.

If a Staff match is made to someone outside of the Biology Section, the DNA Technical Leader and the CODIS Administrator will be notified. The individual and the Detective in the case will be contacted by the Section Supervisor or the CODIS administrator, first by phone and then by email. If the profile is a mixture and it can still be used if the individual is eliminated, then a buccal will be submitted from that person as part of evidence in the case.

Any time a Contamination Contingency Plan is initiated, the Technical Leader, Section Supervisor and Quality Assurance Manager must be notified before and after the problem is solved, and the procedure used to identify the problem and the conclusions must be clearly identified in each relevant case folder. A memo is generated by the Supervisor or the Technical Leader and is placed in the Corrective Action binder or Contamination Log. If the problem is determined to be systemic in nature, the Laboratory Director will also be notified before and after the problem is solved.

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

15.5.1 Isolated Contamination Contingency Plan

1. The analyst must immediately cease casework and inform the Technical Leader and Section Supervisor, or Laboratory Director if the former are unavailable, that he/she has initiated the Isolated Contamination Contingency Plan.

2. Prepare a new sample for re-injection using a fresh aliquot of amplified product. If this resolves the contamination, the re-injection will be utilized.

3. If the sample is contaminated with a known source such as a CMPD employee and re-injection did not resolve the contamination, the sample will be re-extracted. If none of the original stain material remains, if the contamination

persists in the re-extraction, or if the re-extracted profile gives uninterpretable results, the original profile may be utilized at the discretion of the Technical Leader.

4. If the sample was contaminated by another sample in that particular run and re-injection did not resolve the contamination, the affected samples (or the batched extraction set, if necessary) will be re-amplified. Should the contamination persist, the affected samples (or the batched extraction set, if necessary) will be reextracted from the original material.

5. If the reagent blank or the negative control indicates a pattern of contamination it will be re-injected as in Step 2. If re-injection does not resolve the contamination, the reagent blank will be re-amplified. If the contamination persists, all samples in the batched extraction set will be re-extracted from the original material. If insufficient extract and no stain material remain from samples in the batched extraction set, the original profiles of those specific samples may be utilized at the discretion of the Technical Leader.

6. If the amplification positive control indicates any level of contamination, no matter how slight, the affected control will be re-injected as in Step 2. If re-injection does not resolve the contamination, a new amplification will be performed consisting of the positive and negative controls and a known human (non-casework) sample. If no contamination is detected at this point, the casework samples will be re-amplified, or re-extracted if necessary. If insufficient extract and no stain material remain from samples of the amplification set, the original profiles of those specific samples may be utilized at the discretion of the Technical Leader.

7. If the above steps have not cleared the contamination and the sample is not believed to be a true forensic mixture, proceed to the Systemic Contamination Contingency Plan.

15.5.2 Systemic Contamination Contingency Plan

1. All analysts must immediately cease all casework until the source of the contamination is identified or is cleared. The analyst performing the work must immediately inform the Technical Leader and Section Supervisor, or Laboratory Director if the former are unavailable, that he/she has initiated the Systemic Contamination Contingency Plan.

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

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

16. Outsourcing

The CMPD may occasionally need the services of an outside agency to perform STR DNA testing for the purposes of CODIS entry. Outsourcing of DNA testing will comply with Standard 17 of the FBI Director's Quality Assurance Standards for Forensic DNA Testing Laboratories. If the CMPD Crime Laboratory outsources DNA cases for CODIS entry, the following requirements have to be met:

- The vendor has to be an ASCLD-LAB or FQS accredited laboratory and compliant with the current FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.

- A site visit must be performed before cases are sent to a vendor laboratory for analysis at the minimum by the DNA Technical Leader and, if at all possible, by the Casework CODIS Administrator.

- The following elements will be reviewed during a site visit:

    1) QAS Audit documents, findings and responses.
    2) Relevant validations.
    3) Qualifications and proficiencies of laboratory staff.
    4) Manuals and standard operating procedures.

- The vendor laboratory has to follow all technical specifications set down by the CMPD Biology section.

- All data has to undergo a technical review at the CMPD laboratory performed by qualified analysts before upload into CODIS, which will be performed by using the outsourcing checklist.

- The DNA Technical Leader will sign off on the technical specifications. This will be documented by the TL initialing and dating the technical specifications page in the contract.

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

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

- The sample is sent to the FBI, North Carolina State Crime Lab, or some other agency who will input the results in CODIS as a part of their own analysis. Since the external agency “takes charge” of the evidence, the CMPD laboratory is under no obligation as a Subcontractor.

17. Records

17.1 Current Procedures Manual

A copy of the current appropriate analytical testing procedure(s) used in the DNA typing of biological material and/or the identification of body fluids will be found on the R drive.

17.2 Past Analytical Testing Methods, Procedures and Guidelines

A file will be maintained by the Quality Manager containing all out-dated analytical testing methods, procedures, and operating guidelines. Items in this file will be maintained for five years or until their usefulness ceases to exist.

17.3 Batch or Lot Number of Materials Considered Critical to DNA Typing

Batch or lot numbers of materials considered critical to DNA typing will be maintained in a QC notebook in the Section for a period of at least five years. Batch or lot numbers of materials considered critical to DNA typing will also be recorded on the appropriate worksheets and maintained in the case file.

17.4 Quality Assurance and Audit Reports

Copies of external audit reports will be maintained in section files. Internal audit information will be retained according to PM 2.

17.5 Licenses and Certificates

Copies of all licenses and certificates awarded to the Section will be maintained in the Biology Section's files.

17.6 Population Frequency Data

Population frequency data used for statistical calculations in the report will be maintained in the Section files. Other data may be maintained and will be available if the court requests. The original work sheets and computer generated data must be maintained in the Section for any data which was generated by the CMPD laboratory.

17.7 DNA Number

A DNA number will be generated by PLIMS as a unique identifier for each sample extracted. This number will be noted on the DNA extraction worksheet.

17.8 Contamination Records

A record must be retained in the lab pertaining to any contamination which occurred. If the nature of the contamination is localized to an analyst, the records are retained in the Isolated portion of the Contamination Monitoring Record. However, if the contamination is Systemic, the records must be kept in the Systemic portion of Contamination Monitoring Record file.

17.9 Standard Reference Material Records

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

18. Case Acceptance Policy

Exhibits must be submitted in compliance with the case acceptance guidelines of the Charlotte-Mecklenburg Police Department Crime Laboratory. DNA testing will be complete when an association is established from probative evidence (for example an association is established between the subject and the victim.) A scenario must be provided with the submitted evidence. The scenario will establish the value of each item as to its likelihood to provide probative results or an investigative lead. Please submit only evidence that is relevant to the case. The purpose of testing is to establish a transfer of body fluids between the victim and suspect or between the bleeder and crime scene. An example of irrelevant evidence might include looking for the victim's blood on his own clothing or the suspect's semen on his own clothing.

The type and number of items accepted per submission is based on case type. For all case types, known standards from victim(s) or subject(s) will not count against the number of items that may be submitted. An item is expected to be comprised of one piece of evidence (e.g. one piece of clothing, swabbing of blood from a single area, or one weapon). If items are received packaged together, the number of items in the package will be considered to be the number of items submitted (e.g. pants, shirt and shoes packaged together will be considered three items). Typically the flow of evidence starts with the Biology Section.

18.1 Prioritization

The order of analysis of cases will depend on several factors including the needs of the public, courts, and the police department. However, in general, cases for violent crimes which contain all the components necessary for a proper examination will be given priority.

18.2 Examination of Biological Evidence

18.2.1 Sexual Assault Evidence

- The first submission is limited to a sexual assault evidence kit plus one pair of underwear (if not already in the kit) and one condom, if applicable. If necessary, multiple items (limited to 5) may be submitted on this lab request with understanding from both the analyst and the Detective that the additional items will be processed only if no biology results are obtained.

- If probative biology results are obtained, additional items will not be examined, unless case circumstances dictate the need for additional processing.

- If no probative results are found, clothing or bedding may be submitted in separate submissions – limited to 5 items per submission.

18.2.2 Homicides

- Biology evidence is limited to 10 items per submission.

- After a report has been issued on the first set, the next tier of probative items, (maximum of 10 items) may be submitted upon consultation with case analyst, section supervisor or CODIS administrator.

18.2.3 Burglary/Property Crimes

- The first submission is limited to 2 items for biology - typically blood sample(s) from the scene, or items left by the perpetrator (cigarette butt, item of clothing); unless case circumstances (such as multiple suspects) dictate the need for additional analysis.

- If a profile is developed, additional items will not be examined.

18.2.4 Robbery and ADW

- Biology evidence is limited to 5 items per submission.

- After a report has been issued on the first set, the next tier of probative items, (maximum of 5 items) may be submitted upon consultation with case analyst, section supervisor or CODIS administrator.

18.2.5 Touch or Handled Items

- Touch evidence will be accepted for possible STR DNA analysis when there is a high degree of likelihood that the evidence submitted will provide probative results or investigative leads. A high degree of likelihood may be established by means of witness corroboration, visual monitoring systems, or sound deductive reasoning.

- With the exception of violent crimes, touch evidence will be processed only when no other probative evidence exists.

- Touch evidence will be processed by the Biology section only if it has not been previously processed by another discipline.

- Items submitted for touch evidence processing will comply with existing policy relating to the number of items of evidence that may be submitted based upon case type.

- Elimination standards or suspect standards must be submitted with touch evidence where appropriate (e.g. owner of stolen vehicle used in a violent crime such as carjacking).

- Drug packaging, credit cards, money or community areas such as countertops from a hotel/bank for DNA will not be processed due to the number of individuals that have access to these items.

- The gun and magazine found in the gun are the only items that will be processed in possession cases; however, guns that have been taken off of the suspect will not be processed.

18.2.6 Re-examination

- The Biology Section does not accept requests for the same evidence to be re-analyzed in the same fashion. If an item has been processed in another section, it can only be processed by the Biology section for a body fluid (blood, semen, saliva or wear area).

- The CMPD lab policy is available in QM 4.4.7.

18.2.7 Exceptions

- Due to their nature, exceptions may be made for Cold Cases. This will have to be taken under consideration both by the Chief Criminalist of the Biology Section and the Laboratory Director.

- The Chief Criminalist or a DNA Team Leader may approve an exception to this Case Acceptance Policy, but it should be performed sparingly. If a particular exception is employed routinely, this manual should be amended to reflect the new policy.

- If a case has been accepted in PLIMS, then the exception has been approved. The exception will be documented in PLIMS.

19. Case File Forms

It is important to note that while not all forms will necessarily appear in every case folder, the ones that do will be controlled documents. The analysts and reviewers must decide if the information is properly contained within the case folder so that a competent analyst can determine what tests were performed and if the results justify the conclusions. If a form is not used; however, the analyst must document all the necessary controls and the case information on the note sheet.

Pages in this section are not numbered to limit the number of pages printed when corrections or additions are made.

All case file notes will be scanned into PLIMS.

20. COmbined DNA Index System (CODIS)

CODIS (COmbined DNA Index System) is a collection of databases from forensic laboratories across the United States. The CODIS software is designed by and provided to CMPD by the FBI. Updates to the software may periodically be provided by the FBI and/or its contractors. DNA profiles of convicted offenders and forensic evidence are collected and maintained in files and compared to profiles collected from criminal evidence. CODIS consists of three levels: local (LDIS), state (SDIS), and national (NDIS). Profiles collected at the local level are uploaded to SDIS and searched at the state level. Profiles that meet criteria for national searches are then uploaded to NDIS.

20.1 CODIS Administrator

One employee will be designated as the local CODIS Administrator and one employee will be designated as the back-up Administrator. The CODIS Administrator and back-up Administrator must successfully complete CODIS software training within six months of assuming the position and FBI QAS auditor training within one year of assuming the position. The CODIS Administrator and back-up Administrator will maintain the FBI security clearance required to become a CODIS user. The CODIS Administrator will be responsible for management of the local database and will have all administrative rights, including, but not limited to: compliance with CODIS security requirements, compliance with QAS 17, ensuring CODIS users successfully complete the required Annual Review of DNA Data Accepted at NDIS training, upload of profiles to SDIS and review of CODIS generated reports, review and make best efforts to Disposition Matches in accordance with Chapter 6.0 of the NDIS Operational Procedures Manual, review and implementation of all CODIS materials and changes to NDIS Operational Procedures, backup of CODIS data, processing of incoming and outgoing search requests, and communication with other laboratories and law enforcement agencies regarding candidate matches. The CODIS Administrator will be responsible for ensuring the Biology section is in compliance with NDIS sample acceptance policy and for the completion of all paperwork required for participation in NDIS. The CODIS Administrator also has the authority to terminate an analyst's or the laboratory's participation in CODIS until the reliability and security of the computer data can be assured if an issue with the data is identified. Additionally, it is also the CODIS Administrator's responsibility to provide CODIS training to analysts and to inform analysts of any new NDIS procedures and software upgrades.

20.2 Definitions

This list only includes definitions of samples/categories that currently may be in use by the CMPD laboratory. The complete list of NDIS definitions can be found in the NDIS Operational Procedures Manual.

Arrestee: The known sample from a person who has been arrested and in accordance with the law of the applicable jurisdiction is required to provide a DNA sample for analysis and entry into a state DNA database. The term “arrestee” includes persons who have been charged in a formal criminal instrument such as an indictment.

Biological Child: The known reference sample voluntarily provided by an adult child or provided with the parental/guardian consent for a minor child of a reported missing person.

Biological Father: The known reference sample voluntarily provided by the biological father of a reported missing person.

Biological Mother: The known reference sample voluntarily provided by the biological mother of a reported missing person.

Biological Sibling: The known reference sample voluntarily provided by the full or half biological adult sibling or provided with the parental/guardian consent of a full or half biological minor sibling of a reported missing person.

Convicted offender: The known sample from a person who was been convicted of a Federal, Military, or State qualifying offense in a jurisdiction that requires that persons convicted of enumerated crimes or qualifying offenses provide a DNA sample for analysis and entry into a Federal, Military, or State database.

Core Loci: The thirteen loci identified by the FBI for use in CODIS. The core loci are D3S1358, vWA, FGA, D8S1179, D21S11, D18S51, D5S818, D13S317, D7S820, D16S539, TH01, TPOX, and CSF1PO. In addition, the PowerPlex 16 amplification kit provides the user with the pentanucleotide loci Penta D and Penta E. The Identifiler amplification kit provides the user with the D2S1338 and D19S433 loci. These four additional loci are acceptable for searching at the local and state levels.

Deduced Missing Person *or* Deduced Victim Known: The DNA profile of a reported missing person that has been generated by examining intimate items purported to belong to the missing person (such as a toothbrush) and compared to close biological relatives, if possible.

Detainee: The known reference sample from a non-United States (U.S.) person detained under the authority of the U.S. and required by law to provide a DNA sample for analysis and entry into a State/National DNA database.

DNA profile: The genetic constitution of an individual at defined locations (also known as loci) in the DNA.

DNA record: A database record that includes the DNA profile as well as data required to manage and operate NDIS, i.e., the Originating Agency Identifier which serves to

identify the submitting agency; the Specimen Identification Number; and DNA personnel associated with the DNA profile analyses.

DNA sample: Tissue, fluid, or other bodily sample of an individual on which DNA analysis can be carried out.

Forensic Mixture: A specimen category that originates from a forensic sample (biological sample found at the scene of a crime) that contains DNA contributed from more than one source attributable to a putative perpetrator(s).

Forensic Partial: A profile originating from a single source (or a fully deduced profile originating from a mixture) forensic sample attributable to the putative perpetrator with either locus or allelic dropout at any of the 13 core CODIS loci.

Forensic Sample: A biological sample originating from and/or associated with a crime scene and whose source is attributable to a putative perpetrator. These are not known reference samples from known individuals, such as from victims, suspects, and offenders.

Forensic Unknown: A profile originating from a single source (or a fully deduced profile originating from a mixture) forensic sample attributable to the putative perpetrator.

Maternal Relative: The known reference sample voluntarily provided by a maternal biological relative who is not a mother, child, or sibling of a reported missing person.

Missing Person: The known reference sample from an individual that is missing. The source of the DNA has been verified as originating from the missing person.

Paternal Relative: The known reference sample voluntarily provided by a paternal biological relative who is not a father, child, or sibling of a reported missing person.

Pedigree Tree Index: This index consists of DNA records of relatives and spouses of missing persons that are associated with a Pedigree Tree.

Unidentified Human: The DNA profile from the recovered deceased (including body parts and tissue) or an individual who is unidentified (e.g., children who can't and others who can't or refuse to identify themselves).

20.3 Procedures for Sample Entry

20.3.1 Acceptable Samples for Entry

1. Forensic profiles that are unambiguously attributable to victims or to elimination samples will not be entered. If a buccal standard has been submitted and it is not known whether it should be classified as an elimination sample, the

investigator must be contacted and the supporting documentation placed into the case file.

2. Buccal standards submitted either as elimination standards or packaged in elimination envelopes will not be used for statistical calculations or CODIS entry. Although statistics from forensic profiles that are consistent with elimination buccal swabs may be calculated and placed in the case file, these standards may be used for comparison purposes only and a statistic will not be reported. An elimination sample is defined as one collected from an individual known not to be a suspect in the case. Elimination samples can include spouses, boyfriends, girlfriends, witnesses, officers, or any other individual who may have had access to the crime scene or the evidence.

3. Missing Person, Deduced Missing Person, and Deduced Victim Known samples are treated as reference standards and will be entered into the Missing Persons Index.

4. Samples from biological relatives will be stored in the Relatives of Missing Person Index. These profiles are not able to be uploaded to SDIS; therefore, coordination of STR data entry is necessary with other external laboratories (i.e. mitochondrial DNA testing is being conducted on the sample for NDIS upload). Once the individual has been identified for which this biological relative sample is in the index, the biological relative profile must be removed.

5. A forensic unknown DNA record originating from a single source (or a fully deduced profile originating from a mixture) having all 13 core CODIS loci shall not have more than 3 alleles at one locus while the remaining loci can have up to 2 alleles (this allows for one true tri-allelic pattern).

6. A forensic partial DNA record originating from a single source (or a fully deduced profile originating from a mixture) with either locus or allelic dropout at any of the 13 core CODIS loci shall not have more than 3 alleles at one locus while the remaining loci can have up to 2 alleles (this allows for one true tri-allelic pattern).

7. A forensic mixture DNA record shall not have more than 4 alleles at any locus. Forensic Mixtures will consist of ambiguous alleles and/or alleles that are attributable to known suspect(s) and originate from non-suspect sources (vaginal swabs, victim's clothing, etc.). Alleles that can be unambiguously attributed to victims or to elimination samples will not be entered. Any loci in which ambiguity exists in the assignment of alleles to the putative perpetrator (i.e., potential masking, alleles of similar peak height, etc) may be entered at the analyst's discretion.

8. Forensic mixture and forensic partial DNA records submitted to CODIS shall be reviewed to ensure the DNA record(s) satisfy an NDIS statistical threshold for

moderate match estimate (MME) of 10 million (1.000E+007). If these records do not meet the MME at NDIS the profile(s) will be calculated against the SDIS statistical threshold for the MME of 15,000 (1.500E+004).

a) This value will be calculated in PopStats. The MME value is equal to the average inverse match rarity estimate (MRE), which is listed on the Match Estimation Report. The analyst will calculate the average inverse MRE value using the Match Estimation Report and hand write it in scientific notation on the paperwork. This will be done prior to turning the case file in for technical review. The MME and average inverse MRE will be calculated using the NIST combined STR population database.
b) Only the 13 original core CODIS loci shall be used with the MME.
c) Required alleles can be entered in this calculation.
d) All partial profiles being considered for CODIS entry will be searched against the MME. For loci with "allele, any" only the called allele will be entered when conducting the MME. For loci with an obligate allele, the required allele designation will be used.
e) All mixture profiles being considered for CODIS entry that have no more than 4 alleles at any locus will be searched against the MME. Only the portion of the mixture that is used for comparison will be searched.
f) Factors to consider in determining if a mixture or partial profile should be entered into CODIS may include: is the case unsolved, case scenario, would useful information be gained by a search of that profile, etc
g) If a search of multiple profiles in a case show that multiple profiles may be suitable for CODIS entry, the decision of which profile(s) will be entered will be made by the CODIS Administrator or back-up Administrator.
h) The results of any search conducted using the MME will be placed in the Administrative section of the case file. The technical reviewer will initial and date the search results during their review to ensure accuracy of the sample types used in the MME. If deemed necessary during technical review, the MME may be re-calculated and re-checked by the technical reviewer.
i) At the discretion of the CODIS Administrator or back-up Administrator, forensic mixture and forensic partial profiles being considered for CODIS entry that do not meet the MME threshold for upload to NDIS or SDIS may potentially be uploaded and/or searched at LDIS. The MME may be used to assist in this decision.

9. DNA records submitted to the Forensic, Forensic Mixture, or Forensic Partial Indexes at NDIS shall only offer those alleles that are attributed to the putative perpetrator(s). Alleles derived from forensic DNA records that are unambiguously attributed to a victim or individuals other than the perpetrator(s), such as an elimination sample, shall not be offered to NDIS.

10. Known reference samples from individuals identified as a suspect in an investigation will be entered as suspect knowns. In addition, samples that originate from a source attributable to the suspect (such as the suspect's profile

on the suspect's own clothing, cigarette butts, chewing gum, etc.) will also be classified as suspect knowns as opposed to forensic unknowns. For purposes of NDIS eligibility, an item taken directly from a suspect shall not be considered a forensic sample.

11. Mass screening samples (those collected from known individuals that have been obtained through DNA dragnets in an effort to solve a crime) will not be entered.

12. No samples will be entered into the Suspect Known index without proper documentation. This documentation will normally consist of a CMPD laboratory Service Request with the subject's name listed in the Suspect Information box. Written documentation, such as a memo or email from the investigator or the KBCOPS suspect report, will suffice so long as the subject's name is listed in the document and is confirmed to be a suspect. An alternate suspect reference, such as a cigarette butt, may be entered as a suspect known so long as the item is known by the submitting officer to have originated from the suspect. Written communication from the case investigator stating the item originated from the suspect must be in the case file; acceptable documentation includes an email from the investigator or noted on the laboratory Service Request. For both buccal swabs and alternate known standards, oral communication with the case detective and a subsequent communication log is not an acceptable means of documenting the origin of a suspect sample; the exception to this is a case review meeting with the detective(s) to discuss the case as a whole. In the absence of acceptable documentation, the known sample will be treated as an elimination standard and any matching evidentiary profiles will be treated in a corresponding manner.

13. A minimum of five core loci are required for upload of Forensic Unknown, Mixture, and Partial records to SDIS. The CMPD laboratory requires at least seven loci in order to be an interpretable profile; therefore, profiles with any less than seven loci will generally not be entered into CODIS. Documentation of CODIS entry exceptions will be noted in the case file by the CODIS Administrator or back-up Administrator.

14. A minimum of thirteen core loci are required for upload of Forensic, Unknown samples to NDIS. A minimum of eight core loci are required for upload of Forensic, Mixture and Forensic, Partial samples to NDIS.

15. Required alleles may be used for the entry of mixture profiles and partial profiles. Only one required allele may be designated for each locus. The designation of a required allele is indicated by a plus (+) after the allele. Searching profiles with required alleles will only show match candidates that have the designated required allele at a particular locus. Required alleles may not be used for profiles developed from unidentified human remains.

16. No forensic samples will be entered into the Forensic Unknown, Mixture, or

Partial Indexes without proper eligibility documentation. Sufficient eligibility documentation must consist of the following: a crime must have occurred, the profile must be generated from evidence items collected from a law enforcement agency, documentation exists showing how the evidence item is linked to the suspect of the crime, and the item must not have been collected from the suspect's person or in the possession of the suspect when collected. This may entail a review of the item description in plims, the crime scene report, and the investigator's report. It may be necessary to consult with the case investigator if the crime scene report or investigator's report cannot be accessed through the online KBCOPS reporting system. Supporting eligibility documentation will be placed in the case file if not already present. Casework analysts will be responsible during technical review for verifying a profile(s) is allowable for upload to NDIS. A profile will not be entered into CODIS for searching against the Local CODIS database only; the profile must meet NDIS entry eligibility criteria if it is to be entered and maintained in CODIS. If the profile is determined to be unallowable at NDIS (for example, the profile was obtained from evidence that could not be linked to the crime scene), then it will not be entered into CODIS and will be considered suitable for comparison purposes only. If a profile is entered into CODIS and then later found to be unallowable at NDIS, the profile will be removed from CODIS. The CODIS Administrator will provide NDIS-acceptable data training to analysts as needed. Documentation that training was completed will be maintained by the CODIS Administrator.

17. Profiles will not be entered until technical review is complete. Analysts will enter their associated case profiles. The CODIS Administrator or back-up Administrator may enter an analyst's case profiles in place of the analyst and the profiles will be manually assigned to the analyst. The Specimen Detail Report(s) will then be given to the technical reviewer (or another qualified DNA analyst if the technical reviewer is not available) to verify appropriate samples and types have been entered correctly into CODIS. The Specimen Detail Report(s) must be verified prior to the State upload.

18. For forensic profiles developed from "touch" items, elimination standards (i.e. buccal swabs from a car owner(s) whose car was stolen) must be submitted before the profile can be entered into CODIS.

19. If a profile developed from forensic evidence is not initially entered into CODIS and then it is entered at a later time, a laboratory report will be issued to notify the investigator that the profile has been entered into CODIS and is being searched on a routine basis.

20. While NDIS allows for composite DNA profiles to be entered into CODIS, the CMPD Biology section does not currently report composite DNA profiles; therefore, composite DNA profiles will not be entered.

21. Evidence analysis may periodically be outsourced to a vendor laboratory. The

use of the vendor laboratory must comply with Standard 17 of the FBI QAS Standards. In general, CODIS entry eligibility will be reviewed prior to a case being sent for outsourcing; however, in some circumstances CODIS entry eligibility may instead be conducted upon return of the data from the outsourcing laboratory. Upon data review by a qualified analyst(s) in the CMPD laboratory, the evidence profile(s) will first be searched against the CMPD Staff Index before entering the profile(s) into CODIS. The DNA profile will be considered the property and responsibility of the CMPD DNA lab.

22. Missing persons and unidentified human remains cases may be sent to an FBI-approved external laboratory for analysis. Since data may consist of various DNA technologies, data entry will be conducted in coordination with the external laboratory. Data entry may be done exclusively by the external laboratory.

20.3.2 Specimen Identification

Each sample entered into CODIS will be entered into the appropriate index based upon the sample type. Each sample will also receive a unique identifier. Samples generated from casework will be numbered with the twelve digit complaint number followed by the DNA number that has been generated by the PLIMS in the following format: xxxxxx-xxxxxx/yy-yyyyy where "xxxxxx-xxxxxx" is the complaint number and "yy-yyyyy" is the DNA number. Profiles that have been generated by vendor laboratories and whose ownership becomes that of the CMPD DNA lab will be given either a specimen identification number as described above or a unique identification number created by the CODIS Administrator or the back-up Administrator.

The following guidelines will be used to determine specimen category:

If the profile is single source or fully deduced/major from a mixture:

- *Are there results at 13 core loci?*

  Specimen category = Forensic, Unknown
  Partial? = No

- *Are there results at less than 13 core loci?*

  Specimen category = Forensic, Partial
  Partial? = Yes

Any single source profile or major profile that has an "allele, any" with no allele combinations will have the specimen category of Forensic, Partial.

For any locus that has an “allele, any”, the partial indicator at the locus level will be marked as “Yes”.

EXAMPLE 1:

A single source profile has complete results at all loci except D8S1179, which has an allele call of 8, any. This profile will be entered into CODIS as Forensic, Partial. D8 will be marked at the locus level as partial = “Yes”.

EXAMPLE 2:

A single source profile has complete results at all loci except D2S1338, which has an allele call of 19, any. This profile will be entered into CODIS as Forensic, Unknown. D2 will be marked at the locus level as partial = “Yes”.

If the profile is a mixture:

Specimen category = Forensic, Mixture

There can be no more than 4 alleles at any locus.

The designation of a mixture being marked as partial depends on if the whole mixture or a portion of the mixture is being entered. This will be determined on a per profile basis.

In general, only a portion of the mixture will be entered which indicates partial profile = “Yes”.

Entering all called alleles in the profile generally indicates partial profile = “No”.

For any locus that has an “allele, any”, the partial indicator at the locus level will be marked as “Yes”.

EXAMPLE 1:

The profile being entered is a major group. The original interpretation of the mixture indicated three contributors; however, since the end conclusion is a major group of two contributors the partial profile indicator will be set to “Yes”.

EXAMPLE 2:

The profile to be entered is considered to be from one contributor; however, allelic combinations are present (for example, D8S1179 has 13, 14, 15…indicating the possible combinations of 13, 14; 13, 15; and 14, 15). Since

this scenario allows for the possibility of multiple combinations at this locus, the profile will have the specimen category of Forensic, Mixture.

EXAMPLE 3:

The profile to be entered is considered to be from one contributor; however, an obligate allele is present (for example, D8S1179 has 10*, 13…indicating the possible combinations of 10, 10 or 10, 13. Since this scenario allows for the possibility of multiple combinations at this locus, the profile will have the specimen category of Forensic, Mixture.

Single source or mixture profiles that do not fit the above guidelines will be evaluated by the CODIS Administrator or back-up Administrator to determine the appropriate specimen category for entry.

Forensic partial or forensic mixture DNA records that do not meet the statistical threshold of the MME for acceptance at NDIS, but do meet the statistical threshold for acceptance at SDIS only will be classified accordingly as Forensic Partial-State or Forensic Mixture-State.

Any Forensic mixture or partial profiles deemed suitable for entry at LDIS only will be entered into the specimen category Forensic-LDIS.

The Sample ID will be classified as “Yes” if the source of the sample is known or as “No” if the source of the sample is unknown.

Suspect or staff profiles will be classified as partial profile = “No” if results are obtained for all 16 loci. The profile will be classified as partial profile = “Yes” if 15 or less of the loci have results.

For all forensic samples, the type of case will be noted in the Comments box. Case types include ADW (ADW or aggravated assault), Burglary (burglary or larceny), Homicide (homicide or death investigation), Rape (rape or sexual assault), Robbery (robbery), and Other (the type of crime is not described by one of the others listed). If the sample is from a case worked under a grant, then a notation designated by the CODIS Administrator will be placed behind the type of case in the Comments box.

20.3.3 Sample Entry and Upload

1. Called alleles will be entered as designated by the GeneMapper software. Alleles will be entered as determined by the standardized NDIS allelic ladders described below:

Locus	NDIS allelic ranges
CSF1PO	<6, 6-15, >15
D13S317	<8, 8-15, >15
D16S539	<5, 5-15, >15
D18S51	<9, 9-26, >26
D21S11	<24.2, 24.2-38, >38
D3S1358	<12, 12-19, >19
D5S818	<7, 7-16, >16
D7S820	<6, 6-14, >14
D8S1179	<8, 8-18, >18
FGA	<18, 18-30, >30
TH01	<5, 5-10, >10
TPOX	<6, 6-13, >13
vWA	<11, 11-21, >21
Amelogenin	X, Y
D19S433	<9, 9-17.2, >17.2
D2S1338	<15, 15-28, >28
Penta E	<6, 6-24, >24
Penta D	<2.2, 2.2-17, >17

2. All samples that are to be entered into CODIS will be noted on the CODIS Entry Worksheet and technically reviewed prior to entry.

3. Any modifications to previously entered profiles will be documented and noted in the appropriate case file.

4. Incremental uploads will be performed as scheduled in coordination with the State CODIS Administrator. A full upload will be performed yearly in coordination with the State CODIS Administrator.

20.3.4 Cold Case Profile Entry

1. It is recognized that with cold cases the acquisition of any and/or all elimination standards may not be possible. However, requests for elimination standards in cold cases must be made to the assigned investigator and that request must be documented. Requests for CODIS entry will be on a case-by-case basis. All decisions to enter (or not enter) profile(s) developed from cold case evidence will be made by the CODIS Administrator or back-up Administrator and that decision will be documented.

2. Profiles for potential CODIS entry must be reviewed by the CODIS Administrator or back-up Administrator prior to the analyst submitting a file for technical review. No forensic samples will be entered into the Forensic Unknown, Mixture, or Partial Indexes without proper eligibility documentation. Sufficient eligibility documentation

must consist of the following: a crime must have occurred, the profile must be generated from evidence items collected from a law enforcement agency, documentation exists showing how the evidence item is linked to the suspect of the crime, and the item must not have been collected from the suspect's person or in the possession of the suspect when collected. This may entail a review of the item description in plims, the crime scene report, and the investigator's report. It may be necessary to consult with the case investigator if the crime scene report or investigator's report cannot be accessed through the online KBCOPS reporting system. Supporting eligibility documentation will be placed in the case file if not already present.

3. Forensic profiles must meet all other current NDIS entry eligibility criteria in place at the time of sample entry.

4. If a forensic profile is entered into CODIS and then later found to be unallowable at NDIS (i.e. a forensic sample was found to be consistent with a submitted elimination sample), the profile will be removed from CODIS.

5. Requests by investigators to re-evaluate DNA profiles previously generated, but not entered into CODIS (i.e. the case has become classified as a cold case) will be reviewed and eligibility determined by the CODIS Administrator or back-up Administrator.

20.4 Searches

1. Autosearches of complete profiles in the casework LDIS Indexes will be performed at a minimum of twice per week by the CODIS Administrator or back-up Administrator. A one-locus mismatch search and a search of incomplete profiles in the LDIS Indexes will be conducted twice per year. Local keyboard searches of casework profiles may be performed by the CODIS Administrator or back-up Administrator if necessary (i.e. priority cases or profiles not being entered into CODIS). Keyboard searches will only be performed after technical review of the case file has been completed. NDIS procedural guidelines will be followed for any keyboard search request at the State or National level.

2. It is recognized that profiles may be obtained from evidence that do not meet NDIS entry eligibility criteria (i.e. too few loci, question of probative nature, etc); however, the profile may be considered critical to the case. These will be handled on a case-by-case basis by the CODIS Administrator or back-up Administrator to determine if the profile could potentially be entered or if a one-time search could be conducted. Documentation of CODIS entry exceptions will be noted in the case file by the CODIS Administrator or back-up Administrator.

3. If there is potential for a suspect in an unsolved case to have international connections, the CODIS Administrator or back-up Administrator may submit the profile(s) for Interpol searching following NDIS guidelines.

4. Profiles generated from Officer Involved Shooting (OIS) cases will be reviewed on a case by case basis by the CODIS Administrator or back-up Administrator to determine if any profiles are eligible for CODIS entry and/or searching.

20.5 Maintenance of an Employee (Staff) DNA Index

The laboratory will maintain a DNA index of employees for use in comparison to unknown alleles/profiles generated from evidence to determine if any evidentiary profiles originated from a CMPD employee. This database will consist primarily of employees of Crime Scene Search, Crime Scene Officers, Detectives, and the Crime Laboratory, although other volunteers may be added if appropriate.

Employee profiles will only be used for quality control measures or for CMPD forensic protocol development purposes (i.e. validation studies). These profiles will be maintained in a local Staff Index and will not be uploaded to SDIS. Upon entry of an employee's profile into the Staff Index, it will be marked with an anonymous personal identifier code. The CODIS Administrator and Section Administrator shall maintain the only record which correlates individuals' names with personal identifier codes. The back-up Administrator will have access to this record. Although employee standards may be typed by any qualified Biology section analyst, all Staff profiles will be entered into the Staff Index and assigned their personal identifier code by the CODIS Administrator. A qualified DNA analyst will review profile entry and initial and date the Specimen Details Report. As new Staff profiles are entered into the Index the CODIS Administrator will conduct an Autosearch against all previously entered forensic profiles.

20.5.1 Conducting searches against the Staff Index

1. A keyboard search of the Staff Index by the case analyst will be done prior to issuance of a case report. The search will be conducted for all forensic evidence profiles that do not match any known reference samples in the case. Any profiles that are deemed uninterpretable will not be searched against the Index. For mixture profiles, only the portion of the mixture that is being used for comparison will be searched. If a mixture profile is obtained and a major or foreign profile can be determined, the analyst will search both the major or foreign profile and the minor profile (if the minor profile is deemed suitable for comparison).

2. The search will be done at moderate stringency and a copy of the Match Detail Report will be maintained in the case file for documentation.

3. If a single source profile match is made to the Staff Index, the analyst will immediately notify the CODIS Administrator or the back-up Administrator to resolve the match. If a match of the forensic profile to a profile in the Staff Index cannot be resolved the Section Administrator/Technical Leader will be informed.

If the match is to a Biology section employee, a Contamination Contingency Plan will be initiated. If the match is to an employee outside of the CMPD Biology section, that employee and that employee's supervisor will be notified. Documentation of this notification will be maintained in the case file. If sample remains, the sample may be re-extracted. If no sample remains, the profile will be reported as not meeting the quality control measures needed for comparison.

4. If a mixture profile match is made to the Staff Index, the analyst will immediately notify the CODIS Administrator or the back-up Administrator to resolve the match. If a match of the forensic profile in the Staff Index cannot be resolved the Section Administrator/Technical Leader will be informed. If the match is to a Biology section employee, a Contamination Contingency Plan will be initiated. If the match is to an employee outside of the CMPD Biology section, that employee and that employee's supervisor will be notified. If sample remains, the sample may be re-extracted. The profile may be used for interpretation if the employee to whom the match was made provides a buccal standard to be analyzed as a case sample and a direct comparison is conducted. If the employee does not provide a buccal standard, the profile will not be used and will be reported as not meeting the quality control measures needed for comparison.

20.6 Generation of Investigative Leads

Investigative leads may be generated either by LDIS, SDIS, or NDIS matches. A match occurs when CODIS makes an association between two or more DNA profiles and a confirmation process is started. A hit occurs when a confirmed or verified match aids an investigation and one or more of the cases(s) involved in the match is unsolved. The procedure for confirming the match will differ depending on the location of the match. All match reports will be reviewed for administrative and/or technical content before being issued to the investigator. The reviewer must currently be a qualified DNA analyst who is proficient in the current technology.

20.6.1 LDIS Matches

Should a match or matches be determined between cases analyzed within the CMPD laboratory, the following will occur:

1. The source ID of the samples will be checked. If the Source ID = No, the confirmation process will be initiated by the CODIS Administrator or back-up Administrator within 30 days of the match. Any sample with a Source ID = Yes will not require confirmation since the source of the sample has already been identified.

2. The data from the appropriate case files will be examined. A copy of the Match Detail Report will be placed in the appropriate case file(s) if it is determined a hit has occurred.

3. The profile will be checked by the CODIS Administrator or back-up Administrator to ensure that it is allowable at NDIS. A notation, along with initials and date, will be

placed on the Match Detail Report by the CODIS Administrator or back-up Administrator to reflect the profile has been reviewed for NDIS eligibility. Supporting eligibility documentation will be placed in the case file if not already present. If the profile is determined to be unallowable at NDIS (for example, the profile was obtained from evidence that could not be linked to the crime scene), the sample will be deleted from the system and appropriate documentation will be placed in the case file. If the profile is allowable at NDIS, the process will continue.

4. A match report will be issued to the investigator within two weeks of receipt of the match detail report. Copies of all relevant data will be placed in the appropriate file(s) with "unidentified" source samples; this information will also be scanned and uploaded to PLIMS. In case to case matches where both cases are "unsolved" a report addressing the hit will be issued for both cases. In case to case matches where one case has been "solved", a case event recording will be made in the case correspondence section in the PLIMS system under the "solved" case; this will reflect the match identification number, which complaint # the match was reported under, and the issue date of the match report.

5. Should it be determined after the hit that the source of the sample is one that would normally disqualify the sample from CODIS entry (for example, the source would be classified as an elimination), the sample will be deleted and the appropriate documentation will be placed in the case file.

6. Matches will initially be given a disposition of "Pending". Upon match confirmation, the disposition of the match will be changed accordingly. Updates to the match can be viewed in the match audit trail in the CODIS program. The CODIS Administrator or back-up Administrator will change the Source ID field for a specimen from "No" to "Yes" as necessary.

20.6.2 SDIS and NDIS Matches

Should a match be determined between a CMPD case and a sample analyzed outside the laboratory, the following will occur:

1. The source ID of the samples will be checked. If the Source ID = No, the confirmation process will be initiated by the CODIS Administrator or back-up Administrator within 30 days of the match. The appropriate CMPD match data request form (found in Biology QA 19) will be used for confirmation requests. The match data request and the accompanying request email will be maintained in the appropriate case file(s).

2. The data from the appropriate case files will be examined. A copy of the Match Details Report will be placed in the appropriate case file(s) if it is determined a hit has occurred.

3. The profile will be checked by the CODIS Administrator or back-up Administrator to ensure that it is allowable at NDIS. A notation, along with initials and date, will be placed on the Match Detail Report by the CODIS Administrator or back-up Administrator to reflect the profile has been reviewed for NDIS eligibility. Supporting eligibility documentation will be placed in the case file if not already present. If the profile is determined to be unallowable at NDIS (for example, the profile was obtained from evidence that could not be linked to the crime scene), the sample will be deleted from the system and appropriate documentation will be placed in the case file. If the profile is allowable at NDIS, the process will continue.

4. All "unidentified" source sample matches will be confirmed and reported. Copies of all relevant data will be placed in the appropriate file(s) with "unidentified" source samples; this information will also be scanned and uploaded to PLIMS.

5. In the event of an offender hit, the CODIS Administrator or back-up Administrator will request confirmation of the match from the offender laboratory. The hit will be confirmed by re-analysis of the convicted offender sample by the offender databasing laboratory. The CODIS Administrator will receive a match report from the offender laboratory. A CMPD match report will be issued to the investigator within two weeks of receipt of the offender laboratory's report. If the investigator chooses to pursue the investigation, he/she will be required to submit a known sample from the matching individual to the laboratory. Analysis will be performed by the original casework analyst, if available, and a report will be issued detailing the comparison between all DNA profiles generated in the case and the known sample.

In instances where Source ID = Yes and the match is to an offender, the name of the individual must be verified with the offender laboratory. If the names of the individuals are the same the match will be given a disposition of "Conviction Match". The match detail report and the accompanying verification email will be scanned and maintained on the CMPD R drive and electronically by the CODIS Administrator and Section Administrator. Information regarding the confirmation of the offender name will also be maintained on the Conviction Match Verifications spreadsheet on the CMPD R drive.

6. In the event of a casework hit (regardless if source ID = "Yes" or "No"), the CODIS Administrator or back-up Administrator will exchange contact information with the external laboratory. A report regarding the hit will be issued to the investigator within two weeks of receipt of the contact information. If an external laboratory requests CMPD case information, the case information will be released using a match data casework response form (found in Biology QA 19). The match data information will be administratively reviewed by a qualified DNA analyst proficient in the current technology prior to the CODIS Administrator or back-up Administrator sending the information to the external laboratory. The review will consist of checking for clerical errors and accuracy of information being released. Upon completion of the review, the reviewer will initial and date the official correspondence. The correspondence

may be sent to the external lab by mail, fax, or email with either the original or a copy maintained in the case file.

7. Should it be determined after hit confirmation that the source of the sample is one that would normally disqualify the sample from CODIS entry (for example, the source would be classified as an elimination), the sample will be deleted and the appropriate documentation will be placed in the case file.

8. Matches will initially be given a disposition of "Pending". Upon receipt of match confirmation from the external laboratory, the disposition of the match will be changed accordingly. Updates to the match can be viewed in the match audit trail in the CODIS program. The CODIS Administrator or back-up Administrator will change the Source ID field for a specimen from "No" to "Yes" as necessary.

9. The CODIS 7.0 program allows for the entry and search of mitochondrial DNA and Y-STR DNA profiles. If potential hits occur using these technologies, the CODIS Administrator or back-up Administrator will contact the lab where the match occurred for guidance in resolving and dispositioning these matches.

20.6.3. Familial searches

1. The FBI has implemented a Plan for the release of information in the event of a potential familial match at NDIS. The purpose of the Plan is to provide guidance to casework laboratories to pursue potential familial matches identified at NDIS in accordance with applicable State law and policies. The CMPD Biology laboratory will not conduct searches for the purpose of generating potential familial matches and any potential familial matches generated by automatic searches from the CMPD Biology laboratory or by an external laboratory will not be pursued for the following reasons: 1) The State of North Carolina does not currently have any legislation regarding familial searching and, 2) The CMPD Biology laboratory does not conduct and is not trained in the statistical analyses required to interpret and request partial match information; these analyses consist of Individual Expected Match Ratios and Expected Kinship Ratios.

20.6.4 Hit Counts and Investigations Aided

The CODIS Administrator will be responsible for tracking all hits and investigations aided. The NDIS guidelines for hit counting and number of investigations aided will be followed. Suspect hits are not defined at NDIS; therefore, any hits between an unsolved case and the suspect index will be dispositioned as "User defined #1". A match between a solved case and the suspect index will be dispositioned as "Investigative Info". Suspect hit information will be provided to the State CODIS Administrator as a "Forensic hit". Hit counting data will be forwarded as scheduled in coordination with the State CODIS Administrator.

20.7 Data Backup

Incremental back-ups on an encrypted thumb drive will be run weekly. Full back-ups on an encrypted thumb drive will be run monthly. Devices associated with weekly back-ups will be stored in a fire-resistant safe located within a secure room of the laboratory. The CODIS Administrator, back-up Administrator, and Section Administrator will have access to the safe. Devices associated with monthly back-ups will be stored in an off-site, physically separate location. Only the CODIS Administrator, back-up Administrator, Section Administrator, and Laboratory Director will have access to this location.

20.8 Annual Review of DNA Records Acceptable at NDIS

1. NDIS requires that each user in an NDIS participating laboratory be reminded annually of the sample types that are acceptable for entry to NDIS. Each user will participate in annual completion of web-based Annual Review of DNA Data Accepted at NDIS training. A certificate of completion will be issued upon successful completion, copies of which will be filed and maintained by both the State CODIS Administrator and the Local CODIS Administrator.

2. Periodically, no less than twice per calendar year, the CODIS Administrator will conduct an internal CODIS audit on completed case files from each qualified DNA analyst to ensure compliance with NDIS eligibility guidelines for sample entry. The CODIS Administrator will initial, date, and write “audit” in the technical review portion of the CMPD DNA case review checklist as documentation of file review. Any violations and subsequent remediation actions will be handled on a case-by-case basis. Any information related to the internal audit (i.e. date of audit, Complaint #, analyst, etc) will also be maintained electronically by the CODIS Administrator and Section Administrator. The back-up Administrator may assist the CODIS Administrator with internal audits and will follow the same documentation guidelines as the CODIS Administrator.

20.9 Deletion of profiles from CODIS

1. The CODIS Administrator and back-up Administrator will be the only people responsible for deletion of profiles from LDIS. A note as to why the profile was deleted will be added to the Comments section of the Specimen Details Report. The Specimen Delete Report will be maintained in the case file. Additionally, delete reports will also be saved by Complaint # as a .pdf file on the CODIS server;

2. If a case profile is deleted from CODIS after a laboratory report has already been issued stating the profile will be periodically searched, a laboratory report will be issued to notify the investigator that the profile has been removed from CODIS and is no longer being searched.

20.10 CODIS Security

1. The CODIS Server shall be in a locked room within the Biology section. Biology section employees are the only individuals to have routine access to this room. Individuals that have key access on an emergency basis only include the Crime Laboratory Directory, the Lab and Evidence Bureau Major, the Deputy Chief of Support Services, the Chief of Police, and the Facilities Planning Manager. Any individuals that are not Biology section employees (i.e. maintenance and equipment service representatives) that need access to the room containing the CODIS server during work day hours will be monitored by Biology section employees.

2. All CODIS users are responsible for CODIS software security. This includes logging out of the CODIS network upon completion of a CODIS session.

3. The CODIS Administrator and back-up Administrator will be the only individuals with Administrator rights privileges to the CODIS server. If deemed necessary, the Section Administrator may be given Administrator rights. A shared user name and password will be utilized by the CODIS Administrator and back-up Administrator to perform shared Administrative tasks only.

4. The CODIS server will be reserved for administrative functions by the CODIS Administrator and back-up Administrator only. Analysts will use the CODIS workstation for CODIS-related functions.

5. The antivirus software definitions will be updated weekly.

21. Guidelines for Response to DNA Discovery Motions

General guidelines for the release of laboratory information are provided in QM 4.13.1.3. Below is a clarification of these policies as they relate to the Biology section.

21.1 Case File Records

A copy of all records kept in the case file will be given to the appropriate requesting person or agency. This will include all records requested, such as hand written notes, computer generated data, worksheets, and reports. The original documents must remain with the case file in the laboratory file room or with a laboratory analyst.

21.2 Laboratory Validation or Supporting Documentation

Some documentation is too voluminous to be copied upon request. Laboratory manuals, validation records, reference articles, proficiency tests, training records, etc., require a large amount of time and resources to duplicate. These items will not be removed from the laboratory for any reason unless accompanied by a laboratory employee. An external party may view any of the above documentation at the CMPD headquarters building if access has been granted. A departmental official must be present during the review of the data by an external party.

21.3 Digital Records

Any computer records directly related to the case in question may be copied onto disks for distribution to the court. CMPD will not provide access to computers, instrumentation, or software which is licensed to the Charlotte Mecklenburg Police Department.