

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

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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

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10. Protocol Sheet - 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
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

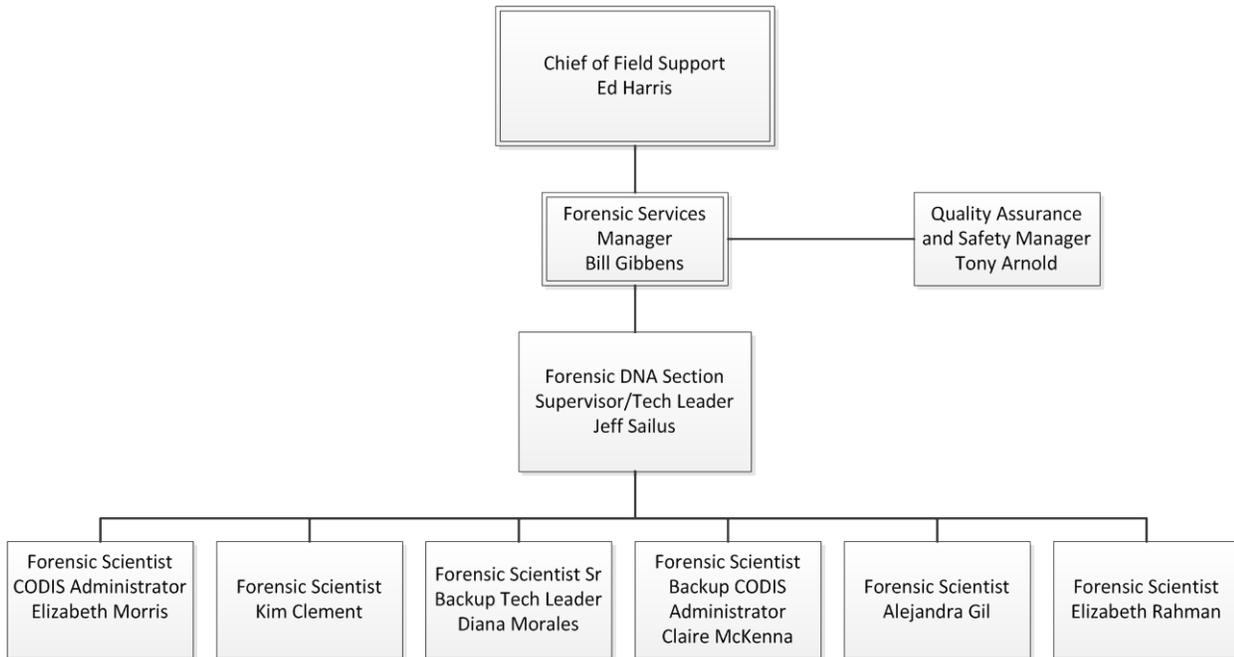
No Supplemental Requirements

1.7 List of Locations, Addresses, and Phone numbers

No Supplemental Requirements

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1.8 Organizational Chart



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

- Forensic DNA Section Supervisor

The DNA Supervisor will have a B.A./B.S. or graduate degree or its equivalent in a

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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 in the event of the position being vacated or extended absence, the following options are available:

1. The Backup DNA Technical Leader may be appointed to assume the duties of technical leader on a temporary basis. The following events would trigger the activation of the Backup DNA Technical Leader and he/she would only be activated to act in this role should the following occur:
 - As deemed necessary by the current DNA Technical Leader in times of planned extended absence and/or if the DNA Technical Leader is expected to be unreachable by phone for a period of more than 3 working days.
 - As appointed by the Laboratory Director if the current DNA Technical Leader must permanently vacate the position for any reason.
 - Another currently employed and active duty DNA analyst, if the backup DNA Technical Leader is unavailable, 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.
2. 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

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including a combination of graduate and undergraduate coursework covering the subject areas 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 DNA 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 (if at one time proficient in the analysis being reviewed) and administrative reviews
- 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 maintains 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 DNA Supervisor
- Recommends procedure manual updates, keeps SOP current
- Monitors courtroom testimony of examiners
- Review and document the review of internal and external audits and, if applicable, approve corrective action
- Approves technical specifications for outsourcing agreements

- Local CODIS Administrator

See appendix 8A 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

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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 or the Forensic Science Division 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.

- 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

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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

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

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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 when manual setups are performed. 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 in the amplified product area are dedicated to this area and will not be removed unless properly decontaminated.

To decontaminate, the following procedure should be performed outside the amplified product area and before entering the general lab area (perform in lab room 2.2.01 Bvii): wipe down all outside and inside parts when possible with 70 % ethanol, then wipe down with 10% bleach, then wipe down with a cloth dampened with water, then towel dry. If a protocol is set forth by a manufacturer for a particular piece of equipment (ie: sending out a piece of equipment for repairs), then that protocol will be used.

2.2 Security

Short term storage of unsealed evidence being examined will be kept in the screening rooms. These screening room 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 for >1 week. 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 bulk sealed evidence will be in the evidence storage areas and may include areas such as the evidence processing rooms, walk in freezer, supplemental freezer, and the evidence shelves for up to 6 months. Sub items such as swabs, cuttings, etc. intended for long term storage for DNA purposes will be retained for at least 50 years in the DNA lab. Exceptions can be made for evidence types that require storage condition that only the DNA laboratory can provide. In these cases, this exception should be noted in the case file and LIMS

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DNA extracts will be stored short term in refrigerators in the extraction lab during processing. After processing, they will be stored in the freezer for at least 50 years in the DNA lab.

The DNA section will maintain a combination code for the DNA walk in Freezer 5. The combination is "xxxxx". It will remain this combination until it is changed by the supervisor or designee. The instructions for changing the combination are attached to the code page. Please see the notebook located in the supervisor' office for the actual code and instructions to change the code.

2.3 Supplemental Reports

For purposes of the Serology/DNA section, the two workflows, serology and DNA, will be considered separate disciplines for the requirement around when to issue a supplemental report as described in the Forensic Science Division Standard Operating Procedure.

This means that if serology is performed on items of evidence then, via a separate report, DNA is performed on some or all of those items of evidence, the DNA report will be considered a new report rather than a supplemental report.

If DNA is performed on a case, then additional DNA tests are performed at a later time on the exact same items of evidence, a supplemental report may be issued. If the second DNA report contains a different list of items (even if a subset of evidence is the same as the initial report), then the second DNA report will not be considered a supplemental of the first. This last example is based on the "same items of evidence" portion of the statement.

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 date that the proficiency test results are submitted to the external provider (such as CTS or Seri) for review is considered to be the date the test was performed and will also serve as the date for calculation of the interval.
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

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"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, if both are used in the laboratory.

3.2 Court Testimony Monitoring

No Supplemental Requirements

3.3 Case Review

All duties identified on the forms DNA 015 and DNA 051 will be performed by the administrative or technical reviewer as required. Signature of the administrative or technical reviewer on the review forms represents the documentation that they agree with all administrative or technical aspects of the case record, respectively.

Case Files

NOTE: This section refers to the routine processing of DNA and serology cases. For cases that included batch processing of reference known samples, refer to the Batch Processing of References portion of this section for additional information.

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 for technical issues as well as reanalysis of the electronic data to confirm genotype calls. The technical reviewer will compare their analysis of the data to the results on the electropherograms in the case file (i.e. original analyst's interpretations). It should be clear in the case file that the technical reviewer agrees with the data interpretation including any inclusions and exclusions, and appropriate statistical analysis.

The casework technical review (not batch reference sample processing) shall include the following elements at a minimum:

- a. A review of all DNA types to verify that they are supported by the raw and/or analyzed data (electropherograms or images).
- b. Review of raw data by performing a second analysis of the original Genemapper data.
- c. A review of all associated controls, internal lane standards and allelic ladders to verify that the expected results were obtained.
- d. A review of the final report to verify that the results/conclusions are supported

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- by the data (Exception: in certain situations where data must be reviewed without a report being written 1st). The report shall address each tested item(or its probative fractions). In the case of outsourcing each item or its probative fraction.
- e. Verification of the DNA types, allele calls, mixture interpretation, eligibility, and the correct specimen category for entry into CODIS.
 - f. A review of the evidence chain of custodies in LIMS and the paper chain of custodies for DNA cuttings and DNA extracts.

Administrative review will include the following elements:

- a. A review of entire case file and report (reanalysis of data not required).
- b. Ensure that all inclusions and exclusions documented on the electropherograms are supported in the report.
- c. Ensure that all allele calls are correctly transcribed onto the CODIS sheet (DNA form 016).
- d. Should remove the CODIS upon completing review and place in the appropriate bin for upload.

The Review Forms will be used to document technical and administrative review completion. Each criterion to be evaluated during the technical review is listed on the Review Forms "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:

Once a case is sent to a reviewer, the following will occur:

1. **The reviewer can initiate the beginning of a review by dating the line when the reviewer begins the review process. A range of dates can be separated with a dash to incorporate several days of reviewing. The final date (there may be only one day) of reviewing will be documented and the case given back to the original analyst**
2. 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 to confirm the issue has been resolved. The reviewer may then remove the sticky note if the issue has been resolved.
3. 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).
The analyst will see all comments (when applicable) made by the reviewer in the comments section prior to returning the case file to the reviewer. (For example, the reviewer states that a CODIS sheet is missing, the reviewer will make the comment in the comments section of the review form and give back to the analyst, once the analyst agrees, the case file will be corrected and the analyst will sign on the date line at the top

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of the review form). If an error occurs and the reviewer has made a comment in the comments section that was not necessary, it can be corrected by simply marking out and initialing the cross out.

- 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.

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

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.

Batch Processing of References

This section provides additional information about the flow of paperwork and information when processing reference samples in a batch format. The same general criteria for technical and administrative reviews still apply, but this section provides additional guidance on handling of the records, notes, and worksheets.

Provided here is a step by step general summary of key points in the process:

- 1. The case working analyst(s) (case analyst) or the DNA supervisor notifies the person who is performing the batch run (batch analyst) which samples need to be

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processed. Case files are also provided. The batch is named according to the date the laboratory work was started followed by the analyst's initials (i.e. 02062015JSS).

2. The batch analyst creates the batch file folder (including date and initials where appropriate). This batch file folder should stay as one entity throughout the entire process until all technical and administrative reviews are complete.
3. The batch analyst fills out the proper paper chain of custody form(s) for the cuttings/swabs and processes the known/reference samples through the laboratory process, performing any repeats/reanalysis as necessary. The batch analyst notifies the case analyst of any failed samples. Chain of custody for extracts will also be created at this stage.
4. The batch analyst saves the samples sheet as a PDF file. This gets titled as the batch file record (with the same naming scheme as the batch) and saved to the network drive in a central location. This represents a central resource regarding which cases were run in the batch, but the official record of the batch run will be stored in LIMS as discussed below.
5. The batch file folder goes to the technical reviewer. The technical reviewer reviews the batch file, performs a reanalysis of the raw data, verifies allele calls, worksheets, etc.
6. The batch analyst makes any corrections as needed after technical review, if necessary.
7. Once the technical review is complete, the batch analyst will pass the batch file folder to an administrative reviewer and the folder will undergo an administrative review.
8. After technical and administrative reviews are complete, the batch analyst will scan the entire batch record to a PDF file and make it available to the case analyst(s). The case analyst(s) will attach the scan of the original batch records to the appropriate assignment in LIMS. **IMPORTANT:** This batch record PDF must be attached to each assignment in each case involved in the batch.
9. The batch analyst will also provide to each case analyst the following for a paper record for each individual case folder:
 - a. The electropherogram(s) pertinent to the case (original)
 - b. Review form (photo copy)
 - c. Chain of Custodies for cuttings/swabs and extracts (original)
10. The casework analyst is responsible for verifying they have all necessary copies/originals in each case folder and that the scanned batch record was uploaded properly to LIMS. This fact will also be confirmed during technical review of the case folder.
11. The case analyst is responsible for recording sample counts in LIMS. The counts

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get attributed to the case analyst, not the batch analyst.

Changes to Original Batch Documentation in LIMS

NOTES: Any change made to any paperwork that affects all samples in the batch, after the copies are distributed to case folders, must be made to all files in the batch run as stored in LIMS. If corrections need to be made to the original scanned batch record documents that are stored in LIMS:

1. Download and print the PDF
2. Make corrections to the printed copy
3. Upload the corrected version to all applicable cases in the batch. Since the original assignment is no longer generally available, attach the scanned PDF to the Reports section of LIMS by clicking on your report and hitting F11. Drag the PDF into the related documents screen that pops up.

Any DNA analyst that is authorized to perform technical or administrative reviews on standard DNA casework, is also authorized to perform technical or administrative reviews on batch file runs as well.

Where practicable, batches should be run one set at a time and not include rush cases.

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.

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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 operational use (i.e. not out of service) and is being used for a procedure on that day. If a device is not in use on that day, 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 be replaced upon the manufacturer's expiration dated located on each device. (NOTE: each device dated may vary)..
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

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be sent for re-calibration or repair at any time. Serological pipettes do not require calibration (QAS 10.2.1.3).

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 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 monitored using a 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 allowable range will be posted on the device.

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

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

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- Microcentrifuges

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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 or criteria	DNA Form
Daily Cleaning (if the device is used that day)	Lab Staff	QIACube User Manual Chapter 6, pg. 4-6	DNA 031
Periodic Maintenance at least every 6 months	Lab Staff	QIACube User Manual Chapter 6, pg5-6	DNA 031
Preventative Maintenance (PM) 1 x year	Qiagen Field Service Engineer	NA	Must be documented and maintained in appropriate log book
Performance Check (PC) At least 1 x year (separate from post PM PC)	Lab Staff	A known sample or a proficiency sample (results are back from testing agency) with a quantitation value >.1 ng/ul	DNA 050, Repair or service 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.
- 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.

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Periodic Maintenance (minimum every six months)

- Perform the daily maintenance procedure
- 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.
- 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.

Apply a few drops of mineral oil with a soft cloth and use to wipe down bucket mount rotor claw and buckets. **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.

- 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.
- 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

O-ring Replacement (By an analyst as needed if there are indications of insufficient pipetting, separate from the manufacturer’s preventative maintenance)

- Move to cleaning position.
- Carefully remove old o-ring(s) and replace with new o-ring(s). Be careful to not

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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

Repair or service must be documented and maintained in appropriate log book

Action	Assigned	Manual Reference or passing criteria	DNA Form
Daily Cleaning (if the device is used that day)	Lab	Follow general care instructions in the SOP	DNA 030
Preventative Maintenance 1 x year	Field Service Engineer or returned to manufacturer site	NA	M
Performance Check (PC) At least 1 x year (separate from post PM PC)	Lab Staff	A known sample or a proficiency sample (results are back from testing agency) with a quantitation value >.1 ng/ul	DNA 050

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% ethanol. Keep the cooling vents in the back of the machine clear of dust.

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- 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. For additional maintenance and care needs when applicable see Maxwell 16 User Manual, Section V Periodic Cleaning and Maintenance.

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.

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Maintenance

Repair or service must be documented and maintained in appropriate log book.

Action	Assigned	Manual Reference or passing criteria	DNA Form
Preventative Maintenance 1 x year	Qiagen Field Service Engineer	NA	M
Performance Check (PC) At least 1 x year (separate from post PM PC)	Lab Staff	Prepare a standard curve using current quantitation method which passes according to the current metrics in the DNA technical manual. For CE QIAgility only: Run one positive control, one negative control, and an allelic ladder with all alleles called successfully and all size standards properly labeled in Genemapper. The negative should have no allele calls.	DNA 050

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.

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Maintenance

Repair or service must be documented and maintained in appropriate log book

Action	Assigned	Manual Reference or passing criteria	DNA Form
Preventative Maintenance 1 x year	Life Technology Field Service Engineer	NA	Must be documented and maintained in appropriate log book
Performance Check (PC) At least 1 x year (separate from post PM PC)	Lab Staff	Prepare a standard curve using current quantitation method which passes according to the current metrics in the DNA technical manual	DNA 050, Repair or service must be documented and maintained in appropriate log book
Periodic Maintenance (every 3 months)	Lab Staff	Applied Biosystems 7500 Real-Time PCR Systems System Maintenance Manual	DNA 008 Must be documented and maintained in appropriate log book
Lamp Check (As needed for poor performance)	Lab Staff	User-Performed Maintenance Manual Chapter 6, pg. 58	DNA 008

Periodic Maintenance (Every 3 months):

- Perform a function test for all systems: Follow the procedure on Pg. **30-31**
- Check sample block for well contamination:
 - In the SDS software, create a new document: If the Quick Startup document dialog box is open, select **Create New Document**. If the Quick Startup document dialog box is not open, select **File ▶ New**). In the New Document dialog box, click **Finish**
 - In the SDS software, select **Instrument ▶ Calibrate**.
 - In the warning dialog box, click to **YES** to move the block.
 - In the ROI Inspector, **Select Filter A**: In the Exposure Time field, enter **1024**.

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- Click **Snapshot**
- If any of the wells are significantly brighter relative to the other wells, show any red spots, or have a significantly higher pixel intensity value, then follow the sample block decontamination procedures on Pg. **112-117 (Steps 1-10)** of the manual
- Create a background calibration plate: Follow all of the steps on Pg. **129** to create a plate with 50 µl of deionized water in each well
- Run a Background Calibration plate: Follow the procedure on Pgs. **54-61-- Starting at Step 6** on Page **54**. Please note that this is being performed with the deionized water plate and not the background plate that comes with the Spectral calibration kit
- Defragment the Hard Drive: Follow the procedure on Pg. **118**

Thermal Cyclers

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

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Maintenance

Repair or service must be documented and maintained in appropriate log book

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

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.

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Maintenance

Repair or service must be documented and maintained in appropriate log book.

Action	Assigned	Manual Reference or passing criteria	DNA Form
Preventative Maintenance 1 x year	Life Technology Field Service Engineer	NA	M
Performance Check (PC) At least 1 x year (separate from post PM PC)	Lab Staff	Run one positive control, one negative control, and an allelic ladder, must have all alleles called successfully and all size standards properly labeled in Genemapper. The negative should have no allele calls.	DNA 050. See manuals and SOPs-page 36 for instructions.
Spatial Calibration & Spectral Calibration (After each new array install)	Lab Staff	NA	DNA 033 See manufacturer's manuals
Instrument Cleaning (As needed)	Lab Staff	NA	DNA 033
Reagents Replaced Buffer (~48 hours) Polymer (As needed)	Lab Staff	NA	DNA 033
Capillary (As needed)	Lab Staff	NA	DNA 033
Data & Hard Drive (As needed, data archived and system disc defragmenter completed)	Lab Staff or Service Engineer	NA	NA

Other Performance Checks

Performance Checks, when needed, will be defined as follows for the remaining equipment below:

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Instrument	Test	Pass Criteria
9700	GeneAmp PCR System 9700 User's Manual, pg. 18-32	Passing criteria defined in the user manual
Balances, Thermal Cycler Temperature Verification System, and Pipettes	Performed by qualified external vendor, additional internal checks not required	Criteria set by external vendor as appropriate per piece of equipment
NIST Traceable Thermometer	None, purchased new yearly	Set by vendor

Water Filtration Unit

Water filtration systems will be monitored and maintained by maintenance or and external vendor. 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. However, calibration of this software to a NIST device is difficult given the Continuum software, so the electronic monitoring system will only be used to notify staff of catastrophic failure, especially during non-work hours. If, at any time, a device appears to be in need of repair, the device will be marked as out of service until it is repaired.

Each required device in the laboratory will use a NIST calibrated thermometer to monitor temperature. The thermometers will be in service until the listed expiration date on the device (each one may vary). Furthermore, these thermometers are not used for performance checks.

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Water baths

Water baths are dedicated equipment whose temperature is routinely maintained at ~56°C for DNA procedures and is monitored via a NIST traceable thermometer and the Andover Electronic monitoring system.

- Allowable Range: 56°C, (+/- 2°C) 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	DNA 032

Heatblocks (1.5 mL and 96 well)

Heatblocks are dedicated equipment whose temperature is routinely maintained at ~70°C for DNA procedures completed in the extraction lab. The NIST thermometers in pre-amp areas can be monitored using a general lab use NIST thermometer (with the aid of mineral oil or water).

- Allowable Range: 70°C (+/- 2°C) for DNA extracts and 50°C- 70°C for drying slides

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

Ovens

Ovens are dedicated equipment whose temperature is routinely maintained at ~70°C for DNA procedures and ~95°C for Serology procedures.

- Allowable Range: 70°C, (+/- 5°C)

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.

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No rotational check is required on this device.

Hoods

The hoods with airflow controls will be checked at least once a year and maintenance is coordinated by the APD Building Services unit. Where UV bulbs are utilized, the bulb use will be monitored using form DNA 025 and bulbs will be changed yearly, which will also be documented on the form.

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 (or similar) for all protocol centrifugations, and the personal benchtop Sprout (or similar) microcentrifuges to perform quick spins of tubes.

No maintenance is needed for the Sprout style devices.

NOTE: The terms Sprout and Mikro 220 are present as examples of two common personal micro centrifuges used in the lab. Exact manufacturer and model numbers may vary. In general, the reference to Mikro 220 devices refers to any larger centrifuges used for high speed centrifugation, whereas the sprout- style devices refers to any small bench top devices used for quick low speed centrifugation.

Cleaning and Maintenance of the High Speed Centrifuges

Microcentrifuge housing, rotor chamber, and rotor accessories should be cleaned with cleaning agents such as 70% ethanol as needed; use of bleach is discouraged unless followed by a cleaning procedure to remove the bleach residue. 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

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Performance Check 1 x every six months	Lab Staff	NA	DNA 012
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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. Please refer to maintenance charts for each instrument for details. This monthly cleaning schedule includes:

- Sweep and mop extraction laboratory area and post amplification laboratory area
- Weekly collect and take out trash and recyclables from the laboratory areas
- Weekly check the status of water in the water bath and replace/replenish as needed (document the status on the log)
- General cleaning of high speed microcentrifuges
- Suggest ordering of supplies and reagents to the DNA supervisor. The DNA supervisor will then order the items needed.
- Ensure that sufficient reagents are prepared. If the person does not know how to make a reagent or is not qualified on a procedure that uses the reagent, it is this person's responsibility to locate a person to make the reagent.
- Checking temperatures of thermal devices weekly.

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. The following in-house reagents will also need to be checked for their quality prior to use in casework DTT (use form DNA 043) and Pro K (use form DNA 044)

Critical Reagents

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

- In house made: DTT (form DNA 043) and ProK (form DNA 044), (follow instructions on these forms for the QC of these reagents).
- Qiagen: G2 Buffer (see form DNA 048) (follow instructions on this form to QC)
- Life Technologies: Quantifiler
- Promega: DNA IQ Casework Sample Kit, Swab Solution kit, Power Plex Fusion kit
- QIAgen: QIAamp[®] DNA Investigator Kit

QIAamp[®] DNA Investigator Kit

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- Each new lot of QIAamp® DNA Investigator kits (or associated supplemental reagents such as G2 buffer) must be subjected to an internal quality control test as outlined below:
- A known blood or saliva sample (or differential if appropriate for the required use of the reagent) 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 any reagent or amplification blank 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 any reagent or amplification blank 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:
- A known 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 any reagent or amplification blank above threshold (75 RFU for RB).

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- 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

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.
 - 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

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. The technical leader will decide if the kit is suitable for use based on these results.
- 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

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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 at a minimum:

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

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

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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
 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

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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 may 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 analysis threshold within an allele calling region. It may be necessary to reinject or resetup a sample and blank in order to see if the suspected alleles 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.

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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, reagents, and reagent bottles may need to be discarded 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.

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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, PentaD, 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

This section details the 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 as part of the case review 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*.

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➤ **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 Disposition Statements**

All serology reports will end with a clarification statement regarding whether DNA testing is proceeding or not, and if not, include an explanation as to why. Exact language may vary, but examples of language is given below and may be altered to suit the needs of the individual circumstances in the case:

Option 1: DNA analysis is proceeding on this case, a separate report will be issued upon completion of the DNA analysis portion of this testing.

Option 2: DNA analysis is not proceeding on this case because...

- a. ...no apparently probative evidence was identified during the serological examination to require DNA testing at this time. Please contact the laboratory should you require DNA testing on this case.
- b. ...insufficient known reference samples were submitted to the laboratory for comparison to the evidence in this case. If you require DNA testing, please submit samples from the following subjects: (types of samples needed; i.e. suspects, victims, elimination, or other samples needed to proceed). Please contact the laboratory if you have questions regarding this request.
- c. ...the request for DNA analysis has been rescinded. Please contact the laboratory if you have questions regarding further DNA testing in this case.

➤ **DNA analysis**

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.

Intimate Samples

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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*.

*NOTE: Intimate Sample, as defined in this lab, is a sample that originates:

- directly from an individual's body such as fingernails, oral swabs, vaginal swabs, a swabbing from any skin surface;

or

- an individual's clothing where documentation exists that this clothing was removed from the individual during evidence collection and/or was worn at the time of the offense.

All other sample types are considered non-intimate samples for this purpose.

Statistical calculations for the results of each test in which a positive association is made must be clearly and properly qualified in the test report. This does not apply to associations made between the profile derived from an intimate sample and the individual from whom that sample was collected. (i.e. the female fraction of a vaginal swab that is consistent with the victim in the case).

All other profiles obtained while testing intimate samples that are not consistent with the person from whom the sample or clothing was taken, must be clearly defined in the report and statistical analysis calculated if an association is made (i.e. an innocent bother of a victim that is part of a mixture on a victim's t-shirt).

Statistical calculations for more than one test (i.e. the same result was obtained on multiple samples) can be reported together if the results of those calculations are the same.

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* 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

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- ...the excessive minimum number of contributors.
- ...due to the potential for allelic drop out and the potential for allelic dropout

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, 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

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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:

- *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 (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 component 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 Component

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- 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. Inventory of items (for example sexual assault kit contents)
- Physical description/observations of items requested for analysis
- Presence or absence of apparent blood and/ or semen
- Estimated evidence processing, or testing, time frames
- 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

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4.5 Archiving Laboratory Case Files

No Supplemental Requirements

4.6 Expunctions

No Supplemental Requirements

4.7 Control of Laboratory Records

No Supplemental Requirements

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.
- 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

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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 entered in the comments section in LIMS. The original analyst should confirm this was done.
- 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.

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 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

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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:

All positive stains tested (at a minimum) 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. It is analyst discretion whether to label individual areas not tested, or tested negative, with stain numbers. Case notes about stains on an item shall be sufficient to support conclusions such that, in the absence of the analyst, another competent reviewer could evaluate what was done and interpret the data. In addition, if evidence packaging is opened, any testing performed on that item, or lack thereof, must be conveyed in the report. If no testing was performed on a particular item,

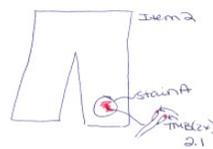
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the report should state this fact. For example, if a request comes in for one item, and the packaging contains 2 items, both items must be listed and referenced in the report, even if only one item was tested. The second item should be reported stating that no analysis was performed. If a package was received by an analyst and it remained sealed in their possession, then simply documenting chain of custody is acceptable as long as the seal on the evidence item was never broken.

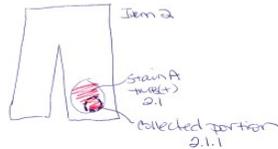
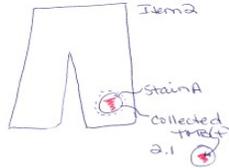
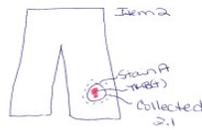
Below is an illustration of proper sub-item labeling.



Swabbings



Cuttings



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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.

➤ **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**

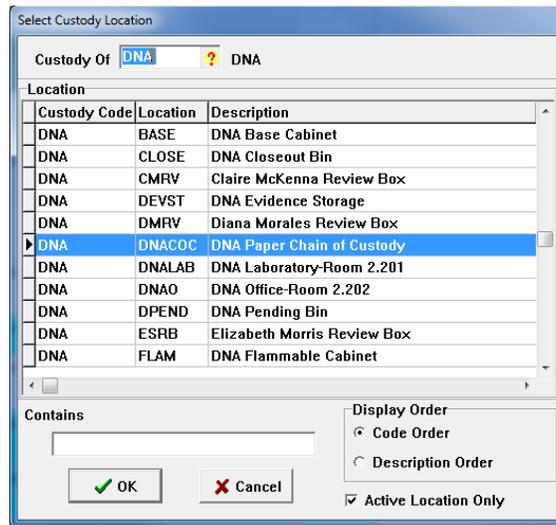
Occasionally, an investigation may be aided by the comparison of a questioned hair to known standards. In most cases, nuclear DNA analysis may only be performed on evidentiary hair when:

- 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 (Start date/time of extraction process) will also be documented on the forms, as applicable. The time of completion for the DNA extracts will be documented on the Completion Date/Time line. The resulting containers in LIMS housing cuttings, swabs, extracts, etc., should be marked with a location of "DNACOC", DNA Paper Chain of Custody. Where possible, separate known samples from questioned samples with a separate paper chain of custody.

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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.

Samples in F5 are generally reserved for samples where no DNA is needed or in long term storage for DNA extracts and cuttings/swabs. Samples in F6 generally samples ready for the DNA process.

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 as having been received from the Central Evidence Locker, (i.e. "rec'd from CEL"). The analyst is expected to do this using the comment field in LIMS at the time of transfer. In the event that it is discovered later that the "rec'd from CEL" is missing, it may be corrected in LIMS by printing a copy of the chain of custody from LIMS, notating the correction on the paper copy with the date that the correction was made, and uploading the corrected paper copy to LIMS. This paper copy correction must be approved by the DNA Supervisor and the original analyst must be certain that the correction is accurate before doing so.

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 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

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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 amplified 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 amplified 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.

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.

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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.

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

Scope

Outsourcing is the utilization of a vendor laboratory to provide DNA services in which the APD DNA laboratory takes or retains ownership of the DNA data for entry into CODIS. Outsourcing, by this definition, does not necessarily always require the existence of a contractual agreement or the exchange of funds, however the APD DNA laboratory will not engage in outsourcing as defined above without a contractual agreement.

Therefore, these guidelines contained within this document are invoked when a contract exists between the APD DNA Laboratory and a vendor laboratory for purposes of upload of the resulting data into CODIS. Samples are not considered to be “outsourced” by this definition if a third party laboratory, whether government related or a private for profit company, is utilized to analyze samples at the direction of the court, the District Attorney’s office, or other APD official not employed by the APD DNA laboratory. Examples of typical types of analysis that do not meet this definition of outsourcing are:

1. Sending samples out for testing on a technique not employed by the APD DNA laboratory such as YSTR testing or mtDNA testing.
2. Sending out samples for a similar type testing that the APD DNA laboratory does perform, but is unable to perform it as requested either due to time constraints or other reasons.

These examples as described in 1. and 2., or other similar examples, do not qualify as outsourced via this policy because the data is owned by the laboratory performing the testing, not the APD DNA laboratory. The APD DNA laboratory will not perform administrative or technical reviews of the data in these types of cases and will not upload and data obtained from

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them into CODIS.

5.5.1 Requirements for Use of a Vendor Laboratory for Outsourcing

2. Any vendor laboratory performing forensic Serology/DNA analysis on contract with this laboratory shall comply with the Quality Assurance Standards for Forensic DNA Testing Laboratories and the accreditation requirements of federal law. We will maintain documentation that the vendor laboratory is in compliance with the Quality Assurance Standards for Forensic DNA Testing Laboratories, and the accreditation requirements of applicable federal laws as it relates to the ability of APD to perform CODIS uploads from vendor generated data.
3. The APD DNA Lab's technical leader shall document approval of the technical specifications of the outsourcing agreement with a vendor laboratory before it is awarded and prior to any work on forensic samples begins.
4. Only results from the vendor laboratory on DNA cases started after the date of the agreement will be accepted.
5. The APD DNA Lab will document acceptance of ownership of the DNA data obtained from the vendor laboratory prior to uploading any data to CODIS. Prior to the upload or search of DNA data in SDIS, an analyst, casework CODIS Administrator or technical reviewer employed by an NDIS participating laboratory shall review the DNA data to verify specimen eligibility and the correct specimen category for entry into CODIS.
6. The APD DNA Lab shall have and follow a procedure to verify the integrity of the DNA data received via a technical review of DNA data from a vendor laboratory. This technical review shall be performed by an analyst or technical reviewer employed by an NDIS participating laboratory who is qualified or previously qualified in the technology, platform and typing amplification test kit used to generate the data and participates in an NDIS laboratory's proficiency testing program.
 - a. Platform is defined as the type of analytical system utilized to generate DNA profiles such as capillary electrophoresis, real-time gel, and end-point gel instruments or systems.
 - b. Technology is defined as the type of forensic DNA analysis performed in the laboratory, such as RFLP, STR, YSTR, or mitochondrial DNA.
 - c. Test kit is defined as a pre-assembled set of reagents that allows the user to conduct a specific DNA extraction, quantitation or amplification.
7. The casework technical review (not batch reference sample processing) shall include the following elements at a minimum:
 - a. A review of all DNA types to verify that they are supported by the raw and/or analyzed data (electropherograms or images).
 - b. Review of raw data by performing a second analysis of the original Genemapper data.
 - c. A review of all associated controls, internal lane standards and allelic ladders to verify that the expected results were obtained.
 - d. A review of the final report (if provided) to verify that the results/conclusions are supported by the data. The report shall address each tested items (or its probative fractions) submitted to the vendor laboratory.
 - e. Verification of the DNA types, eligibility, and the correct specimen category for entry into CODIS.
8. The APD DNA Lab shall have and follow a procedure to perform an on-site visit(s) of any

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vendor laboratory that is performing DNA analysis as a part of this outsourcing policy prior to beginning casework analysis for the APD DNA Lab. (NOTE: If a vendor laboratory is contracted solely for the purpose of technical review services, an on-site visit of the vendor facility is not needed.) The procedure to perform an on-site visit shall include, at a minimum, the following elements:

- a. The on-site visit shall be performed by the APD DNA technical leader, or a designated employee of the APD DNA Laboratory as designated by the APD DNA Lab technical leader. This person must be a qualified, or previously qualified, DNA analyst in the technology, platform and typing amplification test kit, used to generate the DNA data.
- b. If the outsourcing agreement extends beyond one year, an annual on-site visit shall be required. Each annual on-site visit shall occur every calendar year and shall be at least 6 months and no more than 18 months apart.
- c. For either 6a. or 6b, alternatively, the APD DNA Lab technical leader may accept an on-site visit conducted by the FBI, or another NDIS participating laboratory using the same technology, platform and typing amplification test kit, for the generation of the DNA data in lieu of a visit from and APD employee. If this alternate process is used in place of an on-site visit by a qualified APD employee, the APD DNA technical leader:
 - i. shall document the review and approval of such on-site visit.
 - ii. ensure that the use of documentation from another source complies with the Quality Assurance Standards for Forensic DNA Testing Laboratories and the requirements of the FBI CODIS officials.

5.5.2 Shipment

1. Samples/batches shall be sent by shipping carrier with package tracking capabilities or submitted in person to the contract laboratory. Documentation of cases sent to a vendor laboratory shall be maintained in the APD Crime Laboratory.
2. A letter, email, or memo will be generated by APD and sent to the vendor laboratory informing them of the tracking information of the packages shipped.
3. The APD DNA Lab will require that the vendor laboratory provide documentation of the samples/batches when received, including documentation of the vendor laboratory's case numbers and/or barcode information.

5.5.3 Analysis of Outsourced Samples

1. The vendor laboratory shall use APD approved analysis procedures and analysis methods as stated in the contract.
2. The APD DNA Lab is not obligated to accept data from cases analyzed outside the contracted parameters without documented approval from the APD DNA technical leader and other City of Austin officials, as necessary.

5.5.4 Release of Reports

1. Reports received from a contract laboratory shall not be released to the submitting

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agency or legal system until a technical review, including electronic data analysis, of the case has been conducted by a qualified DNA analyst, as previously described.

5.5.5 Courtroom Testimony

1. Testimony will be provided by the vendor laboratory, as necessary, for all analyses performed by the contract laboratory.
2. Fees for testimony will be paid for by the District Attorney's office, or other entity as agreed to by the APD DNA technical leader and the appropriate City of Austin officials. Method and source of payment of these fees should be determined prior to beginning the outsourcing contract.
3. APD DNA Laboratory analysts are not permitted to testify to the analysis performed by a vendor laboratory beyond the extent to which they participated in the analysis of the case. For example, if the vendor laboratory performed all analysis and issued the DNA report and the APD DNA lab performed the administrative and technical review of the case, the APD DNA analyst would only testify to the administrative and technical review portion of the analysis that they performed.

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

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7.7 Employee Training Program

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 pre-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

8.0 Computer Resource Management

8.1 DNA Workflow Spreadsheets

This section describes general situations where software updates occur and the impact on the

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laboratory.

1. DNA extraction robots, pipetting robots, CE instrumentation
 - a. PM or Service based firmware updates – requires post-service performance check.
 - b. Protocol Updates to Run Protocols or Scripts – technical leader decides how the change may impact the analysis and prepares the appropriate studies needed to verify the change, or document that no verifications are needed if deemed a minimal change.
 - i. NOTE: many instruments will have, where possible, the standard run protocols or scripts preserved as controlled documents. These may act as the masters in case of corruption or loss of the original files.
2. DNA Analysis Software (Instruments and Data Analysis), and Operating Systems
 - a. Service Packs for will be generally treated as nominal changes that require no performance check or validation.
 - b. Software version changes in whole integers, such as v2.0 to v3.0, generally require full validation but the amount of testing needed will be determined by the DNA technical leader.
 - c. Software version changes that are less significant are reflected in tenths or hundreds, such as v1.1 to v1.2 or v1.1.1 to v1.1.2, generally only require a performance check but the amount of testing needed will be determined by the DNA technical leader.
3. CODIS
 - a. updates and verification are handled through the CODIS system.
4. Popstats
 - a. a single source and a mixture sample are run to verify concordance.

8.2 DNA Workflow Spreadsheets

Analysts are authorized to document the process from DNA extraction through CE analysis using the existing DNA forms or they may generate case records of this process by the use of the DNA Worksheet Generator (currently version controlled as a controlled document) for printout in the case file. The DNA Workflow Spreadsheet only represents a means to generate the appropriate record to maintain an audit trail. The paper file in the case file is recognized as the official case record and is the document that is verified during technical and administrative review, not the electronic version of the DNA Workflow Spreadsheet Excel file.

The electronic version of the DNA Workflow Spreadsheet need not be maintained as a case record and may be deleted once the paper document is added to the case file. The master copy of the DNA Worksheet Generator will be maintained on the G drive in the same location as the existing forms. Analysts are not authorized to alter the functionality or core content of the DNA Workflow Spreadsheet, but they are authorized to use it to enter data related to their specific casework and generate case records.

In addition, a separate Excel spreadsheet is available for easily creating import files for the 3130

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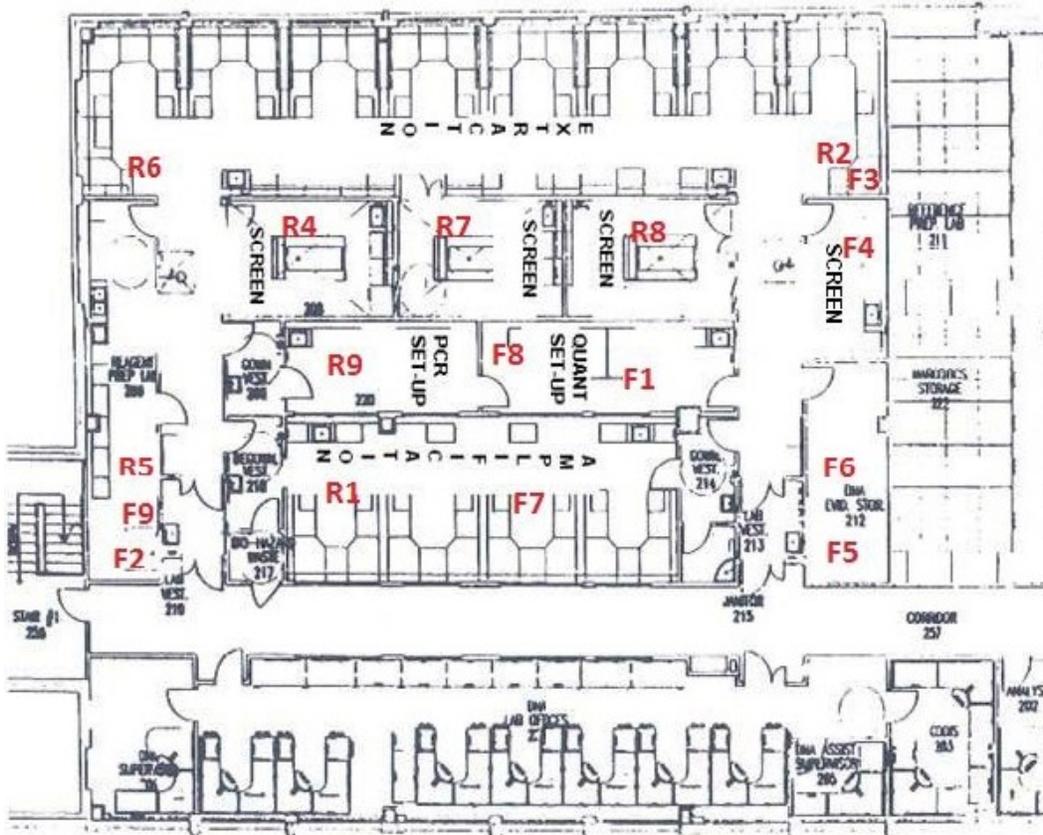
Genetic Analyzer. This is titled the CE Import File Generator and no case file documents will be generated directly from this Excel program. The technical and administrative reviewer will examine the injection list and the plate layout documentation in the case file to confirm that the samples were set up correctly on the 3130 Genetic Analyzer.

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Appendices

Appendix 2A Floor Plan

Laboratory layout and location of the refrigerators (R) and freezers (F)



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.

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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
C	Container
CEL	central evidence locker
C/N	control negative
D	Depleted
Diff	Differential Extraction
Dk	dark
Dnp	Did not possess
dIH ₂ O	deionized water
Disp	Disposition
Env	Envelope
Epi, EC, EF	epithelial cell, epithelial fraction
Evid	evidence
Ext	Extraction
F	frozen
F#	freezer # (where # is the number of the freezer)
FM	Forensic Mixture
FP	Forensic Partial
G	Grey
H	human
H/F	heads per field
K	known standard sample
L	Left

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L2	Crime-Lite 2
LL	Crime-lite 82
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
R#	Refrigerator # (where # is the number of the freezer)
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

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Soln	solution
Sp	sperm
SP	swab packet
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
+	positive
-	negative

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Appendix 5B DNA Laboratory Document Retention Policy

RECORD TITLE AND DESCRIPTION	MINIMUM RETENTION PERIOD	REMARKS
<p style="text-align: center;">AUDIT RECORDS</p> <p style="text-align: center;">Accreditation Reports</p> <p>Annual or biennial cumulative reports, periodic reports not included in cumulative and special audit reports of internal and external Forensics Laboratory audits from any discipline.</p> <p>Includes documentation of accreditation, (ASCLD/LAB certificates, DPS letter of accreditations), all final reports of audits, internal or external, from any discipline (including drug standard audits), corrective/preventive action reports, method validation summary reports, and audit responses</p>	AC + 100 years	AC = Issuance date of the final report Custodian is the Police Forensics Division.
<p style="text-align: center;">AUDIT RECORDS</p> <p style="text-align: center;">Work Papers</p> <p>Work papers, summaries, and similar records created for the purposes of conducting an audit.</p> <p>Includes FBI audit document criteria and quality assurance work papers.</p>	AC + 5 years	AC = After all questions have been resolved. Custodian is the Police Forensics Division.
<p style="text-align: center;">EMPLOYEE RECORDS</p> <p style="text-align: center;">Personnel Quality Audit Files</p> <p>Records providing each employee's employment history with the Forensics Laboratory beginning with initial hire. Includes audit notebooks, proficiency test summaries, court testimony evaluations, casework authorizations, statement of qualifications, training records, and continuing education.</p>	AC + 100 years	AC = Date of separation or termination. Custodian is the Police Forensics Division. Note: When employees transfer from one department to another, their files should be transferred to the new department's human resource unit.

RECORD TITLE AND DESCRIPTION	MINIMUM RETENTION PERIOD	REMARKS

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<p>LABORATORY CASE RECORDS</p> <p>All documentation related to analysis of evidence for a specific case. Includes paper and electronic records.</p>	<p>AC + 100 years</p>	<p>AC = date of final report issuance for the lab number in question.</p> <p>Custodian is the Police Forensics Division.</p>
<p>MAINTENANCE, REPAIR, AND INSPECTIONS RECORDS</p> <p>Laboratory Equipment</p> <p>Documentation of laboratory equipment maintenance and repair records including printouts of work orders. Includes records of instrument calibration documentation, maintenance logs, validations, and manuals of instruments used to conduct toxicology, histology, and other laboratory tests and procedures.</p>	<p>LA + 5 years</p>	<p>LA = Life of the asset.</p> <p>Custodian is the Police Forensics Division.</p>

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RECORD TITLE AND DESCRIPTION	MINIMUM RETENTION PERIOD	REMARKS
<p>OPERATIONAL PERMITS, LICENSES, CERTIFICATIONS, AND APPROVALS</p> <p>Permits, registrations, certifications and other approvals from any local, state, or federal agency, as may be required by law or regulation, including station operation and broadcasting licenses and permits from the FCC. Includes any reports, correspondence, or other documentation bearing directly on the application for, the issuance of, or the renewal of the permit, license or certification; and any variances or exemptions granted to a facility.</p> <p>Includes Controlled Substance Registration Certificate (Texas and DEA), Polygraph Examiner Bond Certificate.</p> <p>Also includes ASCLD/LAB Accreditation Records that support compliance requirements: Laboratory Complaints, Customer Surveys, Proficiency Test Data, Method Validation studies (data, not summary report), Audit Record work papers, Division and Section staff meeting notes, Annual Safety Inspection documents, Management System reviews, Visitor Logs, Purchasing Records (vendor approvals and outsourcing contracts), Controlled Substance and Dangerous drug records (drug standard validation book and reversal logs).</p>	<p>AC + 5 years</p>	<p>AC = Final expiration, cancellation, revocation, or denial of the permit or certification.</p> <p>Custodian is the Police Forensics Division.</p>

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RECORD TITLE AND DESCRIPTION	MINIMUM RETENTION PERIOD	REMARKS
<p style="text-align: center;">POLICY AND PROCEDURE DOCUMENTATION</p> <p style="text-align: center;">Forensics Laboratory Policies and Procedures</p> <p>Executive orders, directives, manuals, and similar documents that establish and define the policies, procedures, rules, and regulations governing the operations or activities of the Forensics Laboratory. Includes policies and procedures related to deviations (approved and rejected), changes by memo, Physical Evidence Handbook, Training Manuals, document authorizations, forms, and employee acknowledgement records.</p>	AC + 100 years	<p>AC = Until superseded, expired or discontinued.</p> <p>Custodian is the Police Forensics Division.</p>
<p style="text-align: center;">QUALITY CONTROL REPORTS OR LOGS</p> <p style="text-align: center;">Forensics Lab</p> <p>Quality audit and quality control reports from any Forensics Laboratory section not contained within a case record.</p> <p>Includes purchase or equipment records, lab equipment and machine certifications, reagent quality control logs, and incident logs.</p>	AC + 5 years	<p>AC = from date of the last entry on the record sheet, log or journal or one accreditation period, whichever is longer.</p> <p>Custodian is the Police Forensics Division.</p>
<p style="text-align: center;">SOFTWARE REGISTRATIONS, WARRANTIES AND LICENSE AGREEMENTS</p> <p>Documentation of registration, warranties and licensing agreements for all software.</p> <p>Includes DNA Analysis Software, Noritsu print machine, polygraph software/license, Firearms software, and Nikon camera software.</p>	LA + 3 years	<p>LA = Life of asset.</p> <p>Custodian is the Police Forensics Division.</p>

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RECORD TITLE AND DESCRIPTION	MINIMUM RETENTION PERIOD	REMARKS
<p style="text-align: center;">TRAINING AND EDUCATIONAL RECORDS</p> <p style="text-align: center;">Training Course Materials</p> <p>Training manuals, syllabuses, course outlines, and similar training aids used for in-house training programs.</p>	AC + 2 years	<p>AC = Until superseded, expired, or discontinued.</p> <p>Custodian is the Police Forensics Division.</p>
<p style="text-align: center;">VISITOR CONTROL REGISTERS</p> <p>Records documenting visitors to limited access or restricted areas including logs and registers. Also includes guest books, registers, logs, or similar records of visitors to museums, historical sites, and other facilities owned or operated by the City.</p>	CYE + 3 years	<p>CYE = Calendar year end.</p> <p>Custodian is the Police Forensics Division.</p>

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Appendix 5C DNA Processing Acceptance Workflow

