

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

TABLE OF CONTENTS

- 1 Scope of Operations**
 - 1.1. DNA section overview
 - 1.2. History
 - 1.3. Mission Statement
 - 1.4. Goals and Objectives
 - 1.5. Code of Ethics
 - 1.6. Organization and Staffing
 - 1.7. List of Locations, Addresses and Phone Numbers
 - 1.8. Organizational Chart
 - 1.9. Section Descriptions and Responsibilities
 - 1.10. Hours of Operation
 - 1.11. Manuals
 - 1.12. Customer Service
 - 1.13. Management System
 - 1.14. Planning and Development
 - 1.15. Purchasing Supplies and Services
 - 1.16. Management Review
 - 1.17. Equipment and Supply Inventory

- 2 Facility Design and Security**
 - 2.1. Physical Plant/Space and Design
 - 2.2. SecurityAppendix 2A Floor Plan

- 3 Quality Assurance**
 - 3.1. Proficiency testing
 - 3.2. Court Testimony Monitoring
 - 3.3. Case Review
 - 3.4. Laboratory Audits
 - 3.5. Validation
 - 3.6. Instruments and Equipment
 - 3.7. Reagents
 - 3.8. Document Management
 - 3.9. Deviation from Documented Procedures
 - 3.10. Preventive and Corrective Actions
 - 3.11. Suggestions/Complaints
 - 3.12. Customer Survey
 - 3.13. Reference Standards/Materials
 - 3.14. Reference Collections and Databases
 - 3.15. Examination Verification
 - 3.16. Contamination Detection and PreventionAppendix 3.15A Decontaminating Procedures
Appendix 3A Approved Vendors and Suppliers

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

4 Laboratory Records

- 4.1 Case Record
- 4.2 Laboratory Reports
- 4.3 Release of Records Information
 - 4.3.1 Release of Information
 - 4.3.2 Release of Information to the News Media
 - 4.3.3 Open Records Request
 - 4.3.4 Discovery Orders
- 4.4 Removal of Records for Court
- 4.5 Archiving Laboratory Case Files
- 4.6 Expunctions
- 4.7 Control of Laboratory Records
- 4.8 Case File Processing

Appendix 4A Offense Codes

5 Evidence Procedures

- 5.1 General Practices
- 5.2 Observation by Outside Experts
- 5.3 Evidence Disposal
- 5.4 Destruction of Hazardous Substances
- 5.5 Outsourcing

Appendix 5A Abbreviations

6 Laboratory Safety

7 Personnel

- 7.1 Documents
- 7.2 Subpoenas
- 7.3 Private Case Consultations
- 7.4 Testimony for Previous Employers
- 7.5 Attendance
- 7.6 Certification of Analysts
- 7.7 Employee Training Program
- 7.8 Employee Approval for Casework
- 7.9 Employee Career Development
- 7.10 Continuing education
- 7.11 Internship Program
- 7.12 Volunteer Program
- 7.13 Rider Program

8 Computer Resource Management

9 Forms

- 001 Serology Worksheet
- 002 REMOVED

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

003	Sexual Assault Examination Worksheet
004	DNA Extract Log
005	Quantifiler Worksheet
006	9700 Amplification Worksheet
007	PCR Setup
008	7500 Log
009	Amplification Kit Reagent Quality Control
010	Reagent Quality Control Form
011	3130 Plate Record
012	Microcentrifuge Tachometer Log
013	Temperature Log
014	CODIS-Interstate Match Form
015	Serology/DNA Review Form
016	CODIS Entry Form
017	Laboratory Information Sheet
018	Communication Log
019	Thermal Cycler Calibration Log
020	STR Record Sheet
021	REMOVED
022	Analysis Count Sheet
023	Quantifiler Kit Reagent Quality Control
024	Incident Log Tracking Form
025	Bulb Log
026	CODIS Hit Follow Up Form
027	Matrix Log
028	PCR SETUP QIAGILITY
029	PHT CHECKOUT LOG
030	Maxwell Cleaning/Maintenance Log
031	QIAcube Cleaning/Maintenance Log
032	Water Bath Log
033	CE Cleaning/Reagents Log
034	Laboratory Information Sheet-Worksheet
035	CE Setup-QIAGility
036	Screening Chain of Custody
037	DNA Extract Chain of Custody
038	QIAcube Loading Chart-Differential
039	AP LOT TRACKING
040	DNA IQ Kit Reagent Quality Control
041	Swab Solution Kit Reagent Quality Control
042	Investigator Kit Reagent Quality Control
043	DTT QC Form
044	Pro K QC Form
045	CODIS-Interstate Offender Match Form
046	DNA Questionnaire
047	REMOVED
048	REMOVED
049	DNA Inventory Sheet

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Chapter 1 Scope of Operations

1.1 DNA section Overview

The DNA section will follow the guidelines set forth in the Forensic Science Division SOP. Supplemental requirements specific to the DNA section are contained within the Serology/DNA Standard Operating Procedures Manual (SOP), the DNA Technical Manual, and the DNA Training Manual. These manuals combined represent guidelines for the Quality System within the DNA section.

It is not possible to anticipate every situation that may arise or to prescribe a specific course of action for every case; therefore, the examiner must exercise good judgment based on experience and common sense, especially when processing evidence. In some cases, the manual offers guidelines for analysis that must be tempered with the experience of the examiner or via consultation with fellow examiners and the DNA Supervisor and Technical Leader.

Controlled Documents from External Sources

The following documents from external sources will be considered controlled documents for this laboratory and used as reference or guidance material for staff. These controlled documents contain information useful for the lab staff to perform their duties. However, it should not be misconstrued that all details of these controlled documents from external sources are binding on this laboratory. Specific areas of the documents that do apply may be referenced in this document, the DNA technical manual, or the DNA training manual. Other aspects of these documents may, but not required to, be used as reference material as needed. The controlled documents from external sources are:

1. Abacus p30 Test for the Forensic Identification of Semen, Abacus Diagnostics, 5/2011
2. Applied Biosystems 7500/7500 Fast Real-Time PCR Systems System Maintenance, Applied Biosystems, 2010
3. Applied Biosystems 3130/3130xl Genetic Analyzers Getting Started Guide, Applied Biosystems, 6/2010
4. GeneAmp® PCR System 9700 96-Well Sample Block Module User's Manual, Applied Biosystems, 8/2010
5. General Principles of Microscopes, Internal, Collated 2014
6. Maxwell® 16 Instrument Operating Manual, Promega, 6/2008
7. Mikro 220 Centrifuge Operating Instructions, Hettich, 2011
8. Optimizer PCR Workstation Instruction Manual, CBS Scientific, 3/2013
9. Protocol Sheet - DNA Pipetting Epithelial And Sperm Cells Separation And Lysis ID2451 V1, Qiagen, 2011
10. ProtocolSheet - DNA QIAamp DNA Investigator Forensic Casework Samples Lysis And Purification V2, Qiagen, 5/2008
11. QIAcube® loading chart, Qiagen, 5/2008
12. QIAcube® User Manual, Version 1.1, Qiagen, June 2008
13. QIAgility™ User Manual, Qiagen, September 2009

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

14. Savant DNA 120 SpeedVac Concentrators, Thermo Scientific, 2008

1.2 History

No Supplemental Requirements

1.3 Mission Statement

No Supplemental Requirements

1.4 Goals and Objectives

No Supplemental Requirements

1.5 Code of Ethics

No Supplemental Requirements

1.6 Organization and Staffing

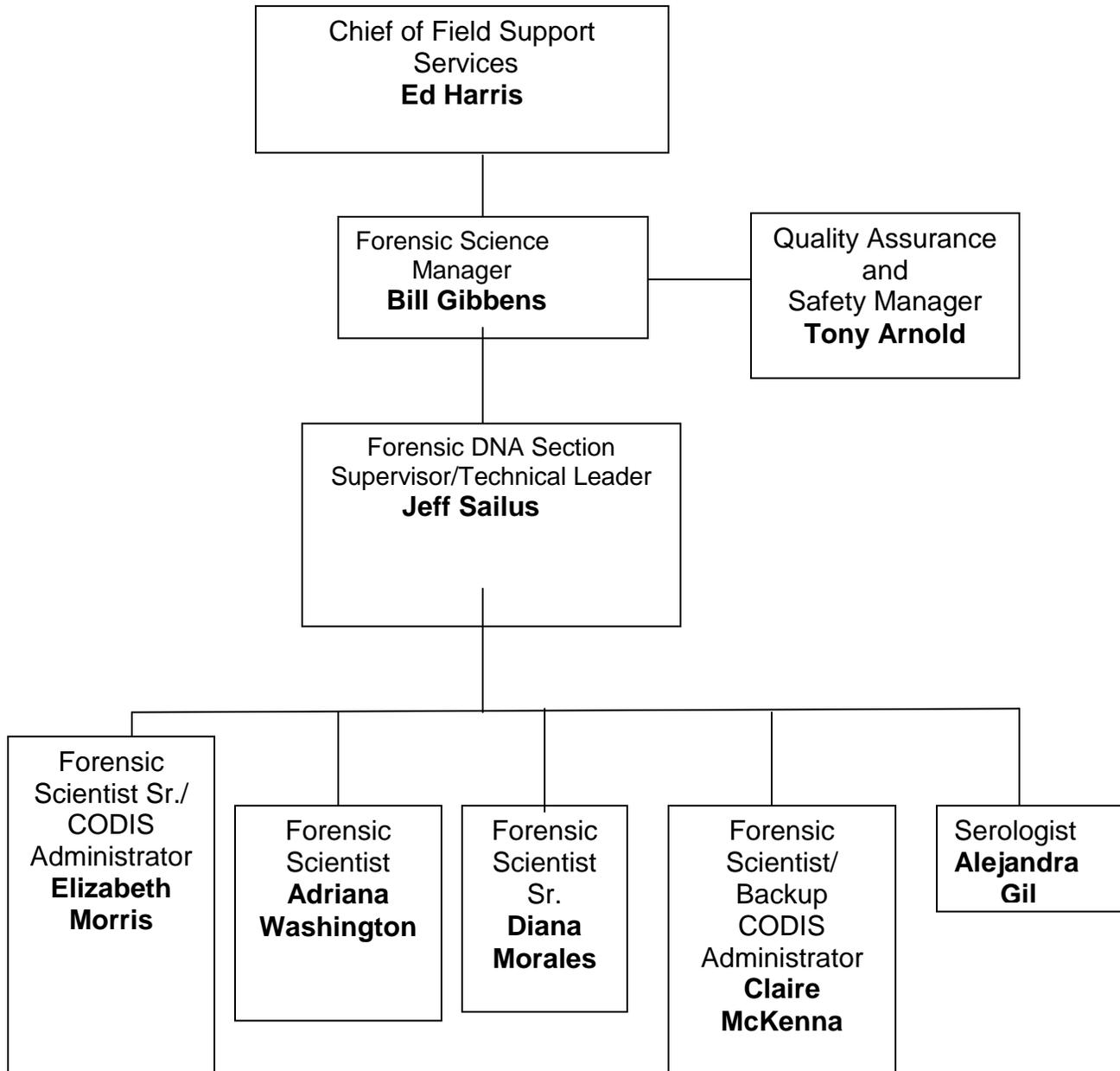
No Supplemental Requirements

1.7 List of Locations, Addresses, and Phone numbers

No Supplemental Requirements

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

1.8 Organizational Chart



**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

1.9 Section Descriptions and Responsibilities

No Supplemental Requirements

1.10 Hours of Operation

No Supplemental Requirements

1.11 Manuals

No Supplemental Requirements

1.12 Customer Service

No Supplemental Requirements

1.13 Management System

Authority/Responsibility for the Management System

- DNA Forensic Scientist Supervisor

The DNA Supervisor will have a B.A./B.S. or graduate degree or its equivalent in a biology, chemistry, or forensic science related area. The DNA Supervisor will also have completed college course work in the areas of Biochemistry, Genetics, and Molecular Biology. College course work or training in the subject area of statistics and/or population genetics is also required. If the Supervisor is a working analyst, he/she will be trained in the appropriate procedures and will be current in proficiency testing.

- DNA Technical Leader

The FBI has mandated that each DNA laboratory employ a Technical Leader. The Technical Leader and Supervisor roles may be combined. The Technical Leader is responsible for implementation and execution of valid analysis procedures as well as oversight of training, quality assurance, safety, and proficiency testing.

The Technical Leader shall be accessible to the laboratory during times of laboratory operation.

The Technical Leader is accountable for the laboratory's quality assurance program to the extent that he/she has the authority to terminate the laboratory's or an individual's testing in the event of a technical problem until the problem is resolved. Technical Leaders have duties as specified by the FBI for technical leaders in general.

In the event that the DNA Technical Leader is no longer able to perform the duties of Technical Leader, the following plan will immediately take effect:

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

- A currently employed and active duty DNA analyst meeting the minimum requirements of the Technical Leader position will be appointed as Interim Technical Leader. The position will then be posted and filled according to City policy within 90 days.
- In the case that no currently employed or active duty analysts meet the minimum requirements of the Technical Leader position, the FBI will be contacted and this contingency plan will be submitted within 14 days. The plan will be that a Technical Leader will be contracted by the laboratory for a maximum of 90 days to allow the City posting and hiring process to take place. During the time that the Technical Leader position becomes vacated and the contingency plan is approved no new DNA casework will be started.

The DNA Technical Leader will have a graduate degree in a biology, chemistry, or forensic science related area and a minimum of 12 credit hours or its equivalent including a combination of graduate and undergraduate coursework covering the subject area of Biochemistry, Genetics, Molecular Biology, and Statistics and/or Population Genetics. If the DNA Technical Leader is a working analyst, he/she will be trained in the appropriate procedures and will be current in proficiency testing.

The Technical Leader is responsible for overseeing the technical operations of the DNA lab and technical problem solving of analytical methods Any technical problem in the laboratory requiring correction beyond routine maintenance by the examiner must be brought to the attention of the Technical Leader.

The duties of the DNA Technical Leader are as follows:

- Keeps lab Supervisor informed on technical issues
- Oversees QA/QC program for section and keeps proper records
- Maintains proficiency in current methods of analysis
- Oversees proficiency testing of analysts
- Performs technical and administrative reviews (if at one time proficient in the analysis being reviewed)
- Responsible for technical problem solving and analytical methods
- Oversees safety practices
- Makes technical decisions on casework
- If technical issues cannot be resolved, informs supervisor of problem
- Evaluate and document approval of validations of new instrumentation and methods
- Oversees training and evaluates competency of analysts and trainees (including transcripts and training records), and recommends trainees for approval to do casework
- Oversees maintenance of equipment and keeps proper records
- Oversees the QA/QC of reagents, kits, and instrumentation
- Recommends continuing education of analysts
- Maintains reference material and library
- Keeps informed on new technologies and legal issues
- Recommends new equipment or facility changes to lab Supervisor
- Recommends procedure manual updates, keeps SOP current

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

- Monitors courtroom testimony of examiners
- Review and document the review of internal and external audits and, if applicable, approve corrective action

- Local CODIS Administrator

See appendix 8 in the DNA Technical Manual

- DNA Forensic Scientist

The DNA Forensic Scientist will have a B.A./B.S. degree or its equivalent in a biology, chemistry, or forensic science related area. The DNA Forensic Scientist will also have successfully completed a minimum of 3 college courses in the areas of Biochemistry, Genetics, and Molecular Biology totaling a minimum of 9 credit hours prior to beginning DNA training. College course work or training in the subject area of statistics and/or population genetics is also required.

The DNA Forensic Scientist will be responsible for preservation, characterization, collection, documentation, and DNA typing of evidence while following guidelines contained within the DNA Section SOP. The DNA Forensic Scientist will also be available to testify in court to present the facts obtained within a case. The DNA Forensic Scientist is responsible for maintaining the chain of custody of the evidence while it is in their possession. The DNA Forensic Scientist will stay proficient in all disciplines in which casework samples are being processed as required by the FBI DNA Quality Assurance Audit Document. The DNA forensic scientist will help with validation, training, QC, reagent preparation, etc. as required by the DNA Supervisor and/or Technical Leader.

- DNA Forensic Scientist Senior

The DNA Forensic Scientist Senior will meet all the requirements of the DNA Forensic Scientist as well as have three years forensic DNA casework experience, not including training. The three years of experience will include all aspects of the typing process from extraction to interpretation with report signing capabilities. Additional requirements set forth by Human Resources may apply.

- Serologist

The Serologist will have a B.A./B.S. degree or its equivalent in a biology, chemistry, or forensic science related area.

The Serologist will be responsible for preservation, characterization, collection, and documentation of evidence while following guidelines contained within the DNA Section SOP. The Serologist will also write reports and be available to testify in court to present the facts obtained within a case. The Serologist is also responsible for maintaining the chain of custody of the evidence while it is in their possession. The Serologist will stay proficient in methods in which casework samples are being processed.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

- Technician

The technician will have a minimum of 48 college credit hours to include a minimum of 8 biology or chemistry credit hours.

The technician will perform laboratory duties to include reagent preparation, equipment QC, validation, and other lab maintenance duties as needed. The technician may also be responsible for preservation, presumptive testing, collection, and documentation of evidence while following guidelines contained within the DNA section SOP. The technician will also maintain the chain of custody of the evidence while it is in their possession and be available to testify in court. The technician will pass a competency test for the techniques he/she will perform on evidence items. The technician will not interpret data, reach conclusions on typing results, or prepare final reports and will be supervised by a qualified analyst.

- Laboratory Technical Support Personnel

Laboratory technical support personnel will have a minimum of a high school degree.

Laboratory technical support personnel will perform laboratory duties exclusive of analytical techniques on forensic evidence. The duties will include reagent preparation, equipment QC, validation, and other lab maintenance duties as needed. They will have documented training specific to their duties (QAS 5.7).

1.14 Planning and Development

No Supplemental Requirements

1.15 Purchasing Supplies and Services

No Supplemental Requirements

1.16 Management Review System

No Supplemental Requirements

1.17 Equipment and Supply Inventory

No Supplemental Requirements

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

2 Facility Design and Security

2.1 DNA Section Physical Plant/Space and Design

The Serology/DNA laboratory will have space for evidence examination, DNA extraction, PCR setup, and amplified DNA product. Refer to Appendix 2A Floor Plan for the location of these areas.

The evidence examination area, DNA extraction area, and PCR setup area will be separate from each other. This can be accomplished by maintaining separate physical spaces for each task or by conducting these tasks at separate times. If conducted in the same space at separate times, the space will be decontaminated between tasks.

The amplified DNA product area will be physically separate from all other areas. Entrances to the amplified product area will have a door.

- Evidence Examination Area

The serological examination of evidence will primarily be performed in the screening rooms. Equipment in the main lab, such as ovens, centrifuges, and microscopes, may also be used. The tasks performed will include all screening, trace evidence collection (if applicable), body fluid identification testing, selection and cutting of stains, and body fluid extraction for serological tests.

- DNA Extraction Area

The extraction of known and questioned evidentiary samples will be performed in the DNA extraction area. The tasks performed will include DNA extraction, purification, and concentration. Microscopy may also be performed in this area.

- Quantitation Setup Area

Quantitation setup will be performed in the quantitation setup area.

- PCR Setup Area

The setup of PCR amplification reactions will be performed in the PCR setup area, or Reagent Prep lab as listed on the floor plan. All amplification setup steps including adding template DNA will be performed in the PCR setup area. A laminar flow hood or PCR setup hood dedicated to amplification setup is recommended. A UV light may be run after setup.

- Amplified DNA Product Area

The generation, analysis, and storage of amplified DNA product will be in the amplified DNA product area. Once amplified, no samples will leave the amplified DNA product area unless securely packaged. Equipment, reagents, and supplies in the amplified product area are dedicated and will not be removed unless properly decontaminated.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

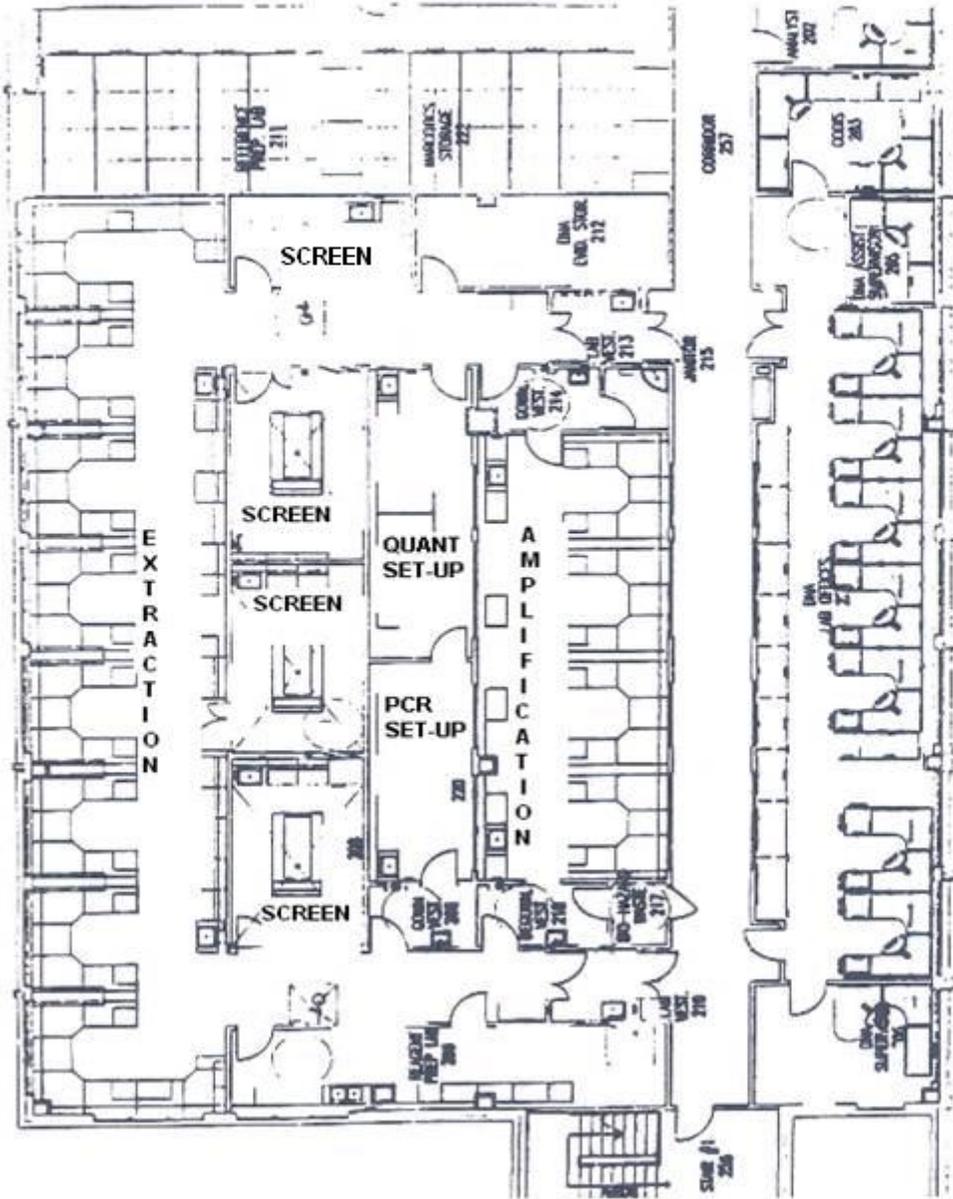
2.2 Security

Short term storage of evidence and cuttings/swabs in the DNA section will be in the screening rooms. These doors will be locked when the laboratory is unoccupied. When screening rooms are shared, the analyst in control of the evidence should not leave open unsealed evidence unattended. If the analyst does need to exit the laboratory (i.e. return to the main hallway or central offices) before the evidence screening is completed, care should be taken to ensure the security of the unsealed evidence (i.e. locking in a cabinet and taking the key, re-sealing the evidence, locking the screening room door with a clear note outside to indicate that the room contains open evidence, etc)

Long term storage of evidence will be in the evidence storage room and will include the walk in freezer, supplemental freezer, and the evidence shelves. The door to this room will be locked when the laboratory is unoccupied. DNA extracts will be stored short term in refrigerators in the extraction lab during processing. After processing, they will be stored in the walk in freezer. Evidence swabs and cuttings will be stored short term (during processing) in the screening room or extraction area refrigerators and will then be stored in the walk in freezer for long term storage.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Appendix 2A



**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

3 Quality Assurance

3.1 Proficiency Testing

The process for administering and completing proficiency tests is outlined in the Division wide SOP. In addition:

1. The interval between consecutive tests must be at least four months and not to exceed eight months. The submitted date of the proficiency test will serve as the date for calculation of the aforementioned time frame.
2. All CODIS core loci will be attempted for all samples on DNA proficiency tests.
3. The DNA Technical Leader will maintain a copy of the analysis documentation for each proficiency test as well as any documentation of discrepancies/errors and subsequent corrective actions.
4. Newly qualified analysts will be proficiency tested within 6 months of the date of their qualification.
5. Each analyst will complete their own proficiency test.

All final reports will be graded as satisfactory or unsatisfactory. A "Satisfactory" rating on the Proficiency Review Form (FSD 009) indicates that all reported inclusions are correct, all reported exclusions are correct, and all reported genotypes and/or phenotypes are correct according to consensus results or within the laboratory's interpretation guidelines. A "Satisfactory" rating will only be applicable when no analytical errors were observed for the DNA profile typing data. The Technical Leader will sign or initial the Proficiency Review Form to indicate knowledge of the results.

Any proficiency result that is reported as inconclusive or not interpretable will be consistent with the laboratory's interpretation guidelines and will be reviewed by the technical leader. Any administrative or technical errors and corrective actions pertaining to the report will be documented.

The Technical Leader will inform the CODIS administrator of all non-administrative discrepancies that affect the typing results and/or conclusions at the time of discovery.

Individuals using both manual and automated methods will be proficiency tested on at least one manual method and one automated method per year.

3.2 Court Testimony Monitoring

No Supplemental Requirements

3.3 Case Review

All case files and reports will be technically reviewed (with the exception of information only reports) and administratively reviewed. Technical review will consist of the review of the entire case file as well as reanalysis of the electronic data. The technical reviewer will compare their results to the results on the electropherograms in the case file (i.e. original analyst's interpretations). The technical reviewer will document the date of review, and that the results agree when complete. The technical reviewer will also identify any inconclusive loci or profiles

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

to show agreement with the call. Inclusions and exclusions will also be verified by the technical reviewer.

Administrative review will include the entire case file and report (reanalysis of data not required). Any Chain of Custodies included in the case file will be reviewed during the review process by the technical and administrative reviewers. The Serology/DNA Review Form (DNA 015) will be used to document technical and administrative review completion. Each criterion to be evaluated during the technical review is listed on the Serology/DNA Review Form (DNA 015). "NA" will be used for criteria not relevant to a particular case.

The intent of the technical and administrative review process is to ensure that notes and results are being properly reviewed and policies are being followed. The process may require several rounds of edits between the original analyst and reviewers and may also, if a question arises, involve the technical leader. During the administrative and technical review process, the following criteria must be followed:

1. Administrative and technical reviewers are permitted to use sticky notes on areas in question to indicate areas where the original analyst must respond. However, when the original analyst has corrected the issue, the sticky note must remain with the case file upon return to the reviewer confirm the issue has been resolved. The reviewer may then remove the sticky note if the issue has been resolved.
2. This process between the reviewer and the analyst will continue until all issues have been resolved. If a case is returned to an analyst or reviewer due to corrections, the analyst and/or reviewer will re-initial and re-date the Review Form (DNA 015).
3. At the end of administrative or technical review process, the reviewer will write a basic summary of the significant issues that were discussed during the review process. This summary may be documented in the paper file or the LIMS but will be drafted by the reviewer, and approved by the original analyst prior to release of the report.
 - a. A significant issue, in this context, is defined as something that, if not detected by the reviewer, would have resulted in a change to the core interpretation or reporting of the result.
 - i. Administrative review details will generally not be considered significant unless the finding rises to the level that could have affected the reported result if it was not detected by the reviewer. If it rises to this level of directly affecting the reported result, then a summary of that situation will be documented as a significant issue.
 - ii. Some general examples, among others, of significant issues are:
 1. an administrative transcription error to the CODIS form that could have resulted in the upload of an improper allele designation being uploaded to CODIS.
 2. A technical interpretation of a DNA mixture that changed as a result of the review process.
 3. Transposing the results of two different items of evidence when writing the report.
 4. A change in the statistical significance assigned to a piece of evidence.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Any disagreements between the analyst and technical reviewer that cannot be resolved will be handled by the Technical Leader.

During administrative review, the count sheets, if used, will be removed from the case folder and stored in the Count Sheet Binders.

CODIS forms may be removed from the case file temporarily for upload to CODIS but will be returned to the case file before being sent to the file room.

Technical reviewers will be employees or contract employees of the DNA laboratory and will be current or previously qualified analysts in the methodologies being reviewed. Each technical reviewer will have successfully completed training for technical review, including a competency test, in the relevant DNA technology prior to performing technical reviews and will participate in the external proficiency testing program of the DNA laboratory to the extent they participate in the review of DNA data..

3.4 DNA Section Audits

The DNA section will undergo an annual audit using the FBI DNA Quality Assurance Audit Document. Every other year a qualified auditor from an external agency must conduct the audit. This individual must currently or previously been qualified in the current DNA technology and platform. Audits must be conducted once per calendar year, can be alternating internal and external audits, with the interval between audits not less than six months and not exceeding 18 months.

For internal audits, the audit will be conducted by a team which includes an individual trained by the FBI in auditing using the Quality Assurance Standards that is currently or previously qualified in the current DNA technology and platform.

Documentation will be maintained showing which individuals have had their education, experience, and training qualifications evaluated and approved by at least 2 external audit teams). Documentation will also be maintained of the validations that have been evaluated and approved for at least 1 external audit cycle.

Audits will be conducted using the current version of the FBI DNA Quality Assurance Standards and the audit documents, including any corrective actions, will be reviewed by the technical leader. All external audit documentation and laboratory responses, if applicable, will be forwarded to the FBI within 30 days of the receipt of the documents at the laboratory. Previous audit documents will be retained and available for review.

Additional audits may occur pursuant to laboratory wide accreditation (i.e. ASCLD/LAB) and CODIS requirements.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

3.5 Validation

Developmental validation studies may have been performed (by either the manufacturer or by another laboratory) prior to use of a technology in this laboratory. Citations and publications of such will be maintained.

Internal validations on new instrument models or technologies (including change in test kit or platform) to the lab will include the following studies when applicable:

- known and non-probative evidence samples or mock samples
- reproducibility and precision
- sensitivity and stochastic studies
- mixture studies
- contamination assessment

Quality assurance parameters and interpretation guidelines will be based on the results of an internal validation.

Validations and modified procedures requiring validation must be approved by the Technical Leader.

3.6 Maintenance & Cleaning

This section outlines the maintenance and cleaning of lab equipment. It will be comprised of a combination of internal tasks and external, or vendor provided, tasks. NOTE: Daily cleaning refers to only cleaning that is needed for each day the device is in used. If a device is not in use, then no cleaning is required that day.

Critical Equipment

The following critical equipment must be maintained and subjected to quality control measures as described below.

1. NIST traceable calibration thermometer
 - a. Used to monitor/supplement the existing temperature measuring devices used on devices such as refrigerators, freezers, and other devices. A NIST traceable thermometer will be used for this purpose and will either be recalibrated yearly or a new one purchased yearly.
2. ABI Prism 3130s
 - a. The CE instruments are externally serviced and maintained by the instrument manufacturer per their recommended schedule. Additional internal maintenance is described in this document.
3. Pipettes
 - a. Pipettes are calibrated yearly by an external vendor at a minimum. If an analyst suspects the pipette may not be functioning correctly, it may be sent for re-calibration or repair at any time.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

4. Balances
 - a. Balances are calibrated yearly by an external vendor at a minimum. If an analyst suspects the balance may not be functioning correctly, it may be sent for re-calibration or repair at any time.
5. Thermal cyclers and thermal cycler temperature verification system
 - a. Thermal cyclers are monitored internally quarterly using a NIST traceable thermometer and probe. The thermometer and probe are calibrated yearly by an external calibration company.
6. RT PCR quantitation instruments
 - a. The RT PCR instruments are externally serviced and maintained by the instrument manufacturer per their recommended schedule. Additional internal maintenance is described in this document.
7. Qiacube and liquid handling robots
 - a. The robots are externally serviced and maintained by the instrument manufacturer per their recommended schedule. Additional internal maintenance is described in this document.

Records will be kept of all calibrations, service records, performance checks, or maintenance. If the instrument is in need of service, the instrument will be taken out of service until repaired and labeled clearly that it is out of service.

Non-Critical Equipment

The following non-critical equipment will be maintained as outlined below. Freezers and refrigerators that contain evidence or important reagents, such as STR kits, will be monitored by the Andover internal electronic monitoring system and checked quarterly against the NIST traceable thermometer. The individual refrigerator or freezer may be adjusted accordingly to ensure that the temperature on the NIST traceable device is reading the correct temperature as required by the items stored within.

The following non-critical equipment will be maintained as outlined in this document:

- Refrigerators/freezers
- Water Baths
- Heatblocks
- Ovens
- Speedvac Concentrators
- Hoods

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

- Microcentrifuges

Maintenance Plans

Extraction Robots

QIACube

The QIACube is designed to perform fully automated processing and purification of samples in the DNA extraction process.

Maintenance

Action	Assigned	Manual Reference	DNA Form
Daily Cleaning	Lab Staff Assigned to QIACube	QIACube User Manual Chapter 6, pg 6-4	Documentation not needed but should be performed.
Monthly Cleaning	Lab Staff	QIACube User Manual Chapter 6, pg 6-5	DNA 031
Planned Maintenance 1 x year	Qiagen Field Service Engineer	NA	Repair or service must be documented and maintained in appropriate log book
Performance Check 1 x year	Lab Staff	NA	Annual performance check following PM must be documented and maintained in appropriate log book
Performance Check (if deemed necessary)	Lab Staff	NA	After repair, a performance check must be documented and maintained in appropriate log book

Daily Maintenance (daily when in use)

- Empty waste drawer
- Remove used disposable labware and reagents from the work table and discard.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

- Replace the lids of the reagent bottles and close tightly. Store appropriately.
- Empty the waste drawer and check that the liner is clean. If necessary, clean with 70% ethanol, and then rinse with distilled water.
- Clean the shaker rack and reagent bottle rack with 70% ethanol and then rinse with distilled water.

Monthly Maintenance (Monthly when in use)

- Perform the daily maintenance procedure before you perform the monthly maintenance procedure.
- Clean the optical sensor by carefully wiping these modules with a soft lint-free cloth moistened with 70% ethanol.
- To gain access to the modules within the robotic arm:
 - Press “Tools” in the main menu
 - Select “Maintenance” by pressing “^” or “v” to scroll through the list until it is highlighted, and then press “Start”
 - Select “Cleaning position” by pressing “^” or “v” to scroll through the list until it is highlighted, and then press “Start”
 - Follow the instructions in the touch screen. You will be asked to remove the waster drawer and then the labware tray
 - The robotic arm will move forward and downwards, enabling the modules to be accessed for cleaning through the opening for the waste drawer

Periodic Maintenance (minimum every six months)

- Remove the buckets from the rotor. Undo the rotor nut on top of the motor using the rotor key and carefully lift the rotor off the unit.
- Remove the shaker adapter by unscrewing the retaining screws.
- Soak the rotor and rotor nut, buckets, shaker adapter, shaker rack, splash guard, labware tray, and reagent bottle rack in a mild detergent solution.
- Apply a few drops of mineral oil with a soft cloth and wipe down bucket mount rotor claw.
- Rinse with distilled water and wipe dry with paper towels.

Important: Make sure to move all traces of detergent from the centrifuge buckets. Detergent residue can cause the buckets to jam.

Important: When replacing the buckets on the rotor, the side of the rotor bucket that must face toward the rotor shaft is marked with a gray line. Hold the bucket at an angle with the gray line facing the center of the rotor and hang the bucket on the motor. Check that all buckets are properly suspended and can swing freely.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

- Clean the inside of the centrifuge and worktable with a soft lint-free cloth moistened with 70% ethanol.
- Check the centrifuge gasket for damage.
- Wipe gripper unit, gripper, stabilizing rod and spin column lid holder with 70% ethanol and a soft cloth.

O-ring Replacement (As needed if there are indications of insufficient pipetting)

- Move to cleaning position.
- Carefully remove old o-ring(s) and replace with new o-ring(s). Be careful to not damage the o-ring during replacement.
- Document on DNA form 031

DO NOT USE ALCOHOL OR ALCOHOL BASED DISINFECTANTS TO CLEAN THE QIACUBE DOOR. USE DISTILLED WATER ONLY!

Maxwell 16 Instrument

The Maxwell 16 Instrument is designed for efficient, automated purification of samples in the DNA extraction process.

Maintenance

Action	Assigned	Manual Reference	DNA Form
Monthly Cleaning	Lab Staff assigned to monthly cleaning lab schedule	Maxwell 16 User Manual, Section V Periodic Cleaning and Maintenance	DNA 030
Planned Maintenance 1 x year	Field Service Engineer	NA	Repair or service must be documented and maintained in appropriate log book
Performance Check 1 x year	Lab Staff	NA	Annual performance check following PM must be documented and maintained in appropriate log book

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Performance Check (if deemed necessary)	Lab Staff	NA	After repair, performance check must be documented and maintained in appropriate log book
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Maxwell 16 Extraction Robots

Internal Cleaning and General Maintenance

It is important to clean the instrument at regular intervals. If samples or reagents have been spilled, it is important to clean the instrument to avoid damage.

General Care

- Wipe up any spills immediately.
- Periodically wipe off the magnetic rod assembly, plunger bar, inside platform and the outside of the instrument using a cloth dampened with deionized water or 70%. Keep the cooling vents in the back of the machine clear of dust.
- Do not remove the Maxwell 16 Instrument case for cleaning. **This will void the warranty.**
- Do not use the spray bottle to soak instrument surfaces for extended periods of time.
- Never allow liquids to sit on instrument surfaces for extended periods of time.
- Keep all moisture away from the heated elution tube slots to prevent damage to the heating elements.
- If the linear slides for the platform need to be cleaned, use only a dry paper towel.
- If any of the hardware accessories need to be cleaned (i.e., cartridges or elution racks), soak the accessories in a 1-2% bleach solution, followed by deionized water to remove residual bleach. Failure to remove residual bleach will result in corrosion of the accessory surfaces

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Corbett CAS-1200 Liquid Handling Robot & QIAgility Liquid Handling Robot

The Corbett CAS-1200 and the QIAgility are compact and precise liquid handling systems that will be used to set up quantitation standards and samples, amplification reactions, and plate set up for capillary electrophoresis.

Action	Assigned	Manual Reference	DNA Form
Planned Maintenance 1 x year	Qiagen Field Service Engineer	NA	Repair or service must be documented and maintained in appropriate log book
Performance Check 1 x year	Lab Staff	NA	Annual performance check following PM must be documented and maintained in appropriate log book
Performance Check (if deemed necessary)	Lab Staff	NA	After repair, performance check must be documented and maintained in appropriate log book

Additional Internal maintenance of the Liquid Handling Robots

The liquid handling robots will be cleaned as necessary during or after procedures. The deck will be thoroughly cleaned with neutral reagents and a damp cloth. Pipette tips will be replaced after the annual performance maintenance performed by service engineer. An integrated UV light functions serves as an additional decontaminating procedure and will be completed after each run on the liquid handling robots.

ABI Prism 7500 Sequence Detection System

The ABI Prism 7500 Sequence Detection System is a real-time PCR process used for quantitation of DNA. The system consists of the 7500 Real-Time Instrument and attached computer with the appropriate software.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Action	Assigned	Manual Reference	DNA Form
Planned Maintenance 1 x year	Life Technology Field Service Engineer	NA	Repair or service must be documented and maintained in appropriate log book
Temperature Verification Check	Life Technology Field Service Engineer	NA	Repair or service must be documented and maintained in appropriate log book
Performance Check 1 x year	Lab Staff	NA	Annual performance check following PM must be documented and maintained in appropriate log book
System Test 1 x year	Lab Staff	Applied Biosystems 7500 Real-Time PCR Systems System Maintenance Manual Chapter 6, pg 57	008
Block Contamination Check 1 x month	Lab Staff	Applied Biosystems 7500 Real-Time PCR Systems System Maintenance Manual Chapter 6, pg 59-62	008
Lamp Check (As needed)	Lab Staff	User-Performed Maintenance Manual Chapter 6, pg 58	008

Thermal Cyclers

Thermal Cyclers automate the polymerase chain reaction (PCR) for amplifying DNA.

Maintenance

Action	Who	Manual Reference	DNA Form

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Cleaning the Sample Block & Exterior Surfaces (Quarterly)	Lab Staff	GeneAmp PCR System 9700 User's Manual pg 16-17	019
Performance Check (2 x year)	Lab Staff	GeneAmp PCR System 9700 User's Manual , pg 18-32	DNA 030
Performance Check (if deemed necessary)	Lab Staff	GeneAmp PCR System 9700 User's Manual , pg 18-32	DNA 030

Temperature Verification System

The temperature verification system is used to perform the thermal cycler temperature calibrations as part of the thermal cycler performance check. This system will undergo an annual calibration by an outside vendor and documentation will be maintained in the thermal cycler log notebook.

ABI Prism 3130 Genetic Analyzers

The ABI Prism 3130 Genetic Analyzers is a capillary electrophoresis instrument used to separate the DNA fragments based upon size and fluorescent tags.

Action	Assigned	Manual Reference	DNA Form
Planned Maintenance 1 x year	Life Technology Field Service Engineer	NA	Repair or service must be documented and maintained in appropriate log book
Performance Check 1 x year	Lab Staff	NA	Annual performance check following PM must be documented and maintained in appropriate log book
Performance Check (if deemed necessary)	Lab Staff	NA	After repair, performance check must be documented and maintained in appropriate log book

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Spatial Calibration & Spectral Calibration (After each new array install)	Lab Staff	NA	DNA 033
Instrument Cleaning (As needed)	Lab Staff	NA	019
Reagents Replaced Buffer (~48 hours) Polymer (As needed)	Lab Staff	NA	019
Capillary (As needed)	Lab Staff	NA	019
Data & Hard Drive (As needed, data archived and system disc defragmenter completed)	Lab Staff	NA	NA

Water Filtration Unit

The water filtration system will be monitored and maintained by the APD Building Services unit. Stand-alone units in the laboratory have a digital display and can be used when the reading is $\geq 18 \text{ MOhm} \cdot \text{cm}$. If the reading is below $18 \text{ MOhm} \cdot \text{cm}$, the unit will not be used and a service technician will be contacted, and the unit will be marked as out of service to notify other laboratory staff.

Temperature Monitoring Plan

Many thermal devices used in the laboratory are capable of having continuous temperature records captured via the Andover Controls' electronic monitoring system, which uses Continuum building automation software.

When necessary, equipment may be adjusted according to a NIST Calibrated thermometer and monitored based on existing measuring devices on or in the device. The NIST thermometer is calibrated, or a new one is purchased, yearly.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

The Andover computer system is monitored by maintenance staff, and the DNA section is notified by page or phone call if there is a malfunction for equipment that is of high importance, namely equipment that contain evidence storage or critical reagents.

For each device, there will be 3 values noted in this document:

- **Expected Temperature:** This is the temperature, with tolerance range, intended to be held by the device. A NIST traceable thermometer may be used to set this baseline temperature or to check the system if a question arises, but depending on the device a NIST thermometer may not be needed.
- **Visible Measurable Temperature:** This represents the device to be used to routinely check the temperature of the device during standard use, often the most visible means for the device. When recordings are made from this device, the offset, based on the reference temperature, will be applied to document the recordable temperature.
- **Reference Temperature:** This represents the temperature of the device used as a first line of check against the Visible Measurable Temperature. If there is an offset between the Visible Measurable Temperature and the Reference Temperature, it should be noted on the device to be used when documenting the recorded temperature. (i.e. If the Reference Temperature is 56 and the Visible Measurable Temperature is 57, there will be an offset of 1. Therefore if the analyst observes a Visible Measurable Temperature of 58, they will record the temperature as 57 on the record.)

Water baths

Water baths are dedicated equipment whose temperature is routinely maintained at ~56°C for DNA procedures.

- **Expected Temperature:** 56°C, (+/- 1°C)
- **Visible Measurable Temperature:** visible thermostat on the device.
- **Reference Temperature:** The Andover electronic probe

Calculate the offset by using the Visible Measurable Temperature minus the Reference Temperature, and apply the offset to routine measurements read from the Visible Measurable Temperature device. The offset will be checked quarterly against the Reference Temperature at a minimum.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

The NIST thermometer may, but is not required, to be used to establish new offsets. If, at any time, the device appears to be in need of repair, the device will be marked as out of service until it is repaired.

Water Condition

The water in the bath should be clean and clear with no evidence of bacterial/fungal growth or rust. If the water becomes dirty, discard and clean the water bath. Replenish with water as needed and document actions on DNA Form 032.

Action	Assigned	DNA Form
Water condition check 1 x a week	Lab Staff assigned monthly lab cleaning schedule	032

Heatblocks

Heatblocks are dedicated equipment whose temperature is routinely maintained at ~70°C for DNA procedures completed in the extraction lab and ~95°C for DNA procedures completed in the post amplification lab.

- Expected Temperature: 70°C / 95°C (+/- 1°C)
- Visible Measurable Temperature: digital thermometer on the device.
- Reference Temperature: physical glass thermometer on the device

Calculate the offset by Visible Measurable Temperature minus the Reference Temperature, and apply the offset to routine measurements read from the Visible Measureable Temperature device. The offset will be checked quarterly against the Reference Temperature at a minimum.

The NIST thermometer may, but is not required, to be used to establish new offsets. If, at any time, the device appears to be in need of repair, the device will be marked as out of service until it is repaired.

Action	Assigned	DNA Form
Observe temperature 1 x week	Lab Staff assigned monthly lab cleaning schedule	013

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Ovens

Ovens are dedicated equipment whose temperature is routinely maintained at ~70°C for DNA procedures.

- Expected Temperature: 70°C, (+/- 1°C)
- Visible Measurable Temperature: glass thermometer on the device.
- Reference Temperature: The Andover electronic probe

Calculate the offset by Visible Measurable Temperature minus the Reference Temperature, and apply the offset to routine measurements read from the Visible Measureable Temperature device. The offset will be checked quarterly against the Reference Temperature at a minimum.

The NIST thermometer may, but is not required, to be used to establish new offsets. If, at any time, the device appears to be in need of repair, the device will be marked as out of service until it is repaired.

Speedvac Concentrators

Speedvac Concentrators are bench top centrifugal vacuum concentration systems for drying low volume ethanol or isopropanol-water precipitates of DNA. The Speedvac Concentrator should be cleaned with a neutral cleaning agent as needed after use.

The speed as measured by a tachometer, if possible, must correspond to a predicable number on the speed control setting or the digital readout. If the two speeds do not correspond within 10%, the centrifuge must either be replaced or repaired. This should be performed yearly at a minimum.

Hoods

Hoods are effective in reducing the potential for exposure of both product and personnel to airborne biological or particulate chemical agents. The hoods with airflow controls will be checked at least once a year and are maintained by the APD Building Services unit. The C.B.S. Scientific Company brand hoods' bulb use will be monitored using form DNA 025.

Microcentrifuges

Microcentrifuges are bench top, unrefrigerated centrifuges designed for centrifugation of tubes in DNA procedures. There are two types of microcentrifuges available to analysts, which does include the Mikro 220 for all protocol centrifugations, and the personal benchtop Sprout microcentrifuges to perform quick spins of tubes. No maintenance is needed for the Sprout style devices.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Cleaning and Maintenance of the Mikro 220 Devices

Mikro 220 microcentrifuge housing, rotor chamber, and rotor accessories should be cleaned with neutral cleaning agents as needed; typically as part of the lab's cleaning schedule. All parts must be dry prior to use.

Action	Assigned	DNA Form
General cleaning 1 x month	Lab Staff assigned monthly lab cleaning schedule	Monthly Lab Cleaning Schedule

The speed as measured by a tachometer and must correspond to a predicable number on the speed control setting or the digital readout. If the two speeds do not correspond within 10%, the centrifuge must either be replaced or repaired.

Action	Assigned	Manual Reference	DNA Form
Performance Check 1 x every six months	Lab Staff	NA	012

Assigned Monthly General Lab Cleaning Duties

An established laboratory monthly cleaning schedule has been placed in the laboratory and will be completed by an analyst on a rotating basis. This monthly cleaning schedule includes:

- Sweep and mop extraction laboratory area and post amplification laboratory area
- Collect and take out trash and recyclables from the laboratory areas
- Check the status of water in the water bath and replace/replenish as needed
- General cleaning of Mikro 220 microcentrifuges
- Monthly maintenance of Maxwell 16 Instrument
- Suggest ordering of supplies and reagents to the DNA supervisor. The DNA supervisor will then order the items needed.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

3.7 Reagents

Preparation of in-house reagents will be documented on the Reagent Preparation Form (DNA 010). All component's names, lot #s, and expiration dates will be tracked on the form.

Critical Reagents

The following are critical reagents for the DNA Laboratory and require a QC check prior to use on casework samples:

Life Technologies: Quantifiler

Promega: DNA IQ Casework Sample Kit, Swab Solution kit, PowerPlex Fusion kit

QIAgen: QIAamp® DNA Investigator Kit

- **Amplification Kits (Fusion)**

Each new lot of an amplification kit must be subjected to an internal quality control test as outlined below:

- The positive control DNA must be run to determine its activity. A full correct profile must be achieved.
- An amplification blank must be run to determine its purity (i.e., no contamination in reagents). No detectable alleles may be present above threshold. If a peak is detected above threshold, the test should be repeated with three replicates. The technical leader will decide if the kit is suitable for use based on the results of the three replicate blanks.
- All reagents in the kit must be evaluated to demonstrate their viability.
- The allelic ladder must be run to determine that all of the appropriate alleles are detected.
 - If any component of the kit does not meet the aforementioned criteria the process will be repeated. If the kit fails the QC a second time the Technical Leader will be informed and the kit will not be used on casework samples.

- Form: DNA 009

- **Quantifiler Kits**

Each new lot of Quantifiler kits must be subjected to an internal quality control test as outlined below:

- A set of standards will be prepared and run according to procedure along with a template control.
- The R² value will be evaluated and must be ≥ 0.98.
- The slope value must be within the range of -2.9 to -3.35.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

- If the kit does not meet the aforementioned criteria, the process will be repeated. If the kit fails the QC a second time the Technical Leader will be informed and the kit will not be used on casework samples.

- Form: DNA 023

-
- QIAamp® DNA Investigator Kit
 -
 - Each new lot of QIAamp® DNA Investigator kits must be subjected to an internal quality control test as outlined below:
 -
 - A known blood or saliva sample and a reagent blank will be processed through the extraction kit to check the quality of the reagents.

 - The DNA extracts will be quantitated (RB optional), amplified, and analyzed to ensure the correct profile was produced and there are no detectable alleles in the RB above threshold (75 RFU for RB).

 -
 - If the kit does not produce the aforementioned results, the samples will be re-extracted and re-analyzed. If the kit fails the QC a second time the Technical Leader will be informed and the kit will not be used on casework samples.

 -
 - Form: DNA 042

- DNA IQ Casework Sample Kit
 -
 - Each new lot of DNA IQ kits must be subjected to an internal quality control test as outlined below:
 -
 - A known blood or saliva sample and a reagent blank will be processed through the extraction kit to check the quality of the reagents.

 -
 - The DNA extracts will be quantitated (RB optional), amplified, and analyzed to ensure the correct profile was produced and there are no detectable alleles in the RB above threshold (75 RFU for RB).

 -
 - If the kit does not produce the aforementioned results, the samples will be re-extracted and re-analyzed. If the kit fails the QC a second time the Technical Leader will be informed and the kit will not be used on casework samples.

 -
 - Form: DNA 040

- Promega Swab Solution Kit
 -
 - Each new lot of Promega Swab Solution kits must be subjected to an internal quality control test as outlined below:

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

- - A known blood or saliva sample and a reagent blank will be processed through the extraction kit to check the quality of the reagents.
 -
 - The DNA extracts will be amplified, and analyzed to ensure the correct profile was produced and there are no detectable alleles in the RB above threshold (75 RFU for RB).
 -
 - If the kit does not produce the aforementioned results, the samples will be re-extracted and re-analyzed. If the kit fails the QC a second time the Technical Leader will be informed and the kit will not be used on casework samples.
- Form: DNA 041

3.8 Document Management

The DNA Technical Leader will maintain the following records:

1. Proficiency test results (supporting documentation, corrective action reports, and proficiency review forms)
2. casework corrective actions
3. internal and external audits specifically for the DNA section
4. training records and competency tests
5. Analyst audit notebooks

The Quality Assurance Manager will maintain ASCLD/LAB audit documentation. Case files will be stored in the file room.

Analyst notebooks will contain the following:

1. Transcripts
2. CV
3. Continuing Education Certificates or documentation,
4. Casework or other Authorization documentation ,
5. Proficiency Testing Review Forms
6. Court Testimony Monitoring Forms
7. professional affiliation documentation

The quality system review as applicable to DNA will be reviewed annually and will be performed under the direction and documented approval of the Technical Leader. This review includes laboratory procedures in the SOP, technical manual, and training manual.

3.9 Deviation from Documented Procedures

No Supplemental Requirements

3.10 Preventive and Corrective actions

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Prior to implementation, all corrective actions will have the documented approval of the Technical Leader.

3.11 Suggestions/Complaints

No Supplemental Requirements

3.12 Customer Survey

No Supplemental Requirements

3.13 Reference Standards/Materials

No Supplemental Requirements

3.14 Reference Collections and Databases

No Supplemental Requirements

3.15 Examination Verification

No Supplemental Requirements

3.16 Contamination Detection and Prevention

DNA contamination is defined as inadvertent transfer of DNA from one sample to another, from a person to a sample, or from a person or sample to bulk reagents or consumables.

- Prevention and decontamination procedures
 1. The preferred method of decontaminating surfaces is wiping down with 10% bleach followed by a wipe down with deionized water to remove residual bleach. Some equipment advises against the use of bleach (such as CE instruments and some robots) so in these cases, ethanol is the preferred cleaning solution.
 2. PPE and contamination control for general laboratory work
 1. Wear disposable gloves and lab coats during all testing. Masks are also highly recommended if the risk of exposure to particles is present or the risk of the analyst contaminating evidence is probable.
 2. Change gloves frequently and whenever gloves may have become contaminated. Double gloving is optional. Discard gloves when leaving a work area.
 3. Use sterile microcentrifuge tubes. Centrifuge all liquid to the bottom of closed microcentrifuge tubes before opening. A de-capper may be used.
 4. Use sterile, disposable pipette tips for general liquid handling.. Use aerosol-resistant pipette tips while working with any sample that may be amplified for DNA testing. Change pipette tips between samples.
 3. Contamination control in the evidence examination area

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

1. clean work surfaces thoroughly with 10% bleach followed by deionized water at least at the end of each evidence examination session, or prior to beginning the examination session.
 2. Use disposable bench paper whenever possible and change the paper between items of evidence or at least at the end of each evidence examination session, whichever is appropriate for the particular evidence.
 3. Use a clean cutting surface such as weighing paper for each piece of evidence that requires cutting. Be careful to protect other supplies in the area of this paper from dust and other particulates or aerosols from the evidence.
 4. Clean instruments (scissors, forceps) between evidence samples with bleach or ethanol or other cleaning device. If chemicals are used to clean utensils, be sure to follow with deionized water before sampling the next item. Alternatively, use a fresh scalpel blade with each sample.
 5. To prevent contamination of other standards or evidence, handle liquid samples such as a blood standard one at a time and with no other evidence open in the vicinity.
4. Contamination control in the DNA area
1. clean work surfaces thoroughly with 10% bleach followed by deionized water at least at the end of each evidence examination session, or prior to beginning the examination session.
 2. In the PCR setup area, add DNA template after the other reagents to the PCR setup tubes to minimize inadvertent transfer between setup tubes and resultant cross contamination.
 3. Limit talking during sample handling.
 4. Where possible, it is recommended that the lab irradiate work surfaces and equipment in the PCR setup area with decontamination lamps. In the amplified DNA product area, wear a dedicated, disposable lab coat when handling amplified samples. Do not wear this lab coat outside the amplified DNA product area.
 5. Visitors to the DNA lab will also wear masks, gloves, and lab coats except in the amplification room. If a visitor needs to visit the amplification room and other parts of the lab, they will visit the amplification room last.

Response to contamination

Samples can become contaminated with DNA from the environment, from other samples during sample preparation, or from amplified DNA product from a previous amplification. Reagent blanks and negative amplification blanks are used to detect contamination.

Any suspected contamination incident must be immediately brought to the attention of the Technical Leader. The Technical Leader may also be required to inform the laboratory supervisor. The Technical Leader will define and direct investigative actions.

Contamination will be suspected and investigated whenever more than two alleles appear at a locus when the sample is believed to be of one source (unless consistent with a tri-allele) or whenever a negative control or reagent blank yields one or more peaks above the minimum

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

analysis threshold within an allele calling region. When possible, amplification of the reagent blank should be repeated to see if the peaks are reproducible. The technical leader will document in the case file his/her determination of whether the peaks seen in the reagent blank hinder the interpretation of the data in the case or not.

If the contamination level is concerning to the individual case or the laboratory in general, in addition to the case file documentation, these contamination events that occur within the DNA section will be summarized in an incident log that will document the details of the contamination. This will include steps taken toward identifying the source or step in the process where the contamination occurred and the cases affected by the contamination.

If the samples cannot be reprocessed from the step where the contamination is deemed to have occurred, the samples may be called inconclusive. In the event the reagent blank shows contamination but samples within a case that are deemed uninterpretable do not show signs of contamination, the analyst may report the uninterpretable results without reprocessing with approval from the technical leader.

Exceptions, to allow reporting of data when contamination was investigated on a case, may be made only by the technical leader.

Contamination detected in the DNA section which occurred from a prior lab source (i.e., other section personnel) will be handled per current division guidelines. Any contaminating source detected and identified may be subtracted and the sample may be able to be interpreted at the discretion of the technical leader.

Some common steps used to investigate possible contamination events are:

- Repeat portions of the procedure (extraction to typing, if necessary) for the set of samples in which contamination was detected to confirm if the result was repeatable or not.
- If the contamination investigation shows contamination is reproducible, the investigation will try to determine the source of the contamination. In this situation, at the discretion of the technical leader:
 - DNA casework may, depending on the scope and severity of the situation, be discontinued until the source of the contamination is uncovered.
 - Suspected buffers and reagents may need to be discarded, reagent bottles thoroughly cleaned, decontaminated and autoclaved; and fresh reagents and buffers prepared.
 - The work areas, glassware, pipettes, etc., may need to be thoroughly cleaned and decontaminated.
 - If necessary, a known sample set will be re-extracted, re-amplified, or re-typed (depending on the nature of the contamination) using fresh reagents to determine if the contamination has been controlled during the cleaning process.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Appendix 3A

Approved Vendors and Suppliers

Vendors and suppliers of some services and supplies have been evaluated via internal processes described in the Division SOP. See the supplier approval forms available with specific details on qualifications.

4 Laboratory Records

4.1 Case Record

All analytical documentation will be retained and hard copy information will be maintained in the case file. All required electronic analysis data will be retained on the APD group drive (which is backed up daily). The data will be electronically stored in folders designated by the year and month of testing. Administrative documentation not in the case file will be stored in the case record in LIMS or in hard copy as necessary.

The start date of an examination will be documented on the Review Form (DNA 015) and must be filled in prior to the case going to administrative or technical review.

4.2 Laboratory Reports

The following items specific to the DNA section must be included in every report

- Description of DNA methodology
 - i.e. These extractions were subjected to the Polymerase Chain Reaction
- Loci analyzed if DNA typing was performed
 - i.e. The following STR loci were examined: D3S1358, D1S1656, D2S441, D10S1248, D13S317, Penta E, D16S539, D18S51, D2S1338, CSF1PO, Penta D, TH01, vWA, D21S11, D7S820, D5S818, TPOX, D8S1179, D12S391, D19S433, FGA, and D22S1045. The non-statistical loci Amelogenin and DYS391 were also examined.
- Disposition of evidence

The DNA section will follow laboratory wide policies regarding report types, including corrected reports.

Reporting Language

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

This section details acceptable verbiage to use for reporting statements. Report wording should follow these standard statements unless the case warrants deviation. Deviation from the general statements below require approval from the technical reviewer and, in the case of dispute, the technical leader.

Under each bold heading of test results is approved verbiage. Example wording that should be changed according to the case is denoted by *italics*.

➤ **Blood examinations**

- No stains having the visual appearance of blood were detected on *Item 1*.
- A presumptive test for the presence of blood was positive/negative on *item 1*.

➤ **Semen examinations**

- No stains having the appearance of semen were detected on *the victim's shirt*.
 - *Optional if used:* Alternate light sources were used to aid in the attempt to detect semen.
- A presumptive test for the presence of semen was positive/negative on *the victim's shirt*.
- No semen was detected on *the vaginal swab*.
- While a presumptive test for the presence of semen was positive, semen could not be confirmed *on the stain on the crotch of the panties*.
- Semen was detected on *the vaginal swab*.
- Semen, including spermatozoa, was detected on *the vaginal swab*.
- Semen was detected on *the vaginal swab*; however, no spermatozoa were detected.
- Semen was detected on *the vaginal specimens*, however minimal spermatozoa were detected.
- p30, a constituent of semen, was/was not detected on *the vaginal swabs*.

➤ **DNA analysis**

It is not necessary for the report to include the DNA alleles, although the analyst may include this information if desired.

If a locus is designated as inconclusive, the profile at that locus will not be compared to reference standards or reported, and will not be included in calculations of statistical significance estimations.

Reporting statements:

Reporting statements must include a statement of inconclusive, exclusion, or inclusion and must be accompanied with a statement of statistical significance for all non-intimate samples.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

NOTE: This laboratory only considers differential extractions from body cavity swabs (i.e. vaginal, anal, and oral) as intimate samples. All other sample types are considered non-intimate samples.

For significance estimates, analysts have the choice of expressing large numbers using numerals or words.

Preferred verbiage statements are:

Uninterpretable/inconclusive profiles

- The *minor component* obtained from *stain A* is too minimal for comparison.
- No conclusive or interpretable DNA profiles were obtained from *stain A* due to...
 - A qualifying reason must be given when using this statement:
 - ...low, or no, signal which makes this result inadequate for ANY comparisons to potential reference sample(s) using currently available techniques.
 - ...the presence of a DNA profile consistent with a departmental employee
 - ...a contamination incident
 - ...laboratory processing error
 - ...the excessive minimum number of contributors.

Exclusion Statements

- The DNA profile from *Item 1*, is not consistent with the DNA profile of *Person A*. *Person A* is excluded as the contributor of this profile.
- The DNA profile from *Item 1*, is consistent with a mixture of at least *number* of individuals. *Person A* is excluded as a contributor to this profile.

Inclusion Statements - Single source, full or partial

- The *full/partial* single source DNA profile from *stain* is consistent with the DNA profile of *Person A*. *Person A* cannot be excluded as the contributor of this profile. [Statistics were calculated at the following loci: *D3S1358, D1S1656, D2S441, D10S1248, D13S317, Penta E, D16S539, D18S51, D2S1338, CSF1PO, Penta D, TH01, vWA, D21S11, D7S820, D5S818, TPOX, D8S1179, D123391, D19S433, FGA, and D22S1045*. At these loci,] The probability of selecting an unrelated person at random who could be the contributor of this DNA profile is approximately 1 in ___ for Caucasians, 1 in ___ for African Americans, and 1 in ___ for Hispanics.

Inclusion Statements - Major component of a mixed source

- The DNA profile from *stain* is consistent with a mixture of at least *number* individuals. *Person A* cannot be excluded as the contributor of the major component in the profile. [Statistics were calculated at the following loci: *D3S1358, D1S1656, D2S441, D10S1248, D13S317, Penta E, D16S539, D18S51, D2S1338, CSF1PO, Penta D, TH01, vWA, D21S11, D7S820, D5S818,*

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

TPOX, D8S1179, D123391, D19S433, FGA, and D22S1045. At these loci,...] The probability of selecting an unrelated person at random who could be the source of the major component in this DNA profile is approximately 1 in ____ for Caucasians, 1 in ____ for African Americans, and 1 in ____ for Hispanics.

Inclusion Statements - Mixed source with no major component

- The DNA profile from *stain* is consistent with a mixture of at least *number* individuals. *Person A* cannot be excluded as a contributor to this profile. [Statistics were calculated at the following loci: *D3S1358, D1S1656, D2S441, D10S1248, D13S317, Penta E, D16S539, D18S51, D2S1338, CSF1PO, Penta D, TH01, vWA, D21S11, D7S820, D5S818, TPOX, D8S1179, D123391, D19S433, FGA, and D22S1045.* At these loci,...] The probability of selecting an unrelated person at random who could be a contributor to this profile is approximately 1 in ____ for Caucasians, 1 in ____ for African Americans, and 1 in ____ for Hispanics.”

Combining statements

Not all scenarios above fit all possible options. For one item of evidence, it may be clearer to combine inclusion, exclusion, and significance statements with the approval of the technical reviewer and, in the case of dispute, the technical leader. This should be done in a way that improves readability without changing the meaning. This is performed at analyst’s discretion.

Example: An example is below of a possible scenario of the inclusion of two people and the exclusion of a third.

- The DNA profile from the *stain* is consistent with a mixture of at least *number* of individuals. *Person A* is excluded as a contributor to this profile. *Person B and Person C* cannot be excluded as possible contributors to this profile. [Statistics were calculated at the following loci: *D3S1358, D1S1656, D2S441, D10S1248, D13S317, Penta E, D16S539, D18S51, D2S1338, CSF1PO, Penta D, TH01, vWA, D21S11, D7S820, D5S818, TPOX, D8S1179, D123391, D19S433, FGA, and D22S1045.* At these loci,] The probability of selecting an unrelated person at random who could be a contributor to this profile is approximately 1 in ____ for Caucasians, 1 in ____ for African Americans, and 1 in ____ for Hispanics.

Alternate reference samples

When no standard reference samples are available, alternate reference samples may be used, *e.g.*, Pap smear, hair from a hair brush, or blood from a piece of clothing. When compared to an evidentiary profile, the appropriate prescribed reporting statement will be modified to reflect the alternate reference sample usage:

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

- *The DNA profile from Item 1, stain 3, is consistent with the DNA profile from the Pap smear. Assuming Person A is the source of the Pap smear, Person A cannot be excluded....*
- *The DNA profile from Item 1, stain 3, is not consistent with the DNA profile of the Pap smear. Assuming Person A is the source of the Pap smear, Person A is excluded....”*

Source Attribution Addition (OPTIONAL)

At the analyst’s discretion, they may choose to apply a source attribution statement as defined in the mathematics calculated in the DNA section technical manual. Source attribution will only be applied in single source or major contributor interpreted profiles. If they do, below are examples of proper wording:

Single Source Profile, not a mixture

- Based on these probabilities, *Person A* is the source of this single source profile (this source attribution statement is calculated assuming unrelated individuals and excluding identical twins. Contact the laboratory for more information if necessary).

Mixture Profile With Major Contributor

- Based on these probabilities, *Person A* is the source of the major component of this profile (this source attribution statement is calculated assuming unrelated individuals and excluding identical twins. Contact the laboratory for more information if necessary).

World Population Statement (OPTIONAL)

For frame of reference, an analyst may choose to provide an estimate for the current population of the world.

- The approximate world population is 7,000,000,000.

4.3 Release of records Information

4.3.1 Release of Information prior of issuance of a report

It is sometimes necessary to provide preliminary status updates to detectives as a case is being processed. When necessary, status updates, on the following topics only, may be provided:

NOTE: When providing these updates, the analyst should be clear with the detective that the information they are providing is preliminary when referring to testing results.

- Presence or absence of apparent blood and/ or semen
- Estimated evidence processing, or testing, time frames

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

- The presence, appearance, or general characteristics of an item of evidence.
- Lack of a CODIS match from a keyboard search
- Mere absence or presence of a CODIS eligible profile
- Notification of a CODIS hit that is being verified

4.3.2 Release of Information to the News Media

No additional information

4.3.3 Open Records Request

No additional information

4.3.4 Discovery Orders

No additional information

4.4 Removal of Records for Court

No Supplemental Requirements

4.5 Archiving Laboratory Case Files

No Supplemental Requirements

4.6 Expunctions

No Supplemental Requirements

4.7 Control of Laboratory Records

No Supplemental Requirements

APPENDIX 4A LISTING OF OFFENSE CODES FOR CASE COUNTING PURPOSES

01 Homicide
01A Attempted Homicide
02 Sexual Assault
03 Robbery
04 Assault
05 Burglary
06 Theft
06C Credit Card Offenses
07 Auto Theft

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

- 08 Arson
- 10 Forgery and Counterfeiting
- 11 Fraud
- 12 Embezzlement
- 13 Stolen Property Offense
- 14 Vandalism
- 15 Weapons Offense
- 17 Sex Offense Other Than Rape
- 18 Controlled Substances Offense
- 18M Controlled Substances Manufacturing
- 20 Offenses Against Family and Children
- 21 Intoxication Offense
- 21D Intoxication Offense (Deceased)
- 22 Liquor Violation
- 23 Drunkenness
- 25 Vagrancy
- 26 Criminal Offense
- 30 Hit and Run
- 31 Traffic Incident
- 32A Questioned Death
- 32B Suicide or Accidental Death
- 33 Non-criminal
- 34 Violation of Probation
- 35 Threatening Correspondence
- 36 Official Misconduct
- 37 Harassment
- 38 Kidnapping
- 39 Officer Involved Shooting

5 EVIDENCE PROCEDURES

5.1 General Practices

➤ **Case acceptance and Evaluation**

Before a case is accepted or worked, the case will be evaluated for the presence of potentially probative evidence. The examiner should be aware of the requested examinations, the reason(s) for the requested analyses, the relevance of the examination in solving the crime or answering certain key questions, and the quality and quantity of the evidence. Because each case is different, only guidelines can be prescribed regarding processing evidence. The case evaluation may include consultation with the investigator/prosecutor, or other individuals, as necessary.

Once a request for analysis has been received in LIMS, the Supervisor will typically assign the case to an analyst based on the submission date and departmental priorities.

➤ **Evidence evaluation**

Before the case is worked, an evaluation should be made to determine the quality and quantity of the evidence that is going to be analyzed. In order to expedite casework, it is

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

recommended that for cases containing large volumes of evidence (excluding sexual assault kits) 5-10 probative items of evidence should be screened. Of those 5-10 items screened, it is recommended that a maximum of 5 evidence stains should continue on to DNA analysis. Additional items/stains may be analyzed at a later date depending on case development and initial DNA analysis results. Decisions have to be made concerning the analytical approach that must be taken to obtain the most useful information. It may be helpful to consult with another qualified examiner, the Technical Leader, and/or the Supervisor. Considerations for case and evidence evaluation are:

- Maximize the meaningful information obtained from the evidence and plan steps to minimize the loss of potentially valuable information
- Determine if the requested examinations are appropriate given the items submitted
- Consider the age of the evidence, especially when the evidence is biological material
- Consider the storage conditions of the samples prior to submission
- Consider the possible dilution of the samples prior to submission
- Whether weapons or other objects require processing in other sections first
- The availability of reference known samples

- Consider the analyses that should be run if sample is limited and the possibility of retaining a portion of the sample for future testing

➤ **Sampling and sample selection**

Sampling is defined as using part of a substance to represent the entire substance. The serology and DNA reports will often state conclusions about “the whole” based on testing a portion when there is the assumption of homogeneity (example, a portion of blood from a blood tube is collected and tested for DNA).

Selecting a sample is based on training, experience, competence, and the case scenario. Selection of samples for testing will be based on an attempt to determine which samples would yield the most probative information based on the case information. No assumption of homogeneity in some samples is made (example, a large blood stain on a shirt that is a mixture of multiple individuals but may vary in concentration of each individual in different portions of the stain).

➤ **Sample labeling**

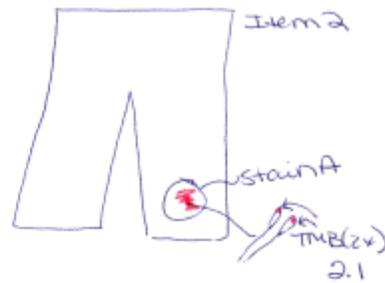
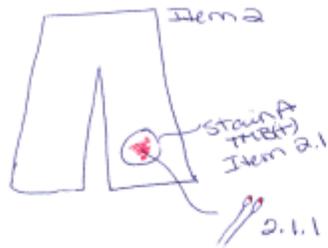
Each sample collected will be identified by the laboratory number and the unique LIMS number or sub-number for the case. The following guidelines also apply:

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

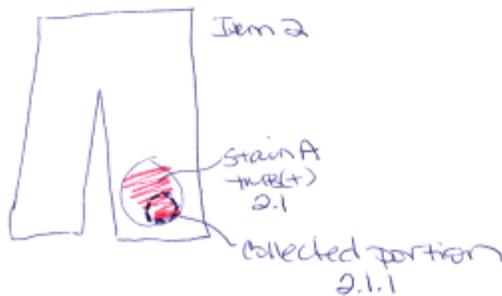
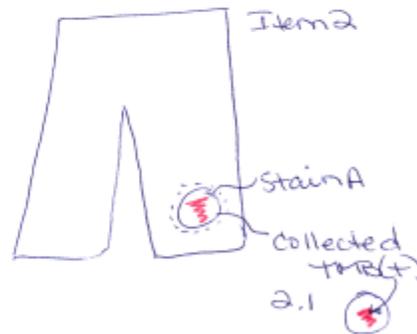
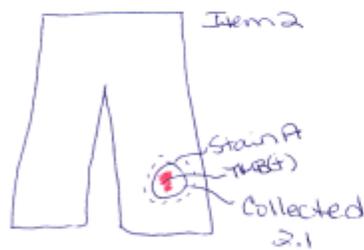
Serology: All positive stains (at a minimum) tested will be given a sub-item number and the report will specifically list which sub-items tested positive for the presumptive or confirmatory test and which ones were collected.

Below is an illustration of proper sub-item labeling.

Swabbings



Cuttings



DNA: All samples tested for DNA will be identified by their sub-item number and will be reported as such. The samples selected for DNA will be based on analyst discretion.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

➤ **Trace evidence**

Collection of trace evidence is at the analyst's discretion, but where possible, when deemed probative, an effort to retain trace evidence for future analysis should be performed.

➤ **Hair**

Occasionally, an investigation may be aided by the comparison of a questioned hair to known standards. In most cases, nuclear DNA analysis may only be performed on evidentiary hair when:

- a microscopic examination of the hair is performed by an approved laboratory.. Some cases with no suspect may require DNA testing without prior microscopic comparison. The following should be considered in evaluation of the case involving hair analysis:

- What is the significance of the particular hair?
- Is it permissible (with the legal teams or investigator) to destroy part of the evidence?
- What is the condition of the hair, e.g., fragment, root, etc.? What is the likelihood of a DNA typing result?
- Would mitochondrial DNA analysis by another laboratory be possible?

➤ **Chain of Custody**

The LIMS system will be used to track the chain of custody of evidence within the Forensic Division with the exception of the packages containing the DNA cuttings and DNA extracts. These will be stored within the DNA lab freezer and will be tracked via paper chains stored in the case file. The time of creation of collected cuttings/swabs and DNA extracts (time at completion of extraction process) will also be documented on the forms, as applicable. Copies of the LIMS chains for parent items should be printed and placed in the case file. If an item is requested and possessed but not analyzed, a notation will be made in the case documentation (for example, on a worksheet or the copy of the chain of custody) and will also be mentioned in the report as receiving no analysis.

Items of evidence received from the Evidence Control Section will follow the Division SOP. When evidence is received from the Evidence Control Section, it will be documented in LIMS or in the paper case file as having been received from the Central Evidence Locker, (i.e. "rec'd from CEL").

DNA Analysis

➤ **DNA Extractions**

The extraction of reference samples must be performed at a separate time or location from the extraction of evidentiary samples to minimize the potential for reference to unknown sample contamination. It is also recommended that items of

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

evidence from the suspect not be extracted adjacent to items of evidence from the victim.

➤ **Controls**

A reagent blank will be extracted concurrently for each set of DNA extractions and will contain all reagents used in that extraction process. The reagent blank will be processed through the entire analysis, except quantitation, with the exception that it will not contain sample. If samples are concentrated on the speed vac the reagent blank will also be concentrated. A reagent blank must be analyzed with each PCR system used to test evidence. Any remaining reagent blank should be stored frozen. The reagent blank shall be amplified on the same instrument model used to test evidence and in such a way that it will detect contamination, if present, in the most dilute evidence sample. For example, if 15 µl is the greatest amount of template amplified for any evidence sample in the batch, 15 µl of reagent blank must be used as template during the amplification. The reagent blank will be run at the highest injection time of any of the samples within a case and on the same instrument model used to test evidence. It will also be analyzed at the analytical threshold RFU value used for the samples within a case.

An amplification blank (negative control) will be introduced at the amplification setup step and will be included with each analysis step thereafter. The amplification blank will contain all PCR setup reagents except DNA template. The amplification blank will be handled in such a way that it will detect contamination occurring during PCR setup. It will be amped concurrently in the same instrument as the samples.

An amplification positive control will also be introduced at the amplification setup step and will be included with each analysis step thereafter. It will be amped concurrently with the samples in the same instrument and with the same loci the samples are analyzed with.

➤ **Consumption of evidence**

The evidence quality and quantity will be preserved as much as possible without sacrificing the quality of the analyses. Whenever possible, at least half of the evidence sample will be preserved for possible re-analysis. Samples (i.e., cuttings or swabs) requiring depletion should have the substrate retained after extraction, when applicable. For questioned samples, an approximate amount of sample used should be documented on the extract log. For reference samples, it will be assumed that at least half of the sample remains. If not, the amount used will be documented.

➤ **Storage of evidence**

Biological evidence should be properly stored to preserve body fluids for DNA testing

Store sexual assault kits, or other sexual assault related evidence, in the refrigerator or in a dry area at room temperature once received in the laboratory. Most clothing, bedding, and other physical evidence can be stored in a dry area at room temperature until examined.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Blood cases containing small, dry items may be stored at room temperature. Refrigerate, do not freeze, liquid whole blood specimens until a sample is dried on FTA paper or swabs. Store larger items such as clothing, bedding, weapons, and other physical evidence containing bloodstains in a dry area at room temperature until examined.

After final analysis, store stains and extracts in the freezer. Repeated freezing and thawing of stains should be minimized. In the event that freezer space is exhausted, archival samples may be removed to a long-term evidence storage area for storage at room temperature. Casework cuttings/swabs and DNA extracts will be retained indefinitely as evidence. Post amplification product is classified as work product and does not need to be retained.

4.8 Case File Processing

This section describes the general path of an ordinary case file as it interacts with analysts and LIMS throughout the testing process. Cases should generally follow this path unless there are exigent circumstances that do not allow for it:

- 1) Analysis is generally requested by the officer, and the case is assigned to an analyst, usually by the DNA section supervisor.
- 2) The requested case starts out listed as "File" (Item 0) in LIMS is sub itemed (Item 0.1). This becomes the "DNA file". A barcode label is printed to put on the outside of folder.
- 3) DNA file begins in the custody of the analyst and the analyst performs the necessary testing.
- 4) After testing is complete and ready for technical review, the file is scanned into the custody of the technical reviewer's review box, and placed on the technical reviewer's work area or proper holding area.
- 5) The technical reviewer then scans the case file to their custody for technical review. The case file may go back and forth between the analyst and technical reviewer to make corrections as needed.
- 6) Once the technical review is completed, the technical reviewer then scans the file to the administrative reviewer's review box, and placed on the admin reviewer's work area or proper holding area.
- 7) The administrative reviewer then scans the case file to their custody for administrative review. The case file may go back and forth between the analyst and administrative reviewer to make corrections as needed.
 - a) If the corrections found during administrative review are technical in nature, the case file must go back to the original technical reviewer for another technical review, and then back to administrative reviewer again.
 - b) Once the administrative and technical review is completed and the report is ready for approval, the administrative reviewer prints out the final report and places it in the completed case file holding area.
- 8) The case file is then transferred and scanned back to original analyst's review possession.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

- 9) The analyst first scans the case file to their custody, then to the custody of the applicable holding bin to either be transferred on to the next phase of testing or to the file room.
- 10) For DNA pending cases, the administrative reviewer should create a new assignment with "E" (Ready For Examination) as the status, and the original request date should be inserted in the comments section in LIMS
- 11) When a case file is ready to be sent to the main file room, the following steps will be performed by the DNA section supervisor:
 - a) Scan the ID badge or barcode (from the speed sheets) of the supervisor.
 - b) Then scan the file to place it in the list. If more than one file will be transferred to the main file room, scan them all into this list. Then save to transfer the file/list of files to the supervisor.
 - i) If a file in the list is in someone else's custody and cannot be transferred to the supervisor, then use the Drop Item button on that item to remove it from the list. The file should be given to the person of custody to resolve the location designation.
 - c) Repeat steps a) and b) again to create the list except scan the To Be Filed barcode rather than the supervisor barcode to indicate an administrative transfer to the To Be Filed area.
 - d) The analyst will check to ensure the CODIS form indicates entry into the CODIS system.
 - e) The physical files will then be taken to the administrative staff for filing into the file room.

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Appendix 5A DNA Section Abbreviations

1, 2, 3, 4	AP strength of reaction weak to strong, e.g., 4+ for strong positive reaction
0	none
agg	aggravated
AE	additional evidence
ALS	alternate light source
AP	acid phosphatase
App	apparent
Bl	Blue
Br	Brown
CEL	central evidence locker
C/N	control negative
D	Depleted
Diff	Differential Extraction
Dk	dark
Dnp	Did not possess
dH ₂ O	deionized water
Disp	Disposition
Env	Envelope
Epi, EC, EF	epithelial cell, epithelial fraction
Evid	evidence
F	frozen
F5	freezer 5
FM	Forensic Mixture
FP	Forensic Partial
G	Grey
H	human
H/F	heads per field
K	known standard sample
L	Left
L2	Crime-Lite 2
LL	Crime-lite 82

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

Lt	light
M	manila
MM	master mix
ND	not done
NFR/PIC	Nuclear Fast Red/ Picroindigocarmine
NONA	not opened, not analyzed
NR	no reaction
NS	no stains seen
NSEV	no stains of apparent evidentiary value
NST, NSTE	no significant trace (evidence)
Obs	observed
p	partial
PB	presumptive blood
PCR	Polymerase chain reaction
PPF	PowerPlex Fusion
PT	purple top (note: different meaning for codis)
PHT	phenolphthalein
Q	questioned sample
QP	quick prep
QNS	quantity not sufficient (for further analysis)
R/B	red/brown
R	Right
Sus	suspect
S	stained
Se	sealed
SA	sexual assault
S/I	sealed/initialed
S/I/D	sealed, initialed, dated
S/D	sealed, dated
SB	swab box
Soln	solution
Sp	sperm
SP	swab packet

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

SF	sperm fraction
ST	Stochastic Threshold (note: different meaning for CODIS)
Std	Standard
Stn	stain
STR	short tandem repeat
TL	Tape lift
TMB	tetramethylbenzidine
TNTC	too numerous to count
U	unstained
UD	Undetected
Unk	Unknown
Vag	Vaginal
V	victim
Vis	visible
w/	with
w	weak reaction
Wh	White
Zip	ziplock
[]	concentrated
~	approximately

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

5.2 Observation by Outside Experts

No Supplemental Requirements

5.3 Evidence Disposal

No Supplemental Requirements

5.4 Destruction of Hazardous Substances

No Supplemental Requirements

5.5 Outsourcing

No Supplemental Requirements

6 Laboratory Safety

No Supplemental Requirements

7 Personnel

7.1 Documents

No Supplemental Requirements

7.2 Subpoenas

No Supplemental Requirements

7.3 Private Case Consultations

No Supplemental Requirements

7.4 Testimony for Previous Employers

No Supplemental Requirements

7.5 Attendance

No Supplemental Requirements

7.6 Certification of Analysts

No Supplemental Requirements

**AUSTIN POLICE DEPARTMENT
SEROLOGY/ DNA SECTION
STANDARD OPERATING PROCEDURES**

7.7 Employee Training Program (QAS 5.1.2)

The DNA section has a training manual that serves as guidance for the training program.

7.8 Employee Approval for Casework

No Supplemental Requirements

7.9 Employee Career Development

No Supplemental Requirements

7.10 Continuing Education

Each examiner approved to perform DNA analyses will attend at least one continuing education training session (minimum of 8 hours) annually for the enhancement of DNA analysis skills. The DNA Technical Leader or Supervisor will recommend to management and coordinate training activities for personnel. Each examiner will place the certificate or agenda in their analyst notebook when he/she has completed any job-related training. For web-based continuing education, the training will be approved by the technical leader, the time of the training will be documented, and the completion of the training will be approved by the Technical Leader. The Technical Leader will have access to and ensure the maintenance of examiner training records in the laboratory.

Supplemental training will be used when remediation is needed. The Technical Leader will identify areas for which remediation is necessary based on the results of proficiency or competency test results, laboratory audits, or peer review activities and oversee or conduct such training using the training manual.

The DNA section staff will document the reading of applicable reading material by initialing the memo associated with the document. These articles will be retained in the Literature Review Binders.

7.11 Internship Program

No Supplemental Requirements

7.12 Volunteer Program

No Supplemental Requirements

7.13 Rider Program

No Supplemental Requirements