

# Alaska Scientific Crime Detection Laboratory

## DNA Quality Assurance Manual

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### **Introduction: General Laboratory Information**

Name of Laboratory: Scientific Crime Detection Laboratory (abbreviated as AK SCDL)

State of Alaska (SOA), Department of Public Safety (DPS)

Approximate population size served: 700,000 (2009)

Does not currently use a contract laboratory.

Performs technical review of data from casework submitted by SOA Law Enforcement agencies to contract/vendor laboratories for potential entry and search in CODIS.

NDIS participant

Technologies used: STRs

Number of staff:

DNA analysts: seven

DNA trainees: 3

DNA Technicians: 1

Laboratory support personnel: 1 (paralegal)

DNA Technical Manager: On-site – 1

CODIS Administrator (Casework + Database): On-site – 1

Last audit conducted on:

Internal Annual – 12-14, September 2011

External Annual – 4-8, October 2010

Audit document discussion used:

2011 Internal annual audit: Revision effective 1 September 2011

2010 External annual audit: Revision effective 1 July 2009

Expert system available for use (platform AB3130xl – PP16 – 32 cycles amplification)

Database laboratory does not routinely process casework known reference samples.

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### Goals and Objectives:

Reference: AK SCDL Laboratory Quality Assurance Manual.

### Chapter 1: Scope

#### References:

- (1) Standard 1 – FBI Quality Assurance Standards (QAS) document for forensic DNA testing and DNA databasing laboratories, version effective 01 September 2011. The AKSCDL DNA QA manual is based on the above FBI QAS document and the reader is advised to refer to the above-mentioned FBI document for detailed discussion and interpretation of the quality standards and their sub-categories.
- (2) AK SCDL Laboratory Quality Assurance Manual for quality standards that are applicable to all disciplines/sections of the crime laboratory.
- (3) AK SCDL Laboratory Safety Manual for documentation of an environmental health and safety program.
- (4) DNA Standard Operating Procedures manual for information pertaining to analytical procedures / work instructions for the specific reagents and instruments for DNA analysis and data interpretation.
- (5) DNA Section Training Manual

### Chapter 2: Definitions

An error is defined as an action or event that leads to an inaccurate conclusion in a DNA report (casework or proficiency test) released by the laboratory. Errors will be addressed and documented in corrective action reports (CARs).

and

#### Reference:

Standard 2 – FBI Quality Assurance Standards (QAS) documents for forensic DNA testing and DNA databasing laboratories, versions effective 01 September 2011.

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### Chapter 3: Quality Assurance Program

The laboratory has an established and maintained documented quality system that is appropriate to the testing activities. The quality system is at least equivalent to and/or more stringent than what is required by FBI Quality Assurance Standards (QAS) document for forensic DNA testing and DNA databasing laboratories, version effective 01 September 2011.

The quality system of the laboratory is documented in manuals that include and/or reference the following elements as listed in the contents page of this quality assurance manual:

Goals and objectives, organization and management, personnel, facilities, evidence/sample control, validation, analytical procedures, equipment calibration and maintenance, documentation/reports, review, proficiency testing, corrective action, audits, safety, and, outsourcing.

The laboratory maintains and follows procedures (please refer to the Laboratory Quality Assurance manual) regarding document retention which addresses policies regarding proficiency tests, analytical results, sample receipt and processing records, sample retention, corrective actions, audits, training records, continuing education, case files and court testimony monitoring.

The policies pertaining to hit confirmation are documented in the laboratory CODIS manual.

The quality system as applicable to DNA is reviewed annually (calendar year) independent of the audit required by Standard 15 (please see chapter 15). The review is performed under the direction and documented approval of the technical manager. A checklist maintained along with the quality manual contains the signatures of the analysts and the date the annual review was completed. This annual review includes the quality manual, training manual, and standard operating procedures manual (Please see Chapter 9: Analytical Procedures). A checklist for this annual review is maintained with each relevant manual in order to document the review and address procedures for updating the manual(s).

### Chapter 4: Organization and Management

The laboratory has a managerial staff with the authority and resources needed to discharge its duties and meet the requirements of the FBI Quality Assurance Standards (QAS) document for forensic DNA testing and DNA databasing laboratories, version effective 01 September 2011. The laboratory has an on-site technical manager who is accountable for the technical operations and an on-site CODIS administrator (database and casework) who is accountable for CODIS operations at the laboratory. In accordance with Appendix B of the FBI Quality Assurance Standards document, a DNA analyst who meets the educational qualifications and work experience to fulfill the duties of DNA technical manager has been identified in the event that position is vacated by the current technical manager. The laboratory meets the requirements of having at least two full time employees who are qualified DNA analysts. Documentation that specifies the responsibility, authority, and interrelation of all personnel who manage perform and/or verify work affecting the validity of DNA analysis is maintained. The Laboratory Quality Assurance manual contains information pertaining to the laboratory organizational chart.

*The DNA Quality Assurance Manual supplements the Laboratory Quality Assurance Manual. Please refer to the Laboratory QA Manual for overall AK SCDL organization and management.*

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### Chapter 5: Personnel

Laboratory personnel have the education, training and experience commensurate with the examination and testimony provided. The laboratory quality manual maintains written job descriptions for all personnel to include responsibilities, duties and skills. The laboratory has a documented training program for qualifying all analysts. The training program includes a training manual and related training checklist that specify applicable DNA analytical procedures that the analyst(s) will perform. Practical exercises that include the DNA methodologies used in database sample analysis and examination of a range of samples routinely encountered in casework. On occasion, database section analysts are authorized to assist casework analysts by performing analytical tasks as directed and monitored by the casework analyst(s). The memorandum addressing this authorization is on file with the laboratory Quality Assurance Manager. The database section of the laboratory does not routinely process known or casework reference samples unless this task is part of duties assigned and carried out as stated in this memorandum.

The laboratory's training program documented in the training manual is designed to teach and assess the technical and scientific skills and knowledge required to perform DNA analysis and it includes documentation of the successful completion of competency test(s). In the event an analyst possessing prior forensic experience in DNA analysis is hired, the technical manager will assess and document the adequacy of the previous training of this analyst. This analyst will complete a modified training program that will be assessed and documented by the technical manager. Prior to participating in independent database analysis and/or DNA casework, all analysts regardless of prior experience will successfully complete competency test(s) covering routine DNA methodologies to be used. In case of an extended absence (equal to or greater than 3 months) from the laboratory, an analyst may be required to successfully complete at least an internal competency test prior to resuming sample processing / DNA analysis duties

The laboratory has a documented program to ensure that technical qualifications are maintained through continuing education. The technical manager, CODIS administrator (database and casework) and every analyst in the section will maintain documented attendance at seminars, courses, professional meetings and/or training sessions that consist of subject areas relevant to developments in genetics and DNA analysis and typing. The cumulative duration of each annual (calendar year) training session(s) will be at least eight hours. This information will be documented in the analyst's SOQ (statement of qualifications).

If continuing education is conducted internally by the laboratory, the retained documentation will include the title of the program, a record of the presentation (electronic and/or hard copy), date(s) of the training, attendance list and curriculum vitae of the presenter(s).

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If continuing education is conducted externally, the laboratory will retain documentation that includes one or more of the following: Certificate of attendance, program agenda/syllabus and travel related documentation. Such documentation will be maintained in the laboratory's LIMS (laboratory information management system).

For continuing education that is based on multimedia or internet delivery, the training

- (i) will be subject to review of and approval by the Technical Manager,
- (ii) duration of the program or time required to complete the program formally recorded in the laboratory's retained document, and, (iii) completion submitted to the technical manager for review and approval.

The laboratory has a program approved by the technical manager for the annual review of scientific literature that documents (hard copy of publication/research article and circulation checklist) the ongoing reading of scientific literature. The laboratory maintains physical and electronic access, as required and applicable, to a collection of scientific literature relevant to DNA analysis.

The technical manager of the DNA section satisfies the requirements for degree/education, experience and duties as follows: The technical manager has a doctoral degree in Human Genetics with semester hours that exceed the minimum requirements stated under Standard 5 in the subject areas of biochemistry, genetics, molecular biology and statistics or population genetics. The technical manager educational requirements as well as the experience requirements comply with Standard 5 of the FBI Quality Assurance Standards (QAS) document for forensic DNA testing and DNA databasing laboratories, version effective 01 September 2011. The technical manager has successfully completed the FBI sponsored auditor training as well as the ASCLD/LAB-International sponsored ISO Assessor Training.

The technical manager of the laboratory oversees the technical operations of the laboratory. The technical manager has the authority to initiate, suspend and resume DNA database and casework analytical operations for the laboratory or an individual. The technical manager evaluates and documents approval of all validations and methods used by the laboratory and proposes new or modified analytical procedures to be used by analysts. The technical manager reviews and documents the review of academic transcripts and training records for newly qualified analysts and approves their qualifications prior to their conducting independent database or casework analysis. The technical manager approves the technical specifications for outsourcing agreements. The technical manager reviews and documents the review of internal and external DNA audit documents and, if and when applicable, approves corrective action(s). The technical manager reviews, at a minimum, annually (calendar year) the laboratory procedures and documents such review.

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In addition, the technical manager reviews and approves the training, quality assurance, and proficiency testing programs in the DNA section of the laboratory.

The technical manager is a full time employee of the laboratory and is available and accessible to the laboratory to provide on-site/ telephonic/ electronic consultation as needed. Please refer to Chapter 4 for technical manager contingency plan.

The CODIS administrator (database and casework) is a full time employee of the laboratory and satisfies the requirements for degree/education, experience and duties. Please refer to the laboratory CODIS manual for detailed information regarding the CODIS administrator.

Each DNA analyst is an employee of the laboratory meets and exceeds the degree and educational requirements stated in Standard 5 of the FBI Quality Assurance Standards (QAS) document for forensic DNA testing and DNA databasing laboratories, version effective 01 September 2011. Every analyst has a minimum of a BA/BS (two analysts have a MS) degree in relevant subject areas. College coursework for analysts covers the subject areas of biochemistry, genetics, molecular biology and statistics and/or population genetics. In the event completed coursework had titles other than those listed in Standard 5, the technical manager reviewed the documentation provided through supporting materials such as transcripts/ syllabus and this review documented towards the approval of compliance with this Quality Assurance Standard. This documentation, a memorandum issued by the technical manager, is maintained by each analyst as part of the training materials.

Each analyst has a minimum of six months of human forensic DNA testing training in a forensic casework/database laboratory prior to beginning independent work. Each analyst has completed training in the analysis of the range of samples routinely encountered in database analysis and/or forensic casework. Each analyst has successfully completed a competency test before beginning independent DNA analysis. Competency tests following extended absences will be, at a minimum, internally evaluated as stated earlier in this chapter.

### Chapter 6: Facilities

The laboratory is designed (please refer to laboratory quality assurance manual) to ensure the integrity of the analyses and samples / evidence. Access to the laboratory is controlled and limited in a manner that prevents access by unauthorized personnel. All exterior entrance/exit points have security control and the distribution of security devices such as keys and cards is documented and limited to personnel designated by laboratory management.

Technical procedures such as sample screening and DNA extraction that precede DNA amplification by PCR (Polymerase Chain Reaction) are conducted in separate spaces. Amplified DNA products (including those generated by Real Time PCR quantification) are generated, processed and maintained in laboratory area (room) separate from evidence examination, DNA extractions and PCR set-up areas. The doors between rooms containing amplified DNA and other areas are closed at all times except for passage.

The laboratory maintains schedules and follows written procedures for cleaning and decontaminating facilities and equipment. Example: DNA extraction worksheet; routine cleaning lists are maintained, cleaning duties performed and documented by the DNA technician.

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### Chapter 7: Sample / Evidence Control

The laboratory has and follows a documented sample inventory and evidence control system to ensure the integrity of database samples and physical evidence. All database samples and evidence items are marked with unique identifiers on the packaging. The laboratory has established criteria for defining the difference between evidence and work product. The laboratory has and follows documented policies for the disposition of evidence and/or extracts and sample consumption.

Work product, is material that that is generated as a function of analysis, which may include extracts, spermatozoa search slides, amplified products and amplification tubes or plates. DNA section work product such as PCR amplified products are discarded once the data reviews have been completed and the material is no longer needed for further analysis. Work product such as DNA extracts will be routinely discarded after data review is completed and the case report issued. This implies that sufficient quantity of the original item remains for retesting, if required. If the entire original item (e.g., penile swabs, fingernail scrapings, hand swabs, miscellaneous contact DNA items) is used for DNA extraction owing to limited amounts of biological material, then, at least fifty percent of the DNA extracted from that item will be tagged as evidence and retained by the laboratory for retesting, if and when required. In situations where the entire evidence has been consumed in the process of DNA extractions and quantitation results suggest that the entire volume of DNA extract will be required for PCR in order to attempt to obtain interpretable data, the laboratory shall contact the Department of Law to request permission to use the extract. Analysis of said sample extract will not proceed until documented approval by the appropriate agency is received by the laboratory. In general, the laboratory retains or returns a portion of the evidence or extract where possible.

Work product such as the amplified products generated as a result of Real Time Quantitation procedures will be routinely discarded irrespective of the amount of the original item of evidence.

Note: In unknown suspect cases, the entire sample may be consumed in analysis without prior Department of Law notification.

The laboratory has various methods to distinguish each sample throughout the processing from extraction through data analysis by the use of a batch related unique identifier.

Information regarding samples such as internal control samples and allelic ladders analyzed in a batch is located in the central log pertaining to that batch of samples. Specific case related information is located in case folders that may be hard copy and/or electronic versions of the information.

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The databasing section does not routinely process known/reference samples from forensic cases. Forensic questioned and reference samples are analyzed by the casework section analysts. The databasing section and/or the evidence section of the laboratory maintain documentation pertaining to the identity, collection, receipt, storage and disposition of database samples. The laboratory retains the database sample for retesting for quality assurance and sample confirmation purposes whenever possible. Database samples are considered as reference material and are not considered as evidence.

For casework samples, an electronic chain of custody record is maintained. The chain of custody includes the signature and/or initials of each individual receiving or transferring evidence, with the corresponding date for each transfer as well as a corresponding identifier that specifies each evidentiary item. This record provides a comprehensive, documented history for each item of evidence over which the laboratory has control from the time that item is transferred to the laboratory's custody. Chain of custody records are sufficiently secure, detailed and accessible for review.

The laboratory has and follows procedures (reference: laboratory quality assurance manual and procedures manual) designed to minimize loss, contamination and/or deleterious change of evidence and work product in progress. The laboratory has secure, controlled-access areas for evidence storage and work product in progress including environment control consistent with the form or nature of the sample.

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### Chapter 8: Validation

The laboratory uses validated methods for DNA analysis. Whenever developmental validation has been completed by the vendor and/or another laboratory, the AK SCDL will perform internal validation as appropriate prior to implementing a process or a product for database and forensic DNA analysis.

If developmental validation is indicated for a product or process, the following studies will be performed as appropriate and relevant and, the documented results will form the basis of the standard operating procedures:

Genetic marker characterization, species specificity, sensitivity studies, stability studies, reproducibility, case-type samples, database-type samples, population studies, mixture studies, precision and accuracy studies, PCR based studies including reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and product detection studies. Peer reviewed publications of the underlying scientific principles will be relied on and documented for performing the appropriate developmental validations. The results of the validations study will be documented.

Internal validation studies of manual and robotic procedures will be conducted, reviewed, and approved by the laboratory technical manager prior to implementation. The results of the internal validation studies will be documented and summarized. Internal validation studies will include as applicable the following: Database-type samples, casework-type samples (known/non-probative evidence/mock evidence samples/old proficiency test samples/), reproducibility and precision, sensitivity and stochastic studies, mixture studies, contamination assessment.

The laboratory maintains (reference: laboratory quality assurance manual and DNA standard operating procedures manual) quality assurance parameters and interpretation guidelines (including mixture interpretation guidelines) that have been defined pursuant to internal validation studies. A change in the detection platform and/or test kit will require an internal validation before the changes are implemented. The analysts will successfully complete a competency test using the DNA analysis procedure prior to its implementation/incorporation into database and/or casework applications.

The modified procedures will be evaluated by comparison to the original procedures using similar DNA samples prior to their implementation in database and/or casework applications.

The laboratory evaluates each additional and/or modified critical instrument by conducting a performance check prior to its use in database or casework analysis (reference: Chapter 10).

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The laboratory evaluates software upgrades by conducting a performance check prior to use in database and/or casework analysis.

### Chapter 9: Analytical Procedures

The laboratory has and follows written analytical procedures approved by the technical manager. The technical manager reviews (as described in Chapter 3) and updates the standard operating procedures (SOP) as needed and, at least once annually (each calendar year). This annual review and any interim period updates are documented and distributed to the analysts generally by electronic (email) methods and incorporated into the manual during the next scheduled manual update. .

The laboratory has a documented SOP for each analytical method used. The analytical procedures (work instructions) specify reagents, sample preparation, extraction methods, equipment, and controls that are standard for DNA analysis and data interpretation. The SOP includes a procedure for differential extraction of stains that contain sperm.

The laboratory uses reagents that are suitable for the methods employed. The laboratory has written procedures for documenting commercial reagents and for formulation of in-house reagents, if applicable. The commercial reagents are labeled in a manner that clearly identifies the reagent as well as the expiration date provided by the manufacturer. If no manufacturer specified expiration date is available, the laboratory will determine and assign an appropriate expiration date for the reagent. Reagents or chemicals purchased in dry powder form may be used up to a period of 15 years (expiration date to coincide with 15 years from date of receipt of the item). Reagents or chemicals purchased as solutions or fluids may be used up to period of 10 years (expiration date to coincide with 10 years from date of receipt of item). In-house reagents, if prepared, will be labeled with the identity of the item, the date of preparation, expiration date and the identity of the individual preparing the reagent. All such information is duly documented and available for review. Non-critical reagents such as Permout or Xylene may be used beyond the manufacturer's recommended expiration dates if the quality of this reagent is assessed and deemed appropriate for the scope of intended use.

The laboratory has identified reagents to be deemed critical reagents (reference: DNA standard operating procedures manual for information and rationale for designating reagents as critical or non-critical).

Critical reagents require evaluation/verification before use in database sample and casework analyses. Critical reagents will include, at a minimum, the following: (i) Test kits or systems for performing quantitative PCR (ii) Test kits or systems for performing genetic typing (iii) Thermostable DNA polymerase if it has not been evaluated as an integral part of the test kit components (iv) Primer sets if they have not been evaluated as an integral part of the test kit

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components (v) Allelic ladders used for genetic analysis if they have not been evaluated as an integral part of the test kit components.

The laboratory has and follows a documented procedure for the resolution, verification, and reporting/notification of database matches (reference: CODIS manual for detailed information).

The laboratory quantifies the amount of human DNA in forensic samples prior to nuclear DNA amplification. DNA quantification is not mandatory for single source known reference samples, database samples and reagent blanks as long as the reagent blanks will be amplified at the most stringent/sensitive set of conditions as a forensic sample in that batch/set of samples..

The laboratory monitors analytical procedures using appropriate controls and standards. Controls and reference standards are used during quantification procedures. Positive and negative amplification controls are associated with the samples being typed. Positive and negative controls associated with the database and forensic samples being typed are processed / amplified concurrently with the samples at all loci using the same primers as the database and forensic samples. Reagent blank controls associated with each extraction set being analyzed are extracted concurrently with the database and forensic samples. The reagent blanks are amplified using the same primers as the database and forensic samples on the same instrument model as the database and forensic samples and at the same concentration conditions as required by the forensic samples containing the least amount of DNA. The reagent blanks are typed using the same instrument model as the database and forensic samples, at the most stringent/sensitive conditions as the forensic samples and the most sensitive volume conditions of the forensic extraction set.

The laboratory checks its DNA procedures annually (and whenever substantial changes are made to a procedure) against an appropriate and available NIST standard reference material (SRM).

The laboratory has and follows established and documented guidelines (reference: DNA standard operating procedures manual) for the interpretation of short tandem repeat (STR) data. The laboratory verifies that all control results meet the laboratory's interpretation guidelines for all reported results and for data to be entered into CODIS.

The 1996 National Research Council report / recommendation is used as a guideline for the statistical interpretation of a DNA profile for a given population and for assessment of relatedness among the individuals in that population. These calculations are derived from established and published population database research studies appropriate for the calculation and the population of the State of Alaska. The laboratory has and follows specific documented statistical interpretation guidelines relevant to population structure, distribution and size relevant to the State of Alaska.

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The laboratory has and follows documented procedures (reference: DNA standard operating procedures manual) for mixture interpretation to include major and minor contributors, inclusions (failure to exclude an individual as a source of DNA in a sample) and exclusions, and, guidelines / recommendations / policies for reporting results, conclusions and statistics.

The laboratory has and follows a documented policy and procedure (reference: laboratory quality assurance manual) for detecting and controlling contamination. Contaminating extraneous / exogenous DNA traceable and attributable to an event (for example, carryover of DNA during extraction stage) and/or individual in the laboratory will be investigated and filed as a Corrective Action Report (CAR) with the laboratory quality assurance manager. Contaminating extraneous / exogenous DNA that cannot be traced or attributed to a laboratory related cause (e.g. disposable "sterile" lab consumables contaminated by a source(s) at the manufacturing or packaging facility) will be filed as an anomaly report after the root cause analysis and supporting documentation has been reviewed and approved by the DNA technical manager.

(Reference: Chapter 14 for more information).

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### Chapter 10: Equipment Calibration and Maintenance

The laboratory uses equipment that is suitable for the methods employed. The laboratory has and follows a documented program for conducting performance checks and calibrating equipment and instruments. A list of instruments along with their location and maintenance documents is maintained and updated by the DNA section technician. The following critical instruments are performance checked at least once every calendar year (annual) as well as when an interim check is deemed necessary:

A thermometer that is traceable to national or international standard(s) and is used for conducting performance checks; Thermal cycler temperature verification system; Monitoring Thermal cyclers including quantitative PCR; Electrophoresis detection systems; Robotic systems; Genetic analyzers; Mechanical pipettes

(Reference: Instrumentation manuals; vendor support information sources; DNA standard operating procedures manual for additional information).

If an NDIS approved expert systems is used for database sample data analysis, the software will be recertified on a quarterly basis. If an NDIS approved expert systems is used for database sample data analysis, it will be deemed a critical instrument and will be subject to similar recertification.

The laboratory has a schedule and follows a documented program to ensure that instruments and equipment are maintained properly. Documentation will be retained for maintenance, service and/or calibration.

The laboratory performance checks new critical instruments and equipment and/or critical instruments and equipment that have undergone repair, service or calibration, before use in database and forensic casework analysis.

At a minimum, the following critical instruments or equipment are performance checked following repair / service / calibration: Genetic analyzers/ Electrophoresis detection systems; Robotic systems; Thermal cyclers including quantitative PCR.

Maintenance/Performance Check schedules/QC plans as well as documentation that these plans were implemented as stated are maintained in log books or binders that are placed near the relevant instruments and in the laboratory area these instruments are located.

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In the event an instrument fails unexpectedly or an incubator or refrigerator/freezer does not maintain the acceptable temperature range, the technical manager will be notified immediately and an appropriate course of action taken immediately.

### Chapter 11: Documentation / Reports

The laboratory has and follows established documented procedures (laboratory quality assurance manual) for taking and maintaining case notes to support the conclusions drawn in the laboratory reports. The laboratory maintains all analytical documentation generated by analysts related to case analyses. The laboratory retains in hard copy or electronic files, as appropriate, sufficient documentation for each technical analysis to support the report conclusions such that another qualified individual could interpret and evaluate the data.

Once casework analysis and technical review of the data and pending case report is completed, and any outstanding technical issue(s), if applicable, have been resolved, the GeneMapperID X project files created may be deleted. However, all raw data files generated in the course of casework analysis shall be retained and archived as appropriate. Only these raw data files along with the appropriate standard operating procedures manual (maintained on the laboratory network) will be made available pursuant to discovery requests when filed with a court order.

The laboratory reports include at the very minimum the following information:

Case identifier(s), description of evidence examined, description of technology, locus or amplification system, results/conclusions/opinions, a qualitative and/or quantitative interpretative statement, date issued, disposition of evidence, signature and title of the person(s) accepting responsibility for the content of the report. The signature on the report routinely belongs to the primary analyst who conducted the analysis and generated the report.

The AK SCDL DNA section report also contains the name of the analyst who peer reviewed (technical review) the case as well as the name of the DNA technical manager.

The case report and the pages that contain the table(s) for STR typing results are treated as administrative documents/records. The bench notes (except for the pages containing the STR typing results table(s)) are treated as technical documents/records.

The laboratory has established and follows documented procedures (laboratory quality assurance manual) to ensure the confidentiality of the database, casework known, or reference samples and the information in DNA databases and DNA records, except as otherwise provided by applicable state or the DNA records and database, casework known or reference samples in accordance with applicable state and federal law.

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The laboratory has and follows established documented procedures for the release of personally identifiable information relating to DNA records in accordance with applicable state or federal law. The laboratory has and follows established documented procedures for the release of personally identifiable information in connection with a database hit. Please refer to the CODIS manual for details pertaining to database sample related documentation and reports.

### Chapter 12: Review

The laboratory has and follows established documented procedures for reviewing DNA records and DNA database information, including the verification and resolution of database matches (reference: CODIS manual).

The laboratory conducts and documents technical and administrative review of all DNA case files and reports/records to ensure that conclusions and supporting data are reasonable and within the constraints of scientific knowledge.

All technical reviews are conducted by individuals who are, or have been, qualified analysts in the methodology being reviewed.

The laboratory documents the completion of the technical review prior to uploading or searching in CODIS (reference CODIS manual).

The laboratory documents (reference: laboratory standard operating procedures manual) the completion of technical review of forensic casework. This includes (a) review of all case notes, worksheets, and electronic and/or printed electropherograms that support the conclusions, (b) review of all DNA typing data to verify that they are supported by raw or analyzed data (electronic and/or printed), (c) review of all genetic profiles to verify correct inclusions and exclusions, as applicable, as well as a review of any inconclusive result for compliance with laboratory guidelines, (d) review of all controls, internal lane standards, and allelic ladders to verify that the expected results were obtained, (e) review of statistical analyses, as applicable, (f) review of the final report to verify that the results/conclusions/opinions are supported by the data and address each tested item and/or its *probative fraction*, (g) verification of eligibility all profiles prior to upload and search in CODIS as to whether they have the correct DNA types and correct specimen category. Eligibility of the profile for CODIS, verification of criteria for correct DNA types and appropriate specimen category of the genetic profile is also done by concordant assessments by a qualified analyst and/or technical manager.

*An example of the probative fraction in a vaginal swab from a sex-assault case would be the data generated from analyzing the male fraction, i.e. the sperm from the suspect in the sample.*

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The laboratory documents (reference: laboratory standard operating procedures) the elements of technical and administrative review in accordance with the standard operating procedures manual. The laboratory has and follows a documented procedure to address unresolved discrepancies in conclusions drawn between analysts and reviewers. The laboratory has a system in place to ensure that the correct CODIS specimen categories have been assigned. Administrative review of forensic casework (aspects of which may overlap and complement technical review) includes a review of the case file and final report for clerical errors and for the presence and accuracy of the information discussed in Chapter 11.

The laboratory documents the completion of the administrative review in accordance with the standard operating procedures.

The laboratory has and follows a program that documents the annual monitoring of court (expert witness) testimony of laboratory personnel in accordance with the laboratory quality assurance manual. Results of expert witness testimony evaluations are maintained by the laboratory quality assurance manager.

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### Chapter 13: Proficiency Testing

Analysts, technical (peer) reviewers and other personnel designated by the technical manager undergo semiannual external proficiency testing (two tests each year) in each technology performed to the extent in which they participate in database and/or forensic casework sample/evidence analysis.

The laboratory quality assurance manager maintains proficiency test information and records.

Database sample analysts and forensic casework analysts using manual and/or automated methods will be proficiency tested in each method as applicable at least once per year to the extent in which they participate in database analysis.

If an analyst is qualified in multiple amplification test kits or systems for a specific technology, the analyst must be proficiency tested on each amplification test kit or system over the course of the year. However, the individual must be proficiency tested on all the CODIS core loci and/or core sequence ranges for each semi-annual proficiency test cycle.

Newly qualified analysts will enter the external proficiency testing program within six months (or earlier) of the date of their qualification. The laboratory has defined, documented, and consistently used the date that the proficiency test is due to the proficiency test provider (reference: Laboratory Quality Assurance Manual). Each analyst is assigned and is expected to complete his/her own external proficiency test. Team approach to proficiency testing is limited and is applicable only for biological screening of test items prior to DNA analysis. The team approach is employed for this aspect of proficiency testing in order to mimic the manner in which real/actual items of evidence are handled by the laboratory. This process ensures that workflow pattern(s) between the biological screening and DNA are kept consistent and similar between proficiency test sample(s) and casework/evidence sample(s) screening and processing. Please refer to the DNA SOP manual for procedures regarding proficiency test report writing format.

The typing of all CODIS core loci are attempted for each technology performed as applicable. The laboratory maintains the following records for proficiency tests: Test set identifier; Analyst(s) identity as applicable; Date of analysis and completion/submission of results; Copies of all data

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and notes supporting the conclusions; Proficiency test results; Discrepancies, if any, noted; Corrective actions, if any, taken.

The laboratory includes, at a minimum, the following criteria for evaluating proficiency test results:

- >All reported inclusions and exclusions are correct,
- >All reported genotypes / phenotypes correct or incorrect according to consensus results and/or consistent with the laboratory's interpretation guidelines,
- >Results reported as inconclusive / not interpretable are consistent with written laboratory guidelines
- >Inconclusive results, in accordance with standard operating procedures have been reviewed by the technical manager for compliance with laboratory guidelines, and
- >Discrepancies / errors, if any, as well as subsequent corrective actions have been documented,
- >Final reports have been graded as satisfactory or unsatisfactory
- >Documentation to show that no analytical errors were observed for the DNA profile typing data in reports graded as satisfactory, and,
- >Documentation showing that corrective actions were applied to administrative errors, if any.

The proficiency test participants will be informed of their final test results and this notification will be documented.

The technical manager will be informed of the results of all proficiency test participants and this notification will be documented.

The technical manager will inform the CODIS administrator of all technical/analytical (non-administrative) discrepancies that affect the typing results and/or conclusions at the time of discovery.

The technical manager shall be responsible for determining whether an error in interpretation or typing shall be classified as an analytical error or not. This decision will be based on review of the analytical data to ensure compliance / consistency with the laboratory interpretation guidelines.

The laboratory will continue to use an external proficiency test provider(s) that complies with the current proficiency testing manufacturing guidelines established by the American Society of

### Chapter 14: Corrective Action

The laboratory quality assurance manual establishes a corrective action plan that is followed to address discrepancies detected in proficiency tests, database and forensic casework analysis. The corrective action plan addresses, at a minimum, the following:

- > Define what level/type of discrepancies are applicable to this practice
- > Identify, when possible, the cause of the discrepancy
- > Effect of the discrepancy
- > Corrective actions taken
- > Preventive measures taken, where applicable, to minimize its occurrence
- > Documentation of all corrective actions maintained in accordance with the laboratory document retention policies and procedures.

Prior to implementation, all corrective actions will have the documented approval of the technical manager.

### Chapter 15: Audits

The laboratory undergoes annual audits in accordance with the FBI DNA Quality Assurance Standards and maintains documentation for this inspection. The documentation will include proof that an external audit has been conducted at least once every two years by a qualified auditor who is a current or previously qualified analyst in the laboratory's current DNA technologies and platform.

At least one member of the audit team will be a current or previously qualified analyst from a databasing laboratory.

The laboratory maintains audit documentation of those individuals (i.e. CODIS administrator – casework and database, technical manager and analysts) that have had their education, experience and training qualifications evaluated and approved during two external audits.

The laboratory maintains documentation for those validations previously evaluated and approved during one external audit.

For internal / annual audits, the laboratory maintains documentation that the auditors for this inspection included a qualified auditor who is a current or previously qualified analyst in the laboratory's current DNA technologies and platform.

Internal and external audits are performed pursuant to Standard 15.1 and conducted using the FBI Quality Assurance Standards Audit Document in effect at the time of the audit.

Internal and external audit documents, and corrective actions, if any, are submitted for review to the technical manager to ensure that findings, if any, are appropriately addressed.

The laboratory, which is an NDIS participating laboratory, will provide all external audit documentation and laboratory responses to the FBI within 30 days of the laboratory's receipt of the audit documents/report.

Previous DNA internal/annual and external audit documents are retained by the technical manager and available for auditor inspection.

### Chapter 16: Safety

The DNA section does not maintain a section specific safety manual.

Please refer to the AK SCDL Laboratory Safety Manual for documentation of an environmental health and safety program that includes, at a minimum, a blood-borne pathogen and chemical hygiene plan as well as a documented training on the blood-borne pathogen and chemical hygiene plan. The laboratory's environmental health and safety plan is reviewed annually and this review is documented.

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### Chapter 17: Outsourcing

If samples are outsourced to vendor laboratories for processing, the vendor laboratory selected shall be one that complies with the FBI Quality Assurance Standards for DNA databasing and forensic DNA testing /casework laboratories and the accreditation requirements of federal law. Documentation of such compliance will be maintained by the AK SCDL laboratory.

When the AK SCDL (NDIS participating laboratory) is the outsourcing entity, the technical manager will document and maintain the approval of the technical specifications of the outsourcing agreement before it is awarded. If the vendor laboratory is performing DNA analysis for a law enforcement agency or entity other than the NDIS laboratory, the vendor laboratory shall obtain documented approval from the technical manager of the NDIS participating laboratory (AK SCDL) accepting ownership of the DNA data generated prior to initiating analysis. AK SCDL will ensure that the vendor laboratory uses the same technology platform and typing amplification kit for its DNA data analysis as does AK SCDL.

Prior to uploading or accepting data for upload and search in CODIS, the technical manager of AK SCDL documents the prior approval of the technical specifications of the outsourcing agreement and/or documents the approval of acceptance of ownership of the DNA data.

When the AK SCDL is the primary outsourcing entity, it follows and documents the established and appropriate quality assurance procedures to verify the integrity of the data received from the vendor laboratory including, but not limited to, random reanalysis of samples (database/forensic casework).

When the primary outsourcing entity is a law-enforcement or other non-NDIS participating agency, the data is received through the outsourcing agency. Prior to acceptance of the data, information pertaining to the nature of the evidence submitted is collected from the case officers and investigators. Eligibility of the sample DNA profiles for entry and search in CODIS is determined by communication with the submitting officers.

Inclusion of Quality Control samples is required to conduct a technical review of outsourced data.

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If AK SCDL is the primary outsourcing entity, an on-site visit plan of the vendor laboratory will be conducted in compliance with the FBI Quality Assurance Standards. This plan will include documentation of the on-site visit prior to initiation of analysis. The on-site visit will be conducted by the AK SCDL technical manager or a qualified analyst designated by the technical manager. The qualifications of the designee will include current or previous qualification in the technology platform and typing amplification test kit used to generate the DNA data.

If the primary outsourcing entity is not the AK SCDL, then, documentation of results pertaining to a site visit conducted by qualified individuals from another NDIS participating laboratory will be obtained and retained for quality assurance purposes and audit requirements. AK SCDL will ensure that the individuals conducting the "proxy site visit" shall be trained and qualified in the same technology platform and typing amplification kit being used by AK SCDL. This policy applies only to those contracts entered into by the participating agencies prior to July 1, 2009.

For contracts that begin after this date, the DNA technical manager or a designated qualified AK SCDL DNA analyst will conduct and document the site visit prior to the date sample processing begins. The person conducting the site-visit will currently or previously qualified in the technology, platform, and typing amplification test kit used to generate the DNA data.

If the outsourcing agreement (AK SCDL or other non-NDIS participating agency) extends beyond one year, an annual site visit will be conducted by the technical manager or by proxy and the results reviewed and documented by the technical manager to acknowledge acceptance of the on-site visit. The elements captured by the on-site visit will include, at a minimum, facilities where the samples are processed, review of the quality assurance / quality control procedures, review of the standard operating procedures, corrective action reports, if applicable, and the interpretation guidelines and report writing conventions employed.

The AK SCDL has procedures for performing an on-site visit of the vendor laboratory. For contracts commencing after 1 July 2009, the site visit will be conducted prior to the initiation of analysis.

AK SCDL has and follows established and documented procedures (reference standard operating procedures manual and outsourced data review checklist) to verify and the integrity of the data received from a vendor laboratory by performing a technical review.

The technical review is performed prior to upload to and search in the DNA database and includes, at a minimum, (1) a review of all DNA types to verify that they are supported by the raw and/or analyzed data (electropherograms / images), (2) a review of associated controls,

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internal lane standards and allelic ladders to verify that expected results were obtained, and, (3) verification of DNA types, eligibility and the correct specimen category for entry into CODIS.

A review of the final report, if provided, is used to verify that the results and conclusions are supported by the data and that each tested item and/or its probative fraction submitted to the vendor is addressed.

Technical review of the vendor laboratory data is generally conducted by the technical manager of AK SCDL who may authorize and designate a qualified analyst to perform the data review.

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### Appendix I

R1 Page	R0 page	Location	Revision made
1	1	Document Structure	Changed Table of Contents to Document Structure
2	2	Introduction	Removed "Supervised casework sample processing is authorized (Appendix C) "
			Removed "Volunteer samples are generally processed by database analysts"
various	various	As applicable	Updated version date "FBI Quality Assurance Standards (QAS) document for forensic DNA testing and DNA databasing laboratories, version effective 01 September 2011"
5	5	Chapter 4	Removed "Please see Appendix A (laboratory organizational charts/respective job descriptions) for this information. A documented contingency plan that has been approved by laboratory management if the technical manager position is vacated is available for review. Please see Appendix B for the memorandum documenting technical manager contingency plan.
5	5	Chapter 4	Updated " In accordance with Appendix B of the FBI Quality Assurance Standards document, a DNA analyst who meets the educational qualifications and work experience to fulfill the duties of DNA technical manager has been identified in the event that position is vacated by the current technical manager "
5	5	Chapter 4	Updated "The Laboratory Quality Assurance manual contains information pertaining to the laboratory organizational chart"
8	8	Chapter 5	Updated "Please refer to Chapter 4 for technical manager contingency plan"
8		Chapter 5	Removed Information regarding Appendix B compliance for Technical Manager contingency plan and updated as shown above.
9	9	Chapter 6	Inserted "Example: DNA extraction worksheet; routine cleaning lists are maintained, cleaning duties performed and documented by the DNA section Technician"
16	16	Chapter 10	Inserted" A list of instruments along with their location and maintenance documents is maintained and updated by the DNA section Technician "