

**OSBI CODIS Unit Policy Manual  
for Databasing Analysis  
Revision 17  
Effective August 1, 2023**



Conforming to the International Standard ISO/IEC 17025:2017 Program of Accreditation & the Federal Bureau of Investigation (FBI) Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories

**ATTENTION:**

**If any portion(s) of this policy manual is/are unclear to any analyst/technician or if a circumstance arises outside the scope of this document, it is the responsibility of each individual to notify the technical manager and the respective supervisor immediately to seek clarification/guidance and obtain approval, if necessary, regarding the issue before proceeding.**

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### Policy Manual Approval

#### Other OSBI Laboratory Procedure References:

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

OSBI Forensic Biology Units' Policy Manual

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## DBQM\_1 SCOPE & APPLICABILITY ([↑ Table of Contents](#))

- 1.1 The Oklahoma State Bureau of Investigation (OSBI) Criminalistics Services Division (CSD) includes the Forensic Biology Discipline, which encompasses multiple forensic biology units and the Combined DNA Index System (CODIS) Unit.
- 1.2 The OSBI CODIS Unit Policy Manual shall apply to work specifically performed by analysts/technicians and support staff working within an officially defined CODIS Unit or by analysts/technicians and support staff working in the capacity of a CODIS analyst or associated technician.
- 1.3 The purpose of this policy manual is to establish and maintain a documented quality system that is appropriate to the CODIS Unit of the OSBI and to ensure the quality and integrity of the data generated by the unit. The OSBI forensic biology units maintain a separate quality manual, which can be found in the OSBI Forensic Biology Units' Policy Manual.
- 1.4 Unless specifically stated, the (QM) of this document only applies to laboratories performing DNA testing on samples obtained from identified subject(s) for the purpose of entering DNA profile(s) into the Combined DNA Index System (CODIS).
  - 1.4.1 DNA testing begins at sample extraction or direct amplification.
  - 1.4.2 If applicable, these requirements apply to DNA databasing laboratories using Rapid DNA instruments/Systems on database, known or casework reference samples. The use of Rapid DNA instruments/Systems is not approved for use on forensic samples.
- 1.5 For the purposes of audit and accreditation processes, the laboratory shall have available objective proof, such as written documentation, of satisfying applicable requirements and demonstrating compliance.
- 1.6 Hyperlink and attachment maintenance, such as the removal, addition, and/or correction of hyperlinks/attachments, shall not constitute a new document revision.

### **Attachment(s):**

None

### **Reference(s):**

OSBI Forensic Biology Units' Policy Manual

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

International Standard ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories

ANAB ISO/IEC 17025:2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125)

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## DBQM\_2 DEFINITIONS ([↑ Table of Contents](#))

Terms in this document follow the definitions set for in Standard 2 of the QAS. In addition, the OSBI CODIS Unit defines the additional following terms as having the meanings specified:

**20 CODIS core loci** include CSF1PO, D3S1358, D5S818, D7S820, D8S1179, D13S317, D16S539, D18S51, D21S11, FGA, TH01, TPOX, vWA, D1S1656, D2S441, D2S1338, D10S1248, D12S391, D19S433 and D22S1045 (excludes Amelogenin).

**Additive stutter (AST)** is a combination of plus and minus stutter. See **Stutter (ST)** below.

**Allele or true allelic peak** is a relatively symmetric pointed arch in an upward direction. It is wider at the base than at the summit and shows an area of non-linear taper to and from the highest point. Generally, the peak should have a height:width ratio of >1. True allelic peaks should be present in only a single color unless pull-up has occurred.

**Analytical threshold (AT)** is the relative fluorescence units (RFU) value above which an observed well-formed peak that is not the result of a diagnosable issue such as stutter, pull-up, spike, minus A, etc. can be assumed to be observed due to the presence of an allele. It is the minimum height requirement, determined through validation testing, at or above which detected peaks/signal can be reliably distinguished from background noise; peaks/signal at or above this threshold are generally not considered noise and are either artifacts or true alleles.

**Annual** is once per calendar year.

**BEAST** is the Barcoded Evidence Analysis Statistics and Tracing program within the OSBI Laboratory Information Management System (LIMS).

**CODIS User** is a government employee who has login access to the CODIS system and is authorized to read, add, modify or delete DNA records in CODIS; or is a qualified DNA analyst responsible for producing DNA profiles stored in the National CODIS Database (NDIS).

**Concurrent** is taking place at the same time with the same conditions.

**Differential extraction** is the process for extracting DNA from all samples testing presumptive or confirmatory positive for seminal fluid (performed by the OSBI forensic biology units).

**DNA analysis** is using the Polymerase Chain Reaction (PCR) to examine Short Tandem Repeats (STR) utilizing capillary electrophoresis; in accordance with the QAS, DNA analysis begins at sample extraction or direct amplification.

**Dye blobs** are disassociated primer dyes that are reproducible artifacts of the PCR process and often observed with a particular lot of amplification kits. Although it is not entirely clear why dye blobs occur, they are believed to be caused when the fluorescent dye tags attached to the amplification kit primers begin to break down over time. The dissociated primer dyes are carried through the PCR amplification step and when injected onto the capillary array can appear as peaks during data analysis. However, dye blobs are usually wider than true allelic peaks and are typically seen in one color although can also be seen in multiple dye colors.

**“End date” of analysis** is the date the technical review form is signed.

**Instrument baseline threshold** is the RFU value below which a peak is indistinguishable from the baseline noise.

**Instrument spike (SP)** is a non-reproducible artifact that occurs occasionally within an electrophoretic run resulting in the appearance of an anomalous peak(s) on the electropherogram. A peak resulting from

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an instrument spike is easily identified upon close examination; such a peak will usually be composed of all colors with approximately equal apparent fluorescent intensity and occur at the same data point and/or scan number in GeneMapper ID-X (GMID-X). Spikes are believed to be caused by scattering of incident light due to the passage of dust particles through the excitation laser beam.

**Intimate sample** is a sample originating/taken directly from an individual's body, such as body swabs (e.g. vaginal swabs, breast swabs, neck swabs, penile swabs, swab of a hand, etc.), fingernails, etc. An intimate sample is expected to yield the DNA profile from the individual the sample is taken from.

**Limit of detection (LOD)**, as it pertains to genetic analysis, is the RFU value below which a peak is unable to be brought up to a peak height useful for interpretation through increased injection time(s). This may or may not be equivalent to the baseline threshold; however, it cannot be less than the baseline threshold and should be relatively close to the baseline threshold to minimize any data loss.

**Low copy number (LCN) DNA analysis**, as referred to by the OSBI, is any DNA analysis where additional amplification cycles beyond the OSBI's internal validation, post-amplification purification, reduced reaction volume, nested PCR, or an increased injection time and/or voltage outside the scope of the OSBI's internal validations were performed. The OSBI does not perform LCN DNA analyses and, as such, any sample subjected to these conditions will not be submitted to NDIS.

**Microvariant alleles** are alleles that contain an incomplete repeat unit (e.g., "9.3" at TH01).

**Minus A (-A)** is a reproducible artifact of the PCR process generated by the inability of thermostable DNA polymerase to catalyze the addition of a single nucleotide (predominately adenosine) to the 3' end of the PCR product during the final extension step.

**Mixture** is when two or more contributors are present in a DNA profile.

**Negative control** is an analytical control used to detect DNA contamination of analytical reagents (e.g., reagent blank control). During amplification, a negative amplification control is the reagents used in the direct amplification process without the intentional addition of any biological sample that is subjected to the same analysis process used during direct amplification of offender database samples.

**Offender** refers to either a convicted person or an arrestee.

**Off-ladder allele (OL)** is an allele whose size is not represented within the allelic ladder.

**Off-scale peak (SOS)** is a reproducible peak above the linear detection of the instrument or any fluorescence signal that exceeds the detection threshold of the instrument. The SOS qualify flag indicates if the camera is saturated at any data point within the analysis range. It is not based on an absolute RFU value (peak height).

**Original 13 CODIS core loci** include CSF1PO, D3S1358, D5S818, D7S820, D8S1179, D13S317, D16S539, D18S51, D21S11, FGA, TH01, TPOX and vWA (excludes Amelogenin).

**Peak height ratio (PHR)** is the ratio of the peak with the lowest RFU to that of the peak with the highest RFU of a heterozygous pair expressed as a percent (truncated).

**Peak stochastic threshold (PST)** is the RFU value above which it can be assumed that peak dropout does not occur and any observed allelic peak that has no sister allele present can reasonably be believed to be homozygous. The peak stochastic threshold for an amplification kit is the RFU level that has been established through internal validation procedures to alert analysts of the possibility of encountering stochastic issues with allelic peaks that have peak heights below this threshold. These effects are due to a low amount of template DNA present that affects the quality of the amplification process.

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**Process step** refers to each step in a process of analysis. This would include, but is not limited to, adding protocol specific reagents at listed volumes or use of any other equipment in the analysis process, and, as such, an associated reagent blank must also be taken through the process concurrent to any samples. However, in some process steps, such as concentrating a sample, although a questioned sample and its associated reagent blank(s) must both be placed into the device, it is acceptable to remove any associated blank(s) from the process step while allowing the sample to continue in the step until an appropriate volume is achieved. Adding reagent to bring any volumes to a working volume is not considered a process step.

**Pull-up (PU)** is when the matrix cannot compensate for an excess of one color, causing the “pulling up” of peaks in another color. In other words, the instrument is not able to resolve spectral overlap. This may be observed as a small peak at a similar scan number as a large peak in another color.

**Reagent** is any substance or mixture used in the analysis process of the Forensic Biology Discipline. Chemicals used to make reagents are not considered “reagents,” but rather chemicals (e.g., NaOH). Reagents will have an expiration date of one year from the date of receipt, unless otherwise specified by the manufacturer or in the OSBI Forensic Biology Units’/CODIS Units’ Policy Manuals and/or their attachments.

**Resubmission (RS)** occurs when a new physical sample, which will be analyzed as an initial sample, is provided for a sample that previously failed on initial analysis.

**Review date** is the completion date of the review of the protocols.

**Serology** is the identification of body fluids including blood, semen, and other biological materials (performed by the OSBI forensic biology units).

**Single-source** is when one donor/contributor is present in a DNA profile.

**Standard extraction** is used for all samples, except those requiring a differential extraction (performed by the OSBI forensic biology units).

**“Start date” of analysis** is the date the sample is punched.

**Stutter (ST)** is a reproducible artifact of the PCR process. It is a minor product peak longer or shorter than the corresponding main allele peak. The stutter peak may be various sizes in relation to the main allele peak dependent on the repeat structure and the amplification kit.

**Technical manager** is the equivalent to “Technical Leader” as defined by the QAS.

**Trailing primer peak (TP)** is a peak or peaks associated with the primer peak that fall within the size calling range.

**Trainee** is an analyst or technician undergoing training in a particular area (e.g., serology or DNA analysis).

**Trisomy** is three alleles at a single-source STR locus.

**Virtual allele** is an allele that is labeled by the software even though it is not present in the allelic ladder. For example, if using the GlobalFiler panel in GMID-X, there is an allelic bin for an 11 at D3S1358, although the ladder alleles range from 12 to 19. Thus, an allele labeled as an 11 at D3S1358 would be considered a virtual allele. The term “virtual allele” does not in any way indicate that the allele is not a true allele but simply indicates it is an off-ladder allele that has been assigned a label.

**Work product** is the material utilized in testing and/or generated as a function of the analysis process that is not subject to a chain of custody.

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**Year** refers to calendar year.

**Attachment(s):**

None

**Reference(s):**

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

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## DBQM\_3 QUALITY ASSURANCE PROGRAM ([↑ Table of Contents](#))

### 3.1 Quality System

The OSBI Criminalistics Services Division (CSD) has established and maintains a documented quality system, which includes a general, unit-neutral quality manual applicable to all members of the OSBI CSD. The CODIS Unit has further established and maintains this documented unit-specific quality manual to specifically address the quality system applicable to the testing activities performed by the laboratory for offender sample analysis.

3.1.1 The quality system will address the following elements:

- 3.1.1.1 Goals and objectives
- 3.1.1.2 Organization and management
- 3.1.1.3 Personnel
- 3.1.1.4 Training
- 3.1.1.5 Facilities and sample control
- 3.1.1.6 Validation
- 3.1.1.7 Analytical procedures
- 3.1.1.8 Equipment
- 3.1.1.9 Documentation
- 3.1.1.10 Review
- 3.1.1.11 Proficiency testing
- 3.1.1.12 Corrective action
- 3.1.1.13 Audits
- 3.1.1.14 Professional development
- 3.1.1.15 Outsourcing ownership

3.1.2 Any document referenced within the quality manual shall be available on-site or be readily accessible (e.g., available online).

### 3.2 Document Retention

The CODIS Unit shall follow OSBI CSD Quality Procedure (QP) 16.1 (Control of Records) and the applicable policies within this policy manual regarding document retention for the following quality records:

- Proficiency tests
- Analytical results
- Sample receipt and processing records
- Sample retention
- Hit confirmation
- Corrective action



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- Audits
- Training records
- Continuing education
- Court testimony monitoring

## 3.3 Annual Review of Quality System

The CODIS Unit will conduct an annual review to be inclusive of the overall quality assurance program, analytical procedures, quality control procedures, training manual, and any other division (CSD) or agency (OSBI) procedures that are applicable to the quality of DNA analysis. This review will be independent of the audit required by Standard 15 (Audits) of the QAS. The review shall be completed under the direction of the technical manager; the completion of the review must be documented and approved by the technical manager.

### 3.3.1 CODIS Unit-Level Documents

- 3.3.1.1 The annual review of the CODIS Unit quality system may be an ongoing process of incorporating any deviations or suggestions submitted through OSBI CSD QP 3 (Deviations) and/or QP 15 (Preventive Action) into the next revision of the OSBI CODIS Unit Policy Manual. A final review of the incorporated changes will be completed before issuance, and approval will be documented in the Approval section of the policy manual.
- 3.3.1.2 The technical manager may conduct the annual review by requesting assistance through the Lead Analysts and Biology Subcommittee, as needed.
- 3.3.1.3 The final documented approval of the annual review (approved by the technical manager) shall correspond sequentially or identically in date with either the issuance of a new policy revision to the current policy or by the insertion of the "Review Date" and the phrase "Annual Review" within the Policy Manual History.
- 3.3.1.4 Changes to the policy shall be outlined in the Policy Manual History and attached to the policy manual (**DBQM\_Policy\_Manual\_Hx**).

### 3.3.2 CSD/OSBI-Level Documents

- 3.3.2.1 Review of these policies/procedures will be documented in a memo (or other written format), and any proposed deviations/changes will be submitted to the appropriate authority.

## 3.4 Annual Review of Sample Processing Records

The CODIS Unit will conduct an annual review of sample processing records determined by the technical manager to be representative of the samples tested. The scope of this review will be defined and approved by the technical manager prior to each annual review and address both the representative sample and the time period of the processing records under review. This annual review may not be replaced by technical reviews as part of Standard 12 (Review) of the QAS. This review will be independent of an external audit conducted under Standard 15 (Audits) of the QAS; however, this review may be conducted concurrently with an internal audit.

## 3.5 Goals & Objectives

Pursuant to Oklahoma Statute Title 74 Section 150.27s, the OSBI is charged with the task of implementing the Combined DNA Index System (CODIS) for the State of Oklahoma. To ensure the quality of the database, it is the policy of the OSBI that all data entered into and/or searched against CODIS is generated in a manner consistent with the FBI QAS and FBI National DNA Index System (NDIS) Operational Procedures. Hence, the OSBI CODIS Unit shall strive to accomplish the following goals and objectives:

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- 3.5.1 Ensuring the quality of data entered into and/or searched against CODIS.
- 3.5.2 Ensure the timely entry of offender and casework data into CODIS.
- 3.5.3 Ensure routine searches of profiles maintained in CODIS.
- 3.5.4 Ensure timely verification of CODIS hits.
- 3.5.5 Maintain national accreditation and NDIS participation.
- 3.5.6 In accordance with the requirements for federal grant funding, the OSBI Forensic Biology Discipline will prioritize the analysis of, to the extent practicable and consistent with public safety concerns, samples from homicides and sexual assaults.

### **Attachment(s):**

OSBI CODIS Unit Policy Manual **DBQM\_Policy\_Manual\_Hx**

### **Reference(s):**

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

FBI National DNA Index System (NDIS) Operational Procedures Manual

International Standard ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories

ANAB ISO/IEC 17025:2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125)

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## DBQM\_4 ORGANIZATION & MANAGEMENT ([↑ Table of Contents](#))

### 4.1 The OSBI CODIS Unit shall have:

- 4.1.1 A managerial staff with the authority and resources needed to discharge their duties and meet the requirements of the FBI Quality Assurance Standards for DNA Databasing Laboratories.
  - 4.1.1.1 In the event that the managerial staff does not have the authority or resources to ensure that the Standards are being met, the technical manager shall suspend DNA laboratory operations, utilizing OSBI CSD QP 13 (Nonconforming Work), until such time that the DNA testing at one laboratory or multiple laboratories re-establishes the managerial authority or resources necessary to meet or exceed the Standards.
- 4.1.2 A technical manager who is accountable for the technical operations. The OSBI Forensic Biology Discipline technical manager is responsible for all technical aspects of the entire OSBI forensic biology multi-laboratory system (discipline), which is comprised of the following laboratories/units, generally handling the case types indicated below, although subject to change, as needed, based on the needs of the OSBI:
  - At the Forensic Science Center (FSC):
    - Forensic Biology Unit (FBU): property crimes and major violent crimes other than sexual assault crimes
    - Specialized Forensic Biology Unit (SFBU): sexual assault crimes
    - Cold Case Unit (CCU): cold cases
    - Combined DNA Index System Unit (CODIS): offender/arrestee database samples
  - At the Northeast Regional Laboratory (NERL):
    - Forensic Biology Unit (FBU): property crimes and major violent crimes other than sexual assault crimes
- 4.1.3 A CODIS administrator who is accountable for CODIS operations on-site at each individual laboratory facility utilizing CODIS in the OSBI forensic biology multi-laboratory system (discipline).
- 4.1.4 At least two full-time employees who are qualified DNA analysts.
- 4.1.5 The responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the validity of the DNA analysis specified and documented.
  - 4.1.5.1 OSBI Policy 103 (Authority and Responsibility) and OSBI CSD QP 1 (Responsibilities and Authority) specify the responsibility and authority of each position within the OSBI Forensic Biology Discipline's chain-of-command. In addition, section DBQM\_5 (Personnel) in the quality manual of this document reflects the responsibilities associated with each position within the Forensic Biology Discipline.
  - 4.1.5.2 The organization and management structure of the OSBI CSD is detailed in the OSBI CSD Quality Manual and reflects the interrelation of all appropriate personnel within the CSD. The "OSBI Forensic Biology Discipline Organization & Management Structure" chart (**DBQM\_Org\_Chart**) is maintained as an attachment to this policy manual and reflects the interrelation of all appropriate personnel within the Forensic Biology Discipline.
- 4.1.6 A documented contingency plan approved by laboratory management that is followed if the technical manager position is vacated or if the number of qualified analysts falls below two full-time employees who are qualified analysts.

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- 4.1.6.1 The memorandum to the Forensic Biology Discipline titled “Contingency Plan for Technical Manager Vacancy or if Number of Qualified DNA Analysts Falls Below Two” reflects the plan to maintain uninterrupted technical leadership over the DNA testing operations within the OSBI Forensic Biology system. Exclusion from the document shall not exclude qualified individuals from participating in a contingency plan during a technical manager position vacancy.
- 4.1.6.2 The memorandum to the Forensic Biology Discipline titled “Contingency Plan for Technical Manager Vacancy or if Number of Qualified DNA Analysts Falls Below Two” reflects the plan in the event that a laboratory ceases to have two full-time qualified DNA analysts.
- 4.2 The OSBI Forensic Biology Discipline uses the date of hire/appointment/promotion as the defined date to use for determining the applicable version of the QAS for requirements to assess education, experience and training of individuals.
- 4.2.1 If an individual does not change his/her role with a promotion or appointment (e.g., Criminalist I to Criminalist II), then reevaluation of his/her education, experience and training is not required. However, if an individual does change his/her role with a promotion or appointment (e.g., Technician to Criminalist, Criminalist to CODIS Administrator, Criminalist to Technical Manager, etc.), then evaluation of his/her education, experience and training for the new role is required.

### **Attachment(s):**

OSBI CODIS Unit Policy Manual **DBQM\_Org\_Chart**

### **Reference(s):**

OSBI Memorandum to the Forensic Biology Discipline: “Contingency Plan for Technical Manager Vacancy or if Number of Qualified DNA Analysts Falls Below Two”

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

FBI National DNA Index System (NDIS) Operational Procedures Manual

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## DBQM\_5 PERSONNEL (↑ [Table of Contents](#))

5.1 The OSBI CODIS Unit shall be staffed with personnel employed by the agency that meet the qualifications contained within this section, as well as within any documents referenced herein, and the qualifications listed in the QAS. Laboratory personnel shall have the education, training and experience commensurate with the examination and testimony provided.

5.1.1 The responsibilities, duties, and skills required for each of the criminalist (analyst) position classifications (Criminalist I, II, III, IV & V) are outlined in general written job descriptions, which are maintained by the Office of Management and Enterprise Services (OMES) Human Capital Management (HCM) Division of the State of Oklahoma and can be found at [https://pf.payfactors.com/client/job-description-management/job-descriptions?jwt=eyJhbGciOiJIUzUxMiIsInR5cCI6IkpXVCJ9.eyJ0eXBlljoxLCJjb250ZXh0Ijp7IktNvbXBhbnlJZCI6NzA5MywiSnd0VHlwZSI6MX19.oal6llllKWFp48YOCWhoWVvkeD\\_9T1\\_jflie4r7PY3rDVpyAVsWdfgz7up1Z57rxv7R6vc9kHPZ6QS3Ypdorr4w](https://pf.payfactors.com/client/job-description-management/job-descriptions?jwt=eyJhbGciOiJIUzUxMiIsInR5cCI6IkpXVCJ9.eyJ0eXBlljoxLCJjb250ZXh0Ijp7IktNvbXBhbnlJZCI6NzA5MywiSnd0VHlwZSI6MX19.oal6llllKWFp48YOCWhoWVvkeD_9T1_jflie4r7PY3rDVpyAVsWdfgz7up1Z57rxv7R6vc9kHPZ6QS3Ypdorr4w)

Additional selective qualifications for analysts within the OSBI Forensic Biology Discipline are also maintained by the OMES HCM Division and referenced at the end of this policy. Criminalist IV analysts in regional facilities may or may not also serve as DNA analysts.

Job descriptions for laboratory analyst (technician) positions and laboratory support staff positions (e.g., administrative technician) are maintained with the OSBI Human Resources Department.

5.1.1.1 Any analyst who is hired to perform DNA analysis that does not meet the qualifications listed in the general job description for a criminalist position, the selective qualifications for the OSBI Forensic Biology Discipline, or the QAS will be brought into compliance with these requirements prior to commencing any independent DNA analysis.

5.1.1.2 For required higher education classes, a passing grade will be a “C” or higher. QAS-required classes previously completed with a grade lower than a “C” will have to be re-taken. Failure to successfully complete required coursework with a grade of “C” or higher may result in progressive discipline up to and including termination.

5.1.2 Records for relevant qualifications, training, skills, and experience of technical personnel shall be retained in accordance with OSBI CSD QP 16.1 (Control of Records). The technical manager shall have access to documentation of qualifications, training, skills and experience that is pertinent for the analysis of DNA.

5.1.2.1 Technical personnel include those individuals who are involved in testing and support of testing (e.g. making reagents, maintaining instruments, etc.) of forensic casework or database samples. Individuals not involved in the stream of testing (e.g. evidence management, sample control, administrative, clerical) are not considered technical personnel.

## 5.2 Technical Manager

Any individual filling the position of the OSBI Forensic Biology Discipline Technical Manager must meet or exceed the minimum education, experience, training requirements, and qualifications as per the QAS (reference DBQM\_4.2). In addition, all requirements of the Criminalist IV classification maintained by the OMES HCM Division of the State of Oklahoma shall also be satisfied. The technical manager shall be a full-time employee of the OSBI CSD and meet the following qualifications:

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- 5.2.1 The minimum educational requirements of the QAS. The technical manager shall have, at a minimum, a master's degree in a biology-, chemistry-, or forensic science-related area and shall have successfully completed twelve cumulative semester hours or equivalent from a combination of undergraduate and graduate coursework covering the following subject areas: biochemistry, genetics, molecular biology, and statistics or population genetics.
- 5.2.1.1 The twelve semester or equivalent credit hours shall include at least one graduate level course registering three or more semester or equivalent credit hours.
- 5.2.1.2 The specific subject areas listed in 5.2.1 shall constitute an integral component of any coursework used to demonstrate compliance.
- 5.2.1.3 Individuals who have completed coursework with titles other than those listed in 5.2.1 shall demonstrate compliance through a combination of pertinent materials, such as a syllabus, letter from the instructor, or other document that supports the course content.
- 5.2.1.4 If the degree requirements of 5.2.1 were waived by the American Society of Crime Laboratory Directors (ASCLD) in accordance with criteria approved by the FBI Director, such a documented waiver shall be permanent and portable.
- 5.2.2 The minimum experience requirements of the QAS. Any technical manager appointed on or after July 1, 2009, shall have a minimum of three years of human DNA (current or previous) experience as a qualified analyst on database or forensic samples.
- 5.2.3 Any technical manager appointed on or after July 1, 2020 shall be a currently or previously qualified analyst in each technology utilized in the laboratory or have documented training in each technology utilized in the laboratory within one year of appointment.
- 5.2.4 The technical manager shall have previously completed or will successfully complete the FBI's DNA auditor training course within one year of appointment.
- 5.2.5 The duties, authority, and responsibilities of the technical manager will be, at a minimum, those designated by the QAS. Additional duties, authorities, and responsibilities can be required of the technical manager, as necessary, to meet the needs of the OSBI. The technical manager shall have the following authority and minimum responsibilities:
- 5.2.5.1 Oversee the technical operations of the OSBI Forensic Biology multi-laboratory system (discipline), which includes the CODIS and forensic biology units.
- 5.2.5.2 Authority to initiate, suspend, and resume technical operations for a laboratory or an individual. Note, while other laboratory personnel, such as the OSBI CSD director or quality manager may also have the authority to suspend technical operations for a laboratory or an individual, the authorization of the technical manager is required to initiate or resume the technical operations for a laboratory or an individual.
- 5.2.5.3 Evaluate and approve all validations and new or modified methods used by the laboratory.
- 5.2.5.4 Review the training records for newly qualified analysts, technicians and technical reviewers and approve their qualifications prior to independent database analysis. Review, verify, and approve the academic transcripts for newly qualified analysts and technical reviewers.
- 5.2.5.5 Approve the technical specifications for outsourcing agreements.

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- 5.2.5.6 Review internal and external DNA Audit documents and, if applicable, approve corrective action(s).
- 5.2.5.7 Review, on an annual basis, the procedures of the laboratory.
- 5.2.5.8 Review and approve the training, quality assurance, and proficiency testing programs in the laboratory.
- 5.2.5.9 Review potential conflicts of interest when contract employees are employed by multiple NDIS participating and/or vendor laboratories.
- 5.2.6 The technical manager shall be accessible to provide on-site, telephone, or electronic consultation as needed. The OSBI Forensic Biology multi-laboratory system will have one technical manager over the system of separate laboratory facilities. The technical manager shall conduct and document a site visit to all satellite laboratories performing DNA analysis in the OSBI Forensic Biology multi-laboratory system at least semi-annually.
- 5.2.7 A newly appointed technical manager will be responsible for the documented review of the following within one year of appointment or preferably sooner, if possible:
  - 5.2.7.1 Validation studies and analytical procedures currently used by the laboratory; and
  - 5.2.7.2 Educational and training records of currently qualified analysts and technical reviewers.

### 5.3 CODIS Administrator

Any individual filling the position of the OSBI CODIS administrator must meet or exceed the minimum education, experience, training requirements, and qualifications as per the QAS (reference DBQM\_4.2) and the NDIS Operational Procedures Manual. The OSBI CODIS administrator shall also function as the state CODIS administrator for the entire CODIS network for the State of Oklahoma. In addition, for the OSBI, the state CODIS administrator will serve as the casework CODIS administrator. The OSBI CODIS administrator/state CODIS administrator/casework CODIS administrator, hereon referred to as simply "CODIS administrator," shall be an employee of the OSBI CSD who may also serve as the CODIS supervisor, a CODIS analyst, or a casework analyst (fulfilling any separate requirements applicable to these positions) and must meet the following qualifications:

- 5.3.1 The minimum educational requirements for an analyst as defined by the QAS (reference 5.4 below). A working knowledge of computers, computer networks, and computer database management is also recommended. A CODIS administrator appointed prior to July 1, 2020 shall be deemed to have satisfied the minimum education requirements; satisfaction of these minimum educational requirements shall be applicable to the specific laboratory by which the CODIS administrator is employed by prior July 1, 2020 and shall not be portable.
  - 5.3.1.1 Note, any alternate CODIS administrator designated after June 1, 2018 shall meet the educational qualifications of a CODIS administrator as specified by the QAS.
- 5.3.2 The minimum experience requirements of the QAS. The CODIS administrator shall be a current or previously qualified forensic or database analyst as defined by the QAS (reference 5.4 below) with documented mixture interpretation training.
  - 5.3.2.1 Note, any alternate CODIS administrator designated after June 1, 2018 shall meet the experience qualifications of a CODIS administrator as specified by the QAS.

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- 5.3.3 The minimum CODIS training requirements of the QAS. The CODIS administrator (and alternate CODIS administrator) shall successfully complete the FBI-sponsored training in CODIS software within six months of assuming CODIS administrator duties if not previously completed. The CODIS administrator (and alternate CODIS administrator) shall successfully complete the FBI's DNA auditor training course within one year of assuming his/her administrator duties if not previously completed.
- 5.3.3.1 The CODIS administrator (and alternate CODIS administrator) shall obtain and maintain the FBI security access required to become a CODIS user and successfully complete the annual training as described in the NDIS Operational Procedures Manual.
- 5.3.4 The duties and responsibilities of the CODIS administrator will be, at a minimum, those designated by the QAS and the NDIS Operational Procedures Manual (sections 2.6.3 – 2.6.5). Additional duties and responsibilities can be required of the CODIS administrator, as necessary, to meet the needs of the OSBI. The CODIS administrator shall have the following minimum responsibilities:
- 5.3.4.1 Administer the laboratory's CODIS network.
- 5.3.4.2 Schedule and document the CODIS computer training of database and casework analysts.
- 5.3.4.3 Ensure that the security of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.
- 5.3.4.4 Ensure that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.
- 5.3.4.5 Ensure that matches are dispositioned in accordance with NDIS operational procedures.
- 5.3.5 The CODIS administrator, in consultation with the OSBI CSD director and quality manager, shall be authorized to terminate an analyst's or laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified. In addition, the CODIS administrator, acting in the capacity of the state CODIS administrator, shall have the authority over all CODIS sites under his/her jurisdiction to terminate, in consultation with the OSBI CSD director and quality manager, an analyst's or a laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified. The CODIS administrator shall be authorized to author and sign all correspondence and required reports for the FBI and NDIS Custodian, as necessary.
- 5.3.6 In the event that the CODIS administrator position is unoccupied, no DNA profiles will be uploaded to NDIS. However, if the alternate CODIS administrator<sup>1</sup> is available to assume the CODIS administrator responsibilities, the laboratory may continue to upload DNA profiles to NDIS.
- 5.3.6.1 In the extended absence of the CODIS administrator, the alternate CODIS administrator will be designated as acting CODIS administrator and perform CODIS-related duties as needed.

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<sup>1</sup> Designation described in the FBI National DNA Index System (NDIS) Operational Procedures Manual.



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## 5.4 Lead Analyst

Lead Analyst: a Senior Criminalist designated to assist the Forensic Biology Discipline Technical Manager in one of the casework or CODIS areas specified below. Lead analysts are expected to spend approximately 25% of their time working on these assignments, and approximately 75% of their time performing casework and/or other assigned duties. Senior Criminalists assigned as Lead Analysts are not required to meet the QAS requirements for a Technical Manager, as the Forensic Biology Technical Manager will retain ultimate responsibility for and authority over the technical operations of the Forensic Biology Units. The Lead Analyst positions may serve as succession planning positions for senior analysts who are interested in and are qualified (or plan to become qualified) to serve in the TM position in the future. Lead analysts must meet the minimum education and experience qualifications of an Analyst, as defined in section 5.5.

### 5.4.1 Lead Analyst – Training:

Oversees training of and/or serves as designated trainer for serology, DNA, and technician trainees. Assists TM in preparation of training and/or competency exercises for newly implemented/ validated analysis methods. Quarterly literature review: finds articles and sends out list to analysts, maintains review documentation. Identifies and sends out notification of relevant CE/training opportunities for analysts. Reviews analyst training documents to verify annual CE requirements are met and documented. Other training-related tasks as assigned by TM. If qualified, serve as Acting Technical Manager when designated by the TM.

### 5.4.2 Lead Analyst – Casework:

Provides technical consultation to analysts for casework questions or issues that do not require TM approval. Assists TM in preparation of casework policy and training manual deviations and revisions. Assists TM in organization of annual review of casefiles. Assists TM and other members of Bio Management with organization of casework outsourcing projects. Assists TM with validations and implementation of new methods for casework. Assists TM with identification and planning of future validation projects for casework. Assists TM in review of Proficiency Test results. Assists with Forensic Genetic Genealogy cases as needed. Other casework-related tasks as assigned by TM. If qualified, serve as Acting Technical Manager when designated by the TM.

### 5.4.3 Lead Analyst – CODIS:

Provides technical consultation to analysts for databasing questions or issues that do not require TM approval. Assists TM in preparation of databasing policy and training manual deviations and revisions. Assists TM in organization of annual review of databasing records. Assists TM and other members of Bio Management with organization of databasing outsourcing projects. Assists TM with validations and implementation of new methods for databasing. Assists TM with identification and planning of future validation projects for databasing. Assists TM in review of Proficiency Test results. Other databasing-related tasks as assigned by TM. If qualified, serve as Acting Technical Manager when designated by the TM.

### 5.4.4 Lead Analyst – QA/QC:

Assists TM and other members of Bio Management with internal audits and external assessments. Works with technicians to organize completion of weekly/monthly/annual QC and maintenance tasks. Reviews QC records to ensure documentation is correct and complete. Reviews equipment maintenance records to ensure documentation is correct and complete. Assists TM with troubleshooting issues with equipment, kits, and reagents. Other

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QA/QC-related tasks as assigned by TM. If qualified, serve as Acting Technical Manager when designated by the TM.

*Note: per QAS 5.2.5, the ultimate authority and responsibility for the following remains solely on the Technical Manager:*

- 5.2.5.1 *Oversee the technical operations of the laboratory.*
- 5.2.5.2 *Authority to initiate, suspend, and resume technical operations for the laboratory or an individual.*
- 5.2.5.3 *Evaluate and approve all validations and new or modified methods used by the laboratory.*
- 5.2.5.4 *Review the training records for newly qualified analysts, technicians and technical reviewers and approve their qualifications prior to independent casework analysis. Review, verify, and approve the academic transcripts for newly qualified analysts and technical reviewers.*
- 5.2.5.5 *Approve the technical specifications for outsourcing agreements.*
- 5.2.5.6 *Review internal and external DNA Audit documents and, if applicable, approve corrective action(s).*
- 5.2.5.7 *Review, on an annual basis, the procedures of the laboratory.*
- 5.2.5.8 *Review and approve the training, quality assurance, and proficiency testing programs in the laboratory.*
- 5.2.5.9 *Review potential conflicts of interest when contract employees are employed by multiple NDIS participating and/or vendor laboratories.*

## 5.5 Analyst

Any individual filling the position of a CODIS Analyst (Analyst) must meet or exceed the minimum education and experience requirements as per the QAS (reference DBQM\_4.2). An analyst shall be an employee or contract employee of the OSBI CSD and meet the following qualifications:

- 5.5.1 The minimum educational requirements of the QAS. The analyst shall have a bachelor's (or its equivalent) or an advanced degree in biology-, chemistry-, or forensic science-related area and shall have successfully completed coursework (graduate or undergraduate level) covering the following subject areas: biochemistry, genetics, and molecular biology. Any analyst hired/appointed/promoted (as defined by DBQM\_4.2) prior to July 1, 2020, shall have coursework and/or training in statistics and/or population genetics as it applies to forensic DNA analysis. Any analyst hired/appointed/promoted on or after July 1, 2020, shall have successfully completed coursework covering statistics and/or population genetics.
  - 5.5.1.1 The specific subject areas listed in 5.4.1 shall be an integral component of any coursework used to demonstrate compliance.
  - 5.5.1.2 Analysts appointed or hired on or after July 1, 2009 shall have a minimum of nine cumulative semester hours or equivalent that cover the required subject areas of biochemistry, genetics, and molecular biology.
  - 5.5.1.3 Analysts who have completed coursework with titles other than those listed in 5.4.1 shall demonstrate compliance through a combination of pertinent materials, such as a syllabus, letter from the instructor, or other document that supports the course content. The technical manager shall approve compliance.
- 5.5.2 The minimum experience requirements of the QAS. The analyst shall have six months of documented human DNA laboratory experience with at least three months in a forensic or database DNA laboratory before release for independent database analysis. If prior human DNA laboratory experience is accepted by the laboratory, the prior experience shall be documented and augmented by additional training, as needed. The analyst shall successfully complete the required training.

## 5.6 Technical Reviewers

Any individual filling the position of a Technical Reviewer must meet or exceed the minimum education and experience requirements for an analyst as per the QAS (reference DBQM\_4.2) and

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listed in 5.4 above. A technical reviewer shall be an employee or contract employee of the OSBI CSD and meet the following qualifications:

5.6.1 A current or previously qualified analyst in the methodologies being reviewed.

5.6.2 Successful completion of documented training.

### 5.7 Technicians

Any individual filling the position of a CODIS Laboratory Analyst (Technician) shall be an employee or contract employee of the OSBI CSD and meet the following qualifications:

5.7.1 Possess a high school diploma with some laboratory experience preferred.

5.7.2 Successful completion of documented training.

### 5.8 Laboratory Support Personnel

Any individual filling the position of Laboratory Support Personnel, such as an administrative technician, shall have documented training specific to their job function(s).

5.9 The technical manager will verify and approve the education, to include a review of academic transcripts, of each analyst and technical reviewer prior to release for independent database analysis and/or technical review.

### Attachment(s):

None

### Reference(s):

OSBI Memorandum to the Forensic Biology Discipline: "Selective Qualifications for Forensic Biologist/CODIS Analyst Positions with the OSBI"

Memorandum of Understanding Between the Federal Bureau of Investigation, Laboratory Division and the Oklahoma State Bureau of Investigation for Participation of the State of Oklahoma in the National DNA Index System (NDIS)

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

OSBI Forensic Biology Units' Policy Manual

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

FBI National DNA Index System (NDIS) Operational Procedures Manual

International Standard ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories

ANAB ISO/IEC 17025:2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125)

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## DBQM\_6 TRAINING ([↑ Table of Contents](#))

### 6.1 Training Program

The training program will comply with OSBI CSD QP 19 (Training) and meet the requirements of QAS. The OSBI DNA CODIS Unit training program for qualifying analysts and technicians is documented in the “OSBI CODIS Unit Training Manual.” The training manual is designed to allow an analyst or technician to successfully complete documented training and be authorized in specific methods, methodologies, or responsibilities independent of the whole manual, where necessary, prior to participating in independent database analysis. Analysts may receive additional training from the FBI regarding CODIS software, if possible. The OSBI CODIS Unit training program shall:

- 6.1.1 Address all DNA analytical and interpretation procedures used in the laboratory.
- 6.1.2 Include practical exercises encompassing the examination of a range of samples routinely encountered in database analysis. Practical exercises are not limited to lab work but can also be in the form of data analysis and review. Examples of a range of samples routinely encountered may include degraded, partial, low template, off-ladder alleles and microvariant samples.
- 6.1.3 Teach and assess the technical skills and knowledge required to perform DNA analysis.
  - 6.1.3.1 The training program for analysts shall include the skills and knowledge required to conduct a technical review.
- 6.1.4 Include an assessment of oral communication skills and/or a mock court exercise. This applies to analysts and technicians.
- 6.1.5 Include requirements for competency testing (see 6.3 below).

### 6.2 Training Program Modifications

The technical manager shall approve any modifications to an analyst's, technical reviewer's, technician's, or laboratory support personnel's required training based on the documented assessment of the individual's previous training and experience with regards to the adequacy and applicability of it to the procedures of the OSBI CODIS Unit.

### 6.3 Competency Testing (for Analysts/Technicians Completing the Training Program)

*This section applies to analysts or technicians completing the laboratory's training program who will be authorized to perform independent database analysis/processing for the first time as an analyst or technician in the laboratory (e.g., a new hire or a technician promoted to analyst).*

All analyst/technician(s), regardless of previous experience, shall successfully complete competency testing covering the routine DNA methods and interpretation procedures that the analyst/technician will perform prior to participating in independent database analysis/processing. The OSBI CODIS Unit considers exams/quizzes, mock samples, mock court exercises and technical question assessments “competency tests.” Any practical component of competency testing should be relevant to the task(s) that the trainee will be authorized to perform on database samples. A passing grade for all types of competency tests will be 80% unless deemed otherwise and documented by the technical manager.

- 6.3.1 Competency testing for a new analyst shall include a practical component and written and/or oral components sufficient to demonstrate that the trainee has achieved the technical skills and knowledge necessary to perform and explain DNA databasing.

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- 6.3.2 Competency testing for a new technician shall include a practical component sufficient to demonstrate that the trainee has achieved the technical skills and knowledge necessary to perform the DNA databasing methods.

### 6.4 Qualification of Currently or Previously Qualified Analyst/Technician in New or Additional Method

*This section will be applicable when an analyst or technician who has completed the laboratory training program is undergoing training in an additional method for which they are not currently qualified or when an analyst or technician is trained in a newly validated and implemented method.*

For an analyst or technician, currently or previously qualified within the laboratory, to be qualified in a new or additional method, the laboratory shall teach and assess the technical skills and knowledge required to perform the additional method. For an analyst who also performs technical review, elements of both roles need to be addressed in the training.

- 6.4.1 Before the use of a new or additional method on database samples, the analyst and/or technician shall successfully complete competency testing to the extent of his/her participation in database analyses. The competency testing shall include a practical component.

### 6.5 Qualification of Currently or Previously Qualified Analyst to Interpret Data & Generate Reports for New or Additional Technology, Typing Test Kit, Platform, or Interpretation Software

*This section will be applicable when a qualified analyst is trained in the interpretation of data using an additional technology, typing test kit, platform, or interpretation software for which they are not currently qualified or when the laboratory analysts are trained in a newly validated and implemented technology, typing test kit, platform, or interpretation software.*

For an analyst, currently or previously qualified within the laboratory, to be qualified to interpret data for a new or additional technology, typing test kit, platform, or interpretation software, the laboratory shall teach and assess the technical skills and knowledge required to interpret data using the additional technology, typing test kit, platform, or interpretation software. For an analyst who also performs technical review, elements of both roles need to be addressed in the training.

The training for interpretation software pertains to the implementation of new or additional software. Updated or modified interpretation software with fundamental changes that requires analysts to learn new skills and knowledge to interpret data would also require training as applicable under this section.

In instances where the technology, typing test kit, platform, or interpretation software also involve training in a new method(s), both section 6.4 (above) and 6.5 apply. In these instances, the competency testing may be combined.

- 6.5.1 Before the use of a new or additional technology, test typing kit, platform or interpretation software on database samples, the analyst shall successfully complete competency testing using the additional technology, typing test kit, platform or interpretation software to the extent of his/her participation in database analyses. The competency testing shall include a practical component.

### 6.6 Technical Reviewer Not Currently Qualified as an Analyst

*This section applies to individuals who will be trained and authorized to conduct technical reviews but are not or will not be authorized as an analyst in the method, technology, typing test kit, platform, or interpretation software.*

A technical reviewer, who is not currently qualified as an analyst in the laboratory, shall receive training on processing records, data analysis and interpretation for any method, technology, typing

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test kit, platform, or interpretation software on which they will conduct reviews of data and/or records and for which they were not previously qualified as an analyst in the laboratory.

6.6.1 The technical reviewer shall successfully complete competency testing before completing a technical review of data and/or documentation using the additional method, technology, typing test kit, platform or interpretation software used in database analyses.

6.6.1.1 For a technical reviewer who is a contract employee conducting reviews for an NDIS participating laboratory, the competency testing shall be administered by the NDIS participating laboratory.

6.7 The technical manager shall review the training records for the analyst, technician, and/or technical reviewer and approve his/her qualifications prior to independent database responsibilities.

## 6.8 Authorization

The analyst, technician, and/or technical reviewer shall be authorized to independently perform assigned job responsibilities and the date(s) shall be documented.

6.8.1 The technical manager will issue a memorandum formally recognizing an individual's successful completion of training and releasing them to perform specific responsibilities. This memorandum will include the scope of the release, clearly stating the approval to conduct independent database analysis using the applicable methods, technologies, typing test kits, and platforms and/or to perform technical reviews.

6.8.2 The technical manager will issue an "Authorization to Work" (ATW) memorandum, when necessary, to include testing, instrumentation/equipment, reporting/authorization of results, technical review, testimony (opinions and interpretations), etc. as required for accreditation.

6.8.3 The technical manager may also authorize individuals to perform specific laboratory activities as listed in QP 19 (Training), including, but not limited to, assisting with development, modification, verification, and internal validation of methods. This authorization does not necessarily have to be included in an ATW but rather can be provided via email or a memorandum.

## 6.9 Laboratory Support Personnel

Laboratory support personnel shall have documented training specific to their job function(s). Training should include, at a minimum, those task(s) that are necessary for performance of or may impact the results of an analytical procedure (e.g., making reagents or preparing an instrument for operation).

## 6.10 Retraining

Retraining of an analyst, technician, or technical reviewer may be necessary as a result of an extended absence from databasing duties, as part of corrective action, or when determined necessary by the technical manager. The laboratory shall have and follow a policy for addressing retraining of personnel when necessary. The technical manager shall be responsible for evaluating the need for and addressing the extent of retraining. The retraining plan shall be documented and approved by the technical manager.

6.10.1 The individual shall successfully complete competency testing prior to his/her return to participation in database analyses. This also applies to individuals who have been on extended leave for a period of time that takes them out of the proficiency test cycle. This competency testing shall include a practical component.

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### 6.11 Maintaining Records

Records on the training of the laboratory personnel, including successful completion of competency testing, shall be maintained in each individual's training notebook and/or on the appropriate network server.

6.11.1 The training and authorization records for each analyst, technician, and technical reviewer must be available for review.

6.11.2 The documented training completed by each laboratory support personnel must be available for review.

#### **Attachment(s):**

None

#### **Reference(s):**

OSBI CODIS Unit Training Manual

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

FBI National DNA Index System (NDIS) Operational Procedures Manual

SWGDM Training Guidelines

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## DBQM\_7 FACILITIES & SAMPLE CONTROL ([↑ Table of Contents](#))

7.1 The OSBI CODIS Unit shall have a facility designed to ensure the integrity of the analyses and the samples.

7.1.1 The laboratory shall have secure, controlled access areas for sample storage.

7.1.2 Except as provided in 7.1.3.1, techniques performed prior to PCR amplification such as sample accessioning, DNA extractions, if applicable, and PCR setup shall be conducted at separate times or in separate physical spaces from each other.

7.1.3 Except as provided in 7.1.3.1, amplified DNA product, including real time PCR, shall be generated, processed, and maintained in a room(s) separate from the sample accessioning, DNA extractions, if applicable, and PCR setup areas. The door(s) between rooms containing amplified DNA and other areas shall remain closed except for passage.

7.1.3.1 If applicable, a Rapid DNA instrument//System used for processing database, known or casework reference samples shall be maintained in rooms outside of sample accessioning areas or those containing amplified DNA.

7.2 The OSBI CODIS Unit will follow the procedures in OSBI CSD QP 20 (Lab Security) for laboratory security.

7.2.1 Access to the laboratory shall be controlled and limited in a manner to prevent access to the operational areas by unauthorized personnel. All exterior entrance/exit points require security controls that limit entry and access into the operational areas. The distribution of all keys, combinations, etc., shall be documented and limited to the personnel designated by laboratory management.

7.3 To ensure the integrity of database samples the OSBI CODIS Unit will follow a documented sample inventory control program.

7.3.1 All database samples shall be marked with a unique identifier (number) on at least the container. This will be performed upon receipt of the samples when logging them into the OSBI Laboratory Information Management System (LIMS) "BEAST" CoDNA program (i.e., sample accessioning). The number assigned to a sample by the LIMS will follow the format of: sample type, last two digits of the year sample is received, and the sequential sample number for the year. Sample types include "C" (convicted offender), "A" (arrestee), and "P" (proficiency). For example, a CODIS sample assigned the number "C15-001000" represents convicted offender sample number 1000 received in the year 2015. At the end of each sample accessioning session, the CODIS analyst, technician, or laboratory support personnel entering the samples must check each sample to ensure they are in numerical order with no duplicates or missing numbers.

If the OSBI CODIS Unit were to process known or casework reference sample(s) as evidence, they shall be marked with case number and item number (unique identifier) and clearly distinguishable from all other evidence at all times throughout processing in accordance with the OSBI CSD Quality Procedures.

Evidence is defined in the OSBI CSD Quality Manual. According to Oklahoma Statutes (Title 74 §150.27a), offender samples are considered reference materials obtained for the purpose of DNA databasing only; they are not evidence and do not have a chain of custody associated with them. Therefore, offender samples shall not be analyzed as a substitute for a legally obtained known reference sample. Work product is defined in DBQM\_2 (Definitions) and 7.3.3 below.



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To distinguish each sample throughout processing, the OSBI CODIS Unit shall use the appropriate worksheets included in the Offender Analysis Excel workbook, including the plate map worksheet (i.e. Offender Sample Analysis 3500 Setup Worksheet).

- 7.3.2 The OSBI CODIS Unit shall maintain documentation of sample identity, collection, receipt, storage, and disposition in the BEAST CoDNA program.
  - 7.3.2.1 If the OSBI CODIS Unit were to process known or casework reference sample(s) as evidence, chain of custody for all evidence will be kept in accordance with OSBI CSD QP 5 (Evidence Intake), QP 6.1 (Evidence Handling), QP 6.2 (Evidence Handling for Non-Casework Purposes), QP 6.3 (Evidence Storage & Maintenance), QP 6.4 (Evidence Refrigerator & Freezer Maintenance), and QP 7 (Evidence Transactions)
- 7.3.3 The CODIS Unit shall follow the procedures outlined in this policy manual for handling and preserving the integrity of samples and work product designed to minimize loss, contamination, and/or deleterious change. Work product will also be handled according to the appropriate sections below:

#### DNA Work Product Utilized in Testing

Punches or portions of biological samples are considered work products utilizing in testing, and following the completion and documentation of the test results, these work products shall be discarded.

#### DNA Work Product Generated as a Function of the Analysis Process

Amplified DNA products (PCR plates and Genetic Analyzer plates containing amplified DNA) are considered work products generated as a function of the analysis process. Following the completion and documentation of the test results and technical review, these work products shall be discarded.

7.3.3.1 Samples and work product in progress will be secured.

7.3.3.2 Samples will be stored in secure areas with environmental control consistent with the form or nature of the sample(s).

7.4 Because database samples are not considered evidence and therefore have no associated chain of custody, the OSBI CODIS Unit may consume database samples, as necessary, for testing purposes based on analyst discretion. If a sample is consumed, a request may be made to have the sample recollected.

- 7.4.1 Where possible, the CODIS Unit will permanently retain all database samples for retesting for quality assurance (e.g., validations, quality control, future testing due to technological advancements) and sample confirmation purposes (e.g., hit verifications) unless meeting the requirements for expungement as outlined in this policy manual. Duplicate samples may be retained at the discretion of the CODIS administrator. Failed samples for which a suitable replacement has been received may be discarded at the discretion of the CODIS administrator or designee.

#### **Attachment(s):**

OSBI CODIS Unit Policy Manual **CODIS\_Offender\_Analysis\_Workbook**

OSBI CODIS Unit Policy Manual **CODIS\_Summary\_Table**

OSBI CODIS Unit Policy Manual **CODIS\_Reanalysis**

OSBI CODIS Unit Policy Manual **CODIS\_3500\_Setup**

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**Reference(s):**

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

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## DBQM\_8 VALIDATION<sup>2</sup> ([↑ Table of Contents](#))

8.1 The OSBI Forensic Biology Discipline shall only use validated methods for DNA analyses.

8.1.1 All validations will be performed in accordance with the requirements of QAS and OSBI CSD QP 21.2 (Evaluation of Methods, Instruments, Equipment, and Software). The type of validation – developmental or internal – will be defined in the validation plan.

8.1.1.1 A developmental validation will follow 8.2.

8.1.1.2 An internal validation will follow 8.3.

8.1.1.2.1 Prior to beginning an internal validation, and if relying upon an externally performed developmental validation, the citations and publications addressing the elements of 8.2.1 must be available and accessible to support the underlying scientific basis.

8.1.1.2.2 The general order of events when conducting an internal validation in the OSBI forensic biology discipline, as per QAS and OSBI CSD QP 21.2 (Evaluation of Methods, Instruments, Equipment, and Software), is as follows:

1. Submit evaluation plan per OSBI CSD QP 21.2.
2. Perform system and site-specific validation studies.
3. Submit documentation and summary for approval.
4. Complete individual analyst/technician competencies per DBQM\_6 (Training).
5. Release validated procedure for database use.

8.1.1.2.3 Individuals assisting with internal validations will be authorized by the technical manager (reference 6.10.3).

### 8.2 Developmental Validation

Developmental validation shall precede the implementation of any new methods used for forensic DNA analysis. The developmental validation documentation may be obtained from an external agency (either commercial vendor or another laboratory) and established through citation and publications as referenced in 8.1.1.2.1.

8.2.1 Developmental validation studies shall include, where applicable, characterization of the genetic marker, species specificity, sensitivity studies, stability studies, database-type samples, population studies, mixture studies, precision and accuracy studies, and PCR-based studies. PCR-based studies include reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and product detection studies. All validation studies shall be documented.

8.2.2 Peer-reviewed publication of the underlying scientific principle(s) of a method shall be required.

### 8.3 Internal Validation

Except as provided in 8.3.1.1, internal validation of all manual and robotic methods shall be conducted by each laboratory with the appropriate sample number and type to demonstrate the reliability and potential limitations of the method.

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<sup>2</sup> Reference DBQM\_10 (Equipment) for when performance checks are required, such as for additional critical instruments or equipment of the same model already validated for use in the laboratory.

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- 8.3.1 Internal validation studies shall include as applicable: known database-type samples, precision and accuracy studies, sensitivity and stochastic studies, and contamination assessment studies (reference 8.4 below as well). Studies determined to be not applicable shall be addressed in the internal validation summaries (refer to 8.3.4). If conducted within the same laboratory, developmental validation studies may satisfy some of the elements of the internal validation.
- 8.3.1.1 Internal validation data may be shared by all locations in the OSBI forensic biology discipline multi-laboratory system. The summary of the shared validation data, including summaries, shall be available at each site and maintained electronically on a secure network server accessible by all laboratories. Each laboratory in the system shall complete, document and maintain their own applicable site-specific precision, sensitivity, and contamination assessment studies. The laboratory responsible for the system internal validation shall incorporate their site-specific studies, as applicable, into the system study.
- 8.3.2 Internal validation shall define quality assurance parameters and interpretation guidelines and incorporate such into applicable analytical procedure(s).
- 8.3.2.1 Mixture interpretation validation studies shall include samples with a range of the number of contributors, template amounts, and mixture ratios expected to be interpreted in casework.
- 8.3.3 Internal validation studies shall be conducted prior to implementing a change in typing test kit or platform instrument model (e.g. to a new capillary electrophoresis instrument model not already used in the laboratory).
- 8.3.4 Internal validation studies shall be documented and summarized. Internal validation shall be reviewed and approved by the technical manager prior to implementing a procedure for database applications.

### 8.4 NIST-Traceable Testing

Newly validated DNA methods (from amplification through characterization), typing test kit, or platform instrument model shall be checked against an appropriate and available certified reference material (or sample made traceable to the certified reference material) prior to the implementation of the method for database analysis.

### 8.5 Modified Procedure Evaluations<sup>3</sup>

The performance of a modified procedure (alteration to validated steps, reagents, or critical instruments that would require a protocol change) shall be evaluated by comparison to the original procedure using similar DNA samples and the evaluation documented. The evaluation shall be reviewed and approved by the technical manager prior to the implementation of the modified procedure into database applications. Note, modifications that impact efficacy or reliability of the analysis may require internal validation studies as well to demonstrate the continued reliability and potential limitations of the method. Modifications to procedures will be handled in accordance with OSBI CSD QP 21.1 (Research) and/or OSBI CSD QP 21.2 (Evaluation of Methods, Instruments, Equipment, and Software). Approval shall occur through the issuance of a deviation in accordance with OSBI CSD QP 3 (Deviations) or a new protocol revision in accordance with OSBI CSD QP 2 (Document Control).

- 8.6 If applicable, an Expert System used to generate NDIS eligible DNA profiles shall be validated in accordance with DBQM\_8 (Validation) and applicable NDIS operational procedures.

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<sup>3</sup> Modifications that do not affect the analytical process only require a performance check.

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8.6.1 An Expert System shall be subject to recertification in accordance with NDIS operational procedures.

8.7 If applicable, a Rapid DNA instrument used for modified Rapid DNA analysis on database samples shall be validated in accordance with QAS.

8.8 If applicable, an NDIS approved Rapid DNA System shall require a performance check prior to use on database samples.

## 8.9 Software Testing

New software or new modules of existing software and modifications to software will first be evaluated to assess the suitability of the software for its intended use in the laboratory and to determine the necessity of validation studies or software testing. For the purposes of this policy, software includes software tool(s) developed by the laboratory.<sup>4</sup> This evaluation shall include the determination of which studies will and will not be conducted and shall be documented.

### 8.9.1 Software Developmental Validation

New software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations, shall be subject to developmental validation prior to implementation in DNA database analysis.

8.9.1.1 With the exception of legally protected information, the underlying scientific principle(s) utilized by software with an impact on the analytical process, interpretation, or statistical calculations shall be publicly available for review or published in a peer-reviewed scientific journal.

8.9.1.2 Developmental software validation studies for new software or new modules of existing software used as a component of instrumentation shall include a minimum, functional testing and reliability testing.

8.9.1.3 Developmental software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data shall include at a minimum, functional testing, reliability testing, and as applicable, accuracy, precision, sensitivity, and specificity studies.

8.9.1.4 Developmental software validation studies for new software or new modules of existing software for statistical calculations shall include at a minimum, functional testing, reliability testing, and as applicable, accuracy, and precision studies.

### 8.9.2 Software Internal Validation

New software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations shall be subject to internal validation specific to the laboratory's intended use prior to implementation in DNA database analysis.

8.9.2.1 Internal software validation studies for new software or new modules of existing software used as a component of instrumentation shall include functional testing and reliability testing.

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<sup>4</sup> For commercial off-the-shelf (COTS) software products (e.g. word processing, electronic spreadsheets, database management) that the laboratory uses to create software tools (e.g. macros, workbooks, databases), the COTS software does not require a developmental validation but the laboratory developed tool must be validated as appropriate for its intended use in the laboratory.

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- 8.9.2.2 Internal software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data shall include functional testing, reliability testing, and, as applicable, precision and accuracy studies, sensitivity, and specificity studies.
- 8.9.2.3 Internal software validation studies for new software or new modules of existing software for statistical calculations shall include functional testing, reliability testing, and, as applicable, precision and accuracy studies.
- 8.9.2.4 Software that does not impact the analytical process, interpretation, or statistical calculations (e.g., LIMS or other inventory/sample tracking software) shall require at a minimum, a functional test.
- 8.9.3 **Software Modifications**  
Modifications to software as described in 8.9.1 and 8.9.2 shall be evaluated to determine if the modifications result in major or minor revisions to the software. Release notes from software developers can be used to assist in determining if a modification results in a major or minor revision. Examples of major revisions include, but are not limited to, changes to any algorithm, any statistical and/or calculation equation, sequence alignment strategy, data reports, and/or export of results. Examples of minor revisions include, but are not limited to, cosmetic modifications, improved printing or viewing features, and/or fixing invalid error messages.
- 8.9.3.1 A major revision to software used as a component of instrumentation shall require validation prior to implementation. Software validation studies shall include functional testing, reliability testing, and regression testing.
- 8.9.3.2 A major revision to software used for the analysis and/or interpretation of DNA data shall require validation prior to implementation. Software validation studies shall include functional testing, reliability testing, regression testing, and, as applicable, precision and accuracy studies, sensitivity, and specificity studies.
- 8.9.3.3 A major revision to software used for statistical calculations shall require validation prior to implementation. Software validation studies shall include functional testing, reliability testing, regression testing, and, as applicable, precision and accuracy studies.
- 8.9.3.4 A minor revision to software that does not impact the analytical process, interpretation, or statistical calculations shall require at a minimum, a functional test.
- 8.9.4 Software validation studies and software testing may be shared by all locations in the OSBI forensic biology discipline multi-laboratory system. The summary of the shared validation data shall be available at each site and maintained electronically on a secure network server accessible by all laboratories. Each laboratory in the system shall complete, document and maintain their own applicable site-specific reliability testing. The laboratory responsible for the system software validation studies and software testing shall incorporate their site-specific reliability testing into the system study.
- 8.9.5 Software validation and testing shall be documented. Software validation and testing shall be reviewed and approved by the technical manager prior to implementation.
- 8.10 Developmental validation studies, internal validation studies, modified procedure evaluations, and software testing, including the approval of the technical manager, shall be retained and available for review.

## Quality Manual

**Attachment(s):**

None

**Reference(s):**

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

SWGDM Validation Guidelines for DNA Analysis Methods

# Quality Manual

## DBQM\_9 ANALYTICAL PROCEDURES ([↑ Table of Contents](#))

9.1 The OSBI CODIS Unit shall follow analytical procedures supported by the internal validations and approved by the technical manager, in addition to any other corresponding documents referenced within this policy manual, as applicable.

9.1.1 The laboratory will follow the standard operating procedures outlined in this policy manual for each analytical method used, including the appropriate analytical controls required for DNA analysis and data interpretation. All procedures shall be current, readily available, adhere to OSBI CSD QP 2 (Document Control), and contain the following, as applicable:

- Scope
- Reagents & Supplies
- Equipment
- Sample/Reagent Preparation
- Extraction Method
- Controls
- Individual Steps of the Procedure
- Interpretation of Results (reference CODIS\_7)
- Notes

## 9.2 Reagents

The OSBI CODIS Unit shall use reagents that are suitable for the methods employed.

9.2.1 The laboratory shall follow OSBI CSD QP 8.1 (Ordering, Receiving, and Verifying Reagents and Supplies) and the appropriate procedures within this policy manual for documenting commercial reagents and for the formulation of in-house reagents, as applicable.

9.2.1.1 The following will be documented on the appropriate quality control reagent (QCR) OSBI Chemical Receipt/Function Verification Worksheet for critical commercial reagents:

- Receipt Information
- Storage
- Function Verification
- Unsatisfactory Reagent Performance
- Expiration – The date or guidance as provided by the manufacturer or as determined by the laboratory. If the expiration date is determined to be longer by the OSBI CODIS Unit, the justification documentation shall be maintained with the quality records for the reagent.

9.2.1.2 The following will be documented on the appropriate QCR OSBI Chemical Formulation/Function Verification Worksheet for in-house reagents:

- Chemical Formulation & Preparation – The amounts of chemicals necessary to prepare each reagent are provided for a standard formulation; however, the final amount of the chemicals used may be changed as long as the proportions of each remain unaltered.
- Storage
- Function Verification
- Unsatisfactory Reagent Performance
- Expiration – If any ingredient of the reagent has an expiration date earlier than that of the prepared reagent, the expiration date shall be determined by such ingredient with the earliest expiration

9.2.1.3 The technical manager and/or lead analyst will be notified if changes have been made to the product insert for any reagent.



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- 9.2.1.4 Items that are too small to legibly record all required information are exempt from the labeling and date opened requirements as long as the storage container is labeled with all of the appropriate information. (This generally only applies to tubes from kits.)
- 9.2.1.5 Reagents shall be considered expired at 11:59 pm on the expiration date. Reagents with a manufacturer's expiration date of month/year shall expire at 11:59 pm on the last day of the indicated month.
- 9.2.1.6 All supporting documentation for function verification tests should include the reagent name or set of reagents (if tested together), date, initials and page number.
- 9.2.2 Commercial reagents shall be labeled with the identity of the reagent and the expiration date as provided by the manufacturer or as otherwise determined by the laboratory, if applicable, in addition to the requirements of OSBI CSD QP 8.1 (Ordering, Receiving, and Verifying Reagents and Supplies).
- 9.2.3 In-house reagents shall be labeled with the identity of the reagent, the date of preparation (lot number) and expiration, if applicable, and the identity of the individual preparing the reagent.

### 9.3 Critical Reagents

The OSBI CODIS Unit identifies the following reagents used in DNA database analysis as critical reagents and shall evaluate them prior to use in database sample processing:

- 9.3.1 Test kits or systems for DNA quantification or amplification (including master mix, primer sets, and allelic ladders, where applicable):
  - GlobalFiler™ Express System for direct PCR amplification
- 9.3.2 Thermostable DNA polymerase, primer sets and allelic ladders used for genetic analysis that are not tested as test kit components under 9.3.1, if applicable.
- 9.3.3 Rapid DNA cartridges, if applicable.
- 9.3.4 Other laboratory defined critical reagents:
  - Prep N Go™ Buffer

Note: If a critical reagent is evaluated according to the FBU Policy Manual by authorized individuals, it is not necessary to re-evaluate according to the CODIS policy. The results of the initial evaluation will be accepted. If this occurs, the QC documentation will be copied into the CODIS QC documents.

### 9.4 Monitoring Analytical Procedures Using Controls & Standards

Except for Rapid DNA instruments/Systems used to analyze database, known or casework reference samples pursuant to 9.7 and/or 9.8 (if applicable), the OSBI CODIS Unit shall, at a minimum, monitor the analytical procedures using the following analytical controls and standards. Additionally, criteria for monitoring analytical procedures, including acceptable results for standards and controls, will be specified in the applicable analytical procedures in this policy manual.

- 9.4.1 Reagent blank controls associated with each extraction set being analyzed shall be:
  - 9.4.1.1 Extracted concurrently and treated with the most sensitive conditions as the samples;
  - 9.4.1.2 Amplified utilizing the same typing test kit, instrument model, and sensitivity conditions as required by the sample(s) containing the least amount of DNA; and

## Quality Manual

- 9.4.1.3 Typed utilizing the same instrument model, injection conditions and most sensitive volume conditions of the extraction set.
- 9.4.2 If applicable, where quantification is used, quantification standards shall be used. If a virtual or external standard curve is utilized, a calibrator must be ran concurrently with the samples.
- 9.4.3 Positive and negative (reagent blank) amplification controls associated with samples being typed shall be amplified concurrently using the same typing test kit on the same instrument as the samples. A reagent blank may be used concurrently as a negative amplification control for direct amplification.
  - 9.4.3.1 Except as provided in 9.4.4.1, all samples typed shall also have the corresponding amplification controls typed.
- 9.4.4 If applicable, laboratories performing sequencing shall use positive and negative sequencing controls concurrently sequenced using the same typing test kit on the same instrument as the samples.
  - 9.4.4.1 If the positive amplification control is not used as the positive sequencing control, the laboratory shall have and follow procedures for the evaluation of the positive amplification control.
- 9.4.5 Allelic ladders and internal size standards for PCR-based systems, as applicable.
- 9.5 The OSBI CODIS Unit shall have and follow written guidelines for the interpretation of data that are based on and supported by internal validation studies. An NDIS approved and internally validated Expert System may be used to complete the data interpretation process, if applicable. As specified in the applicable procedures in this policy manual including, but not limited to, CODIS\_6 (DNA Interpretation Guidelines for Database Samples), the CODIS Unit shall:
  - 9.5.1 Have criteria to evaluate internal size standards, allelic ladders and analytical controls.
  - 9.5.2 Have criteria for the interpretation of non-allelic peaks/signal.
  - 9.5.3 Have criteria for the interpretation of allelic peaks/signal.
  - 9.5.4 Define the thresholds used for interpretation. As appropriate to the interpretation model utilized (i.e., binary), the laboratory shall establish the following thresholds:
    - 9.5.4.1 Analytical Threshold
    - 9.5.4.2 Stochastic Threshold
  - 9.5.5 Define criteria for uninterpretable data.
- 9.6 If applicable, for modified Rapid DNA analysis, a laboratory shall:
  - 9.6.1 Have and follow written guidelines for the manual interpretation of data.
    - 9.6.1.1 The laboratory shall verify that the internal size standard and allelic ladder results meet the laboratory's interpretation guidelines.
  - 9.6.2 Have and follow procedures to address the use of positive sample controls and negative sample controls.

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9.7 If applicable, for Rapid DNA analysis, a laboratory shall have and follow procedures to address the use of positive sample controls and negative sample controls.

9.7.1 The Rapid DNA cartridge shall include an internal size standard with each sample.

9.8 The OSBI CODIS Unit shall follow all applicable procedures in this policy manual for the detection and control of contamination including, but not limited to, CODIS\_6 (DNA Interpretation Guidelines for Database Samples).

9.8.1 The CODIS Unit shall follow QC\_1 (Cleaning, Decontamination & Sterilization) for cleaning and decontaminating facilities and equipment.

**Attachment(s):** OSBI CODIS Unit Policy Manual QCR\_GFE  
OSBI CODIS Unit Policy Manual QCR\_PreNGo

**Reference(s):**

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

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## DBQM\_10 EQUIPMENT ([↑ Table of Contents](#))

10.1 The OSBI CODIS Unit shall use equipment suitable for methods employed.

10.1.1 The laboratory shall follow OSBI CSD QP 24 (Calibration and Handling of Equipment) and the applicable procedures outlined in this policy manual.

10.1.2 Laboratory equipment and instruments shall be used as recommended by the manufacturer or as specified in the applicable analytical protocols.

10.1.3 If laboratory equipment or instruments do not function as expected, OSBI CSD QP 24 (Calibration and Handling of Equipment) shall be followed, and the technical manager, lead analyst, unit supervisor or designee will arrange for service or replacement.

10.1.3.1 In the event that a laboratory does not have suitable equipment for the methods in use, the technical manager or designee (e.g. OSBI CSD director, quality manager, etc.) will suspend technical operations, in accordance with 5.2.5.2 and utilizing OSBI CSD QP 13 (Nonconforming Work), if applicable, until the laboratory re-establishes the suitability of the equipment.

### 10.2 Critical Equipment/Instruments

The OSBI CODIS Unit shall identify critical equipment or instruments and follow a program of quality control procedures, as outlined in this policy manual, to ensure all critical equipment and instruments are maintained.

10.2.1 At minimum, the OSBI CODIS Unit identifies the following as critical:

10.2.1.1 Handheld mechanical pipettes

10.2.1.2 A thermometer traceable to national or international standard(s) (includes any thermometer used for conducting performance checks)

10.2.1.3 Incubators/heat blocks used in analytical procedures

10.2.1.4 Robotic systems

10.2.1.5 Thermal cyclers, including quantitative PCR

10.2.1.6 Thermal cycler temperature verification systems (TVS)

10.2.1.7 Electrophoresis detection systems, including Genetic Analyzers

10.2.1.8 Rapid DNA instruments/Systems, if applicable

10.2.1.9 Any additional instruments or equipment that produce DNA typing results, if applicable

### 10.3 Performance Checks

The OSBI CODIS Unit shall have procedures for conducting performance checks of critical equipment or instruments, as outlined in this policy manual, including evaluating results (to include acceptable ranges), addressing unacceptable data, and documenting the completion and subsequent

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approval/rejection of the performance check. Calibration may be utilized to performance check equipment as well.<sup>5</sup>

10.3.1 New critical equipment or instruments, not requiring validation, shall undergo a performance check before use in database analysis. Each additional critical instrument, of the same instrument model validated for use in the laboratory, shall require a performance check prior to use in database analysis. This initial performance check may be used to demonstrate compliance with 10.3.2 for the current calendar year.

10.3.2 The following critical equipment or instruments shall require annual performance checks:

10.3.2.1 Handheld mechanical pipettes

10.3.2.2 Incubators/heat blocks used in an analytical procedure

10.3.2.3 Robotic systems

10.3.2.4 Thermal cyclers, including quantitative-PCR

10.3.2.5 Thermal cycler temperature verification systems (TVS)

10.3.2.6 Electrophoresis detection systems, including Genetic Analyzers

10.3.2.7 Any additional instruments or equipment that produce DNA typing results, if applicable

10.3.2.8 Other critical equipment or instruments defined by laboratory, if applicable

10.3.3 The following critical equipment or instruments shall require a performance check after repair or service before returning to use in database analysis:

10.3.3.1 Robotic systems

10.3.3.2 Thermal cyclers, including quantitative-PCR

10.3.3.3 Electrophoresis detection systems, including Genetic Analyzers

10.3.3.4 Rapid DNA instruments/Systems, if applicable

10.3.3.5 Any additional instruments or equipment that produce DNA typing results, if applicable

10.3.3.6 Other laboratory defined critical equipment or instruments, if applicable

10.3.4 If applicable, a Rapid DNA instrument/System shall require a performance check upon installation.

10.3.5 If applicable, a Rapid DNA instrument/System shall undergo a performance check if the Rapid DNA instrument remains idle longer than the period recommended by the instrument specifications or as established by the laboratory.

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<sup>5</sup> If performed in accordance with the applicable procedures of this policy manual and meeting the requirements of the OSBI CSD Quality Manual, including, but not limited to, OSBI CSD QM 6.4 (Equipment), OSBI CSD QM 6.5 (Metrological Traceability), OSBI CSD QM 6.6 (Externally Provided Products & Services), OSBI CSD QP 9 (Evaluation of Suppliers), OSBI CSD QP 23 (Measurement Traceability), and OSBI CSD QP 24 (Calibration and Handling of Equipment).

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## 10.4 Documentation

The OSBI CODIS Unit shall maintain documentation of maintenance, service, repair, and performance checks.

10.4.1 The schedule and maintenance program for equipment and instruments shall follow the requirements described herein DBQM\_10 (Equipment) and the applicable quality control procedures outlined in this policy manual.

10.4.2 Any maintenance, service, repair or calibration performed on laboratory equipment or instruments must be recorded on the appropriate equipment and maintenance log and maintained by the laboratory.

10.4.3 All performance checks must be documented.

10.4.4 The records associated with equipment or instruments should be portable in the event of equipment or instrument transfers within the OSBI forensic biology multi-laboratory system.

10.4.5 If equipment or instrument is permanently removed from service, the associated records should be archived and accessible for historical purposes.

10.4.6 Each piece of equipment or instrument shall be marked to allow the user to readily identify the date of the last performance check as well as the due date for the next required performance check.

### Attachment(s):

OSBI CODIS Unit Policy Manual **QC\_Decontamination\_Log**

OSBI CODIS Unit Policy Manual **QC\_Equip\_Maint\_Log**

OSBI CODIS Unit Policy Manual **QC\_Temp\_Log**

OSBI CODIS Unit Policy Manual **QC\_Pipet\_PC\_Log**

OSBI CODIS Unit Policy Manual **QC\_Pipet\_PC\_Reproducibility\_Log**

OSBI CODIS Unit Policy Manual **QC\_Thermometer\_PC\_Log**

OSBI CODIS Unit Policy Manual **QC\_Thermomixer\_PC\_Log**

OSBI CODIS Unit Policy Manual **QC\_ProFlex\_Maint\_Log**

OSBI CODIS Unit Policy Manual **QC\_ProFlex\_PC\_Log**

OSBI CODIS Unit Policy Manual **QC\_3500xL\_Maint\_&\_PC\_Log**

### Reference(s):

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

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## DBQM\_11 DOCUMENTATION ([↑ Table of Contents](#))

11.1 The OSBI CODIS Unit shall follow the procedures outlined in this policy manual, in addition to the applicable sections of OSBI CSD QP 16.2 (Contents of Case Records), for maintaining documentation for database samples (i.e., completed plate workbooks and associated data files). The laboratory shall maintain all analytical documentation generated by analysts and/or technicians related to database analyses. The laboratory shall retain, in written, printed, or electronic format, sufficient documentation for each technical analysis to support the profile data such that another qualified individual can evaluate what was done and interpret the data.

11.1.1 The OSBI CODIS Unit “Abbreviation List” shall be maintained in accordance with the OSBI CSD Quality Manual.

11.1.2 In the OSBI CODIS Unit, a PDF version of a completed plate workbook is considered the completed examination documentation submitted for review for offender sample analysis. The documentation in the network folder designated for hit verification files is considered the completed examination documentation submitted for review for hit verifications.

11.1.2.1 All original testing documentation (or a scanned copy of the original testing documentation), such as worksheets, electropherograms, data/files, etc. will be retained with the examination documentation.

11.1.2.2 All technical review comments and any changes made to completed examination documentation will be clearly documented/tracked on the appropriate sheet in the Offender Analysis Excel workbook and converted to PDF to be attached to the completed plate workbook upon final approval of the plate.

11.1.2.3 The PDF version of completed plate workbooks may be archived into a designated network folder.

11.2 The OSBI CODIS Unit shall have and follow a documented procedure for the resolution, verification and reporting/notification of database matches.

11.3 Except as otherwise provided by state or federal law, the information in DNA records and DNA databases shall be confidential.<sup>6,7</sup> The OSBI CODIS Unit shall follow to the procedures herein and the applicable sections of OSBI CSD QP 16.1 (Control of Records) to ensure the confidentiality of database samples, DNA records, and the information contained within the CODIS database. The OSBI CODIS Database is specifically exempt from any statute requiring disclosure of information to the public; the information contained in the database is confidential, privileged from discovery, inadmissible as evidence in any civil court proceeding, and shall not be released to the public.<sup>8</sup>

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<sup>6</sup> DNA profiles will not be transmitted outside the OSBI network electronically. The OSBI network is secure (internal email and servers); therefore, NDIS allows these electronic transmissions. However, DNA profiles will not be emailed outside of the OSBI network without prior authorization from the Technical Manager.

<sup>7</sup> Any person charged with the custody and dissemination of information from the database shall not divulge or disclose any such information except to federal, state, county or municipal law enforcement or criminal justice agencies. Any person violating the provisions of this section upon conviction shall be deemed guilty of a misdemeanor punishable by imprisonment in the county jail for not more than one year.

<sup>8</sup> The OSBI shall promulgate rules concerning the collection, storage, expungement and dissemination of information and samples for the OSBI CODIS Database per Oklahoma Statutes (Title 74 §150.27a).

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- 11.3.1 The OSBI CODIS Unit shall have and follow policies and/or procedures for the release of DNA records and databases, in accordance with applicable state or federal law. In accordance with Oklahoma Statutes (Title 74 §150.27a), Federal DNA Identification Act ('Federal DNA Act'; 34 U.S.C. §12592), and the Memorandum of Understanding (MOU) between the OSBI and FBI, stored DNA samples and analyses may only be released as follows:
- To criminal justice agencies for law enforcement identification purposes;
  - In judicial proceedings, if otherwise permissible pursuant to applicable statutes or rules;
  - For criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged; or
  - If personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes.
- 11.3.2 The OSBI CODIS Unit shall have and follow policies and/or procedures for the release of personally identifiable information in accordance with applicable state and federal law. In accordance with Oklahoma Statutes (Title 74 §150.27a) and the MOU between the OSBI and FBI, the following information may be released to individuals representing any law enforcement agency, including but not limited to, the Department of Corrections, Probation and Parole, court clerks, and the District Attorney's Office:
- Information regarding whether or not an offender sample was received;
  - The date a sample was received; or
  - Whether or not the profile from a sample has been entered into the CODIS database.
- 11.3.2.1 The OSBI CODIS Unit will follow the procedures detailed in CODIS\_2 (Hit Verifications) of this policy manual and comply with the NDIS Operational Procedures Manual for the release of personally identifiable information in connection with a database hit.

### **Attachment(s):**

OSBI CODIS Unit Policy Manual **DBQM\_Abbreviation\_List**

OSBI CODIS Unit Policy Manual **CODIS\_Offender\_Analysis\_Workbook**

### **Reference(s):**

Memorandum of Understanding Between the Federal Bureau of Investigation, Laboratory Division and the Oklahoma State Bureau of Investigation for Participation of the State of Oklahoma in the National DNA Index System (NDIS)

FBI National DNA Index System (NDIS) Operational Procedures Manual

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories



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## DBQM\_12 REVIEW<sup>9</sup> ([↑ Table of Contents](#))

12.1 The OSBI CODIS Unit shall have and follow procedures for reviewing DNA records and database information, including the verification and resolution of database matches.

12.1.1 An individual conducting technical reviews shall meet the requirements described in OSBI CSD QP 31 (Reviews); shall be an analyst or technical reviewer qualified in the method, technology, typing test kit, platform, and interpretation software being reviewed; and shall participate in semi-annual external proficiency testing. The individual conducting the technical review shall not be the original (examining) analyst and must be authorized (released) by the technical manager to perform technical reviews.

12.1.1.1 Individuals whose sole responsibility is technical review shall be proficiency tested in the technical review of each applicable technology and typing test kit in accordance with DBQM\_13 (Proficiency Testing).

### 12.2 Offender Samples

The OSBI CODIS Unit shall perform a technical review of all offender sample DNA records prior to uploading into or searching against the CODIS database, except when using an NDIS approved Rapid DNA System to analyze database, known or casework reference samples, if/as applicable. Completion of the technical review shall be documented using the Offender Sample Analysis Technical Review Form and the technical review of a DNA record shall include the following elements, at a minimum:

12.2.1 A review of all notes, all worksheets, and the electronic data (or printouts of such data) supporting the results.

12.2.2 A review of all analytical controls, internal size standards, and allelic ladders to verify that the expected results were obtained, except when using an NDIS approved and internally validated Expert System, if applicable.

12.2.3 A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images), except when using an NDIS approved and internal validated Expert System, if applicable. In addition to a review of the CODIS specimen categories assigned to all samples included in the .cmf file for correctness.

### 12.3 Hit Verifications

The release of personally identifiable information associated with a database hit shall require an administrative review of the official correspondence (i.e., hit letter). Completion of the administrative review shall be documented using the Forensic Hit Verification Administrative Review Form, Offender Hit Verification Administrative Review Form, or Duplicate Offender Hit Verification Administrative Review Form, as applicable, and shall include the following elements, any or all of which may be included within the technical review:

12.3.1 A review of the supporting administrative documentation and the correspondence for clerical errors, accuracy of information and adherence to agency policy.

12.3.2 A review of chain of custody for known or casework reference samples processed as evidence, if applicable.

12.3.3 A review of the individual's biographical data, qualifying offense, and DNA profile generated from reanalysis, as applicable.

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<sup>9</sup> This applies to data generated within the OSBI CODIS Unit. The review of data generated external to the OSBI is governed by DBQM\_17 (Outsourcing Ownership).

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### 12.4 Unresolved Issues &/or Unresolved Discrepant Interpretations/Conclusions

The OSBI CODIS Unit shall address unresolved issues and/or unresolved discrepant interpretations or conclusions between the analysts and reviewer(s) as follows:

12.4.1 If an analyst does not agree with the opinion of the reviewer, they must make it known to the reviewer at that time.

12.4.2 Unresolved issues between an analyst and reviewer shall be handled on an individual basis and with the assistance of the supervisor and/or technical manager, as necessary.

12.4.3 Unresolved discrepant interpretations/conclusions will be resolved using the following methods:

12.4.3.1 In cases where the issue can be resolved by reanalysis of the sample(s) in question, that should be performed first.

12.4.3.2 In cases where the issue cannot be resolved by reanalysis, the technical manager will make the final determination.

12.4.3.3 In accordance with OSBI CSD QP 31 (Reviews), any issues that cannot be resolved by the supervisor and/or technical manager will be brought to the attention of the applicable criminalistics administrator and the quality manager for further evaluation.

12.5 The OSBI CODIS Unit shall have a system in place to ensure that the correct CODIS specimen categories have been assigned.

#### **Attachment(s):**

OSBI CODIS Unit Policy Manual **CODIS\_Offender\_Analysis\_Workbook**

OSBI CODIS Unit Policy Manual **CODIS\_Offender\_Analysis\_TR**

OSBI CODIS Unit Policy Manual **CODIS\_Forensic\_Hit\_AR**

OSBI CODIS Unit Policy Manual **CODIS\_Offender\_Hit\_AR**

OSBI CODIS Unit Policy Manual **CODIS\_Dup\_Offender\_Hit\_AR**

#### **Reference(s):**

OSBI Memorandum to the Forensic Biology Discipline: "Analysts Qualified for Technical Review"

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

OSBI Forensic Biology Units' Policy Manual

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

FBI National DNA Index System (NDIS) Operational Procedures Manual

# Quality Manual

## DBQM\_13 PROFICIENCY TESTING ([↑ Table of Contents](#))

- 13.1 Analysts, technical reviewers, technicians, and other personnel designated by the technical manager shall undergo semi-annual<sup>10</sup> external proficiency testing per calendar year. The OSBI CODIS Unit shall follow OSBI CSD QP 30 (Proficiency Tests).
- 13.1.1 Analysts qualified in more than one technology<sup>11</sup> (e.g., STR, Y-STR, etc.) shall be proficiency tested in each technology at least once per calendar year. All applicable samples in a single proficiency test shall be worked for each technology.
- 13.1.1.1 Typing of all 20 CODIS core loci or CODIS core sequence ranges shall be attempted for each technology at least once per calendar year.
- 13.1.2 Analysts qualified in more than one typing test kit shall be proficiency tested in each typing test kit at least once per calendar year.
- 13.1.2.1 If applicable, analysts qualified to perform modified Rapid DNA analysis shall be externally proficiency tested on the interpretation of data generated by each Rapid DNA instrument model for each PCR STR typing test kit at least once per calendar year.
- 13.1.3 Individuals (analysts, technicians, and other personnel designated by the technical manager) that perform analytical procedures on database, known, or casework reference samples shall be proficiency tested on at least one method<sup>12</sup> in each methodology<sup>13</sup> for which they are qualified to perform database analysis at least once per calendar year.
- 13.1.4 Except as provided in 13.1.4.1, each external proficiency test shall be assigned to and completed by one analyst.
- 13.1.4.1 Laboratories that employ technicians and/or use a team approach for database analysis may do so on external proficiency tests. However, each analyst shall be assigned a proficiency test to complete the interpretation and report the results.
- 13.1.4.1.1 If a methodology is performed by a technician or another analyst (other than the analyst assigned the proficiency test) on one test in the calendar year, the assigned analyst must perform the methodology on the other (second) test in the calendar year them self.

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<sup>10</sup> Per QAS, *semi-annual* requires testing to take place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year, and where the interval between the events is at least four months and not more than eight months.

<sup>11</sup> Per QAS, *technology* is used to describe the type of forensic DNA analysis performed in the laboratory, such as RFLP, STR, Y-STR, XSTR, SNP, microhaplotypes or mitochondrial DNA.

<sup>12</sup> Per QAS, *method* is a combination of procedural steps used to perform a specific technical process. The method includes the validated steps, reagents, and critical instruments needed to perform the process or portion of a process. The same method may be conducted using different equipment (automated vs manual) when appropriately validated.

<sup>13</sup> Per QAS, *methodology* refers to the categories of methods used to perform a stage of a DNA typing technology or technologies. For example, methodologies for STR technologies can include extraction, quantification, amplification, and detection.

## Quality Manual

- 13.1.5 Individuals whose sole responsibility is technical review shall be proficiency tested in the technical review of each technology and typing test kit at least once per calendar year.<sup>14</sup>
- 13.1.5.1 The proficiency testing shall cover the 20 CODIS core loci or CODIS core sequence ranges attempted for each technology at least once per calendar year.
- 13.1.5.2 If applicable, technical reviewers qualified to review modified Rapid DNA analysis shall be externally proficiency tested on the technical review of data generated by a Rapid DNA instrument model for each PCR STR typing test kit at least once per calendar year.
- 13.1.5.3 If the technical reviewer is a contract employee conducting technical reviews for an NDIS participating laboratory the proficiency testing shall be administered by an NDIS participating laboratory and shall be reviewed and approved by the technical manager of the NDIS participating laboratory for which the technical manager is conducting reviews.
- 13.1.6 Newly qualified individuals (analysts, technicians, and other personnel designated by the technical manager) shall undergo semi-annual external proficiency testing within eight months of their qualification date.
- 13.2 The OSBI CODIS Unit shall use an external proficiency test provider that is accredited to the current applicable standard of the International Organization for Standardization and the applicable test is included on the proficiency test provider's scope of accreditation. The laboratory shall follow OSBI CSD Quality Manual 6.6.2 (Determining Suitability of External Providers) for external proficiency test providers. External proficiency testing shall be an open proficiency testing program and shall be submitted to the proficiency testing provider in order to be included in the provider's published external summary report.
- 13.2.1 If an analyst participates in a proficiency test provider's pre-distribution program, the pre-distribution test can be counted as one of the two external proficiency tests for the calendar year; however, the analyst must resubmit the pre-distribution test results during the general distribution testing phase for that specific test in order to be included in the provider's published external summary report.
- 13.3 For purposes of tracking compliance with the proficiency testing requirements, the OSBI CODIS Unit defines and consistently uses the due date as the date that the proficiency test is performed.
- 13.4 In accordance with OSBI CSD QP 30 (Proficiency Tests), the OSBI CODIS Unit shall maintain the following records for proficiency tests:
- 13.4.1 The test set identifier;
- 13.4.2 Identity of the analyst, and other participants, if applicable;
- 13.4.3 Date of analysis and completion;
- 13.4.4 Copies of all data and notes supporting the interpretations or conclusions;
- 13.4.5 The proficiency test results;
- 13.4.6 Any discrepancies noted; and

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<sup>14</sup> A qualified analyst proficiency tested in the specific technology may serve as a technical reviewer without needing to take an additional proficiency test as a technical reviewer.

## Quality Manual

13.4.7 Corrective actions taken.

13.5 The OSBI CODIS Unit shall evaluate proficiency test results and shall include, at a minimum, the following criteria:

13.5.1 All reported genotypes, phenotypes, and/or sequences are correct or incorrect according to consensus results or are compliant with the laboratory's interpretation guidelines.

13.5.2 All reported uninterpretable results are compliant with written laboratory guidelines.

13.5.3 All final proficiency tests shall be evaluated as satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the DNA typing data or reported conclusions.

13.5.3.1 All discrepancies or errors, to include the occurrence of administrative errors, and subsequent corrective actions, as applicable, shall be documented. This includes retaining correspondence with an accrediting body's proficiency review committee, if applicable. Non-administrative discrepancies and errors will be handled in accordance with DBQM\_14.

13.6 The following shall be informed of the results of the proficiency test and documented as per OSBI CSD QP 30 (Proficiency Tests):

13.6.1 The proficiency test participant(s)

13.6.2 The technical manager

13.6.3 The CODIS administrator in the event of non-administrative discrepancies that affect the typing results.

**Attachment(s):**

None

**Reference(s):**

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

International Standard ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories

ANAB ISO/IEC 17025:2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125)

# Quality Manual

## DBQM\_14 CORRECTIVE ACTION ([↑ Table of Contents](#))

- 14.1 The OSBI CODIS Unit shall follow OSBI CSD QP 13 (Nonconforming Work), QP 14.1 (Class II Nonconforming Work), QP 14.2 (Corrective Action – Class III Nonconforming Work), and QP 14.3 (Corrective Action – Class IV Nonconforming Work), as well as OSBI Agency Policy #110 (OSBI Progressive Discipline), as needed, to address nonconformities detected in database analysis, proficiency tests, testimony, and audits. Nonconformities not requiring a corrective action plan may be remediated with documented correction or other documentation. The aforementioned policies define when a nonconformity requires documentation and/or a corrective action plan.
- 14.1.1 Corrective action plans developed to evaluate and remediate a nonconformity shall be documented and include the elements listed below in 14.2. The technical manager shall have access to all final, completed corrective actions as applicable to casework, databasing and/or proficiency tests for every individual within the OSBI Forensic Biology Discipline.
- 14.2 The laboratory's documented corrective action plan shall include the identification (when possible) of the cause(s) of the nonconformity, corrective actions taken with timeframes (where applicable), and preventive measures taken (where applicable) to minimize its reoccurrence.
- 14.2.1 Corrective action plans shall be approved by the technical manager prior to implementation. If necessary, the technical manager has the authority to initiate, suspend and resume technical operations for the laboratory or an individual in accordance with DBQM\_5.2.5.2.
- 14.2.2 The CODIS administrator shall be notified when the nonconformity impacts DNA records entered into CODIS. If necessary, the CODIS administrator, in consultation with the OSBI CSD director and quality manager, may terminate an analyst's or laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified in accordance with DBQM\_5.3.5.

### Attachment(s):

None

### Reference(s):

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

OSBI Agency Policies and Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

# Quality Manual

## DBQM\_15 AUDITS ([↑ Table of Contents](#))

- 15.1 The OSBI CODIS Unit shall be audited annually, at a minimum, in accordance with the QAS. In addition, all internal audits shall be conducted in accordance with OSBI CSD QP 17 (Audits). The annual audits shall occur every calendar year and shall be at least six months and no more than eighteen months apart. The audit must entail the review of documentation since at least the last annual audit to assess compliance to the QAS.
- 15.2 At least once every two years, an external audit shall be conducted by one or more auditor(s) from a second agency(ies) who has/have successfully completed the FBI's DNA auditor training course. At least one auditor shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.
- 15.2.1 Each analyst, technical reviewer, CODIS administrator, and technical manager shall have his/her education, experience, and training qualifications evaluated and approved during two successive, separate external audits. Approval of an individual's education, experience, and training qualifications shall be documented in the Audit Document.
- 15.2.1.1 An analyst or technical reviewer that receives additional qualification in an additional technology(ies), typing test kit(s), or platform(s) shall have the additional training qualifications evaluated and approved during one external audit. Approval of additional training qualifications shall be documented in the Audit Document.
- 15.2.2 Each validation study shall be evaluated and approved during one external audit. Approved validation studies shall be documented in the Audit Document.
- 15.3 Internal audits shall be conducted by an audit team that includes at least one auditor who has successfully completed the FBI's DNA auditor training course. At least one audit team member shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.
- 15.4 Internal and external audits shall be conducted utilizing the QAS Audit Document in effect at the time of the audit.
- 15.5 Internal and external audit documentation and, if applicable, corrective action(s) shall be reviewed by the technical manager to ensure that findings, if any, were appropriately addressed and this review shall be documented.
- 15.5.1 Internal and external audit documentation, and if applicable, corrective action(s) shall be provided to the CODIS administrator.
- 15.5.2 For NDIS participating laboratories, all external audit documentation and laboratory responses shall be provided to the FBI within thirty days of laboratory receipt of the Audit Document or report.
- 15.6 Internal and external audit documentation shall be retained and available for inspection during subsequent audits.

### Attachment(s):

None

# Quality Manual

**Reference(s):**

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards Audit for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories



# Quality Manual

## DBQM\_16 PROFESSIONAL DEVELOPMENT ([↑ Table of Contents](#))

16.1 The OSBI CODIS Unit shall follow OSBI CSD QP 16.1 (Control of Records), OSBI CSD QP 19 (Training), and the requirements listed in this policy to ensure technical qualifications are maintained and documented through participation in continuing education.<sup>15</sup>

16.1.1 The technical manager, CODIS administrator, analyst(s), and technical reviewers shall stay abreast of topics relevant to the field of forensic or databasing DNA analysis by attending seminars, courses, professional meetings, or other documented lectures or classes in relevant subject areas for a minimum of eight cumulative hours each calendar year.<sup>16</sup>

16.1.1.1 The continuing education hours shall be documented. Attendance at a regional, national, or international conference with content including topics relevant to the field of forensic or databasing DNA analysis shall be deemed to provide a minimum of eight hours of continuing education.

16.1.1.2 Documentation of attendance, such as certificates, attendance lists, and/or travel documentation, shall be maintained.

16.1.1.3 With the exception of a regional, national, or international conference, documentation of content, such as agenda/syllabus, record of presentation content, and/or the curriculum vitae of the presenter, shall be maintained.

16.1.1.4 Continuing education based on multimedia or internet delivery shall be subject to the approval of the technical manager and documented.

16.1.2 Analysts and technicians shall participate in annual ongoing reading of scientific literature covering topics relevant to the field of forensic DNA analysis; laboratory support personnel (e.g. administrative technicians) are exempt, as this falls outside the scope of their duties.<sup>17</sup> The technical manager and/or Lead Analyst will approve and distribute applicable scientific literature ("literature reviews") each quarter for individuals to review before the next quarter or by the due date set by the technical manager and/or Lead Analyst. Individuals will verify completion of literature reviews by signing an associated completion form provided by the technical manager and/or Lead Analyst. All literature review documentation, including signed completion forms, will be maintained by the technical manager and/or Lead Analyst.

16.1.2.1 The laboratory shall maintain or have physical or electronic access to a collection of current books, reviewed journals, or other literature applicable to DNA analysis.

16.2 The OSBI CODIS Unit shall follow OSBI CSD QP 32 (Testimony) to document the annual review of the testimony of each analyst.

16.2.1 OSBI CSD QP 32 (Testimony) and its associated attachments define the elements and mechanisms for testimony review.

16.2.2 The testimony review shall be documented and provided to the testifying individual.

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<sup>15</sup> Assignments and activities required as part of the laboratory's training program and/or that are required for establishing an individual's competency do not count toward the continuing education hours.

<sup>16</sup> An individual who completes the laboratory's initial training program within the calendar year is not expected to complete the 8 hours of continuing education until the next calendar year.

<sup>17</sup> Reading of scientific literature and subsequent lab-sponsored discussions (e.g., journal club, article presentation, etc.) do not count toward the continuing education hours required by 16.1.1.

## Quality Manual

16.2.2.1 Any deficiency and subsequent corrective actions, as applicable, shall be documented.

**Attachment(s):**

None

**Reference(s):**

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

# Quality Manual

## DBQM\_17 OUTSOURCING OWNERSHIP<sup>18, 19</sup> ([↑ Table of Contents](#))

17.1 A vendor laboratory performing database DNA analysis shall comply with the current QAS and the accreditation requirements of federal law. Except as provided by 17.2.2, failure to comply with the procedures listed herein will preclude the entry, searching or uploading of outsourced DNA data into CODIS. In addition, per OSBI CSD Quality Manual 6.6.2, any vendor laboratory utilized by the OSBI forensic biology multi-laboratory system (discipline) must comply with the accreditation requirements in O.S. 74-150.37 and be accredited through an organization that adheres to the ISO/IEC 17025 guidelines; a copy of the accreditation certificate shall be provided to the OSBI CSD quality manager.

17.1.1 As a NDIS participating laboratory, when outsourcing to a vendor laboratory (or if the criteria of ownership applies), the OSBI forensic biology discipline, which includes the CODIS Unit, shall require the vendor laboratory to provide documentation of compliance with the QAS and the accreditation requirements of federal law. The OSBI forensic biology discipline technical manager shall review and retain the documentation of the vendor laboratory's compliance with the QAS and the accreditation requirements of federal law.

17.1.2 If applicable, a vendor laboratory performing Rapid DNA analysis using an NDIS approved Rapid DNA System shall have a system in place to ensure that the correct CODIS specimen categories have been assigned.

17.2 Except as provided in 17.2.1 and 17.2.2, the OSBI forensic biology discipline technical manager shall document approval of the technical specifications of the outsourcing agreement with the vendor laboratory before it is awarded, and the date of the technical manager's documented approval and/or the documented prior approval as specified in 17.2.1 must be maintained. In addition, when bid specifications are written by any individual other than the technical manager, the technical manager shall be consulted for input and approval.

17.2.1 A vendor laboratory that is performing DNA analysis on behalf of a law enforcement agency (other than the OSBI) or other entity for the purposes of ownership by the OSBI laboratory, shall not initiate analysis until written approval has been obtained from the OSBI forensic biology discipline technical manager.

17.2.2 The OSBI CODIS Unit shall not upload or accept DNA data for upload to CODIS from any vendor laboratory or agency without the prior approval of the technical specifications of the outsourcing agreement and/or approval of acceptance of ownership of the DNA data by the OSBI forensic biology discipline technical manager.

17.2.3 Bid specifications should include the following requirements, at a minimum

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<sup>18</sup> Ownership applies if any of the following will occur, including in situations where a vendor laboratory subcontracts:

1. The OSBI will use any samples, extracts, or materials from the vendor laboratory for the purposes of forensic testing (e.g., a vendor laboratory prepares an extract that will be analyzed by the OSBI);
2. The OSBI will interpret the data generated by the vendor laboratory;
3. The OSBI will issue a report describing or drawing conclusions on the results of the DNA analysis performed by the vendor laboratory; or
4. The OSBI will enter or search a DNA profile in CODIS from data generated by the vendor laboratory.

<sup>19</sup> DNA data from outsourced forensic casework samples will be handled in accordance with the procedures outlined in the OSBI Forensic Biology Units' Policy Manual prior to uploading or searching against SDIS.

## Quality Manual

- 17.2.3.1 Prior to conducting DNA analysis, the vendor laboratory must guarantee compliance with confidentiality requirements set for by the OSBI.
  - 17.2.3.2 The vendor laboratory shall only use procedures approved by the OSBI CODIS administrator and/or OSBI forensic biology discipline technical manager to analyze OSBI offender samples.
  - 17.2.3.3 DNA analysis of OSBI offender samples will be performed at all 20 CODIS core loci. Offender samples will not be considered complete unless results are obtained for all 20 CODIS core loci. Any profile not meeting standards will either be reanalyzed by the vendor laboratory or analyzed in-house by the OSBI to obtain an acceptable profile prior to uploading or searching against SDIS.
  - 17.2.3.4 All data generated during analysis by a vendor laboratory is property of the State of Oklahoma and will be returned to the OSBI after analysis is complete; the data may include, but is not limited to: original run data files generated during the course of analysis; software files, such as GeneMapper ID-X; common message format (.cmf) data files; etc.
  - 17.2.3.5 The vendor laboratory is responsible for providing evidence analysis and testimony regarding their analyses.
  - 17.2.3.6 The vendor laboratory is prohibited from repackaging samples sent for analysis in order to reduce the potential for sample switches by the vendor laboratory.
  - 17.2.3.7 The vendor laboratory will destroy all DNA extracts, dilutions and amplified DNA products, as applicable, after analysis has been completed. Documentation of the destruction must be provided to the OSBI.
  - 17.2.3.8 OSBI personnel may conduct an audit at the discretion of the OSBI forensic biology discipline technical manager, if necessary.
- 17.3 The OSBI CODIS Unit will verify the integrity of the DNA data received for the purposes of taking ownership of DNA data from a vendor laboratory by performing a technical review (i.e. ownership review) following the procedures described in DBQM\_12 (Review) and completing a technical review form, in addition to the quality assurance procedures described herein.
- 17.3.1 The OSBI CODIS Unit shall follow quality assurance procedures to verify the integrity of the DNA data received from a vendor laboratory including, but not limited to, the random reanalysis of database, known or casework reference samples and the inclusion of quality control samples (described below). The sum of the samples randomly selected for reanalysis and any quality control samples provided to the vendor laboratory must be approximately five percent of the total number of offender samples analyzed by the vendor laboratory.
    - 17.3.1.1 **Random reanalysis of database, known or casework reference samples:**  
Samples previously analyzed by the vendor laboratory will be randomly selected for reanalysis for quality control purposes. Reanalysis may be performed by the OSBI CODIS Unit or by a vendor laboratory, and the results obtained must be the same as the initial results provided by the vendor laboratory. Any discrepancies must be resolved to the satisfaction of the CODIS administrator before the profile(s) will be accepted by the OSBI. If the same vendor laboratory that performed the original analysis performs the reanalysis, the sample numbers will be changed so that the results will not be known beforehand. All reanalysis documentation will be maintained by the OSBI CODIS Unit.

## Quality Manual

- 17.3.1.2 **Inclusion of quality control samples:** new batches of OSBI offender samples sent to a vendor laboratory for analysis must contain a random selection of samples with a known DNA profile (e.g. blood/buccal sample from individuals for which their DNA profile is already known) for quality control purposes. Other quality control samples may be sent at the discretion of the CODIS administrator. The results of the analysis of the quality control samples by the vendor laboratory must be the same as the results known by the OSBI. Any discrepancies must be resolved to the satisfaction of the CODIS administrator before the data set will be accepted by the OSBI.
- 17.3.2 Prior to the search of DNA data in SDIS, an analyst, CODIS administrator or technical reviewer in the OSBI forensic biology discipline (or OSBI contract employee) shall review the DNA data to verify the correct specimen category for entry into CODIS.
- 17.3.3 Prior to the upload of DNA data to SDIS or the reporting of search results, an analyst or technical reviewer in the OSBI forensic biology discipline (or OSBI contract employee) who is qualified in the technology, platform and typing test kit used to generate the data and participates in the OSBI laboratory's proficiency testing program shall perform a technical review (ownership review) of the DNA data from the vendor laboratory. A portion of this review may be accomplished through the use of an NDIS approved and internally validated Expert System, if available, but only if the data was produced using the same amplification kit, instrument model, and data collection software as the NDIS participating laboratory; additional validation studies may be necessary before using an Expert System on outsourced data.
- 17.3.3.1 If the proficiency testing is administered by another NDIS participating laboratory, such as for a contracted technical reviewer, the OSBI forensic biology discipline technical manager (i.e., the NDIS participating laboratory for which the reviewer is conducting ownership reviews) shall review and approve the reviewer's participation in an NDIS participating laboratory's proficiency testing program.
- 17.3.4 Except as provided in 17.3.5, the technical review (ownership review) shall include the following elements:
- 17.3.4.1 A review of all DNA types that the OSBI CODIS Unit will take ownership of to verify that they are supported by the raw and/or analyzed data (electropherograms or images).
- 17.3.4.2 A review of all associated analytical controls, internal size standards and allelic ladders to verify that the expected results were obtained.
- 17.3.4.3 For samples to be entered into CODIS, verification of the DNA types, eligibility, and the correct specimen category.
- 17.3.4.3.1 Verification of eligibility must be performed by a current CODIS user.
- 17.3.5 If applicable, for an NDIS participating laboratory that outsources to a vendor laboratory performing Rapid DNA analysis on database, known or casework reference samples using an NDIS approved Rapid DNA System, the ownership review for data generated by the Rapid DNA System shall include:
- 17.3.5.1 A review of the final report (if provided) to verify that the results/conclusions are supported by the Rapid DNA System data.
- 17.3.5.2 For samples to be entered into CODIS, verification of the eligibility and the correct specimen category.

## Quality Manual

17.3.5.2.1 Verification of eligibility shall be performed by a current CODIS user.

17.3.5.3 A review of the data associated with applicable Rapid DNA System performance checks.

17.4 When the OSBI CODIS Unit outsources DNA sample(s) to a vendor laboratory or accepts ownership of DNA data from a vendor laboratory, an on-site visit(s) of the vendor laboratory shall be performed and documented, provided, however, that an on-site visit shall not be required when only technical review services are being provided.<sup>20</sup> Documentation must include the date the visit was performed, who performed the visit, and a summary of the visit in an OSBI memorandum copied to the OSBI CSD director. The procedure to perform an on-site visit shall include, at a minimum, the following elements:

17.4.1 A documented initial on-site visit, to assess the vendor laboratory's ability to perform analysis on outsourced database samples, prior to the vendor laboratory's beginning of DNA analysis for the OSBI CODIS Unit.

17.4.1.1 The on-site visit shall be performed by the OSBI forensic biology discipline technical manager, or a designated employee of a NDIS participating laboratory, who is a qualified or previously qualified analyst in the technology, platform and typing test kit used to generate the DNA data. Alternatively, the OSBI forensic biology discipline technical manager shall evaluate and approve an on-site visit coordinated by a designated FBI employee.

17.4.2 If the outsourcing agreement extends beyond one year, an annual on-site visit shall be required by the OSBI forensic biology discipline technical manager, or a designee, as described above. Each annual on-site visit shall occur every calendar year and shall be at least six months and no more than eighteen months apart.

17.4.2.1 The OSBI CODIS Unit may accept an on-site visit conducted by another NDIS participating laboratory using the same technology, platform or typing test kit for the generation of the DNA data, or coordinated by a designated FBI employee, and the OSBI forensic biology discipline technical manager shall review and approve such on-site visit.

### **Attachment(s):**

None

### **Reference(s):**

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

International Standard ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories

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<sup>20</sup> While an on-site visit is not required when only technical review services are being provided, the OSBI forensic biology discipline technical manager shall evaluate how and where such services are being performed and document their approval to ensure compliance with the QAS, Standard 11.3.

# Quality Manual

ANAB ISO/IEC 17025:2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125)

# Standard Operating Procedures

## CODIS\_1 DATA ENTRY & SEARCH PROCEDURES ([↑ Table of Contents](#))

### Quick links:

#### **Specimen Categories/Indexes**

- Forensic, Unknown/Forensic
  - DNA Index of Special Concern (DISC)*
- Forensic Partial/Forensic Partial
- INC. Forensic STR/Incomplete Forensic
- Forensic Mixture/Forensic Mixture
- INC. For. Mixture/Incomplete Forensic Mixture
- Forensic Targeted/Forensic Targeted
- SDIS Forensic Targeted/SDIS Targeted
- Missing Person & Deduced Missing Person/Missing Person
- Biological Relatives/Relatives of Missing Person
- Unidentified Person/Unidentified Human (Remains)
- Convicted Offender/Offender
  - Reanalysis of Convicted Offender Samples*
- INC. Offender STR/Incomplete Offender
- Arrestee/Arrestee
  - Reanalysis of Arrestee Samples*
- INC. Arrestee/Incomplete Arrestee
- Multi-Allelic Offender/Multi-Allelic Offender
  - Reanalysis of Multi-Allelic Offender Samples*
- Legal/Legal
- INC. Legal/Incomplete Legal
- Staff/Employee
- Contaminant Profile/Contaminant
- Y-STR Forensic Unknown/Y-STR Forensic
- Y-STR Legal/Y-STR Legal

#### **Acceptable DNA Profiles (Definition)**

#### **Analysis of Casework Samples (Calculating MME & MRE)**

#### **Analysis of Offender Samples**

#### **Creating Specimen ID Numbers**

- Casework Samples
- Offender Samples

#### **CODIS Data Entry Request & Documentation**

- OSBI Casework Profiles
  - Eligibility*
  - CODIS Data Entry Forms*
- Local CODIS Laboratory Casework Profiles
- Offender Profiles

#### **John Doe Warrants & Release of DNA Profiles**

#### **Conducting CODIS Searches**

- Remote Search Requests (Keyboard Searches)
- Batch Target Searches
- Familial Searches/Partial Matches
- Routine Index to Index Searches (Tables)

#### **Processing CODIS Matches**

#### **Profile Removal**

- Match to Elimination or Victim Profile
- CODIS Match to Ineligible Forensic Profile
- Removal of Duplicate Offender & Legal Samples

#### **Annual Review/Updates**



# Standard Operating Procedures

## 1.1 Scope

Defines allowed profiles, indexes and searches of the state CODIS database (SDIS) and specifically addresses the procedures a CODIS user must follow to request the entry of DNA data into SDIS.

## 1.2 Individual Steps of the Procedure

### 1.2.1 Specimen Categories & Indexes Maintained at SDIS<sup>21</sup>

In order to facilitate proper database searches, DNA profiles stored at SDIS are organized into several categories or indexes. Each index has certain criteria that must be met before a profile may be entered into the database or searched against other profiles stored in the database. The indexes maintained at SDIS and accepted profiles for each index are listed below. For all indices, inclusion requires analysis to be attempted at all core CODIS loci.

#### 1.2.1.1 Forensic, Unknown Specimen Category/Forensic Index

1.2.1.1.1 The **Forensic, Unknown specimen category** contains single source DNA profiles or full major components of mixture DNA profiles (provided that no loci are marked as obligate) originating from and associated with evidence found at crime scenes and with no locus or allelic dropout at any of the 20 CODIS core loci.

1.2.1.1.2 The **Forensic Index** consists of DNA profiles in the Forensic, Unknown specimen category. Profiles maintained in the Forensic Index will be forwarded to the FBI for inclusion in NDIS.

#### 1.2.1.1.3 DNA Index of Special Concern (DISC)

1.2.1.1.3.1 To take advantage of the new Rapid DNA search technology, certain DNA profiles may be “Rapidly Enabled” in the CODIS software. “Rapidly Enabled” profiles will be automatically entered into the **DNA Index of Special Concern (DISC)** and will be searched at high stringency upon enrollment of an offender/arrestee profile from a rapid DNA instrument. To be eligible for DISC, profiles:

1.2.1.1.3.1.1 Must be in the Forensic, Unknown specimen category;

1.2.1.1.3.1.2 Must be from an unsolved act of terrorism, kidnapping, rape or homicide;

1.2.1.1.3.1.3 Must qualify for extradition; and

1.2.1.1.3.1.4 Must have contact information for the person to be notified in the event of a rapid hit.

1.2.1.1.3.2 If a profile is to be “Rapidly Enabled,” analysts must consult with the CODIS administrator to ensure all required information is available prior to CODIS data entry.

1.2.1.1.3.3 Major component profiles entered into the Forensic Mixture specimen category prior to March 1, 2018 that meet the above criteria for entry into the Forensic, Unknown specimen category and are eligible to be “Rapidly Enabled” for search

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purposes will have the specimen category changed to Forensic, Unknown following review by the CODIS administrator or designee. Otherwise, major component profiles entered into the Forensic Mixture specimen category prior to March 1, 2018, will remain in the Forensic Mixture specimen category.

### 1.2.1.2 Forensic Partial Specimen Category/Forensic Partial Index

1.2.1.2.1 The **Forensic Partial specimen category** contains partial, single source DNA profiles originating from and associated with evidence found at crime scenes that have locus or allelic dropout at any of the 20 CODIS core loci. Profiles in this category:

1.2.1.2.1.1 Consist of at least 8 or more of the original 13 CODIS core loci.

1.2.1.2.1.2 Satisfy a Moderate Match Estimate (MME) value of at least  $1 \times 10^7$  (10,000,000) calculated without a mismatch.

1.2.1.2.2 The **Forensic Partial Index** consists of DNA profiles in the Forensic Partial specimen category. Profiles maintained in the Forensic Partial Index will be forwarded to the FBI for inclusion in NDIS.

1.2.1.2.3 Loci where a partial profile is indicated shall be referenced with a "(p)" on the CODIS Data Entry Form.

1.2.1.2.4 Casework analysts should keep in mind the reported inclusions/statistical values should a match occur to entries in this specimen category. If there would be no inclusion/statistical value for any profile matching to this specimen, the profile should not be entered into the CODIS database.

### 1.2.1.3 INC. Forensic STR Specimen Category/Incomplete Forensic Index

1.2.1.3.1 The **INC. Forensic STR specimen category** contains partial, single source DNA profiles originating from and associated with evidence found at crime scenes that have locus or allelic dropout at any of the 20 CODIS core loci. Profiles in this category:

1.2.1.3.1.1 Consist of at least 8 or more of the original 13 CODIS core loci.

1.2.1.3.1.2 Do not meet the NDIS Moderate Match Estimate (MME) or NDIS Match Rarity Estimate (MRE) thresholds of  $1 \times 10^7$ .

1.2.1.3.1.3 Satisfy a Moderate Match Estimate (MME) of at least  $5 \times 10^4$  (50,000) (SDIS MME) when calculated with no mismatch.

1.2.1.3.2 The **Incomplete Forensic Index** consists of DNA profiles in the INC. Forensic STR specimen category. Profiles maintained in the Incomplete Forensic Index will be searched routinely against SDIS only and will not be forwarded to the FBI for inclusion in NDIS.

1.2.1.3.3 Loci where a partial profile is indicated shall be referenced with a "(p)" on the CODIS Data Entry Form.

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- 1.2.1.3.4 Casework analysts should keep in mind the reported inclusions/statistical values should a match occur to entries in this specimen category. If there would be no inclusion/statistical value for any profile matching to this specimen, the profile should not be entered into the CODIS database.

### 1.2.1.4 Forensic Mixture Specimen Category/Forensic Mixture Index

- 1.2.1.4.1 The **Forensic Mixture specimen category** contains mixture DNA profiles from forensic samples that contain DNA contributed from more than one source, such as major components of mixture DNA profiles with dropout or obligate alleles, minor components of mixture DNA profiles, and deduced profiles from intimate samples. Profiles in this category:
  - 1.2.1.4.1.1 Consist of at least 8 or more of the original 13 CODIS core loci.
  - 1.2.1.4.1.2 Must not have more than 4 alleles at any locus.
  - 1.2.1.4.1.3 Satisfy a Moderate Match Estimate (MME) value of at least  $1 \times 10^7$  (10,000,000) calculated without a mismatch.
- 1.2.1.4.2 The **Forensic Mixture Index** consists of DNA profiles in the Forensic Mixture specimen category. Profiles maintained in the Forensic Mixture Index will be forwarded to the FBI for inclusion in NDIS.
- 1.2.1.4.3 Alleles that are unambiguously attributed to a victim or individuals other than the perpetrator (e.g., elimination sample) shall not be included.
- 1.2.1.4.4 Casework analysts should keep in mind the reported inclusions/statistical values should a match occur to entries in this specimen category. If there would be no inclusion/statistical value for any profile matching to this specimen, the profile should not be entered into the CODIS database.

### 1.2.1.5 INC. For. Mixture Specimen Category/Incomplete Forensic Mixture Index

- 1.2.1.5.1 The **INC. For. Mixture specimen category** contains mixture DNA profiles from forensic samples that contain DNA contributed from more than one source, such as major components of mixture DNA profiles with dropout or obligate alleles, minor components of mixture DNA profiles, and deduced profiles from intimate samples. Profiles in this category:
  - 1.2.1.5.1.1 Consist of least 8 or more of the original 13 CODIS core loci.
  - 1.2.1.5.1.2 Must not have more than 4 alleles at any locus.
  - 1.2.1.5.1.3 Do not meet the NDIS Moderate Match Estimate (MME) or NDIS Match Rarity Estimate (MRE) thresholds of  $1 \times 10^7$ .
  - 1.2.1.5.1.4 Satisfy an SDIS Moderate Match Estimate (MME) of  $5 \times 10^4$  (50,000) when calculated with one mismatch.

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- 1.2.1.5.2 The **Incomplete Forensic Mixture Index** consists of DNA profiles in the INC. For. Mixture specimen category. Profiles maintained in the Incomplete Forensic Mixture Index will be searched routinely against SDIS only and will not be forwarded to the FBI for inclusion in NDIS.
- 1.2.1.5.3 Alleles that are unambiguously attributed to a victim or individuals other than the perpetrator (e.g., elimination sample) shall not be included.
- 1.2.1.5.4 Casework analysts should keep in mind the reported inclusions/statistical values should a match occur to entries in this specimen category. If there would be no inclusion/statistical value for any profile matching to this specimen, the profile should not be entered into the CODIS database.
- 1.2.1.6 **Forensic Targeted Specimen Category/Forensic Targeted Index (NDIS)**
- 1.2.1.6.1 The **Forensic Targeted specimen category** contains forensic partial and forensic mixture profiles that do not meet the NDIS Moderate Match Estimate (MME) of  $1 \times 10^7$  but are NDIS eligible when searched "stringency by locus" at NDIS. Loci marked partial (i.e. dropout) and loci with more than 2 alleles will be searched at moderate stringency and all other loci are searched at high stringency. Profiles in this category:
- 1.2.1.6.1.1 Consist of at least 8 or more of the original 13 CODIS core loci.
- 1.2.1.6.1.2 Do not meet the NDIS Moderate Match Estimate (MME) of at least  $1 \times 10^7$ .
- 1.2.1.6.1.3 Satisfy a Match Rarity Estimate (MRE) (stringency by locus) value of at least  $1 \times 10^7$  (10,000,000) when calculated with no mismatch.
- 1.2.1.6.2 The **Forensic Targeted Index** consists of DNA profiles in the Forensic Targeted specimen category. Profiles maintained in the Forensic Targeted Index will be forwarded to the FBI for inclusion in NDIS.
- 1.2.1.6.3 Loci which have more than two alleles will automatically be searched at moderate stringency. All other loci to be searched at MODERATE stringency MUST be marked with a "(p)" on the CODIS Data Entry Form. Obligate alleles cannot be designated in Targeted specimen categories.
- Note: For any locus which will be searched at high stringency, it should be probable that the genotype is attributable to a single individual.*
- 1.2.1.7 **SDIS Forensic Targeted Specimen Category/SDIS Targeted Index**
- 1.2.1.7.1 The **SDIS Forensic Targeted specimen category** contains forensic partial and forensic mixture profiles that do not meet the NDIS Moderate Match Estimate (MME) of  $1 \times 10^7$ , the SDIS MME of  $5 \times 10^4$ , or the NDIS Match Rarity Estimate (MRE) of  $1 \times 10^7$  but are SDIS eligible when searched "stringency by locus" at SDIS. Loci marked partial (i.e. dropout) and loci with more than 2 alleles will be searched at moderate and all other loci are searched at high stringency. Profiles in this category:

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- 1.2.1.7.1.1 Consist of at least 8 or more of the original 13 CODIS core loci.
- 1.2.1.7.1.2 Do not meet the NDIS Moderate Match Estimate (MME) of  $1 \times 10^7$ , the SDIS MME of  $5 \times 10^4$ , or the NDIS Match Rarity Estimate (MRE) of  $1 \times 10^7$ .
- 1.2.1.7.1.3 Satisfy a Match Rarity Estimate (MRE) (stringency by locus) value of  $5 \times 10^4$  (50,000) when calculated with no mismatch.
- 1.2.1.7.2 The **SDIS Targeted Index** consists of DNA profiles in the SDIS Forensic Targeted specimen category. Profiles maintained in the SDIS Targeted Index will be searched routinely against SDIS only and will not be forwarded to the FBI for inclusion in NDIS.
- 1.2.1.7.3 Loci which have more than two alleles will automatically be searched at moderate stringency. All other loci to be searched at MODERATE stringency MUST be marked with a "(p)" on the CODIS Data Entry Form. Obligate alleles cannot be designated in Targeted specimen categories.
- 1.2.1.8 **Missing Person & Deduced Missing Person Specimen Categories/Missing Person Index**
  - 1.2.1.8.1 The **Missing Person specimen category** contains DNA profiles developed from samples known to have been collected directly from missing persons (e.g., medical specimens). Profiles in this category must be single source and consist of at least 7 or more of the original 13 CODIS core loci plus Amelogenin with a second technology (e.g., Y-STRs or mito) recommended. In order to comply with NDIS recommendations, rapidly mutating YSTR loci (DYS449, DYS518, DYS570, DYS576, DYS627 and DYF387S1) will not be entered into the State or National databases.
  - 1.2.1.8.2 The **Deduced Missing Person specimen category** contains DNA profiles obtained from intimate items purported to belong to missing persons (e.g., toothbrush). Profiles in this category must be single source and consist of at least 7 or more of the original 13 CODIS core loci plus Amelogenin with a second technology (e.g., Y-STRs or mito) recommended.
  - 1.2.1.8.3 The **Missing Person Index** consists of DNA profiles in the Missing Person and Deduced Missing Person specimen categories. Profiles maintained in the Missing Person Index will be forwarded to the FBI for inclusion in NDIS.
  - 1.2.1.8.4 Any locus with known dropout (an allele visible below threshold) will not be used for entry.
  - 1.2.1.8.5 Metadata including but not limited to the age, and last known contact of the missing person should be included in the data entry request to be entered in appropriate fields in the database to aid in potential match evaluation.

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### 1.2.1.9 **Biological Child, Biological Father, Biological Mother, Biological Sibling, Maternal Relative & Paternal Relative Specimen Categories/Relatives of Missing Person Index**

1.2.1.9.1 The **Biological Child, Biological Father, Biological Mother, Biological Sibling, Maternal Relative, and Paternal Relative specimen categories** contain DNA profiles from the known reference samples of biological relatives and are stored in the specimen category that describes the relationship between the missing person and the relative. Profiles in this category must be single source and consist of all 20 CODIS core loci plus Amelogenin.

1.2.1.9.1.1 The Maternal Relative specimen category contains profiles provided from a maternal biological relative who is not a child, mother or sibling of the missing person.

1.2.1.9.1.2 The Paternal Relative specimen category contains profiles provided from a paternal biological relative who is not a child, father or sibling of the missing person.

1.2.1.9.2 The **Relatives of Missing Person Index** consists of DNA profiles belonging to the following specimen categories: Biological Child, Biological Father, Biological Mother, Biological Sibling, Maternal Relative, and Paternal Relative. Profiles maintained in the Relatives of Missing Person Index will be forwarded to the FBI for inclusion in NDIS; however, once the individual corresponding to the reference sample has been identified, the specific DNA profile must be removed from this index. In order to comply with NDIS recommendations, rapidly mutating YSTR loci (DYS449, DYS518, DYS570, DYS576, DYS627 and DYS627 and DYS627 and DYF387S1) will not be entered into the State or National databases.

1.2.1.9.3 The Federal DNA Identification Act of 1994 [34 U.S.C. section 12592(a)(4)] authorizes the inclusion of DNA records from “analyses of DNA samples voluntarily contributed from relatives of missing persons.” To ensure eligibility for upload to and searching at NDIS of the biological relative reference DNA sample, there must be documentation of the voluntariness in the form of a signed written consent form in the presence of law enforcement.

### 1.2.1.10 **Unidentified Person Specimen Category/Unidentified Human (Remains) Index**

1.2.1.10.1 The **Unidentified Person specimen category** contains DNA profiles obtained from recovered deceased individuals (including body parts and tissue) or from an individual who is unidentified (e.g., children who cannot and others who cannot or will not identify themselves). Profiles in this category must be single source and consist of at least 1 of the 20 CODIS core loci plus Amelogenin. In order to comply with NDIS recommendations, rapidly mutating YSTR loci (DYS449, DYS518, DYS570, DYS576, DYS627 and DYF387S1) will not be entered into the State or National databases.

1.2.1.10.2 The **Unidentified Human (Remains) Index** consists of DNA profiles in the Unidentified Person specimen category. Profiles maintained in the Unidentified Human (Remains) Index will be forwarded to the FBI for inclusion in NDIS.

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- 1.2.1.10.3 Loci with apparent dropout shall not be included in the profile.
  - 1.2.1.10.4 At least 7 or more of the original 13 CODIS core loci plus Amelogenin allows for more robust searching at NDIS.
  - 1.2.1.10.5 Metadata including but not limited to the approximate age and location of the unidentified remains should be included in the data entry request for these specimens to be entered into the database to assist in match evaluation.
- 1.2.1.11 **Convicted Offender Specimen Category/Offender Index**
- 1.2.1.11.1 The **Convicted Offender specimen category** contains DNA profiles obtained from individuals convicted of a state qualifying offense as indicated in Oklahoma Statute Title 74 Section 150.27a. Profiles in this category must be single source and consist of at least 12 of the original 13 CODIS core loci.
  - 1.2.1.11.2 The **Offender Index** consists of DNA profiles from in the Convicted Offender specimen category. Profiles maintained in the Convicted Offender Index will be forwarded to the FBI for inclusion in NDIS.
    - 1.2.1.11.2.1 For convicted offender samples consisting of 12 of the original 13 CODIS core loci, although they can be uploaded to NDIS, they will only be searched once a year when NDIS performs a 12 original CODIS core loci search.
    - 1.2.1.11.2.2 Convicted offender samples consisting of 12 of the original 13 CODIS core loci will be searched in the regular SDIS Autosearches of the Offender Index.
  - 1.2.1.11.3 As long as an attempt was made to genotype at all loci, profiles that are complete at least 12 of the original 13 CODIS core loci, even if dropout is exhibited at any other loci (including but not limited to D1S1656, D2S441, D10S1248, Penta E, D2S1338, Penta D, DYS391, D12S391, D19S433, or D22S1045), may be included in the Offender Index.
  - 1.2.1.11.4 **Reanalysis of Convicted Offender Samples**
    - 1.2.1.11.4.1 If through any type of reanalysis (e.g., research, hit verification, validation etc.), additional genetic information is generated at loci that were not originally included in a convicted offender sample record, the new profile may be imported on the common message format (.cmf) file for the plate on which the reanalysis occurred.
    - 1.2.1.11.4.2 If reanalysis of a sample results in any discordant genotype at loci that were already included, the CODIS analyst shall investigate the potential reason for discrepancy and document any findings on a CODIS Sample Reconciliation Form (**CODIS\_Sample\_Reconciliation**), which will be retained. If necessary, the incident will be handled according to OSBI CSD Quality Manual QP 13 (Nonconforming Work).

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1.2.1.11.4.3 If the reanalysis of a sample demonstrates dropout, any additional loci that do not demonstrate dropout or possible dropout should be manually added to the original DNA record and documented via the CODIS Manual Offender Data Entry Form (**CODIS\_Manual\_Offender\_Data\_Entry**).

1.2.1.11.4.4 These profiles are allowable under the NDIS definition of "composite" as long as they are from the same offender card. Data from separate offender cards from the same individual will not be combined.

### 1.2.1.12 **INC. Offender STR Specimen Category/Incomplete Offender Index**

1.2.1.12.1 The **INC. Offender STR specimen category** contains partial DNA profiles obtained from individuals convicted of a state qualifying offense as indicated in Oklahoma Statute Title 74 Section 150.27a. Profiles in this category must be single source profile and consist of at least 8 or more of the original 13 CODIS core loci.

1.2.1.12.2 The **Incomplete Offender Index** consists of DNA profiles in the INC. Offender STR specimen category. Profiles maintained in the Incomplete Offender Index will be searched routinely against SDIS only and will not be forwarded to the FBI for inclusion in NDIS.

1.2.1.12.3 Loci that exhibit suspected dropout will not be used for entry.

1.2.1.12.4 These profiles may be temporarily assigned to this specimen category until additional analysis is performed or a new sample is submitted to the OSBI. The specimen will be re-assigned to the Convicted Offender specimen category once results at all original 13 CODIS core loci have been obtained.

### 1.2.1.13 **Arrestee Specimen Category/Arrestee Index**

1.2.1.13.1 The **Arrestee specimen category** contains DNA profiles from individuals arrested of a state qualifying offense as indicated in Oklahoma Statute Title 22 Section 210. Profiles in this category must be single source and consist of at least 12 of the original 13 CODIS core loci.

1.2.1.13.2 The **Arrestee Index** consists of DNA profiles in the Arrestee specimen category. Profiles maintained in the Arrestee Index will be forwarded to the FBI for inclusion in NDIS.

1.2.1.13.2.1 For arrestee samples consisting of 12 of the original 13 CODIS core loci, although they can be uploaded to NDIS, they will only be searched once a year when NDIS performs a 12 original CODIS core loci search.

1.2.1.13.2.2 Arrestee samples consisting of 12 of the original 13 CODIS core loci will be searched in the regular SDIS Autosearches of the Arrestee Index.

1.2.1.13.3 As long as an attempt was made to genotype at all loci, profiles that are complete at least 12 of the original 13 CODIS core loci, even if dropout is exhibited at any other loci (including but not limited to D1S1656,



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D2S441, D10S1248, Penta E, D2S1338, Penta D, DYS391, D12S391, D19S433, or D22S1045), may be included in the Arrestee index.

### 1.2.1.13.4 Reanalysis of Arrestee Samples

1.2.1.13.4.1 If through any type of reanalysis (e.g., research, hit verification, validation etc.), additional genetic information is generated at loci that were not originally included in an arrestee sample record, the new profile may be imported on the .cmf file for the plate on which the reanalysis occurred.

1.2.1.13.4.2 If reanalysis of a sample results in any discordant genotype at loci that were already included, the CODIS analyst shall investigate the potential reason for discrepancy and document any findings on a CODIS Sample Reconciliation Form (**CODIS\_Sample\_Reconciliation**), which will be retained. If necessary, the incident will be handled according to OSBI CSD Quality Manual QP 13 (Nonconforming Work).

1.2.1.13.4.3 If the reanalysis of a sample demonstrates dropout, any additional loci that do not demonstrate dropout or possible dropout should be manually added to the original DNA record and documented via the CODIS Manual Offender Data Entry Form (**CODIS\_Manual\_Offender\_Data\_Entry**).

1.2.1.13.4.4 These profiles are allowable under the NDIS definition of “composite” as long as they are from the same offender card. Data from separate offender cards from the same individual will not be combined.

### 1.2.1.14 **INC. Arrestee Specimen Category/Incomplete Arrestee Index**

1.2.1.14.1 The **Inc. Arrestee specimen category** contains partial DNA profiles obtained from individuals arrested of a state qualifying offense as indicated in Oklahoma Statute Title 22 Section 210. Profiles in this category must be single source and consist of at least 8 or more of the original 13 CODIS core loci.

1.2.1.14.2 The **Incomplete Arrestee Index** consists of DNA profiles in the Inc. Arrestee specimen category. Profiles maintained in the Incomplete Arrestee Index will be searched routinely against SDIS only and will not be forwarded to the FBI for inclusion in NDIS.

1.2.1.14.3 Loci that exhibit suspected dropout will not be used for entry.

1.2.1.14.4 These profiles may be temporarily assigned to this specimen category until additional analysis is performed or a new sample is submitted to the OSBI. The specimen will be re-assigned to the Arrestee specimen category once results at all original 13 CODIS core loci have been obtained.

### 1.2.1.15 **Multi-Allelic Offender Specimen Category/Multi-Allelic Offender Index**

1.2.1.15.1 The **Multi-Allelic Offender specimen category** contains DNA profiles obtained from individuals arrested or convicted of a state qualifying offense as indicated in Oklahoma Statute Title 74 Section 150.27a that

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have three or more alleles at two or more loci. Profiles in this category must consist of all original 13 CODIS core loci.

1.2.1.15.2 The **Multi-Allelic Offender Index** consists of DNA profiles in the Multi-Allelic Offender specimen category. Profiles maintained in the Multi-Allelic Offender Index will be forwarded to the FBI for inclusion in NDIS.

1.2.1.15.3 As long as an attempt was made to genotype at all loci, profiles that are complete at the original 13 CODIS core loci, even if dropout is exhibited at any other loci (including but not limited to D1S1656, D2S441, D10S1248, Penta E, D2S1338, Penta D, DYS391, D12S391, D19S433, or D22S1045), may be included in the Multi-Allelic Offender index.

### 1.2.1.15.4 Reanalysis of Multi-Allelic Offender Samples

1.2.1.15.4.1 If through any type of reanalysis (e.g., research, hit verification, validation etc.), additional genetic information is generated at loci that were not originally included in a multi-allelic offender sample record, the new profile may be imported on the .cmf file for the plate on which the reanalysis occurred.

1.2.1.15.4.2 If reanalysis of a sample results in any discordant genotype at loci that were already included, the CODIS analyst shall investigate the potential reason for discrepancy and document any findings on a CODIS Sample Reconciliation Form (**CODIS\_Sample\_Reconciliation**), which will be retained. If necessary, the incident will be handled according to OSBI CSD Quality Manual QP 13 (Nonconforming Work).

1.2.1.15.4.3 If the reanalysis of a sample demonstrates dropout, any additional loci that do not demonstrate dropout or possible dropout should be manually added to the original DNA record and documented via the CODIS Manual Offender Data Entry Form (**CODIS\_Manual\_Offender\_Data\_Entry**).

1.2.1.15.4.4 These profiles are allowable under the NDIS definition of “composite” as long as they are from the same offender card. Data from separate offender cards from the same individual will not be combined.

### 1.2.1.16 Legal Specimen Category/Legal Index

1.2.1.16.1 The **Legal specimen category** contains DNA profiles obtained from known suspects in criminal investigations and other DNA samples from individuals collected under applicable legal authorities. As of January 1, 2006, suspect profiles are eligible for entry into SDIS in accordance with Oklahoma Statute Title 74 Section 150.27a. Profiles in this category must be single source and consist of all 20 CODIS core loci (excluding Amelogenin).

1.2.1.16.2 The **Legal Index** consists of DNA profiles in the Legal specimen category. Profiles maintained in the Legal Index will be searched routinely and uploaded to NDIS per approval from the NDIS Custodian.

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- 1.2.1.16.3 For the purposes of this policy, a suspect is defined as any individual listed as a suspect or subject in the BEAST, on a request for Laboratory Examination form (RFLE) or on a OSBI Criminalistics Examination Report. This does not include exclusionary samples collected from individuals for elimination purposes only; exclusionary samples shall not be entered into CODIS.
  - 1.2.1.16.4 Suspect samples may include known reference samples collected from the person, or secondary reference samples, such as cigarette butts, chewing gum, razors, and toothbrushes.
  - 1.2.1.16.5 If the suspect profile matches a casework profile that will be entered into CODIS, or the suspect profile is already in CODIS from an arrestee or convicted offender sample, the suspect profile will not be added to the Legal Index.
  - 1.2.1.16.6 If a suspect known/legal specimen is entered into CODIS, and subsequent analysis yields a CODIS eligible forensic profile that matches or is consistent with the legal specimen, the legal specimen will be removed from CODIS. A CODIS Request for Profile Removal Form should be filled out for the legal specimen and submitted with the CODIS Data Entry Form for the forensic sample.
  - 1.2.1.16.7 If a CODIS hit has led to the submission of a suspect known/legal specimen, that legal specimen should not be entered into the CODIS database.
  - 1.2.1.16.8 Suspect name and date of birth (if available) should be sent to the CODIS Unit for the purpose of determining if the sample already exists in the CODIS database. This information can be included on the Data Entry Form or separately via email, etc.
- 1.2.1.17 **INC. Legal Specimen Category/Incomplete Legal Index**
- 1.2.1.17.1 The **INC. Legal specimen category** contains partial DNA profiles obtained from known suspects in criminal investigations and other DNA samples from individuals collected under applicable legal authorities. Profiles in this category must be single source and consist of at least 8 or more of the original 13 CODIS core loci.
  - 1.2.1.17.2 The **Incomplete Legal Index** consists of DNA profiles in the INC. Legal specimen category. Profiles maintained in the Incomplete Legal Index will be searched routinely against SDIS only and will not be forwarded to the FBI for inclusion in NDIS.
  - 1.2.1.17.3 Loci where a partial profile is indicated shall be left blank on the CODIS Data Entry Form.
  - 1.2.1.17.4 These profiles may be temporarily assigned to this index until additional analysis is performed. The specimen will be re-assigned to the Legal Index once results at all 20 CODIS core loci have been obtained.
- 1.2.1.18 **Staff Specimen Category/Employee Index**
- 1.2.1.18.1 The **Staff specimen category** contains DNA profiles from known reference samples voluntarily provided by employees of the law

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enforcement agencies. The profiles must be single source and consist of all 20 CODIS core loci.

- 1.2.1.18.2 The **Employee Index** consists of DNA profiles in the Staff specimen category. Profiles maintained in the Employee Index will be searched routinely against SDIS only and will not be forwarded to the FBI for inclusion in NDIS. This search is conducted to exclude the possibility that a forensic DNA profile originated from a law enforcement employee who was in close proximity to the sample at the crime scene or during analysis of the evidence.

### 1.2.1.19 Contaminant Profile Specimen Category/Contaminant Index

- 1.2.1.19.1 The **Contaminant Profile specimen category** contains DNA profiles originating from sample contamination in one of the Oklahoma CODIS participating DNA laboratories and from nationally recognized consumable (plastics) contamination. The profile eligibility for this category is determined by the CODIS administrator on a case-by-case basis.
- 1.2.1.19.2 The **Contaminant Index** consists of DNA profiles in the Contaminant Profile specimen category. Profiles maintained in the Contaminant Index will be searched routinely against SDIS only and will not be forwarded to the FBI for inclusion in NDIS. This search is conducted to expedite identification and remediation of a contamination problem.

### 1.2.1.20 Y-STR Forensic Unknown Specimen Category/Y-STR Forensic Index

- 1.2.1.20.1 The **Y-STR Forensic Unknown specimen category** contains DNA profiles from forensic samples consisting solely of alleles derived from Y-STR genetic markers. These profiles can be included at SDIS but must be single source (or a full major component profile originating from a mixture) and consist of at least 24 of the 25 Y-STR loci.
- 1.2.1.20.2 The **Y-STR Forensic Index** consists of DNA profiles in the Y-STR Forensic Unknown specimen category. Profiles maintained in the Y-STR Forensic Index will be entered into SDIS but will not be searched at this time. These profiles will not be forwarded to the FBI for inclusion in NDIS.

### 1.2.1.21 Y-STR Legal Specimen Category/Y-STR Legal Index

- 1.2.1.21.1 The **Y-STR Legal specimen category** contains DNA profiles from known suspects consisting solely of alleles derived from Y-STR genetic markers. These profiles can be included in SDIS, even if there is an existing STR profile in CODIS from an offender or previous legal sample, but must be single source and consist of all 25 Y-STR loci.
- 1.2.1.21.2 The **Y-STR Legal Index** consists of DNA profiles in the Y-STR Legal specimen category. Profiles maintained in the Y-STR Legal Index will be entered into SDIS but will not be searched at this time. These profiles will not be forwarded to the FBI for inclusion in NDIS.
- 1.2.1.21.3 Legal profiles with Y-STR alleles should only be entered in the Y-STR Legal specimen category if there is already an STR profile in CODIS from an offender sample. Otherwise, these profiles should be entered in

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the Legal Index where they will be searched against all other STR profiles and uploaded to NDIS.

1.2.1.21.4 If the STR profile is associated with a specimen already in the Legal Index, the Y-STR profile will be added to that specimen.

1.2.1.21.5 If the Y-STR profile is associated with an individual who has been entered as an offender or arrestee, then a new specimen consisting of only the Y-STR profile will be added to the Y-STR Legal Index.

### 1.2.2 Definition of Acceptable DNA Profiles

Before a DNA profile can be uploaded, entered into, or searched against SDIS, the following criteria must be met:

1.2.2.1 The DNA profile must be developed by an accredited forensic DNA laboratory.

1.2.2.2 The DNA profile must be developed in compliance with the DNA Identification Act of 1994 and FBI approved Quality Assurance Standards.

1.2.2.3 The DNA profile must be subjected to a thorough technical review by a qualified DNA analyst.

1.2.2.4 All DNA profiles must be associated with an accurate result for PCR DNA controls and reagent blanks.

1.2.2.5 All DNA profiles must be derived from analysis using an NDIS accepted PCR kit.

1.2.2.6 OSBI casework analysts will use the most complete results for entry into CODIS if there are multiple amplifications of the same DNA extract. Allelic data from separate extractions will not be combined.

1.2.2.7 Low template or low copy DNA analyses shall not be submitted to SDIS.

1.2.2.7.1 Low template or low copy DNA analyses has been defined as: based on a laboratory's internal validation, any DNA typing results generated from limited quantity and/or quality DNA template using conditions that have demonstrated increased stochastic effects. Stochastic effects may include: allelic drop-in or dropout, increased stutter, and increased intra-locus peak height imbalance.

### 1.2.3 Analysis of Casework Samples

The following applies to DNA analysis performed at the OSBI by the forensic biology casework units on casework samples:

1.2.3.1 Analysis performed on casework samples will comply with all applicable OSBI policies and the OSBI Forensic Biology Units' Policy Manual.

1.2.3.1.1 In the event the OSBI uses a contract laboratory for analysis, the contract laboratory will only use procedures approved by the OSBI Forensic Biology Discipline Technical Manager.

1.2.3.2 Analysis at all 20 CODIS core loci will be attempted on the victim reference sample and any other reference sample necessary to deduce a suspect profile from a mixture.

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- 1.2.3.3 Casework DNA profiles must be subjected to a thorough technical review by qualified OSBI personnel (in accordance with the OSBI Forensic Biology Units' Policy Manual) prior to entry or search against SDIS.
- 1.2.3.4 A casework DNA profile must be referenced in an OSBI Criminalistics Examination Report to be eligible for entry into or searched against SDIS. Additionally, there must be documentation in the case record of each of the following three criteria:
  - 1.2.3.4.1 A crime has been committed;
  - 1.2.3.4.2 The DNA sample was recovered directly from the crime scene and is attributed to the putative perpetrator; and
  - 1.2.3.4.3 Elimination sample(s) have been requested, if applicable.
- 1.2.3.5 For any profile that must meet a Moderate Match Estimate (MME) threshold, the CODIS Popstats Match Estimation calculation will be used to determine the MME (match rarity).
  - 1.2.3.5.1 The Moderate Match Estimate (MME) is the inverse of the Match Rarity Estimate (MRE).
  - 1.2.3.5.2 Only the original 13 CODIS core loci will be used in the calculation.
  - 1.2.3.5.3 The revised NIST 2017 combined population database will be used for this calculation with a theta value of 0.01.
  - 1.2.3.5.4 The results should be provided in the case record and will be reviewed by the technical reviewer.
- 1.2.3.6 For any profile that must meet a Match Rarity Estimate (MRE) threshold, the CODIS Popstats Match Estimation calculation will be used to determine the MRE.
  - 1.2.3.6.1 The Match Rarity Estimate (MRE) is the inverse of the Rarity Estimate (MRE) when calculated with a specified stringency by locus (high or moderate).
  - 1.2.3.6.2 Only the original 13 CODIS core loci will be used in the calculation.
  - 1.2.3.6.3 The revised NIST 2017 combined population database will be used for this calculation with a theta value of 0.01.
  - 1.2.3.6.4 All STR loci will be evaluated at high stringency with the exception of:
    - 1.2.3.6.4.1 STR loci that are marked partial will be evaluated at moderate stringency. Dropout, alleles below peak stochastic threshold, etc. should be considered when determining whether to mark STR loci as partial.
    - 1.2.3.6.4.2 STR loci with more than 2 alleles will be evaluated at moderate stringency.
  - 1.2.3.6.5 If the profile in question is a single source minor component of a mixture, all homozygous loci should be presumed to have dropout and be evaluated at moderate stringency.

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- 1.2.3.6.6 When calculating the MRE, it is necessary to change the stringency at each locus in the grid in Popstats.
- 1.2.3.6.7 The results should be provided in the case record and will be reviewed by the technical reviewer. For cases that require MME calculation, a copy of the match estimation report will be uploaded to the BEAST documents tab.
- 1.2.3.7 Additional eligibility criteria included in the NDIS Operational Procedures Manual will also be considered when determining eligibility.
- 1.2.3.8 All DNA profiles developed by the casework unit that meet eligibility guidelines for inclusion in the database must be forwarded to the CODIS unit for entry unless the CODIS administrator has been consulted and has given approval for the profile to be left out.
- 1.2.4 **Analysis of Offender Samples**

The following applies to DNA analysis performed at the OSBI by the CODIS Unit on offender (database) samples (including convicted offender and arrestee samples):

  - 1.2.4.1 All analysis performed on offender samples will comply with all applicable OSBI policies and the OSBI CODIS Unit Policy Manual.
    - 1.2.4.1.1 In the event a contract laboratory is used for analysis, the contract laboratory will only use procedures approved by the OSBI CODIS Administrator and OSBI Forensic Biology Discipline Technical Manager.
  - 1.2.4.2 Offender profiles must be subjected to a thorough technical review by qualified OSBI personnel (in accordance with the OSBI CODIS Unit Policy Manual) prior to entry or search against SDIS.
- 1.2.5 **Creating Specimen ID Numbers**
  - 1.2.5.1 **Casework Samples**
    - 1.2.5.1.1 If a casework sample is analyzed by the OSBI, the CODIS Specimen ID number will consist of the state abbreviation, the DNA analyst's initials, the OSBI case number, and the OSBI item number.  
Example: OK-RLP-18-1000-B1.
    - 1.2.5.1.2 If a vendor laboratory analyzes a casework sample, a prefix identifying the vendor and the year of the contract may be used instead of the state abbreviation and analyst's initials.  
Example: XX06-18-1000-B1.
  - 1.2.5.2 **Offender Samples**
    - 1.2.5.2.1 If an offender sample is analyzed by the OSBI, the CODIS Specimen ID number will consist of the offender sample number.  
Example: C18-001000.
    - 1.2.5.2.2 If a contract laboratory analyzes an offender database sample, a prefix identifying the vendor and the year of the contract may be added to the CODIS Specimen ID number to identify the vendor laboratory.  
Example: XX06-C18-001000.

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### 1.2.6 CODIS Data Entry (Request & Documentation)

The CODIS Unit is responsible for the integrity and security of all data entered into SDIS. Any discrepancies will be forwarded to the CODIS administrator for determination of profile eligibility prior to entry into or search against SDIS.

#### 1.2.6.1 OSBI Casework Profiles

##### 1.2.6.1.1 Profile Eligibility Considerations

1.2.6.1.1.1 Careful consideration should be taken to ensure profiles meet all applicable NDIS guidelines before entry into the database. To help with this determination, the FBI's "Guide to Determining What is Allowable in the Forensic Index at NDIS" (flowchart) should be used.

1.2.6.1.1.1.1 No profile from an evidentiary sample that matches the victim known or an exclusionary known (e.g., husband, boyfriend, etc.) shall be entered into CODIS.

1.2.6.1.1.1.2 A profile that matches a suspect obtained from an item belonging to that suspect (e.g., clothing or other article that would be expected to yield the owner's profile) is not considered an evidentiary sample and shall not be entered into CODIS.

1.2.6.1.1.2 In conjunction with the FBI's "Guide to Determining What is Allowable in the Forensic Index at NDIS," the following guidelines should be used in determining profile eligibility:

1.2.6.1.1.2.1 If there are multiple, similar profiles from a case, only the most complete and probative profile will be entered into CODIS.

1.2.6.1.1.2.1.1 If there are mixtures with clear major and minor profiles, it is preferable to put in the clear major or minor profile than to put in an indistinguishable mixture profile that has consistent information.  
Example: Mixture on jacket, clear major/minor, major not consistent w/victim. Mixture on jeans, not distinguishable, with 2 additional alleles (1 each at 2 loci) than major profile from jacket. Put in major profile from jacket.

1.2.6.1.1.2.2 A mixture profile may be entered in its entirety provided that there are no more than 4 alleles at any locus and it meets the



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appropriate Moderate Match Estimate (MME) threshold or Match Rarity Estimate (MRE) threshold.

- 1.2.6.1.1.2.3 A known DNA profile can be subtracted from an otherwise indistinguishable mixture if the mixture profile is from an intimate sample. A known DNA profile from an intimate sample can only be subtracted from a two-person mixture.
- 1.2.6.1.1.2.3.1 This DNA profile will be considered a Forensic Mixture.
- 1.2.6.1.1.2.3.2 For the purposes of this policy, any sample from a person's body will be considered as an intimate sample (i.e., vaginal swabs, oral swabs, fingernail scrapings, etc.).
- 1.2.6.1.1.2.3.3 **Obligate alleles:** In deducing mixture profiles, if it is possible that a portion of the locus contains an allele shared between the victim and suspect, any portion of the locus that could not be contributed by the victim should be marked as obligate by marking that allele with a plus (+) sign.
- Note: Obligate alleles cannot be designated in Targeted specimen categories.
- 1.2.6.1.1.2.3.4 A known profile cannot be subtracted out from an intimate, indistinguishable mixture if that known has been excluded from the mixture.
- 1.2.6.1.1.2.4 The request for a known reference sample from an elimination individual must occur prior to entry of the DNA profile into CODIS and may be in the form of a phone conversation or e-mail documented in the case record.
- 1.2.6.1.1.2.5 Provided that there is documentation that a known reference sample has been requested from any consensual partner prior to entry into CODIS, an unknown male profile from a sexual assault case may be

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entered into CODIS, as long as the profile meets all other eligibility criteria.

### 1.2.6.1.2 CODIS Data Entry Forms

1.2.6.1.2.1 The casework analyst will fill out all applicable areas of an electronic version of the CODIS Data Entry Form (**CODIS\_Data\_Entry\_Form**) for each profile determined to be eligible for entry into SDIS and/or NDIS and electronically sign and date the form.

1.2.6.1.2.1.1 The “Description of Profile Entered” will match the description of evidence in the report (forensic) or the full name of the individual (legal, parentage), if available.

1.2.6.1.2.1.2 A DNA profile from a mixture major component with designated obligate alleles, minor component, or indistinguishable will be considered a Forensic Mixture profile.

1.2.6.1.2.1.3 Major components from a mixture (with no locus or allelic dropout or obligate alleles) will be considered a Forensic Unknown.

1.2.6.1.2.1.4 A “clean” sperm or epithelial fraction will be considered a single source profile or Forensic Unknown profile.

1.2.6.1.2.2 During technical review, the reviewer will verify that the profile is eligible for CODIS, the accuracy of the profile and item number, and the appropriate specimen category listed on each CODIS Data Entry Form, along with any Moderate Match Estimate threshold and Match Rarity Estimate threshold calculation(s), if applicable, and ensure the appropriate supporting documentation is present in the case record. Once verified, the reviewer will electronically sign and date the CODIS Data Entry Form(s) indicating their verification of the previously mentioned items.

1.2.6.1.2.3 Once each CODIS Data Entry Form has been technically reviewed (verified and signed) the reviewer will route the assignment to the case analyst for CODIS Entry using the routing code “CODIS” in the BEAST. The casework analyst will then forward the CODIS Data Entry Form(s) to the CODIS Unit for review and entry of the eligible profile(s) into SDIS by a CODIS analyst. After each profile is entered into CODIS, the CODIS analyst who entered the profile will electronically sign and date the CODIS Data Entry Form verifying the profile has been entered into CODIS.

1.2.6.1.2.4 The CODIS Unit will return the CODIS Data Entry Form to the casework analyst along with the Specimen Details Report for each profile entered into CODIS.

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1.2.6.1.2.5 **It is the responsibility of the casework analyst to verify that the profile and specimen category shown on each Specimen Details Report are accurate.** Once verified, the casework analyst will electronically sign and date the CODIS Data Entry Form and retain it electronically in the BEAST case record by uploading to the BEAST Documents tab. Any hard-copy documentation can be shredded, including the Specimen Details Report, once the CODIS Data Entry Form has been successfully uploaded (i.e., attached) to the appropriate BEAST case record and verified as present. The casework analyst will then route the assignment back to the technical reviewer using the routing code "TR". The technical reviewer will verify that the Data Entry Form(s) have been completed and attached to the BEAST case record. Once this has been verified, the technical reviewer will complete the technical review by signing the TR form in the BEAST, and then route the assignment to the case analyst for approval using routing code "RA".

1.2.6.1.2.6 The case assignment can then be closed by the casework analyst and the official report issued.

### 1.2.6.2 Local CODIS Laboratory Casework Profiles

1.2.6.2.1 All other casework profiles will be entered into SDIS by processing an upload from an approved local CODIS laboratory (LDIS), such as Tulsa Police Department or Oklahoma City Police Department.

1.2.6.2.2 Each LDIS laboratory must complete and return a Memorandum of Understanding to the OSBI CODIS administrator guaranteeing compliance with the same standards and procedures regarding acceptable data prior to uploading data to the OSBI.

### 1.2.6.3 Offender Profiles

1.2.6.3.1 Offender data received from a contract laboratory or processed in-house will be uploaded in bulk using CODIS Import (.cmf file).

1.2.6.3.2 Individual offender profiles may be entered into CODIS by keyboard instead of .cmf file. This will be documented by filling out a CODIS Manual Offender Data Entry Form (**CODIS\_Manual\_Offender\_Data\_Entry**) for each profile entered.

## 1.2.7 Release of DNA Profiles for John Doe Warrants

1.2.7.1 The CODIS Unit will not release mixture profiles for use in John Doe warrants. However, the major component of a mixture may be released.

1.2.7.2 Deduced profiles or minor components of a mixture may be released in consultation with the CODIS administrator and the technical manager.

1.2.7.3 To facilitate notification of DNA profile release, the BEAST Laboratory Information Management System (LIMS) program will be used:

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- 1.2.7.3.1 The CODIS analyst will create an assignment for the CODIS Unit (C) within the BEAST. This can be done on the “Assignments” tab.
- 1.2.7.3.2 To ensure consistency, the description of the evidence in the profile release letter should match the description of evidence used in the applicable forensic biology unit DNA Report.
- 1.2.7.3.3 The CODIS analyst will generate a “Notification of Profile Release for John Doe Warrant” letter clearly listing the DNA profile to be used in the John Doe warrant. The “Notification of Profile Release for John Doe Warrant” letter is not a report.
- 1.2.7.3.4 The CODIS Analyst will route the assignment to the casework analyst (or designee) that developed the DNA profile for administrative review.
- 1.2.7.3.5 The administrative review will be performed as per CSD QP 31 (Reviews). Care should be taken to ensure the correct DNA profile is released.
- 1.2.7.3.6 If corrections are necessary, the casework analyst will route the assignment back to the CODIS analyst.
- 1.2.7.3.7 After completion of the administrative review, the casework analyst will approve the “Notification of Profile Release for John Doe Warrant” letter and mail any required hard copy letters to the submitting agency.
- 1.2.7.3.8 Clicking the “Approve” button will document the completion of the administrative review.

### 1.2.8 Conducting CODIS Searches

- 1.2.8.1 Before a DNA profile may be searched against SDIS, the criteria listed in section [1.2.2 \(Definition of Acceptable DNA Profiles\)](#) of this policy must be met.
- 1.2.8.2 The DNA profiles maintained at SDIS will only be searched using approved FBI CODIS software.
- 1.2.8.3 **Intentional viewing of a specimen record with the intent of performing a manual DNA comparison to another profile (not eligible to otherwise be searched) is not permitted.**
- 1.2.8.4 The CODIS Unit will maintain a record (paper or electronic) of any search conducted unless deemed not necessary by the CODIS administrator (e.g., searches conducted during training).
- 1.2.8.5 Possible search types of SDIS include:
  - 1.2.8.5.1 **Keyboard Searches**  
Keyboard searches are designed to expedite a search against DNA profiles maintained at SDIS that are not part of the routine Autosearch. A keyboard search is a manual search of SDIS executed after receipt of a written request, and will be performed at the discretion of the CODIS administrator (or designee). If requests are received from any source other than a criminal justice agency, the keyboard search will only be performed if pursuant to a court order. A copy of the court order must be

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provided to the CODIS administrator for approval prior to conducting the search. To perform a keyboard search:

- 1.2.8.5.1.1 The CODIS Keyboard Search Request Form (**CODIS\_Keyboard\_Search**) shall be completed and submitted to the CODIS administrator for approval.
- 1.2.8.5.1.2 Before performing the search, the CODIS administrator will ensure that the search request is in compliance with all applicable laws and OSBI policy. If the request does not comply with these provisions, the CODIS administrator will notify the requestor and explain why the search was not conducted.
  - 1.2.8.5.1.2.1 Notification shall be in the form of a letter (on official OSBI letterhead) if the search request is from an OSBI criminalist, the Tulsa Police Department Forensic Laboratory, or the Oklahoma City Police Department Laboratory. All other notifications may be made via email.
- 1.2.8.5.1.3 If the search request has been approved by the CODIS administrator, the DNA profile(s) may be searched against SDIS using the same search combinations as allowed in a routine index-to-index search.
- 1.2.8.5.1.4 If the search is conducted, the CODIS administrator will notify the requestor as to the result of any search and provide a copy of any potential CODIS Match Reports generated as a result of the search.
  - 1.2.8.5.1.4.1 Notification shall be in the form of a letter (on official OSBI letterhead) if the search request is from an OSBI criminalist, the Tulsa Police Department Forensic Laboratory, or the Oklahoma City Police Department Laboratory. All other notifications may be made via email.
- 1.2.8.5.1.5 A keyboard search against NDIS is performed in accordance with NDIS Operational Procedures.

### **1.2.8.5.2 Emergency Upload and Search Request**

- 1.2.8.5.2.1 To expedite upload and search of high priority profiles, the CODIS software now allows an NDIS participating laboratory to immediately upload and search DNA records at NDIS when public safety requires such immediacy and cannot wait for the routine upload to and search at NDIS. The following criteria must be met:
  - 1.2.8.5.2.1.1 The forensic DNA record to be searched is eligible for NDIS pursuant to section 3.1.1.1 of the NDIS Operational Procedures Manual

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- 1.2.8.5.2.1.2 The forensic DNA record to be searched satisfies a statistical threshold for match rarity as described in section 4.2.1.7 of the NDIS Operational Procedure Manual
- 1.2.8.5.2.1.3 The forensic DNA record to be searched was generated in accordance with Federal law as specified in section 5.0 of the NDIS Operational Procedures Manual
- 1.2.8.5.2.1.4 After initial upload and search, the profile will remain at NDIS and searched in the routine scheduled autosearches
- 1.2.8.5.2.1.5 Samples for EUSR will be searched at SDIS prior to upload for EUSR, when possible.
- 1.2.8.5.2.1.6 Samples uploaded using EUSR may not contain any of the special characters listed in Table 1, which includes spaces. For this reason, analysts submitting a specimen for EUSR MUST let the CODIS Unit know when submitting the profile for data entry so none of the special characters are used in the specimen ID.

**Table 1: Forbidden Special Characters**

# pound	< left angle bracket	\$ dollar sign	+ plus sign
% percent	> right angle bracket	! exclamation point	` backtick
& ampersand	* asterisk	' single quotation mark	bar or pipe
{ left curly bracket	? question mark	" double quotation mark	= equal sign
} right curly bracket	/ forward slash	: colon	\ backslash
Blank spaces	@ at sign		

### 1.2.8.5.3 Batch Target Searches

Batch Target Searches are designed to search a specific group of DNA profiles against SDIS (such as training samples). These types of searches may be executed at the discretion of the CODIS administrator (or designee). The search stringency and minimum number of loci to report a match are determined by the CODIS administrator (or designee) on case-by-case basis.

### 1.2.8.5.4 Familial Searches/Partial Matches

1.2.8.5.4.1 Familial searching is a term applied to intentionally searching a forensic DNA profile against an offender DNA profile in the attempt to identify a potential family member of the offender. These types of searches are not performed at the OSBI. However, a familial search is very different from a partial match (see below).

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1.2.8.5.4.2 A partial match is defined as a moderate stringency match between two single source profiles having at each locus at least one allele in common. A partial match is not an exact match of the two profiles in question, but in certain cases, the partial match may indicate a potential familial relationship exists between the offender sample and the forensic DNA profile. Although an exceptional event, partial matches may be reported to law enforcement agencies if they are discovered during a normal routine search of the CODIS database. The procedure for reporting partial matches is outlined in [CODIS\\_2 \(Hit Verifications\)](#) of this policy.

### 1.2.8.5.5 Routine Index to Index Searches

1.2.8.5.5.1 At the discretion of the state CODIS administrator, Table 2 below lists the routine SDIS Autosearches and the match criteria for each.

1.2.8.5.5.2 Tables 3 -8 below list the indices searched in each Autosearch of SDIS.

1.2.8.5.5.3 These routine Autosearches should be performed weekly, at minimum, following the addition of new DNA profiles to SDIS.

1.2.8.5.5.4 The CODIS administrator may change the search stringency and minimum number of loci to report a match on a case-by case basis.

**Table 2: Routine SDIS Autosearch Criteria**

<b>Autosearch Name</b>	<b>Minimum # Loci</b>	<b>Stringency</b>	<b># of Allowed Mismatches</b>
New Inc Offender to Offender	8	Moderate	0
New Against Employee	8	Moderate	1
New Offender to Offender	13	High	1
New STR Specimens 1 Mismatch	8	Moderate	1
New MP/UHR	6	Moderate	1
New Targeted Forensic	8	By Locus	0

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**Table 3: New Inc Offenders to Offender Autosearch**

Index	Offender	Inc Offender	Legal	Inc Legal	Arrestee	Inc Arrestee	Multi-Allelic Offender
Inc Offender	X	X	X	X	X	X	X
Inc Legal	X	X	X	X	X	X	X
Inc Arrestee	X	X	X	X	X	X	X

**Table 4: New Against Employee Autosearch**

Index	Forensic	Forensic Partial	Inc Forensic	Forensic Mixture	Inc Forensic Mixture	Offender	Inc Offender	Unidentified Human (Remains)	Missing Person	Relatives of Missing Person	Employee	Legal	Inc Legal	Arrestee	Inc Arrestee	Multi-Allelic Offender	Contaminant	Forensic Targeted	SDIS Targeted
Employee	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Contaminant	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

**Table 5: New Offender-to-Offender Autosearch**

Index	Offender	Legal	Arrestee	Multi-Allelic Offender
Offender	X	X	X	X
Legal	X	X	X	X
Arrestee	X	X	X	X
Multi-Allelic Offender	X	X	X	X

**Table 6: New STR Specimens 1 Mismatch Autosearch**



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Index	Forensic	Forensic Partial	Inc Forensic	Forensic Mixture	Inc Forensic Mixture	Offender	Inc Offender	Legal	Inc Legal	Arrestee	Inc Arrestee	Multi-Allelic Offender
Forensic	X	X	X	X	X	X	X	X	X	X	X	X
Forensic Partial	X	X	X	X	X	X	X	X	X	X	X	X
Inc Forensic	X	X	X	X	X	X	X	X	X	X	X	X
Forensic Mixture	X	X	X	X	X	X	X	X	X	X	X	X
Inc Forensic Mixture	X	X	X	X	X	X	X	X	X	X	X	X

**Table 7: New MP/UHR Autosearch**

Index	Forensic	Forensic Partial	Offender	Inc Offender	Unidentified Human (Remains)	Missing Person	Relatives of Missing Person	Employee	Legal	Inc Legal	Arrestee	Inc Arrestee	Multi-Allelic Offender	Contaminant
Unidentified Human (Remains)	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Missing Persons	X	X	X	X	X	X	X	X	X	X	X	X	X	X

**Table 8: Targeted New Autosearch**

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Index	Forensic	Offender	Inc Offender	Legal	Inc Legal	Arrestee	Inc Arrestee	Multi-Allelic Offender
<b>Forensic Targeted</b>	X	X	X	X	X	X	X	X
<b>SDIS Targeted</b>	X	X	X	X	X	X	X	X

### 1.2.9 Processing CODIS Matches<sup>22</sup>

The CODIS Unit shall carefully examine any potential database match prior to releasing any identifying information to law enforcement personnel.

1.2.9.1 The CODIS Unit or a casework DNA analyst will review any potential CODIS matches and disposition each match appropriately. The FBI's flowchart titled "Hit Disposition Quick Reference" should be used when dispositioning potential CODIS matches.

1.2.9.2 Any matches for which the disposition is unknown will be dispositioned as "Pending" until further information is obtained.

1.2.9.3 When possible, comments should be added in Match Manager explaining the disposition once the permanent disposition has been assigned.

1.2.9.4 Matches that are deemed to be Offender, Arrestee, Legal, Forensic or Familial Hits will be verified as outlined in [CODIS\\_2 \(Hit Verifications\)](#) of this policy.

1.2.9.5 In order to provide statistical data from CODIS hits, the OSBI will also record the number of investigations aided for each CODIS hit obtained. The FBI's flowchart titled "Investigations Aided Quick Reference" should be used when counting investigations aided.

### 1.2.10 Profile Removal

#### 1.2.10.1 Match to Elimination or Victim Profile

1.2.10.1.1 **It is the responsibility of the casework analyst to notify the CODIS Unit if a previously entered profile matches to a known reference sample from an elimination or victim analyzed after the fact.**

1.2.10.1.2 The CODIS Request for Profile Removal Form (**CODIS\_Profile\_Removal\_Request**) shall be completed and forwarded to the CODIS Unit.

1.2.10.1.3 The original CODIS Request for Profile Removal Form and a Delete Specimen Report (if the profile is removed from CODIS) will be returned to the casework analyst to be added to the case record.

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<sup>22</sup> The terms **match** and **hit** are used throughout this document. Matches and hits are not interchangeable terms or events. A match occurs when the CODIS software makes an association between two or more DNA profiles. A hit occurs when a match adds value to the investigation of a criminal case.

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1.2.10.1.4 It is the responsibility of the casework analyst to verify that the profile shown on the Delete Specimen Report is accurate by completing the appropriate section of the CODIS Request for Profile Removal Form.

1.2.10.1.5 It is the responsibility of the casework analyst to notify the customer of the removal of the profile from CODIS via amended report or a new report listing the specific item's profile that was removed.

### 1.2.10.2 **CODIS Match to Ineligible Forensic Profile**

1.2.10.2.1 If, during the course of a match evaluation, it is found that the forensic profile involved is no longer CODIS eligible due to changes in eligibility criteria, the profile in question will be removed from CODIS as outlined above.

1.2.10.2.2 If the match in question is determined to need verification, verification will be requested and completed. A statement will be added to the verification report to reflect the fact that the profile has been removed from the database due to it no longer being eligible.

1.2.10.2.3 For matches to samples ineligible for other reasons, the profile in question will be removed from CODIS, as outlined above. Hit verification reporting will be determined on a case-by-case basis by the state CODIS administrator and/or the technical manager.

### 1.2.10.3 **Removal of Duplicate Offender & Legal Samples**

Duplicate Offender and Legal Samples may be removed at the discretion of the CODIS administrator, and a CODIS Request for Profile Removal Form does not need to be completed.

### 1.2.11 **Annual Review/Updates**

1.2.11.1 In accordance with NDIS Procedures, all CODIS users will certify annually that they have reviewed and comply with requirements for DNA profiles acceptable at NDIS.

1.2.11.2 To satisfy this requirement, each CODIS user must successfully complete the FBI's training module within the time designated by the CODIS administrator.

1.2.11.3 Once complete, a certificate may be printed for each CODIS user as proof the training was successfully conducted.

1.2.11.4 The CODIS administrator is responsible for ensuring this required annual training is completed for all OSBI CODIS users.

#### **Attachment(s):**

OSBI CODIS Unit Policy Manual **CODIS\_Sample\_Reconciliation**

OSBI CODIS Unit Policy Manual **CODIS\_Data\_Entry\_Form**

OSBI CODIS Unit Policy Manual **CODIS\_Manual\_Offender\_Data\_Entry**

OSBI CODIS Unit Policy Manual **CODIS\_Keyboard\_Search**

OSBI CODIS Unit Policy Manual **CODIS\_Profile\_Removal\_Request**

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### **Reference(s):**

FBI National DNA Index System (NDIS) Operational Procedures Manual

FBI National DNA Index System (NDIS) Operational Procedures NDIS Security Requirements

OSBI CODIS Unit Training Manual

OSBI Forensic Biology Units' Policy Manual

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

# Standard Operating Procedures

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### Legal Hits

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### Familial Hits (Partial Matches)

### Hit Tracking

## 2.1 Scope

This protocol outlines the proper course of action to be taken in the event a hit is obtained to the state CODIS database (SDIS) or the National CODIS database (NDIS). This policy includes the procedures to be used in the verification of database sample(s), the release of information to other laboratories and/or investigative agencies, and the proper documentation maintained at the OSBI laboratory. In all cases, the CODIS Laboratory will make the best effort to resolve matches within 30 business days of the match report; this includes verifications and dispositions.

## 2.2 Individual Steps of the Procedure

### 2.2.1 Forensic Hits

A forensic hit occurs when two or more DNA profiles developed from crime scene evidence match one another, and the match provides new or confirms existing information to an unsolved crime.<sup>23</sup> The following procedures are to be used in the event the match involves a DNA profile developed by one of the OSBI forensic biology units.

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<sup>23</sup> If two or more cases are submitted and analyzed with the prior knowledge that they are associated, and a CODIS match occurs, this is not considered a forensic hit. Instead, it should be dispositioned as a “benchwork match.”

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### 2.2.1.1 Forensic Hit Verification

- 2.2.1.1.1 A qualified analyst will evaluate the matched forensic profiles and determine if they may have originated from the same source.
  - 2.2.1.1.1.1 If the potential match has any loci matching at less than high stringency or contains a mismatch, the analyst must be currently or previously qualified in mixture interpretation.
  - 2.2.1.1.1.2 For mixture profiles, the determination may require careful examination of the original electropherogram(s) when evaluating potential CODIS matches, and, when applicable, analysts must comply with the requirements for reinterpreting legacy data as described in the “SWGDM Clarification on the Reinterpretation of Data Typed with Legacy Amplification Test Kits” and the OSBI Forensic Biology Units’ Policy Manual. For example, moderate stringency matches between a candidate and target DNA profile where: 1) one or both of the DNA profile(s) originate from legacy data; and 2) the match involves comparisons of the original image(s) or electropherogram(s) to assess the match is considered reinterpretation. If the evaluation of a potential match requires examination of the electropherogram(s), as described above, the analyst must be currently qualified (trained and proficiency tested) in the amplification test kit used for the original analysis to reinterpret the data. If the match contains data from an amplification test kit no longer in use, the analyst reviewing the match must be in compliance with the requirements for the reinterpretation of legacy amplification test kit data per the “SWGDM Clarification on the Reinterpretation of Data Typed with Legacy Amplification Test Kits.”
  - 2.2.1.1.1.3 If the match evaluation was performed by a CODIS analyst, the casework analyst may be consulted, as needed.
- 2.2.1.1.2 If it is determined that the matching profiles did not originate from the same source, the analyst will mark the Match Details Report “No Match and return it to the CODIS Unit, if applicable, so the match can be dispositioned accordingly.
- 2.2.1.1.3 If it is determined that the matching profiles may have originated from the same source, the CODIS analyst responsible for verifying the hit will complete the Forensic Hit Verification Request Form (**CODIS\_Forensic\_Hit\_Verification\_Request**) for each OSBI case involved in the forensic match. The CODIS Unit will then contact the appropriate personnel from other laboratories, if necessary, and compile the necessary information for reporting the forensic hit.

### 2.2.1.2 Reporting Forensic Hits

- 2.2.1.2.1 In addition, in SDIS forensic hits, a forensic hit letter will be sent by the CODIS Unit (via mail, fax, and/or email) to each agency involved in the hit.

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- 2.2.1.2.1.1 Information in the letter shall include, at minimum, the investigating agency, type of case, and point of contact for each case.
- 2.2.1.2.1.2 The forensic hit letter should clearly state if the casework profile was either incomplete or a mixture. This may be accomplished by amending the first sentence of the Forensic Hit Letter to read "...a potential DNA match was obtained between your mixture/partial profile, specimen ID..."
- 2.2.1.2.1.3 The forensic hit letter should state if the match was high or moderate stringency. This may be accomplished by amending the first sentence of the Forensic Hit Letter to read "a potential high/moderate Stringency DNA match was obtained..."
- 2.2.1.2.1.4 For NDIS Forensic hits, analyst discretion will be used in how to convey the case information to the NDIS Laboratory involved in the hit. If they simply require case information to populate their internal report, that is all that is required to be sent.

### 2.2.1.3 Documenting Forensic Hits

- 2.2.1.3.1 All forensic hit documentation will be retained in the laboratory DNA case record(s) in the BEAST system corresponding to the forensic specimen(s) involved in the hit. This includes, at minimum, the following:
  - 2.2.1.3.1.1 A copy of the CODIS Match Details Report,
  - 2.2.1.3.1.2 A copy of the forensic hit letter(s),
  - 2.2.1.3.1.3 A copy of the Forensic Hit Verification Request Form (**CODIS\_Forensic\_Hit\_Verification\_Request**),
  - 2.2.1.3.1.4 All conversation correspondence (phone, fax, and/or e-mail), and
  - 2.2.1.3.1.5 Any additional information as determined by the CODIS administrator.
- 2.2.1.3.2 Information reported by telephone must be documented as a narrative in the BEAST system.
- 2.2.1.3.3 Forensic hits obtained at NDIS will be handled in the same manner as SDIS forensic hits; however, additional documentation may be required according to NDIS Procedures. A copy of any additional documentation will be retained electronically in the appropriate laboratory DNA case record(s).

### 2.2.1.4 Dispositioning Forensic Hits

When selecting the proper disposition for a database match, the CODIS Unit will refer to the FBI's "Hit Disposition Quick Reference Flowchart."

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### 2.2.2 Offender Hits

An offender hit occurs when a DNA profile from crime scene evidence (forensic profile) matches an offender's DNA profile and the match provides new or confirms existing information to an unsolved crime.

#### 2.2.2.1 Offender Hit Verification

- 2.2.2.1.1 When a potential candidate match is identified, a qualified analyst will evaluate the match to determine if they may have originated from the same source.
  - 2.2.2.1.1.1 If the potential match has any loci matching at less than high stringency or contains a mismatch, the analyst must be currently or previously qualified in mixture interpretation.
  - 2.2.2.1.1.2 For mixture profiles, the determination may require careful examination of the original electropherogram(s) when evaluating potential CODIS matches, and, when applicable, analysts must comply with the requirements for reinterpreting legacy data as described in the "SWGDM Clarification on the Reinterpretation of Data Typed with Legacy Amplification Test Kits" and the OSBI Forensic Biology Units' Policy Manual. For example, moderate stringency matches between a candidate and target DNA profile where: 1) one or both of the DNA profile(s) originate from legacy data; and 2) the match involves comparisons of the original image(s) or electropherogram(s) to assess the match is considered reinterpretation. If the evaluation of a potential match requires examination of the electropherogram(s), as described above, the analyst must be currently qualified (trained and proficiency tested) in the amplification test kit used for the original analysis to reinterpret the data. If the match contains data from an amplification test kit no longer in use, the analyst reviewing the match must be in compliance with the requirements for the reinterpretation of legacy amplification test kit data per the "SWGDM Clarification on the Reinterpretation of Data Typed with Legacy Amplification Test Kits."
  - 2.2.2.1.1.3 If the match evaluation was performed by a CODIS analyst, the casework analyst may be consulted, as needed.
- 2.2.2.1.2 If it is determined that the matching profiles did not originate from the same source, the analyst will mark the Match Details Report "No Match" and return it to the CODIS Unit, if applicable, so the match can be dispositioned accordingly.
- 2.2.2.1.3 If it is determined that the matching profiles may have originated from the same source, the CODIS analyst responsible for verifying the hit will complete the Offender Hit Verification Request Form (**CODIS\_Offender\_Hit\_Verification\_Request**).
- 2.2.2.1.4 If the offender associated with the hit is an Oklahoma offender, the CODIS analyst will reanalyze the offender sample as indicated below. If the hit involves an out-of-state offender, the CODIS Analyst will establish



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contact with the appropriate CODIS laboratory and facilitate the reporting of the hit according to NDIS Procedures.

### 2.2.2.2 Reanalysis of Offender Samples

2.2.2.2.1 If an offender sample has been previously reanalyzed by qualified OSBI personnel and documented as part of a hit verification or validation, then reanalysis is not necessary. Documentation of the previous reanalysis will be referenced or included in the case record and a letter regarding the new hit will be sent. If the offender sample was reanalyzed as part of a validation, the fingerprint and qualifying offense will still need to be verified and the offender hit verification reported in letter format as specified in this protocol.

2.2.2.2.2 If an offender sample has not been previously reanalyzed as indicated above, it will be pulled from storage and reanalyzed according to applicable OSBI and CODIS Unit policies to verify the result. Analysis will be performed on all 20 CODIS core loci to ensure that no error occurred due to a sample being switched.

2.2.2.2.3 Samples that are reanalyzed for hit verification purposes must be named with the same specimen ID on the Match Details Report.

2.2.2.2.4 Acceptable reanalyzed profiles from samples originally analyzed with less than the 20 CODIS core loci will be included on the .cmf file for the plate on which they were analyzed under specimen category "Convicted Offender." In many cases, the reanalysis of offender samples yields additional information that was not captured in the original SDIS record. Upon being imported, any additional information/loci will be added to the record already in the database.

2.2.2.2.5 If there is any discrepancy, the import report will reflect this. The analyst shall investigate any discrepancies and document the process and results using the CODIS Sample Reconciliation Form (**CODIS\_Sample\_Reconciliation**). These forms will be retained.

2.2.2.2.5.1 **Investigating potential sample switches:** If the verification analysis of the offender sample in question does not yield the same result, it will be assumed a sample switch error occurred.

2.2.2.2.5.1.1 An attempt will be made to identify the correct convicted offender sample by first determining the number(s) of the convicted offender samples analyzed immediately before and after the sample in question.

2.2.2.2.5.1.2 These convicted offender sample(s) will be analyzed to determine which one matches the forensic profile in question. Additional convicted offender samples will be reanalyzed, as needed, to identify the correct match.

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- 2.2.2.2.5.1.3 Once the correct convicted offender sample is identified, the result will be properly verified.
- 2.2.2.2.5.1.4 If dropout occurs during reanalysis, an attempt should be made to achieve a full profile, as described below, before proceeding,
- 2.2.2.2.6 Variations in profile results due to amplification kit differences, mutations, etc., are still considered to be consistent with each other. These types of variations, as well as any partial profiles obtained during the verification process, will be carefully evaluated using the criteria listed below.
- 2.2.2.2.7 **When reanalysis yields dropout or a less complete profile than originally achieved:** If the reanalysis of the hit verification offender sample yields dropout, or a less complete profile than originally achieved, analysis shall be attempted once more on the next available first pass (FP) plate. In some instances, the hit verification offender sample may have been replicate punched to allow for multiple analyses on a single plate. In these instances, the sample does not need to be reanalyzed on a subsequent plate.
  - 2.2.2.2.7.1 If further analysis yields an incomplete profile, the best profile will be selected for verification purposes.
  - 2.2.2.2.7.2 An incomplete profile may be used for the hit verification without technical manager approval if the following criteria are met:
    - 2.2.2.2.7.2.1 If the original analysis for database entry was performed prior to the use of the expanded CODIS loci, there must be at least 10 shared CODIS core loci compared from the reanalysis of the sample for hit verification to be considered consistent with the original analysis.
    - 2.2.2.2.7.2.2 If the original analysis for database entry included the expanded CODIS loci, there must be at least 15 shared loci compared with the reanalysis of the sample for the hit verification to be considered consistent with the original analysis.
  - 2.2.2.2.7.3 If the reanalysis of the hit verification does not yield enough information for the hit verification to be considered consistent with the original analysis, the technical manager shall be consulted to determine what, if any, troubleshooting should be performed or to approve the results.

### 2.2.2.3 Verification of Offender Fingerprints

- 2.2.2.3.1 A qualified OSBI latent evidence analyst will check the fingerprint exemplar of the offender specimen to verify the identity of the sample donor.

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- 2.2.2.3.2 The latent evidence analyst will sign on the appropriate line of the CODIS Offender Hit and Fingerprint Verification Form **(CODIS\_Offender\_Hit\_&\_Fingerprint\_Verification)** after indicating the result of the examination.
- 2.2.2.3.3 If the identity of the fingerprint donor is found to be different from the person listed on the offender specimen card, a request will be made to search the offender exemplar through AFIS in an effort to determine the donor of the offender sample.
- 2.2.2.3.4 If the fingerprint is of insufficient quality for comparison purposes, it will be noted on the CODIS Offender Hit and Fingerprint Verification Form that a comparison was attempted, but the fingerprint was of insufficient quality. This will not preclude the CODIS Unit from reporting the identity of the offender, but it shall also be noted in the offender hit letter that the fingerprint could not be verified.

### 2.2.2.4 Verification of Qualifying Offense & Biographical Information

- 2.2.2.4.1 A copy of the Oklahoma and National Criminal History Reports of the offender in question will be requested in an attempt to verify that the offender sample was collected in accordance with Oklahoma Statue Title 74 Section 150.27a. If no criminal history record(s) exists for the offender, this will be noted in the hit verification file.
- 2.2.2.4.2 In the event that no qualifying offense can be identified for the offender, the hit information may still be reported pursuant to Oklahoma Statutes Title 74 Section 150.27a (known as the “Good Faith Clause”).
- 2.2.2.4.3 The verifying analyst will compare the biographical information on the offender record in CoDNA with the information available on state and national criminal history reports and on the Department of Corrections (DOC) web page for the offender. An initial comparison shall be made to ensure that the correct records have been obtained. Aliases found on the state criminal history report will be included on the hit letter. If no DOC number is available on the CoDNA record or the state criminal history reports, it will be included from the DOC page, if applicable.

### 2.2.2.5 Reporting Offender Hits

- 2.2.2.5.1 Information contained in the hit letter shall include (if available) the offender’s name, date of birth, race, sex, Social Security number, Department of Corrections number, state ID number, FBI number, and the qualifying offense. This information can be obtained from the offender specimen card, the LIMS system, and/or the appropriate criminal history reports for the individual.
  - 2.2.2.5.1.1 Additional identifying information from the criminal history report(s) may also be included in the report at the discretion of the CODIS administrator.
- 2.2.2.5.2 The hit letter should clearly state if the forensic profile was either incomplete, a mixture, or both. This may be accomplished by amending the first sentence of the letter to read “a potential DNA match was obtained between your mixture/partial profile, specimen ID...”

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- 2.2.2.5.3 The hit letter should clearly state if the match was moderate or high stringency. This may be accomplished by amending the first sentence of the letter to read “a potential moderate/high stringency DNA match was obtained...”
- 2.2.2.5.4 If an incomplete offender profile resulted during reanalysis for hit verification purposes, partial wording will be used in the hit letter that clearly indicates that the reanalysis yielded an incomplete profile, which was used for comparison.
- 2.2.2.5.5 A .pdf version of the hit letter, CODIS Match Report, and the Offender Hit Request Form should be attached to the appropriate electronic case record in the BEAST system. Any information reported by telephone must also be documented as a narrative in the BEAST system.
- 2.2.2.5.6 **Offender hits are investigative leads only!** The investigative agency will be requested to use the information provided in the hit letter as probable cause to obtain a court order compelling the individual identified by the database search to provide a known reference sample for forensic testing. A casework analyst will report the result of this subsequent DNA testing to the requesting agency in the form of an OSBI Criminalistics Examination Report.
- 2.2.2.5.7 **Collection errors:** If a collection error is identified through the hit verification process, i.e., this will likely be characterized by a confirmation of the DNA profile but a fingerprint belonging to someone other than who is identified on the card, the hit may still be reported at the discretion of the CODIS administrator.
  - 2.2.2.5.7.1 If such an error occurs, the offender hit letter will include the identity of the offender as indicated on the collection card, as well as the identification of the individual determined to be the source of the fingerprint after the AFIS search conducted by the Latent Evidence Unit.
  - 2.2.2.5.7.2 The letter will contain language indicating that a potential error at the collection site has been identified and the source of the DNA from the evidence could be either one of the individuals associated with the card.
  - 2.2.2.5.7.3 The letter will request that the investigating agency collect known DNA reference samples from both individuals for submittal to the appropriate casework laboratory for determination of the actual potential contributor.
- 2.2.2.5.8 **Exceptions:** At the discretion of the state CODIS administrator, information regarding an offender’s identity may be released prior to the completion of the verification and administrative review, especially in circumstances where the offender is not incarcerated, or if the verification will take more than 30 days.
  - 2.2.2.5.8.1 If the offender’s identity is released prior to verification, the individual notified shall be informed that the verification procedure has not been completed and the conversation will be documented in the BEAST system (narrative), if possible.

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2.2.2.5.8.2 The fingerprints should be checked before the release of an offender's identity prior to the completion of verification, if possible.

### 2.2.2.6 Distributing Offender Hits

2.2.2.6.1 **For cases in which the forensic DNA profile is assigned in CODIS to an OSBI DNA casework analyst:** Following verification and administrative review, the hit letter will be distributed via email as an encrypted .pdf to appropriate parties. The password for the .pdf will be sent by email as well. The distribution list will include:

2.2.2.6.1.1 From the original requesting agency, the original submitting officer and the head of the department. If email addresses are not available for one or both of these individuals, an appropriate substitution may be made;

2.2.2.6.1.2 The District Attorney for the district in which the original requesting agency is located;

2.2.2.6.1.3 The designated OSBI agent in the OSBI regional office for the region in which the original requesting agency is located;

2.2.2.6.1.4 A representative of the Oklahoma Attorney General's Office (when applicable); and

2.2.2.6.1.5 Any additional individuals as requested by OSBI administration.

2.2.2.6.2 **For cases in which the forensic DNA profile is owned by a laboratory with a different ORI number:** Following verification and administrative review, the hit letter will be distributed via email as an encrypted .pdf to the contact designated by the laboratory requesting the verification. The password for the .pdf will be sent by email as well.

2.2.2.6.3 **For offender hits where the offender sample is from another state:** The hit will be reported by sending a copy of the offender hit letter (from the state that verified the offender sample) to the investigating agency in Oklahoma via mail, fax, and/or email. A .pdf version of the hit letter should be attached to the appropriate electronic case record in the BEAST system along with a copy of the appropriate CODIS Match Report.

2.2.2.6.4 **For all hits:** If the receiving party requests that hits be mailed or faxed instead of emailed, the process will be amended on a case-by-case basis. This will typically only be the case if the receiving party is unable to open the attached .pdf. An unencrypted copy will not be emailed.

### 2.2.2.7 Documenting Offender Hits

2.2.2.7.1 All offender hit documentation will be retained in the appropriate CODIS hit verification file(s). These files may be either hard copy or electronic.

2.2.2.7.2 **Hits Involving Oklahoma Offenders**

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2.2.2.7.2.1 For hits involving an Oklahoma offender, the CODIS Unit will retain required documents in offender hit verification files, including the following, at a minimum:

- 2.2.2.7.2.1.1 A copy of the CODIS Match Details Report;
- 2.2.2.7.2.1.2 A copy of the offender hit letter(s);
- 2.2.2.7.2.1.3 A copy of the offender hit verification request;
- 2.2.2.7.2.1.4 Offender Hit Verification Administrative Review Form (**CODIS\_Offender\_Hit\_AR**) or Duplicate Offender Hit Verification Administrative Review Form (**CODIS\_Dup\_Offender\_Hit\_AR**);
- 2.2.2.7.2.1.5 CODIS Offender Hit and Fingerprint Verification Form (**CODIS\_Offender\_Hit\_&\_Fingerprint\_Verification**);
- 2.2.2.7.2.1.6 Photo(s) of the offender specimen card showing identifying information, or the appropriate CoDNA data sheet;
- 2.2.2.7.2.1.7 A copy of the signed technical review form from the plate on which the offender sample was reanalyzed;
- 2.2.2.7.2.1.8 A copy of the electropherograms(s) from the DNA verification;
- 2.2.2.7.2.1.9 All appropriate conversation correspondence (phone, fax, and/or e-mail); and
- 2.2.2.7.2.1.10 Any additional information as determined by the CODIS administrator.

2.2.2.7.2.2 Also for hits involving an Oklahoma offender, the following documents will be maintained as attachments to the electronic hit verification record in CoDNA. They may also be included in the hit verification file at analyst discretion:

- 2.2.2.7.2.2.1 A copy of the Oklahoma Department of Corrections offender look-up sheet (if available);
- 2.2.2.7.2.2.2 A copy of the Oklahoma Criminal History Report for the offender (if available); and
- 2.2.2.7.2.2.3 A copy of the National Criminal History Report for the offender (if available).

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### 2.2.2.7.3 Hits Involving Other State Offenders

For hits involving offenders from another state, the information will be retained in the laboratory DNA case record(s) corresponding to the forensic specimen that was involved in the hit. These records will include the following, at a minimum:

2.2.2.7.3.1 A copy of the CODIS Match Details Report;

2.2.2.7.3.2 A copy of the offender hit letter from the respective offender laboratory;

2.2.2.7.3.3 A copy of the offender hit verification request;

2.2.2.7.3.4 All appropriate conversation correspondence (phone, fax, and/or e-mail);

2.2.2.7.3.5 Any documentation required according to NDIS procedures; and

2.2.2.7.3.6 Any additional information as determined by the CODIS administrator.

### 2.2.2.8 Dispositioning Offender Hits

When selecting the proper disposition for a database match, the CODIS Unit will refer to the FBI's "Hit Disposition Quick Reference Flowchart."

## 2.2.3 Legal Hit

A legal hit occurs when a DNA profile from crime scene evidence (forensic profile) matches a legal sample's DNA profile and the match provides new or confirms existing information to an unsolved crime.

### 2.2.3.1 Legal Hit Verification

2.2.3.1.1 A qualified analyst will evaluate the match and determine if the profiles may have originated from the same source.

2.2.3.1.1.1 If the potential match has any loci matching at less than high stringency or contains a mismatch, the analyst must be currently or previously qualified in mixture interpretation.

2.2.3.1.1.2 For mixture profiles, the determination may require careful examination of the original electropherogram(s) when evaluating potential CODIS matches, and, when applicable, analysts must comply with the requirements for reinterpreting legacy data as described in the "SWGDM Clarification on the Reinterpretation of Data Typed with Legacy Amplification Test Kits" and the OSBI Forensic Biology Units' Policy Manual. For example, moderate stringency matches between a candidate and target DNA profile where: 1) one or both of the DNA profile(s) originate from legacy data; and 2) the match involves comparisons of the original image(s) or electropherogram(s) to assess the match is considered reinterpretation. If the evaluation of a potential match requires examination of the electropherogram(s), as described above, the analyst must be currently qualified (trained and proficiency tested) in the

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amplification test kit used for the original analysis to reinterpret the data. If the match contains data from an amplification test kit no longer in use, the analyst reviewing the match must be in compliance with the requirements for the reinterpretation of legacy amplification test kit data per the "SWGDM Clarification on the Reinterpretation of Data Typed with Legacy Amplification Test Kits."

2.2.3.1.1.3 If the match evaluation was performed by a CODIS analyst, the casework analyst may be consulted, as needed.

2.2.3.1.2 If it is determined that the matching profiles did not originate from the same source, the analyst will mark the Match Details Report "No Match" and return it to the CODIS Unit, if applicable, so the match can be dispositioned accordingly.

2.2.3.1.3 If it is determined that the matching profiles may have originated from the same source, the CODIS analyst responsible for verifying the hit will complete the Forensic Hit Verification Request Form (**CODIS\_Forensic\_Hit\_Verification\_Request**) for each OSBI case involved in the legal match. If the legal sample originated from an OSBI case, the name, DOB and any additional demographic information should be included in the description box for that case on the Forensic Hit Verification Request form. The CODIS Unit will then contact the appropriate personnel from other laboratories, if necessary, and compile the necessary information for reporting the forensic hit.

### 2.2.3.2 Reporting Legal Hits

2.2.3.2.1 In addition, in all cases, a legal hit letter will be sent by the CODIS Unit (via mail, fax, and/or email) to each agency involved in the hit.

2.2.3.2.1.1 Information in the letter shall include, at minimum, the investigating agency, type of case, any available demographic information and the name associated with the legal sample, and point of contact for each case.

2.2.3.2.1.2 The legal hit letter should clearly state if the casework profile was either incomplete or a mixture. This may be accomplished by amending the first sentence of the Legal Hit Letter to read "...a potential DNA match was obtained between your mixture/partial profile, specimen ID..."

2.2.3.2.1.3 The legal hit letter should also clearly state the stringency of all matches.

### 2.2.3.3 Documenting Legal Hits

2.2.3.3.1 All legal hit documentation will be retained in the laboratory DNA case record(s) in the BEAST system corresponding to the forensic and legal specimen(s) involved in the hit. This includes, at minimum, the following:

2.2.3.3.1.1 A copy of the CODIS Match Details Report,

2.2.3.3.1.2 A copy of the legal hit letter(s),



## Standard Operating Procedures

2.2.3.3.1.3 A copy of the Forensic Hit Verification Request Form (**CODIS\_Forensic\_Hit\_Verification\_Request**),

2.2.3.3.1.4 All conversation correspondence (phone, fax, and/or e-mail), and

2.2.3.3.1.5 Any additional information as determined by the CODIS administrator.

2.2.3.3.2 Information reported by telephone must be documented as a narrative in the BEAST system.

2.2.3.3.3 Legal hits obtained at NDIS will be handled in the same manner as SDIS legal hits; however, additional documentation may be required according to NDIS Procedures. A copy of any additional documentation will be retained electronically in the appropriate laboratory DNA case record(s).

### 2.2.3.4 Dispositioning Legal Hits

When selecting the proper disposition for a database match, the CODIS Unit will refer to the FBI's "Hit Disposition Quick Reference Flowchart."

## 2.2.4 Familial Hits (Also Known as Partial Matches)

2.2.4.1 A partial match occurs when a single source DNA profile from crime scene evidence (forensic profile) matches an offender's DNA profile at moderate stringency, having at least one allele in common at each locus. Upon careful examination of other information associated with the two profiles, it may be determined that a potential familial relationship exists between the two profiles (known as a **Familial Hit**).

2.2.4.2 Potential familial hits (partial matches) at SDIS or NDIS will be handled on a case-by-case basis, according to any current Scientific Working Group on DNA Analysis Methods (SWGDM) and NDIS guidelines.

2.2.4.3 Familial hits (partial matches) will only be reported in the event that all other investigative options have been exhausted.

## 2.2.5 Hit Tracking

Whenever possible, hit information should be recorded for statistical purposes. At a minimum, the match date, specimen ID's, laboratory names and/or ORI numbers, qualifying offense, and type of case aided should be noted.

## 2.3 Notes

2.3.1 **During the verification process, if it is determined that the hit does not need to be reported (i.e., case file match), the analysis (DNA reanalysis and fingerprint verification) should be completed so that if an informative match occurs in the future, the section is not duplicating work.**

### Attachment(s):

OSBI CODIS Unit Policy Manual **CODIS\_Sample\_Reconciliation**

OSBI CODIS Unit Policy Manual **CODIS\_Forensic\_Hit\_Verification\_Request**

OSBI CODIS Unit Policy Manual **CODIS\_Offender\_Hit\_Verification\_Request**

OSBI CODIS Unit Policy Manual **CODIS\_Offender\_Hit\_&\_Fingerprint\_Verification**

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OSBI CODIS Unit Policy Manual **CODIS\_Forensic\_Hit\_AR**

OSBI CODIS Unit Policy Manual **CODIS\_Offender\_Hit\_AR**

OSBI CODIS Unit Policy Manual **CODIS\_Dup\_Offender\_Hit\_AR**

### **Reference(s):**

FBI National DNA Index System (NDIS) Operational Procedures Manual

FBI National DNA Index System (NDIS) Operational Procedures NDIS Security Requirements

OSBI CODIS Unit Training Manual

OSBI Forensic Biology Units' Policy Manual

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

SWGDM Clarification of the Reinterpretation of Data Typed with Legacy Amplification Test Kits

# Standard Operating Procedures

## CODIS\_3 DIRECT AMPLIFICATION OF DNA USING GlobalFiler Express SYSTEM ([↑ Table of Contents](#))

### Quick links:

[DBQM\\_7 \(Facilities & Sample Control\)](#)  
[DBQM\\_9 \(Analytical Procedures\)](#)  
[Sample Type & Recommended Punches](#)  
[Preparation of Samples/Controls for Direct Amplification](#)  
[Direct Amplification Using the ProFlex™ PCR System](#)  
[Documentation](#)  
[Notes](#)

### 3.1 Scope

The CODIS Unit uses direct amplification for all offender samples. This protocol is for the setup and direct amplification of DNA from sample punches using the GlobalFiler Express System and ProFlex™ PCR System.

### 3.2 Reagents & Supplies

- 3.2.1 GlobalFiler Express System for direct PCR amplification
- 3.2.2 Prep-N-Go™ Buffer
- 3.2.3 TE<sup>-4</sup>
- 3.2.4 1.2 mm Harris Punch (or equivalent)
- 3.2.5 96-well plate
- 3.2.6 Adhesive plate seal

### 3.3 Equipment

- 3.3.1 Centrifuge
- 3.3.2 Eppendorf ThermoMixer® C
- 3.3.3 Applied Biosystems™ ProFlex™ PCR System

### 3.4 Sample Preparation

- 3.4.1 Offender samples consist of dried blood or buccal cells on FTA® cards and blood on non-FTA® cards (filter paper). The following table details the appropriate number of punches for each sample type.

**Sample Type & Recommended Punches**

Sample Type	Harris Punch Size	# of Punches	Notes
Blood Card on FTA	1.2mm	1	One punch should be used.
Buccal Card on FTA	1.2mm	1	An alternate light source may be used to aid in locating the stain. One punch should be used.
Blood Card on non-FTA	1.2mm	1	One punch should be used

## Standard Operating Procedures

- 3.4.2 The quantity and quality of DNA recovered from each specimen will vary. For samples exhibiting dropout or incomplete profiles, reanalysis or recollection may be necessary.
- 3.4.3 Sometimes it is possible for analysts to identify samples that may need additional, upfront attention during analysis. These samples may include, but are not limited to, the following:
- Hit verifications on previously failed samples
  - Hit verifications from samples that only passed after subsequent analysis on a re-punch (RP) or last-try (LT) plate
  - Hit verifications with indications of an amplification kit difference
  - Rush hit verifications
  - Hit verifications on older samples
  - Offender cards with little or discolored visible staining
  - Proficiency test samples

The analyst may use discretion, based upon their experience and expertise, when encountering these types of samples and choose to analyze multiple (replicate) punches on the same plate in anticipation of the sample(s) yielding less than ideal results. The analysts may also decide to analyze replicate punches on separate plates, when necessary and appropriate.

### 3.5 Controls

- 3.5.1 Each set of amplified samples must include positive and negative amplification controls, which shall be analyzed using the 3500xL Genetic Analyzer.
- 3.5.2 Positive control: 3 $\mu$ L (2ng/ $\mu$ L) of 007 control DNA. A positive control must be included with every plate of samples.
- 3.5.3 Negative control: 15 $\mu$ L of PCR amplification mix (reagent blank). A reagent blank will also serve as the negative amplification control and must be included with every plate of samples.
- 3.5.3.1 If a plate contains sample(s) requiring the use of Prep-n-Go™ Buffer, Prep-n-Go™ Buffer must also be included in the negative control for the plate.

### 3.6 Individual Steps of the Procedure

#### 3.6.1 Preparation of Samples/Controls for Direct Amplification

- 3.6.1.1 Label the 96-well plate with the appropriate "Plate Name" as defined below:
- 3.6.1.1.1 **First Pass Plates:** Original analysis plates will be labeled as "calendar year – first pass (FP) – plate number." Plate numbers will be in sequential numerical order. This plate number will be assigned when samples are punched and will remain the same throughout amplification and capillary electrophoresis. Example: **2018-FP-0001**
- 3.6.1.1.2 **Re-Punch Plates:** Samples that are to be re-punched will be placed on the next available re-punch plate. The plate will be named by "calendar year – re-punch (RP) – plate number." Plate numbers will be in sequential numerical order. Example: **2018-RP-0001**
- 3.6.1.1.3 **Reinject Plates:** Entire plates that need to be re-setup for genetic analysis will be labeled as a reinject plate. The plate will be named by "calendar year – reinject (RI) – plate number." Plate numbers will be in sequential numerical order. Example: **2018-RI-0001**

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3.6.1.1.4 **Last Try Plates:** Samples that have been previously analyzed 2 times and still fail to produce a full DNA profile will be analyzed for a third and final time. These samples will be placed on the next available last try plate. The plate will be named by “calendar year – last try (LT) – plate number.” Plate numbers will be in sequential numerical order. Example: **2018-LT-0001**

3.6.1.2 Punch all non-FTA samples into the designated wells of a 96-well plate first and pre-treat to lyse the samples by adding 3µL of Prep-n-Go™ Buffer to each well containing non-FTA sample punches. It may be necessary to spin the plate briefly to ensure all liquid and the punch(es) in (are) in the bottom of the well. Incubate the plate at ~70°C until the well is dry (~15 minutes). Use the Offender Analysis Excel workbook to record all sample information in the Offender Sample Analysis Summary Table, Offender Sample Reanalysis Worksheet, if applicable, and Offender Sample Analysis 3500 Setup Worksheet.

3.6.1.2.1 If a plate contains sample(s) requiring Prep-n-Go™ Buffer, it will be included in the negative control for the plate.

3.6.1.3 If necessary, prepare the GlobalFiler™ Express kit by adding the following volume of Master Mix Additive to the GlobalFiler™ Express Master Mix Tube/ Bottle:

Kit	Master Mix Additive Volume
GFE 200 reaction	80uL
GFE 1000	390uL

Gently invert the Master Mix Tube ~10 times. Mark the cap of the master mix with a “+” to indicate the additive has been added. Discard the additive tube.

3.6.1.4 Make the appropriate volume of PCR amplification mix according to the volumes listed below (per sample):

3.6.1.4.1 For All Sample Types:

Master Mix	6µL
Primer Mix	6µL
TE <sup>-4</sup>	3µL
Total Reaction Volume	15µL

3.6.1.4.2 For one full plate of samples, use the following volumes:

Master Mix	600µL
Primer Mix	600µL
TE <sup>-4</sup>	300µL
Total Reaction Volume	1,500µL

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- 3.6.1.5 Vortex the PCR amplification mix for 5-10 seconds and add 15µL to each reaction well in the 96-well plate.
- 3.6.1.6 Punch all FTA samples into the designated wells of the 96-well plate. Clean the Harris Punch after each sample punch and between samples by taking two punches of a clean area of the sample card and discarding the blank punches. To prevent potential cross-contamination, the clean punches must be taken from the same card that the sample was taken from or from a clean sheet of filter paper. Use the Offender Analysis Excel workbook to record all sample information in the Offender Sample Analysis Summary Table, Offender Sample Reanalysis Worksheet, if applicable, and Offender Sample Analysis 3500 Setup Worksheet.
- 3.6.1.7 Prepare the positive and negative amplification controls.
  - 3.6.1.7.1 For the positive amplification control, vortex the tube of 007 control DNA and add 3µl (2ng/µL) to a reaction well containing 15µL of PCR amplification mix.
  - 3.6.1.7.2 The reagent blank (15µL of PCR amplification mix only) will serve as the negative amplification control.
- 3.6.1.8 Seal the plate and briefly centrifuge to bring the sample punches to the bottom of the wells and remove air bubbles.

### 3.6.2 Direct Amplification Using the ProFlex™ PCR System

- 3.6.2.1 Turn on the ProFlex™ PCR System (thermal cycler).
- 3.6.2.2 Select “Open Method” on the touch screen.
- 3.6.2.3 Select the amplification program for GlobalFiler™ Express on the touch screen. The amplification program will be displayed on the screen:

Temperatures/Times for GlobalFiler Express System Direct PCR Amplification				
Initial Step	Denature	Anneal/Extend	Final Extension	Final Step
1 CYCLE	27 CYCLES		Hold	
95°C 1 min	94°C 3 sec	60°C 30 seconds	60°C 18 min	4°C ∞

9700 Simulation Mode must be used

- 3.6.2.4 Place the sealed 96-well plate in the thermal cycler, close the lid, and select “Verify Block” on the touch screen.
- 3.6.2.5 Select “Start Run.”
- 3.6.2.6 After the amplification is complete, select “Stop Run.” The instrument screen will then display “Stop Current Run?”, select “OK.”

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3.6.2.7 Wait for the instrument to cool. When the instrument is cool enough for shut down, the screen will display “Done”; select “Done” and remove the plate from the instrument block and power down the thermal cycler.

### 3.6.3 Documentation

3.6.3.1 Sample information shall be recorded at the time of punching in the Offender Sample Analysis Summary Table (**CODIS\_Summary\_Table**), Offender Sample Reanalysis Worksheet (**CODIS\_Reanalysis**), if applicable, and Offender Sample Analysis 3500 Setup Worksheet (**CODIS\_3500\_Setup**) using the Offender Analysis Excel workbook (**CODIS\_Offender\_Analysis\_Workbook**).

3.6.3.1.1 Recorded information will include the sample number or other identifying information (e.g., staff name, etc.) and sample type.

3.6.3.1.2 Sample types should be recorded at the time of punching and can include but are not limited to: **I** for initial analysis, **RS** for resubmission, **HV** for hit verification, **R** for research, or **EL** for expanded loci.

3.6.3.1.3 Analysts will indicate whether the samples are non-FTA by marking the appropriate box on the Offender Sample Analysis Summary Table.

3.6.3.2 Complete the appropriate sections of the Offender Sample Analysis Lot Numbers Worksheet (**CODIS\_Lot\_Numbers**) in the Offender Analysis Excel workbook (**CODIS\_Offender\_Analysis\_Workbook**). Required lot numbers/expiration may include:

3.6.3.2.1 GlobalFiler Express System direct PCR amplification kit

3.6.3.2.2 TE<sup>-4</sup>

3.6.3.2.3 Prep-N-Go™ Buffer

### 3.7 Notes

3.7.1 Analysts should pay careful attention during sample punching to avoid the accidental addition of the paper backing into the reaction wells of the 96-well plate; this can affect the quality of the profile obtained, as observed during the OSBI Internal Validation.

3.7.2 Failure to pre-treat non-FTA samples before adding PCR amplification mix may result in incomplete profiles.

3.7.3 Failure to vortex the PCR amplification mix sufficiently can result in poor amplification or locus-to-locus imbalance.

3.7.4 The GlobalFiler Express System direct PCR amplification program on the ProFlex™ PCR System must be run in “9700 simulation mode.”

3.7.5 Sealed plates of amplified DNA product may be stored at -20°C (or frozen) in a light protected box for short periods of time. Long storage periods of amplified samples at 4°C or higher may produce artifacts.

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- 3.7.6 Amplification plates will be discarded after technical review is complete. If the plate contains samples that are to be reinjected, the plate will be retained and appropriately stored until this process has been completed and then discarded.
- 3.7.7 For troubleshooting purposes, sample(s) can be re-punched or reinjected.

### **Attachment(s):**

OSBI CODIS Unit Policy Manual **QCR\_GFE**  
OSBI CODIS Unit Policy Manual **QCR\_PrepNGo**  
OSBI CODIS Unit Policy Manual **CODIS\_Offender\_Analysis\_Workbook**  
OSBI CODIS Unit Policy Manual **CODIS\_Summary\_Table**  
OSBI CODIS Unit Policy Manual **CODIS\_Reanalysis**  
OSBI CODIS Unit Policy Manual **CODIS\_3500\_Setup**  
OSBI CODIS Unit Policy Manual **CODIS\_Lot\_Numbers**

### **Reference(s):**

Applied Biosystems™ GlobalFiler™ Express PCR Amplification Kits User Guide  
Eppendorf ThermoMixer® C Operating Manual  
Life Technologies™ ProFlex™ PCR System User Guide  
FBI Quality Assurance Standards for DNA Databasing Laboratories  
SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories  
OSBI CODIS Unit Training Manual



# Standard Operating Procedures

## CODIS\_4 3500xL GENETIC ANALYZER ANALYSIS ([↑ Table of Contents](#))

### Quick links:

[DBQM\\_9 \(Analytical Procedures\)](#)

[Preparing Samples, Controls & Ladders for the 3500xL Genetic Analyzer](#)

[Manual Setup](#)

[Heat Denature/Snap Cool](#)

[Loading Samples onto the 3500xL Genetic Analyzer](#)

[Electrophoresis of Samples Using the 3500xL Genetic Analyzer](#)

[Documentation](#)

[Notes](#)

### 4.1 Scope

This protocol establishes the procedures for obtaining a genetic profile using capillary electrophoresis and the 3500xL Genetic Analyzer from offender DNA database samples previously amplified with the GlobalFiler Express direct PCR amplification kit.

### 4.2 Reagents & Supplies

4.2.1 96-well optical reaction plate

4.2.2 96-well septa

4.2.3 Plate base and retainer

4.2.4 Microcentrifuge tube(s)

4.2.5 GlobalFiler Express Allelic Ladder

4.2.6 Hi-Di™ Formamide

4.2.7 GeneScan™ LIZ Internal Lane Standard 600 (LIZ ILS 600)

4.2.8 3500xL Genetic Analyzer consumables: capillary array, Performance Optimized Polymer 4 (POP-4™), and Anode/Cathode Buffer Containers (ABC/CBC)

### 4.3 Equipment

4.3.1 Mechanical pipettors

4.3.2 Vortex

4.3.3 MiniSpin

4.3.4 Centrifuge

4.3.5 Available equipment for performing heat denature/snap cool (e.g., thermal cycler/freezer, ice or cold block)

4.3.6 Applied Biosystems™ 3500xL Genetic Analyzer

### 4.4 Individual Steps of the Procedure

4.4.1 **Preparing Samples, Controls & Ladders for the 3500xL Genetic Analyzer**

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### 4.4.1.1 Manual Setup

- 4.4.1.1.1 Prepare the appropriate volume of master mix according to the volumes per sample listed below and based on the number of samples to be analyzed:

**Per Sample:**

GeneScan™ 600 LIZ	0.4µL
Hi-Di™ Formamide	9.6µL
Total Volume/Well	10µL

**For one whole plate:**

GeneScan™ 600 LIZ	40µL
Hi-Di™ Formamide	960µL
Total Volume	1000µL

- 4.4.1.1.2 Vortex the master mix for 10-15 seconds and aliquot 10uL into the appropriate wells of the 96-well plate.
- 4.4.1.1.3 Add 1.0µL of PCR product or GlobalFiler Express Allelic Ladder to the appropriate well.
- 4.4.1.1.4 Cover wells with appropriate septa and centrifuge plate briefly to ensure the samples are seated at the bottom of the wells and no air bubbles are present.

### 4.4.1.2 Heat Denature/Snap Cool

- 4.4.1.2.1 Denature the samples by heating the plate in a thermal cycler at 95°C for ~3 minutes. The thermal cycler lid should not be locked down during this step, as the heated lid can melt the plate septa on the reaction plate.
- 4.4.1.2.2 Quickly chill the plate in a freezer, cold block or ice for ~3 minutes.
- 4.4.1.2.3 Inspect the plate for the presence of bubbles. If necessary, briefly centrifuge the plate again to remove air bubbles.

### 4.4.2 Loading the 3500xL Genetic Analyzer

- 4.4.2.1 Place the 96-well plate onto a 96-well plate base.
- 4.4.2.2 Snap the plate retainer onto the plate and plate base, verifying that the holes of the plate retainer and the septa mat are aligned.
- 4.4.2.3 Load plate apparatus onto the 3500xL Genetic Analyzer.

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### 4.4.3 Capillary Electrophoresis Using the 3500xL Genetic Analyzer

- 4.4.3.1 Prepare the 3500xL Genetic Analyzer for operation, including performing any required maintenance, as per the quality control procedures in this policy manual.
- 4.4.3.2 Open the 3500xL Data Collection Software and wait for the service console to start all application services.
- 4.4.3.3 After the Dashboard screen launches, press the “Refresh” button to ensure the most up-to-date information is displayed for the instrument.
- 4.4.3.4 (Optional) Preheat the oven to 60°C from the main dashboard.
- 4.4.3.5 To import a new plate from the template in the Offender Analysis Excel workbook:
  - 4.4.3.5.1 Click on the “template” tab in the Excel workbook. Ensure that all cells have been properly filled.
  - 4.4.3.5.2 Click “File” > “Save As” and select the appropriate location to which you want to save the file. In the “Save As” dialogue box, type the plate name in the “File name” and select “Text (Tab delimited)” in the “Save as type” drop down list.
  - 4.4.3.5.3 Click “Save” and then “OK” and “Yes” in the following two dialogue boxes, in that order.
  - 4.4.3.5.4 On the computer workstation for the instrument, click the “library” tab from the main dashboard.
  - 4.4.3.5.5 Select “Import” from the toolbar.
  - 4.4.3.5.6 Navigate to the location of the saved file. It may be necessary to choose “.txt” in the file extension dropdown for the saved plate to be visible.
  - 4.4.3.5.7 Select the appropriate plate and choose “OK.” The dialogue box will indicate whether the plate was imported successfully.
  - 4.4.3.5.8 Select “Edit” from toolbar to bring up the plate record. If any injections need to be deleted due to a partial plate, etc., highlight the cells to be deleted, right click, and select “Delete.”
  - 4.4.3.5.9 Select “Link Plate for Run.”
  - 4.4.3.5.10 Once the Load Plate window appears, select “Yes.”
  - 4.4.3.5.11 In the Run Information window, assign the plate name for “Run Name” and select “Start Run.”
- 4.4.3.6 To create a new plate:
  - 4.4.3.6.1 Navigate to the Library. From the Manage menu, select “Plates,” then “Create.”
  - 4.4.3.6.2 Assign a Plate Name. Select the plate type “HID” from the drop-down menu.

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- 4.4.3.6.3 Select “Assign Plate Contents” and assign sample names and sample types to wells.
- 4.4.3.6.4 Select the appropriate Assay, File Name Convention, and Results Group for the samples.
- 4.4.3.6.5 Select “Link Plate for Run.”
- 4.4.3.6.6 Once the Load Plate window appears, select “Yes.”
- 4.4.3.6.7 In the Run Information window, assign the plate name for “Run Name” and select “Start Run.”

### 4.4.4 Documentation

4.4.4.1 Complete the appropriate sections of the Offender Sample Analysis Lot Numbers Worksheet (**CODIS\_Lot\_Numbers**) in the Offender Analysis Excel workbook (**CODIS\_Offender\_Analysis\_Workbook**). Required lot numbers/expiration include:

- 4.4.4.1.1 Hi-Di™ Formamide
- 4.4.4.1.2 GeneScan™ 600 LIZ®
- 4.4.4.1.3 3500xL Performance Optimized Polymer 4
- 4.4.4.1.4 3500xL Anode/Cathode Buffer Containers

### 4.5 Notes

- 4.5.1 **Reinject Plates:** Entire plates that need to be re-setup for genetic analysis due to original genetic analysis failure will be labeled (named) as a reinject plate. The plate will be named by “calendar year – reinject (RI) – plate number.” Plate numbers will be in sequential numerical order. Example: **2018-RI-0001**
- 4.5.2 Air bubbles in samples on plates for 3500xL genetic analysis can interfere with the electrokinetic injection process.
- 4.5.3 All samples will be injected at a standard default injection time of 24 seconds. Analysts may also perform 16 second and/or 32 second injections of samples or the entire plate, if desired, or as needed, keeping in mind that any sample injected at 32 seconds must have the associated reagent blank/negative amplification control injected at 32 seconds to evaluate for acceptability.
- 4.5.4 Upon completion of the technical review process, 3500xL Genetic Analyzer plates should be discarded. If the plate contains samples that are to be reinjected, the plate should be retained and stored appropriately until this process has been completed.
- 4.5.5 Hi-Di™ Formamide should be stored frozen (~ -10°C to -30°C) upon receipt and refrigerated (~2 to 10°C) after initial use. It will have an expiration date of six months from date of aliquot.

#### Attachment(s):

OSBI CODIS Unit Policy Manual **CODIS\_Offender\_Analysis\_Workbook**

OSBI CODIS Unit Policy Manual **CODIS\_3500\_Setup**

## Standard Operating Procedures

OSBI CODIS Unit Policy Manual **CODIS\_Lot\_Numbers**

### **Reference(s):**

Applied Biosystems™ GlobalFiler™ Express PCR Amplification Kits User Guide

Applied Biosystems™ 3500/3500xL Genetic Analyzer User Guide

Applied Biosystems™ DNA Fragment Analysis by Capillary Electrophoresis User Guide

Applied Biosystems™ 3500/3500xL Genetic Analyzer with 3500 Series Data Collection Software 3.1 User Guide

FBI Quality Assurance Standards for DNA Databasing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

OSBI CODIS Unit Training Manual

# Standard Operating Procedures

## CODIS\_5 GENEMAPPER® *ID-X* DATA ANALYSIS ([↑ Table of Contents](#))

### Quick links:

[Creating a New GMID-X Project](#)  
[Analyzing Sample Files in the GMID-X Project](#)  
[Examining Samples for GeneScan™ 600 LIZ Peaks](#)  
[Viewing Sample Plots](#)  
[Reanalysis](#)  
[Evaluating PQVs](#)  
[Documentation](#)

### 5.1 Scope

The purpose of this protocol is to provide information on how to analyze electronic data pertaining to offender database samples. The GeneMapper® *ID-X* (GMID-X) Software is used to analyze the data collected by the 3500xL Genetic Analyzer to size and quantify the DNA fragments.

### 5.2 Equipment

5.2.1 Computer with GeneMapper® *ID-X* Software Version 1.6

### 5.3 Individual Steps of the Procedure

#### 5.3.1 Create a New GMID-X Project

5.3.1.1 Launch the **GeneMapper ID-X** application and log on.

5.3.1.1.1 Each analyst must log on using their assigned GMID-X user name to ensure that the analyzed samples and \*.cmf files have the correct “read by” and “assigned to” user.

5.3.1.1.2 The GMID-X user name must be the same as the CODIS database user name to allow importing of data.

5.3.1.2 Select **File**, then **New Project**.

5.3.1.3 Select **Edit**, then **Add Samples to Project**.

5.3.1.4 Browse to the location of the run files. Highlight the desired file(s) and then select **Add to List**, followed by **Add**.

5.3.1.5 In the Sample Type column, use the drop-down menu to select **Allelic Ladder**, **Sample**, **Positive Control** or **Negative Control** as appropriate for the sample if not already selected.

5.3.1.6 In the **Analysis Method** column, select “**GFE\_OSBI\_Databasing**” All settings have been predetermined during CODIS validations. Double click the Analysis Method to confirm the following settings for **27 cycles/16, 24 & 32 second injections**:

5.3.1.6.1 **General Tab Settings:**

- Name: **GFE\_OSBI\_Databasing**
- Instrument: **3500xL**
- Analysis Type: **HID**

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## 5.3.1.6.2 Allele Tab Settings:

Analysis Method Editor

General | **Allele** | Peak Detector | Peak Quality | SQ & GQ Settings

Bin Set: AmpFLSTR\_Bins\_v6X

Use marker-specific stutter ratio and distance if available

Marker Repeat Type:	Tri	Tetra	Penta	Hexa
Global Cut-off Value	0.2	0.2	0.0	0.0
MinusA Ratio	0.0	0.0	0.0	0.0
MinusA Distance	From	0.0	0.0	0.0
	To	0.0	0.0	0.0
Global Minus Stutter Ratio	0.0	0.0	0.0	0.0
Global Minus Stutter Distance	From	0.0	0.0	0.0
	To	0.0	0.0	0.0
Global Plus Stutter Ratio	0.0	0.0	0.0	0.0
Global Plus Stutter Distance	From	0.0	0.0	0.0
	To	0.0	0.0	0.0

Amelogenin Cutoff: 0.0

Range Filter... Factory Defaults

Save As Save Cancel Help

## 5.3.1.6.3 Peak Detector Tab Settings:

Analysis Method Editor

General | Allele | **Peak Detector** | Peak Quality | SQ & GQ Settings

Peak Detection Algorithm: Advanced

Ranges

Analysis: Full Range Sizing: Partial Sizes

Start Pt: 0 Start Size: 65

Stop Pt: 10000 Stop Size: 460

Smoothing and Baseline

Smoothing:  None  Light  Heavy

Baseline Window: 33 pts

Size Calling Method

2nd Order Least Squares

3rd Order Least Squares

Cubic Spline Interpolation

Local Southern Method

Global Southern Method

Peak Detection

Peak Amplitude Thresholds:

B: 120 R: 120

G: 120 P: 120

Y: 120 O: 120

Min. Peak Half Width: 2 pts

Polynomial Degree: 3

Peak Window Size: 13 pts

Slope Threshold

Peak Start: 0.0

Peak End: 0.0

Normalization

Use Normalization, if applicable

Factory Defaults

Save As Save Cancel Help

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## 5.3.1.6.4 Peak Quality Tab Settings:

The screenshot displays the 'Analysis Method Editor' window with the 'Peak Quality' tab selected. The window contains several sections of settings:

- Min/Max Peak Height (LPH/MPH):**
  - Homozygous min peak height: 200.0
  - Heterozygous min peak height: 120.0
  - Max Peak Height (MPH): 50000.0
- Peak Height Ratio (PHR):**
  - Min peak height ratio: 0.5
- Broad Peak (BD):**
  - Max peak width (basepairs): 1.5
- Allele Number (AN):**
  - Max expected alleles:
    - For autosomal markers & AMEL: 2
    - For Y markers: 1
- Allelic Ladder Spike:**
  - Spike Detection: Enable
  - Cut-off value: 0.2
- Sample Spike Detection:**
  - Spike Detection: Enable

At the bottom right of the settings area is a 'Factory Defaults' button. At the bottom of the window are 'Save As', 'Save', 'Cancel', and 'Help' buttons.



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### 5.3.1.6.5 SQ and GQ Tab Settings:

The screenshot shows the 'Analysis Method Editor' dialog box with the 'SQ & GQ Settings' tab selected. The dialog has a title bar with a close button (X) and a tabbed interface with 'General', 'Allele', 'Peak Detector', 'Peak Quality', and 'SQ & GQ Settings'. The 'SQ & GQ Settings' tab contains the following sections:

- Quality weights are between 0 and 1.**
- Sample and Control GQ Weighting** (collapsible section):
  - Broad Peak (BD): 0.8
  - Out of Bin Allele (BIN): 0.8
  - Overlap (OVL): 0.8
  - Marker Spike (SPK): 0.3
  - AMEL Cross Check (A...): 0.0
  - Allele Number (AN): 1.0
  - Low Peak Height (LPH): 0.3
  - Max Peak Height (MPH): 0.3
  - Off-scale (OS): 0.8
  - Peak Height Ratio (P...): 0.3
- Control Concordance (CC) Weight = 1.0 (Only applicable to controls)
- SQ Weighting** (collapsible section):
  - Broad Peak (BD): 0.5
- Allelic Ladder GQ Weighting** (collapsible section):
  - Spike (SSPK/SPK): 1 (dropdown)
  - Off-scale (OS): 1 (dropdown)
- SQ & GQ Ranges** (collapsible section):
  - Pass Range: (highlighted in green)
  - Low Quality Range: (highlighted in red)
  - Sizing Quality: From 0.75 to 1.0 (Pass Range) and From 0.0 to 0.25 (Low Quality Range)
  - Genotype Quality: From 0.75 to 1.0 (Pass Range) and From 0.0 to 0.25 (Low Quality Range)

Buttons at the bottom: Save As, Save, Cancel, Help, and a 'Reset Defaults' button.

5.3.1.7 Ensure that the “GlobalFiler\_Express\_v1.4.1X Panel is selected.

5.3.1.8 Ensure that the “LIZ 600 ILS (60-460)” Size Standard is selected. Double click to confirm the following settings:

- Size Standard Dye: **Orange**
- Size in Base Pairs: **60, 80, 100, 114, 120, 140, 160, 180, 200, 214, 220, 240, 250, 260, 280, 300, 314, 320, 340, 360, 380, 400, 414, 420, 440, 460**

5.3.1.9 Click **View > Raw Data** to view the raw data for each ladder and check for any bad injections. If any are found, they should be removed from the project and listed in the Offender Sample Analysis Technical Notes.

### 5.3.2 Analyze Sample Files in the GMID-X Project

5.3.2.1 Select **Analyze** (green arrow button).

5.3.2.2 A new window will open asking for a **Project name**. Enter the designated plate name and other information, as directed below:

5.3.2.2.1 Analysts shall save two types of GMID-X projects: one will contain the unedited GMID-X data, prior to any changes being made (other than size quality overrides), and the other will contain the reported GMID-X data, which will only include passed samples (if multiple injections are performed, only one passed sample should be saved, with the exception of applicable controls). Each project should be named as follows,

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respectively: **Plate Name (Unedited Data)** and **Plate Name (Reported Data)**.

5.3.2.2.2 There may be times when more than one reported data project is needed. In this case, each reported data project should also include a sequential number at the end to distinguish it from other projects, e.g., **Plate Name (Reported Data)** and **Plate Name (Reported Data 2)**.

5.3.2.2.3 In the event a plate fails analysis and no data is accepted, a reported data project will not be created.

5.3.2.2.4 Any blank wells on the plate (i.e., formamide and ILS only) will not be included in the project.

5.3.2.3 Click **OK**. The progress status bar at the bottom of the window will fill in as the samples are analyzed.

### 5.3.3 Examine Samples for GeneScan™ 600 LIZ® Peaks

5.3.3.1 Examine all samples to confirm that the sizes for the peaks in the LIZ® ILS 600 size standard have been correctly assigned and no peaks are missing by highlighting all the samples in the **Sample** window and clicking the **Size Match Editor** under the **Tools** menu. If the SQ column (located at the far right of the **Samples** window) has a green square (Pass), then the size quality meets the predetermined requirements; skip to step 5.3.4.

5.3.3.1.1 Only 26 peaks from 60 to 460bp. should be found within the analysis range of each sample's LIZ® ILS 600 peaks.

5.3.3.1.2 Additional peaks, such as pull-up or other artifacts, should be carefully examined to ensure they do not interfere with sample profiling. Any discrepancies will be brought to the attention of the technical manager and/or Lead Analyst.

5.3.3.1.3 The size quality will not be overridden for any samples without prior technical manager approval.

5.3.3.2 If any LIZ® ILS 600 peaks have been excluded at either end of the analysis range, the analysis range can be expanded to include the peaks in question (as described below); however, this will affect the analysis range of all samples and controls within the project. Alternatively, analysts may reanalyze the problem sample(s) in a new project with a new analysis range to include the peak(s) in question. If this alternate method is used, at least one allelic ladder must be included in the new project, and the new project should be named in a manner to distinguish it from other projects, e.g., **Plate Name (Reported Data 2)**.

5.3.3.2.1 Determine the correct analysis range for the first sample by highlighting the sample on the **Samples** tab. Examine the raw data for the sample by choosing **Raw Data** in the **View** menu. Alternatively, the sample can be highlighted in the navigation pane on the left side of the window. The object is to exclude the over-blown primer peak typically found at < 1600 scan numbers while including the size standard range from 60 to 460bp.

5.3.3.2.2 A closer examination can be made by placing the cursor on the left or top scale until the magnifying glass appears. Click and drag the magnifying

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glass to include the area desired. To return to the original scale, double click the appropriate scale. This will aid in choosing scan number values less than the 60bp and greater than the 460bp LIZ® ILS 600 standard peaks as observed in the raw data. The other scans can be evaluated after highlighting the first scan and placing the cursor on the correct scan number and using the down arrow (↓) to scroll.

- 5.3.3.2.3 Once these values have been determined, return to the **Samples** window by clicking on the **Project** icon in the navigation pane or by clicking on **Samples** in the **View** menu and modify the analysis range values accordingly.
- 5.3.3.2.4 Reanalyze the sample files according to 5.3.2 above. **No other GMID-X setting should be modified.**
- 5.3.3.2.5 Once the analysis range values have been changed, they will become the new default settings for future projects. If this is not desired, ensure the original default settings are re-entered when analyzing future projects.

### 5.3.4 View Sample Plots

- 5.3.4.1 From the **Samples** tab, highlight each allelic ladder and select **Display Plots** from the **View** menu. Carefully evaluate each ladder to determine if all ladder alleles are called appropriately. Remove any incorrect or failed ladders from the GMID-X project and document in the Offender Sample Analysis Technical Notes.
- 5.3.4.2 From the **Samples** tab, highlight the controls and select **Display Plots** from the **View** menu. Carefully evaluate each control according to [CODIS\\_6 \(DNA Interpretation Guidelines for Database Samples\)](#).
- 5.3.4.3 From the **Samples** tab, highlight the samples and select **Display Plots** from the **View** menu. Carefully evaluate each sample according to [CODIS\\_6 \(DNA Interpretation Guidelines for Database Samples\)](#). Document the results of sample analysis on the Offender Sample Analysis Technical Notes and determine if reanalysis is needed.

### 5.3.5 Reanalysis

- 5.3.5.1 All reasonable attempts to remediate samples not meeting reporting guidelines will be made.
- 5.3.5.2 Individual samples which do not meet guidelines for reasons that do not extend to the entire plate will typically be assigned to the next available re-punch plate. The most common reason for re-punch is dropout.
- 5.3.5.3 If a sample fails again after being assigned to a re-punch plate, it will be assigned to a last try plate. An exception to this would be a sample that has no data on two separate amplifications. If a sample has no discernable allelic peaks on two subsequent runs, it may be marked as failed and a replacement sample should be requested
- 5.3.5.4 If a sample on a last try plate fails to produce a full DNA profile, or if a card yields no discernable allelic peaks on two subsequent amplifications, it will be considered failed.

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- 5.3.5.4.1 Failed samples will be documented on the Offender Sample Analysis Technical Notes for the plate on which they failed.
- 5.3.5.4.2 Failed samples may be manually entered into the Offender, Incomplete Offender, Arrestee or Incomplete Arrestee Index using the most complete profile if meeting the eligibility requirements as listed in this policy.
- 5.3.5.4.3 Failed samples that are entered into CODIS will be entered as "SAMPLE#" to indicate the profile is incomplete.
- 5.3.5.4.4 A comment for all failed samples should be entered into the BEAST indicating the sample failed analysis and requesting an additional sample be collected from that offender.
- 5.3.5.5 If an entire plate fails due to amplification failure or electrophoresis failure, the plate may be re-amplified as a re-punch plate or re-injected as a re-inject plate.
- 5.3.6 **Evaluate Process Component-Based Quality Values (PQVs)**
  - 5.3.6.1 After careful examination of all samples, ladders and controls, the analyst should use the GMID-X PQR flags as an additional quality check of the reported data. The PQR markers are not to be used as a substitute for the analyst's evaluation of the data but as a tool to help ensure no additional sample problems went undetected.
  - 5.3.6.2 From the **Genotypes** tab in the **Project** window, the samples will be separated by marker. The available PQVs will be displayed at the far right side of the table. Each PQR will be marked with a green square (Pass), a yellow triangle (Check), or a red octagon (Low Quality).
    - 5.3.6.2.1 The samples can be sorted with the low quality samples taken to the top by clicking **Low Quality to Top** under the **View** menu. This will sort the samples into low quality, check, and pass.
  - 5.3.6.3 Each sample with a red octagon (Low Quality) or a yellow triangle (Check) must be examined to determine what action needs to be taken. Highlight the sample and click **Display Plots** under the **View** menu.
- 5.3.7 **Documentation**
  - 5.3.7.1 Complete the appropriate areas of the applicable Offender Sample Analysis Technical Notes (**CODIS\_Tech\_Notes\_1**, **CODIS\_Tech\_Notes\_2**, or **CODIS\_Tech\_Notes\_3**) in the Offender Analysis Excel workbook (**CODIS\_Offender\_Analysis\_Workbook**).

### Attachment(s):

OSBI CODIS Unit Policy Manual **CODIS\_Offender\_Analysis\_Workbook**

OSBI CODIS Unit Policy Manual **CODIS\_Tech\_Notes\_1**

OSBI CODIS Unit Policy Manual **CODIS\_Tech\_Notes\_2**

OSBI CODIS Unit Policy Manual **CODIS\_Tech\_Notes\_3**

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### Reference(s):

Life Technologies™ GeneMapper® *ID-X* Software Version 1.6 Reference Guide

Life Technologies™ GeneMapper® *ID-X* Software Version 1.6 Installation Guide

FBI Quality Assurance Standards for DNA Databasing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

OSBI CODIS Unit Training Manual

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## 6.1 Scope

The purpose of this protocol is to provide STR interpretation guidelines for DNA profiles generated from offender database samples. DNA typing results should be “verified and interpreted” (SWGDM Interpretation Guidelines) by reviewing peak designations and other software-generated information, internal size standards, ladders, positive amplification controls, negative amplification controls (reagent blanks), and samples.

## 6.2 Individual Steps of the Procedure

### 6.2.1 Evaluation of Associated Standards, Ladders & Controls

Analysts should review and verify the following:

#### 6.2.1.1 Software-Generated Information

- 6.2.1.1.1 Correct spectral
- 6.2.1.1.2 Correct panel
- 6.2.1.1.3 Correct size standard
- 6.2.1.1.4 Correct genotyping parameters (Analysis Method)

#### 6.2.1.2 Internal Size Standard & Allelic Ladders

- 6.2.1.2.1 The internal size standard performed as expected and is present in all ladders, controls, and samples.
- 6.2.1.2.2 All ladders selected for comparison to controls and samples performed as expected with all alleles sized and labeled correctly.

#### 6.2.1.3 Extraneous/Unexplained Peaks

- 6.2.1.3.1 All samples, controls and allelic ladders will be evaluated to ensure no extraneous or unexplained peaks are present within the analysis range of 60-460bp for the GlobalFiler Express System unless approved by the technical manager and/or Lead Analyst. This does not include known artifacts as defined within this policy.
- 6.2.1.3.2 Samples containing unexplained peaks will be handled in accordance with the applicable policies of this manual.

#### 6.2.1.4 Analytical Controls: Positive and Reagent Blank/Negative Amplification Controls

- 6.2.1.4.1 The positive and reagent blank/negative amplification controls will be verified to ensure that the results obtained are acceptable.
- 6.2.1.4.2 The correct profile must be obtained for the positive amplification control.
- 6.2.1.4.3 The reagent blank/negative amplification control must have no peaks indicating the presence of contamination in accordance with this policy and DBQM\_9 (Analytical Procedures).

### 6.2.2 Interpretation of Non-Allelic Peaks/Possible Artifacts

The following are defined as artifacts (non-allelic peaks) by the CODIS Unit and will be designated as indicated. Peaks that do not fit any of the following designations will be

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considered extraneous and will be handled on a case-by-case basis in consultation with the technical manager and/or Lead Analyst.

### 6.2.2.1 PCR Products

#### 6.2.2.1.1 Stutter

- 6.2.2.1.1.1 Generally, when the height of a peak in the stutter position exceeds the stutter filter set in the GMID-X software, the peak is consistent with being of allelic origin and should be designated as an allele.
- 6.2.2.1.1.2 A universal 20% stutter filter shall be utilized by the CODIS Unit for filtering stutter at all loci.
- 6.2.2.1.1.3 With higher than recommended amounts of template DNA, stutter may sometimes be called as a peak by the GMID-X software by exceeding the stutter filter. Analysts must evaluate the profile as a whole to determine whether the peak is a true allele or a stutter peak.
- 6.2.2.1.1.4 Combined stutter ( $n + X$  and  $n - X$ ) may be present in samples.
- 6.2.2.1.1.5 If the stutter peak is not causing any interpretation problems (i.e. no allele calls are affected), and there is no indication of a possible mixture, analysts may delete the allele call from the stutter peak in the GMID-X project. All deletions must be documented in the Offender Sample Analysis Technical Notes, and the technical reviewer must agree. Analysts may also document the stutter peak ratio(s), if desired.
- 6.2.2.1.1.6 In the event a stutter peak interferes with the analysis of an electropherogram or interferes with an allele call, the sample shall be reinjected and/or re-amplified.

#### 6.2.2.1.2 Minus A

- 6.2.2.1.2.1 The amplification procedure used in this policy manual (i.e. 60°C for 8 minutes) facilitates the addition of adenosine 'A' to the 3' end of the PCR product. However, with higher than recommended amount of template DNA, lack of non-template nucleotide addition, i.e., minus A ( $n - 1$ ) peaks, may be observed as a "shoulder" of the main allele peak.
- 6.2.2.1.2.2 If the minus A is not causing any interpretation problems (i.e. no allele calls are affected), analysts may delete the allele call from the minus A peak in the GMID-X project. All deletions must be documented in the Offender Sample Analysis Technical Notes, and the technical reviewer must agree.
- 6.2.2.1.2.3 In the event minus A interferes with the analysis of an electropherogram or interferes with an allele call, the sample shall be reinjected and/or re-amplified.



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6.2.2.1.2.4 If profiles with minus A are interpreted, analysts shall not utilize any quantitative aspects of interpretation (such as stutter and peak height ratios).

### 6.2.2.1.3 Trailing Primer Peaks

6.2.2.1.3.1 Analysts may delete the allele call(s) from trailing primer peaks in the GMID-X project. All deletions must be documented in the Offender Sample Analysis Technical Notes, and the technical reviewer must agree.

### 6.2.2.2 Known GlobalFiler Express System Amplification Kit-Specific Artifacts

6.2.2.2.1 Reproducible kit-specific artifacts for the GlobalFiler Express System have been reported by the manufacturer as outlined below:

Dye Channel	Locus	Artifact ID	Approximate bp Size	Typical Allele Call
6-FAM™	D3S1358	GF D3-1	132 bp	OL, 17.2 or 17.3
		GF D3-2	126-127 bp	Varies
	vWA	GF vWA-1	204 bp	OL or 22.3
	D16S539	GF D16-1	228 bp	OL
	TPOX	GF TPOX-1	N-24 bp	Varies
VIC™	N/A	GF VIC-1	94 bp	Outside Marker Range (OMR)
		GF VIC-2	95 bp	Outside Marker Range (OMR)
	Y indel	GF Yindel-1	84 bp	OL
	D8S1179	GF D8-1	114-121 bp	Varies
		GF D8-2	124 bp	OL or 7.2
		GF D8-3	113 bp	OL
	D21S11	GF D21-1	207 bp	29.3 or 30
	D18S51	GF D18-1	286 bp	13.1
GF D18-2		N-2 bp	Varies	
DYS391	GF DYS391-1	N-5 bp	Varies	
NED™	N/A	GF NED-1	63 bp	N/A
	D2S441	GF D2NED-1	91-100 bp	Varies
		GF D2NED-2	N-2 to N-2.5 bp	Varies
		GF D2NED-3	76 bp	8
	D19S433	GF D19-1	N-6 bp	Varies
		GF D19-2	N+2 to N+4 bp	Varies
	TH01	GF TH01-1	N-10 to N-12 bp	Varies
FGA	GF FGA-1	N+2 bp	Varies	
FGA	GF FGA-2	N-8	Varies	
TAZ™	N/A	GF TAZ-1	250 bp	Outside Marker Range (OMR)
	D5S818	GF D5-1	180 bp	OL
		GF D5-2	142 bp	OL or 7.3
	SE33	GF SE33-1	N-90 bp	Varies
		GF SE33-2	352.5 bp	15.2
GF SE33-3		424 bp	OL	
SID™	D2S1338	GF D2SID-1	345 bp	OL

6.2.2.2.2 If kit-specific artifacts are not causing any interpretation problems (i.e. no allele calls are affected), analysts may delete the allele call(s) from these artifacts (if observed above threshold) in the GMID-X project. All deletions must be documented in the Offender Sample Analysis Technical Notes and the technical reviewer must agree.

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6.2.2.2.3 In the event any of these artifacts interferes with the analysis of an electropherogram or interferes with an allele call, the sample shall be reinjected and/or re-amplified.

### 6.2.2.3 Non-Specific Amplification Artifacts

6.2.2.3.1 Non-specific amplification products (artifacts) may occur due to excessive template amplification and/or the presence of co-extracted bacterial or microbial DNA. These artifacts may or may not have morphology similar to that of a true allele; however, they do not exhibit the presence of the characteristic stutter peak that accompanies the amplification of true human DNA.

6.2.2.3.2 These artifacts will be handled in consultation with the technical manager and/or Lead Analyst.

### 6.2.2.4 Analytical Artifacts

#### 6.2.2.4.1 Instrument Spikes

6.2.2.4.1.1 If an instrument spike is not causing any interpretation problems (i.e., no allele calls are affected), analysts may delete the allele call from the instrument spike peak in the GMID-X project. All deletions must be documented in the Offender Sample Analysis Technical Notes, and the technical reviewer must agree.

6.2.2.4.1.2 In the event an instrument spike interferes with the analysis of an electropherogram or interferes with an allele call, the sample shall be reinjected to obtain a clean electropherogram.

#### 6.2.2.4.2 Raised Baseline

6.2.2.4.2.1 In the event a raised baseline interferes with the analysis of an electropherogram or interferes with an allele call, the sample in question shall be reinjected to obtain a clean electropherogram.

### 6.2.2.5 Instrument Limitations

#### 6.2.2.5.1 Off-scale Peaks (Oversaturation)

6.2.2.5.1.1 An examination of the Oversaturation/Off-scale (SOS) PQV in the 'Genotypes' tab is acceptable for determining whether a peak is off-scale. All samples will be evaluated for oversaturation/off-scale data and examined closer if the PQV is anything other than passing.

6.2.2.5.1.2 If the off-scale peak is not causing any interpretation problems (i.e., no allele calls are affected), the injection may be used as long as off-scale peak(s) is/are documented.

6.2.2.5.1.3 If the off-scale peak is causing any interpretation problems, the analyst shall attempt to alleviate the problem by

## Standard Operating Procedures

reinjecting the sample at a lower injection time, if possible, and/or re-amplifying.

6.2.2.5.1.4 Analysts will document samples affected by oversaturation/off-scale peaks, along with any resulting actions taken, in the Offender Sample Analysis Technical Notes.

6.2.2.5.1.5 If samples with peaks flagged as off-scale are interpreted, analysts should not utilize any quantitative aspects of interpretation (such as stutter and peak height ratios) from the artificial peak height value assigned to the off-scale peak at the location.

6.2.2.5.1.6 Max Peak Height Flags (MPH) do not need to be documented unless there is a cause for concern.

### 6.2.2.5.2 Pull-Up

6.2.2.5.2.1 Pull-up may be observed with peaks near the linear detection limit of the instrument but technically not off-scale, with the presence of off-scale peaks, or as a result of a poor spectral on the instrument.

6.2.2.5.2.2 If the pull-up peak is not causing any interpretation problems (i.e., no allele calls are affected), and there is no indication of a possible mixture, analysts may delete the allele call from the pull-up peak in the GMID-X project. All deletions must be documented in the Offender Sample Analysis Technical Notes, and the technical reviewer must agree.

6.2.2.5.2.3 In the event a pull-up peak interferes with the analysis of an electropherogram or interferes with an allele call, the sample shall be reinjected and/or re-amplified.

### 6.2.2.5.3 Carryover

6.2.2.5.3.1 Carryover can occur when a profile from the sample previously injected on a capillary is observed in the subsequent sample. This usually occurs due to a high concentration of DNA in the first sample, but can also begin to occur more frequently as the capillary array nears its injection limit.

6.2.2.5.3.2 Carryover is not considered contamination, and therefore, a sample exhibiting carryover, as long as there is no reason to suspect a physical route of contamination, need not be documented as non-conforming work. If the technical reviewer agrees that the source of the peaks is most likely carryover, the sample does not need technical manager approval or to be documented on the non-conforming work log.

6.2.2.5.3.3 Carryover should be communicated to the lead analyst and the supervisor so that the frequency can be monitored to determine if a capillary array change is necessary.

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## 6.2.2.6 GMID-X Software Limitations

Occasionally the GMID-X software may label a true allele as an artifact. If this occurs, the analyst shall manually add the correct allele call back into the profile. All changes must be documented in the Offender Sample Analysis Technical Notes, and the technical reviewer must agree. The allele will not be accepted or uploaded unless the technical reviewer agrees.

## 6.2.2.7 Introduction into the Analysis Process

### 6.2.2.7.1 Dye Blobs

6.2.2.7.1.1 Dye blobs observed above threshold outside of allele call ranges shall be deemed acceptable without further analysis.

6.2.2.7.1.2 If a dye blob is observed above threshold within the allele calling range but not causing any interpretation problems (i.e., no allele calls are affected), analysts may delete the allele call from the dye blob peak in the GMID-X project. All deletions must be documented in the Offender Sample Analysis Technical Notes, and the technical reviewer must agree.

6.2.2.7.1.3 In the event a dye blob interferes with the analysis of an electropherogram or interferes with an allele call, the sample shall be re-injected and/or re-amplified.

## 6.2.3 Interpretation of Allelic Peaks

The evaluation of allelic peaks includes allele designations given by the analysis software (GMID-X) and consideration of peak heights and peak height ratios at each locus and across the entire profile.

### 6.2.3.1 Heterozygote Peak Height Ratios

6.2.3.1.1 When a locus displays two alleles in a single source offender sample, the allele with the lower peak height must display at least 50% or more of the peak height of the higher peak at the locus. An examination of the Peak Height Ratio (PHR) PQR in the 'Genotypes' tab will indicate whether the peak height ratio meets the appropriate percentage (i.e.,  $\geq 50\%$ ).

6.2.3.1.2 Peak height balance is affected by the amount and quality of template DNA available, so lower template samples may experience peak height balance less than the general percentage. Samples displaying less than 50% peak height ratios at one or more locations will be re-injected to verify the results.

6.2.3.1.3 If the sample still contains a peak height ratio below 50% after re-injection, the sample may still be accepted as long as the results are documented in the Offender Sample Analysis Technical Notes and the technical reviewer agrees with determinations outside these criteria. If there is discrepancy, the technical manager and/or Lead Analyst should be consulted.

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- 6.2.3.1.4 Regardless of peak height, peaks determined to be the result of stutter, pull-up, minus A, elevated baseline, spikes, or background will not be designated as true alleles.

### 6.2.3.2 Off-Ladder Alleles

- 6.2.3.2.1 With the exception of microvariants, as described below, unless otherwise indicated, samples containing off-ladder alleles will be reinjected and/or re-amplified to verify the result.

#### 6.2.3.2.2 Types of Off-Ladder Alleles

6.2.3.2.2.1 **Standard Alleles:** Alleles that fall **outside** the range of the ladder alleles. These alleles are smaller than the smallest allele of the ladder or larger than the largest allele of the ladder at a locus. The GMID-X software typically labels these alleles as "< (smallest ladder peak)" or "> (largest ladder peak)" when within the marker range of the locus.

6.2.3.2.2.1.1 Since the CODIS database software does not recognize allele values outside the range of ladder alleles, the label assigned by the GMID-X software will be accepted (after the result has been verified).

6.2.3.2.2.1.2 Occasionally, an apparent allelic peak may be observed outside of or in between two loci marker ranges. Following manual calculations, these allele calls may be added, and the peaks re-assigned to the correct locus. Such edits will require the approval of the technical reviewer, and will not require approval from a lead analyst or the technical manager.

6.2.3.2.2.1.3 The approximate base size may be calculated, if desired, and documented in the Offender Sample Analysis Technical Notes.

6.2.3.2.2.2 **Microvariant Alleles:** Alleles that fall **inside** the range of the smallest and largest ladder alleles at a locus. These microvariant alleles contain an incomplete number of repeats, such as X.1, X.2 or X.3, and are labeled as "OL" by the GMID-X software if not present in the allelic ladder or a virtual bin.

6.2.3.2.2.2.1 Microvariants may be calculated without re-injection or re-amplification. If the allele is labeled as "OL," the sizing value may be calculated and the appropriate allele value assigned. Remember that Penta D and Penta E are penta-nucleotide loci and D22S1045 is a tri-nucleotide locus.

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6.2.3.2.2.2 If the sample is reanalyzed and the GMID-X software has assigned an allele label, the sample will be accepted as valid. If the allele is still labeled as "OL," the sizing value will be calculated and the appropriate allele value assigned. All verified microvariant alleles shall be documented in the Offender Sample Analysis Technical Notes.

6.2.3.2.2.3 **Virtual Alleles:** Alleles assigned a label by the GMID-X software due to the presence of a bin even though the allele itself is not represented in the allelic ladder.

6.2.3.2.2.3.1 No additional analysis is required for virtual alleles; the GMID-X allele call will be accepted and used.

### 6.2.3.2.3 Locus Designation

6.2.3.2.3.1 When an off-ladder allele is observed between loci, and one neighboring locus appears to be homozygous while the other is heterozygous, the off-ladder allele most likely is a sister allele paired with the locus that appears to display homozygosity.

6.2.3.2.3.2 When an apparent allelic peak is observed outside of or in between two loci marker ranges, a manual calculation will be performed. The allele call should be verified on STR base, and following that verification, the peak can be re-assigned to the correct locus, and the allele call can be added. This edit will require approval from the technical reviewer. Additional approval from a Lead Analyst or Technical Manager is not required.

6.2.3.2.3.3 An off-ladder allele may sometimes be labeled in the wrong locus. These instances may be observed as false tri-alleles or have inconsistent peak heights. To confirm the suspected incorrect locus assignment:

6.2.3.2.3.3.1 The analyst should calculate the value of the allele from the ladder of the correct locus and verify the previous observation in STRbase. If verified, the analyst may then delete the allele to reduce the chance of an erroneous no-match due to incorrect profiling at the affected locus. This deletion, as well as its observation in STRbase, must be noted in the Offender Sample Analysis Technical Notes and the technical reviewer must agree. If there is a discrepancy, the technical manager and/or Lead Analyst will be consulted.

6.2.3.2.3.3.2 If the allele is not observed in STRbase, the sample will be reanalyzed to confirm the result, and this confirmation will be

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documented in the Offender Sample Analysis Technical Notes.

### 6.2.3.2.4 Allele Designation

6.2.3.2.4.1 When necessary, off-ladder alleles will be assigned an allele value according to the following:

6.2.3.2.4.1.1 Designation of the alleles should refer to the total number of full repeats.

6.2.3.2.4.1.2 Designation of incomplete repeat motifs should include the number of complete repeats, and separated by a decimal point, the number of base pairs in the incomplete repeat. For example, allele 9.3 at TH01 has nine complete repeats and one incomplete repeat of 3 base pairs.

6.2.3.2.4.2 Occasionally, due to a sample not satisfactorily aligning with the average bins calculated from the ladder(s), an allele may be labeled as off-ladder by the GMID-X software even though its actual allele designation is recognized within the ladder. If this happens, the analyst should analyze the sample in a separate project with a different combination of ladder(s) to try to reconcile the sample, and this action shall be documented in the Offender Sample Analysis Technical Notes.

### 6.2.3.2.5 Calculating Off-Ladder Alleles

6.2.3.2.5.1 **Standard Alleles:** Determine the base pair size of the off-ladder allele. Determine the size difference between the off-ladder allele and the nearest ladder peaks. Round the size to the nearest whole number and then divide by the repeat size for that locus. Add or subtract this number to the nearest ladder allele (as appropriate) to determine the off-ladder allele designation. For example, in D3S1358 the smallest ladder allele is 96.75 base pairs, designated as "9." The off-ladder allele is 88.81 base pairs.  $96.75 - 88.81 = 8$ . The size repeat for D3S1358 is 4 base pairs.  $8/4 = 2$ ,  $9 - 2 = 7$ . The off-ladder allele would be designated as "7."

6.2.3.2.5.2 **Microvariant Alleles:** Determine the base pair size of the microvariant peak, and then compare the base pair size of the microvariant to the base pair size of the two bracketing ladder peaks. If the peak falls before or after the last peak in the ladder, the calculation will be handled in consultation with the technical manager and/or Lead Analyst. Determine the size difference between the microvariant and the smaller of the ladder peaks and round to the nearest whole number. For example, if a green off-ladder allele peak sizes at 233.57 bases and the "36" allele of the D21S11 ladder is 231.64 bases, the peak in question shall be labeled as "36.2" because the difference is 2.07, or 2 bases in length.

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6.2.3.2.5.3 Any off-ladder allele more than 8 base pairs away from the nearest ladder allele should be calculated with caution since tetranucleotide repeats do not always size exactly 4 base pairs apart.

6.2.3.2.5.4 All calculations must be documented on an electropherogram with sizes labeled or in the Offender Sample Analysis Technical Notes and maintained with the plate workbook.

### 6.2.3.3 Trisomy

6.2.3.3.1 If a profile is suspected to have trisomy (tri-allelic) at a locus, the sample shall be reinjected and then re-amplified, unless indicated otherwise below, to verify this event. Once verified, the trisomy (tri-allele) can be accepted as valid.

6.2.3.3.2 Peak height ratios may not be calculated for a locus with a verified trisomy (tri-allele).

### 6.2.3.4 Insertion/Deletion/Null Alleles

6.2.3.4.1 In rare instances, an insertion/deletion close to the STR repeat region may result in discordant results between two separate amplification kits due to the use of differing primers for the locus. Null alleles may occur due to primer binding site mutations, and alleles fail to amplify due to a sequence difference in a primer binding site mutation.

6.2.3.4.2 If an apparent null allele exists, such as no 'X' detected, for example, the sample may be reanalyzed and documented in the Offender Sample Analysis Technical Notes. The necessity for reanalysis will depend on the overall results for the sample, including the result at *DYS391*, and in consultation with the technical manager and/or Lead Analyst.

## 6.2.4 Thresholds Used for Interpretation

### 6.2.4.1 Limit of Detection

6.2.4.1.1 Limit of detection for GlobalFiler Express direct PCR amplification kit (27 cycles) for the following injection times using the 3500xL Genetic Analyzer per internal validation studies:

Limit of Detection (MTS)		
16 Second	24 Second	32 Second
60 RFU	60 RFU	60 RFU

### 6.2.4.2 Analytical Threshold

6.2.4.2.1 Analytical threshold the GlobalFiler Express direct amplification kit (27 cycles) for all injection times using the 3500xL Genetic Analyzer per internal validation studies:

Analytical Threshold		
16 Second	24 Second	32 Second
120 RFU	120 RFU	120 RFU



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6.2.4.2.2 Any peaks above the analytical threshold must be evaluated to determine if the peak is an allele or present due to an artifact. Criteria found within this policy should be utilized to determine if a peak is an artifact.

6.2.4.2.3 No peaks below the analytical threshold will be sized as alleles.

### 6.2.4.3 Peak Stochastic Threshold

6.2.4.3.1 Peak stochastic threshold for GlobalFiler Express direct PCR amplification kit (27 cycles) using the 3500xL Genetic Analyzer per internal validation studies:

Peak Stochastic Threshold (PST)		
16 Second	24 Second	32 Second
200 RFU	200 RFU	200 RFU

6.2.4.3.2 Samples may be classified as displaying stochastic effects if:

6.2.4.3.2.1 The profile has unpaired allelic peaks that have peak heights above the analytical threshold but below the stochastic threshold.

6.2.4.3.2.2 The profile has lower peak height ratios than would be expected between two paired allelic peaks.

6.2.4.3.2.3 The profile has extreme sloping.

6.2.4.3.2.4 The profile has extreme sloping.

6.2.4.3.3 Peaks observed below the peak stochastic threshold that do not appear to have a paired allelic peak cannot be assumed to be homozygous. There may be dropout of a sister allele.

6.2.4.3.4 Peak height ratios of paired allelic peaks below peak stochastic threshold may also be lower than normal.

6.2.4.3.5 The peak stochastic threshold does not apply to Amelogenin, DYS391, or the Yindel.

6.2.4.3.6 Samples exhibiting potential dropout (i.e., peaks below peak stochastic threshold) may be acceptable if the locus is heterozygous and both peaks are present. This should be noted in the Offender Sample Analysis Technical Notes.

6.2.4.3.7 If a sample has an apparent homozygous peak(s) below peak stochastic threshold, it should be further analyzed by evaluating an additional injection (24 or 32 second injection), if available, or by re-punching/re-amplifying the sample.

## 6.2.5 Interpretation of Offender Profiles

### 6.2.5.1 General Considerations

6.2.5.1.1 **Acceptability:** By nature, offender database samples are single source. A sample can be determined to have originated from a single source if

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no more than two alleles are present at all loci examined, recognizing that three peak (trisomy/tri-allele) patterns can occur.

6.2.5.1.1.1 DNA profiles from all samples, controls and ladders must meet the criteria outlined within this policy manual to be considered acceptable.

6.2.5.1.1.2 All profiles should be carefully evaluated for indications of a mixture, which could indicate possible contamination.

6.2.5.1.1.3 If any profile has resolution issues or any other abnormality, the analyst will consult with the technical manager and/or Lead Analyst before accepting the data.

6.2.5.1.2 **Degradation:** If a sample is degraded, higher molecular weight alleles may not amplify due to preferential degradation of larger alleles.

6.2.5.1.3 **Allelic (locus) dropout:** If an insufficient (or excess) quantity of human DNA template is used/available, there is a possibility for preferential amplification of certain loci/alleles over others, which may result in allelic (locus) dropout. The result may generate some loci/alleles not amplifying at all. Inhibitors may also produce allelic dropout.

### 6.2.5.2 Complete Offender Profiles

6.2.5.2.1 An offender profile is considered complete when all alleles are above analytical and/or stochastic thresholds at all amplification kit loci tested, which includes the core CODIS loci, and otherwise meet the requirements of this policy.

6.2.5.2.2 If a single source sample has two alleles detected at a locus, the analyst can be confident that the DNA profile at that locus is complete, regardless of the peak stochastic threshold. Likewise, if only one allele is detected at a locus and the allele is above the peak stochastic threshold, the analyst can be confident that there is no allelic dropout.

6.2.5.2.3 Upon completion of technical review, all complete offender profiles will be entered into the Offender or Arrestee Index, as applicable.

### 6.2.5.3 Incomplete Offender Profiles

6.2.5.3.1 An offender profile is usually considered incomplete when not all alleles are above analytical and/or stochastic thresholds at each of the amplification kit loci tested.

6.2.5.3.2 An offender profile shall be considered incomplete if there are peaks below the analytical threshold at any locus (i.e. partial profile).

6.2.5.3.3 If a single source sample has only one allele detected at a locus that is below the peak stochastic threshold, the analyst cannot be confident that the DNA profile is complete at that locus. Therefore, an offender profile shall be considered incomplete if there is a single peak below stochastic threshold at any locus.

6.2.5.3.4 Incomplete offender samples shall be reanalyzed in the attempt to obtain a full profile. Reanalysis may include re-punching the sample using the

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same number of amplification cycles or a request to have the sample recollected (reference [CODIS\\_5.3.5 \[Reanalysis\]](#)).

- 6.2.5.3.5 If a complete offender profile is not obtained after two reanalysis attempts (three analyses total), the sample will be considered failed. An exception to this is if a sample has exhibited no discernable allelic peaks on two subsequent amplifications. In that case, a sample can be assumed to have not been collected satisfactorily and deemed failed.

### 6.2.6 Criteria for Uninterpretable Data

- 6.2.6.1 Offender sample profiles shall be uninterpretable if they do not contain sufficient allelic information at the required number of loci for inclusion in an applicable specimen category/index after exhausting all reanalysis attempts.

Some technical issues may prevent the complete interpretation of a DNA profile or a locus/loci in a profile, thereby making these profiles or locus/loci uninterpretable. Examples of such situations may include:

- Accurate allele designations not possible due to poor quality injection, oversaturation, severe peak height imbalances, the allelic ladder, or the sample itself
- Alleles that cannot be definitively assigned to a locus
- Controls for the sample did not perform properly
- Data potentially affected by contamination

- 6.2.6.2 Uninterpretable data shall not be entered into CODIS.

### 6.2.7 Monitoring Analytical DNA Procedures Using Controls (Frequency & Tolerance of Controls)

#### 6.2.7.1 Control Requirements

##### 6.2.7.1.1 Reagent Blank Controls/Amplification Negative Controls (NC)

6.2.7.1.1.1 A reagent blank control will also serve as the negative amplification control.

6.2.7.1.1.2 At least one negative amplification control must be included with every amplification set and shall be amplified concurrently using the same typing test kit on the same instrument as the samples.

6.2.7.1.1.3 Each negative amplification control shall be typed.

6.2.7.1.1.4 The negative amplification control used by the CODIS Unit is 15µL of PCR amplification mix (reagent blank).

6.2.7.1.1.4.1 If a plate contains sample(s) requiring the use of Prep-n-Go Buffer, Prep-n-Go Buffer must also be included in the negative control for the plate.

6.2.7.1.1.5 The negative amplification control should have no unexplained peaks that exceed the limit of detection within

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the analysis range. If peaks above the limit of detection are observed, but they are outside of any allele bin/virtual bin or outside a marker's range, the data may be accepted with appropriate documentation in the technical notes, as well as agreement by the technical reviewer. If peaks above LOD are observed that fall into bins, the technical manager must be consulted prior to any data being reported from the plate.

6.2.7.1.1.5.1 Offender plates are injected at a default injection time of 24 seconds. As an option, plates may also be injected at 16 seconds and/or at 32 seconds; however, if offender sample data from a 32 second injection is accepted (in lieu of the data from a 16 or 24 second injection), the reagent blank/negative amplification control injected at 32 seconds must also be evaluated and produce the expected results.

### 6.2.7.1.2 Amplification Positive Controls (PC)

6.2.7.1.2.1 At least one positive amplification control must be included with every amplification set and shall be amplified concurrently using the same typing test kit on the same instrument as the samples.

6.2.7.1.2.2 Each positive amplification control shall be typed.

6.2.7.1.2.3 The CODIS Unit will use the control DNA provided in the GlobalFiler Express System kit (007 control DNA).

6.2.7.1.2.4 The positive amplification control should yield the following expected male DNA profile:

**GlobalFiler Express  
Positive Control 007 Allele Designations**

Locus	Alleles	Locus	Alleles
D3S1358	15,16	D19S433	14,15
vWA	14,16	TH01	7,9.3
D16S539	9,10	FGA	24,26
CSF1PO	11,12	D22S1045	11,16
TPOX	8,8	D5S818	11,11
Y-Indel	2	D13S317	11,11
Amelogenin	X,Y	D7S820	7,12
D8S1179	12,13	SE33	17,25.2
D21S11	28,31	D10S1248	12,15
D18S51	12,15	D1S1656	13,16
DYS391	11	D12S391	18,19
D2S441	14,15	D2S1338	20,23

6.2.7.1.2.5 The positive amplification control shall not contain any unexplained peaks that exceed the analytical threshold within the analysis range.

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### 6.2.7.1.3 Allelic Ladders & Internal Size Standards

6.2.7.1.3.1 Allelic ladders and internal size standards must be used to appropriately assign DNA types to fragments produced in PCR-based systems.

6.2.7.1.3.2 Allelic ladders and internal size standards should not contain any unexplained peaks that exceed the analytical threshold within the analysis range.

### 6.2.7.2 Failure of Controls

6.2.7.2.1 In the event a control fails one of the above criteria, it will be reinjected to verify the result.

6.2.7.2.2 If the reinjection is acceptable, the control will be considered valid.

6.2.7.2.3 If the reinjection is not acceptable and the same condition is observed, the entire set of samples processed with the same reagents will be considered invalid. The incident will be brought to the attention of the technical manager and unit supervisor and handled in accordance with the procedures outlined in this policy manual and OSBI CSD QP 13 (Nonconforming Work), where applicable, to determine the source of the problem and the corrective action required.

6.2.7.2.4 If an amplification control fails due to the presence of unexplained peaks above the limit of detection (LOD), the possibility of contamination shall be evaluated as outlined below.

6.2.7.2.5 If a plate contains more than one of each control and only one fails (e.g., due to a bad injection, artifact, dropout, low peak height ratio or possible contamination), the failed control does not need remediated, as long as a second control was good. However, if possible contamination above the LOD is present in the failed control, (peaks falling into bins) the incident shall be evaluated as outlined below and in accordance with OSBI CSD QP 13 (Non-Conforming Work), where necessary. In this case, no profiles from the affected plate will be imported into the CODIS database until the evaluation of the incident has been resolved and finalized. If peaks are observed above LOD, but not falling into any defined bins, the data may be accepted with documentation in the technical notes, and agreement by the technical reviewer

## 6.2.8 Contamination/Unexplained Peaks

### 6.2.8.1 General Considerations

6.2.8.1.1 The CODIS Unit shall monitor for contamination, follow decontamination procedures to minimize/prevent contamination, and follow procedures for interpreting data potentially affected by contamination.

6.2.8.1.2 The CODIS Unit shall follow procedures for uniformly evaluating controls and samples to verify expected results as well as remediating instances of control failure or sample contamination.

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- 6.2.8.1.3 Interpretation of data potential affected by contamination or failed PCR controls will be evaluated in conjunction with the technical manager and unit supervisor. The data provided by the internal validation of interpretation thresholds will be taken into account during these types of evaluations.

### 6.2.8.2 Monitoring for Contamination

- 6.2.8.2.1 All amplified samples shall be evaluated for potential contamination. Although not always readily apparent, unlike in controls, contamination shall be monitored through sample data analysis.

### 6.2.8.3 Detection & Control of Contamination

- 6.2.8.3.1 Analysts will adhere to the procedures within this policy manual, including QC\_1 (Cleaning, Decontamination & Sterilization), in an effort to limit the potential for contamination. When necessary, following a contamination event, the CODIS Unit shall follow a decontamination procedure determined by the technical manager that is proportional to the level/type of contamination observed.
- 6.2.8.3.2 If possible contamination is present, the technical manager and unit supervisor will be notified immediately. The incident will be evaluated by the technical manager in accordance with the procedures outlined in this policy manual and OSBI CSD QP 13 (Nonconforming Work), where necessary. During this evaluation, the technical manager, or designee, may review the spreadsheet of DNA profiles from employees.<sup>24</sup> No profiles from the affected plate will be imported into CODIS until the evaluation of the incident has been resolved and finalized.
- 6.2.8.3.3 If an amplification control fails due to the presence of unexplained peaks above the LOD, the contamination may be confirmed by examining sample profiles for the presence of peaks consistent with those observed in the contaminated control(s).
- 6.2.8.3.4 Any control with unexplained peaks above the limit of detection will be evaluated in consultation with the technical manager. The use of data from any affected plate may only be used with technical manager approval.
- 6.2.8.3.5 Samples containing unexplained peaks will be re-injected and/or reanalyzed (re-amplified) to verify the result.
- 6.2.8.3.6 If the contamination is determined to be due to a splash, the reagents may be acceptable for use and the affected samples must be reanalyzed.
- 6.2.8.3.7 If the contamination is determined to be due to reagent contamination, the contamination must be eliminated by either immediately replacing all

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<sup>24</sup> The OSBI Forensic Biology Discipline Employee DNA Profile Spreadsheet is a limited access, controlled Excel spreadsheet, uniquely identified and verified for accuracy, located on the secure Biology server. It consists of DNA profiles from OSBI employees and family members that have provided a buccal swab for inclusion in this reference spreadsheet for comparison purposes (i.e. contamination, training, etc.), when necessary.

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reagents currently in use or by systematically replacing one reagent at a time until the affected control(s)/samples(s) show no contamination upon reanalysis.

- 6.2.8.3.8 If the source of the contamination is found to be in the GlobalFiler™ Express kit, all affected samples must be reanalyzed using a new kit.
- 6.2.8.3.9 If a contaminant profile is observed and not attributable to any sample in the batch of offender samples being analyzed or to OSBI employees, the profile will be evaluated for entry into the Contaminant Index (SDIS only). The CODIS administrator, or designee, will evaluate these profiles to determine eligibility for entry into CODIS.

### 6.3 Notes

- 6.3.1 All technical issues and non-conforming work must be brought to the attention of the technical manager immediately. This includes, but is not limited to, contamination, sample-switch, plate record linked to incorrect plate, etc. The technical manager will determine the appropriate response per OSBI CSD QP 13 (Non-Conforming Work).

#### **Attachment(s):**

OSBI CODIS Unit Policy Manual **CODIS\_Offender\_Analysis\_Workbook**

OSBI CODIS Unit Policy Manual **CODIS\_Tech\_Notes\_1**

OSBI CODIS Unit Policy Manual **CODIS\_Tech\_Notes\_2**

OSBI CODIS Unit Policy Manual **CODIS\_Tech\_Notes\_3**

#### **Reference(s):**

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

FBI Quality Assurance Standards for Forensic DNA Testing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

SWGDM Interpretation Guidelines for Autosomal STR Typing by Forensic DNA Testing Laboratories

OSBI CODIS Unit Training Manual

ThermoFisher Scientific Technical Note: Artifacts Identified Post-Developmental Validation: GlobalFiler™ and GlobalFiler™ IQC PCR Amplification Kits

# Standard Operating Procedures

## CODIS\_7 MANAGEMENT OF DNA DATA ([↑ Table of Contents](#))

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### 7.1 Scope

The purpose of this protocol is to provide information on managing electronic data pertaining to offender database samples.

### 7.2 Individual Steps of the Procedure

#### 7.2.1 Creating a \*.cmf File for CODIS Import

7.2.1.1 A Windows-compatible Common Message Format (\*.cmf) file must be created from each reported GMID-X project that contains offender database samples that need to be imported into the CODIS database as follows:

7.2.1.1.1 All offender database samples that have been successfully profiled will be marked for export. In the **Samples** tab, select "**Convicted Offender**," "**Arrestee**," or "**Proficiency**," as appropriate, from the **Specimen Category** menu. This marks the specimen to be assigned to the appropriate index in the CODIS database.

7.2.1.1.2 All controls and ladders will be set to "No Export."

7.2.1.1.3 Any sample that does not meet the requirements outlined in [CODIS\\_6 \(DNA Interpretation Guidelines for Database Samples\)](#) will not be added to the \*.cmf file. This will prevent any unacceptable samples from being entered into the CODIS database.

7.2.1.1.4 After all samples have been marked appropriately, they should be exported following these steps:

7.2.1.1.4.1 Click **File > Export Table for CODIS** and make the following selections:

- Export File As: **CMF 3.2 (.xml)**
- Source: **OKOBI0000**
- Destination: **OKOBI0000**
- File name: **GMID-X Project Name (cmf file)**
- Files of type: **CODIS formats CMF 1.0, CMF, 3.0, CMF 3.2 (\*.dat, \*.xml)**



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7.2.1.1.4.2 Select the appropriate destination where the file will be saved and Click **Export**.

7.2.1.2 If the reported data project is edited during technical review, a new \*.cmf file must be created.

### 7.2.2 Storage of Electronic Data

7.2.2.1 The original run data files and GMID-X files generated during the course of analysis will be archived in an electronic format, such as CD-R, DVD, etc., and/or maintained on a dedicated storage server.

7.2.2.2 When possible, DNA profile data to be imported directly into CODIS will be recorded sequentially in an electronic format in Windows-compatible Common Message Format (\*.cmf file).

7.2.2.3 The original electronic data will be archived by the OSBI laboratory. A designated storage server can be utilized to store archived electronic data on a long-term basis; however, the server must be backed up on a regular basis. This may include daily tape backups stored on-site, weekly tape backups stored on-site, and/or monthly tape backups stored off-site.

#### 7.2.2.4 Data Storage on the CODIS Server

7.2.2.4.1 The DNA\_Profiles partition of the CODIS server ([\\vm-fsc-files\OSBI-CODIS\DNA\\_Profiles](#)) will be organized by year, and each completed plate will have its own subfolder within the appropriate year folder. Example: **2017 > 2017-FP-0001**

7.2.2.4.2 After the completion of sample analysis, the following data should be made available electronically to the technical reviewer:

7.2.2.4.2.1 GMID-X project(s);

7.2.2.4.2.2 \*.cmf file(s) exported from GMID-X;

7.2.2.4.2.3 3500xL run folder(s); and

7.2.2.4.2.4 A copy of plate record(s) imported to the 3500xL.

7.2.2.4.3 Upon completion of the technical review, the completed plate folder in [\\vm-fsc-files\OSBI-CODIS\DNA\\_Profiles](#) will contain the items listed above.

### 7.2.3 Storage of Hard Copy Data

7.2.3.1 All offender data and/or records received in hard copy form from a vendor laboratory will be archived by the OSBI and maintained for inspection. However, if both electronic and hard copy documentation exists, the hard copy may be destroyed and only the electronic documentation retained for inspection.

7.2.3.2 All offender data and/or records generated in hard copy form by the OSBI laboratory during analysis may be archived electronically and maintained for inspection.

7.2.3.3 A designated storage server can be utilized to store archived electronic data on a long-term basis; however, the server must be backed up on a regular basis. This

## Standard Operating Procedures

may include daily tape backups stored on-site, weekly tape backups stored on-site, and/or monthly tape backups stored off-site.

### 7.2.4 CODIS Database Security Measures

7.2.4.1 It is the responsibility of the CODIS administrator, or designee, to ensure the integrity and security of the CODIS database. This will be accomplished by ensuring the following procedures/practices are followed:

7.2.4.1.1 Only CODIS users, as defined in DBQM\_2 (Definitions), shall have access to the CODIS database.

7.2.4.1.2 The CODIS administrator, or designee, will issue each CODIS user his/her own CODIS user account and password.

7.2.4.1.2.1 It will be the responsibility of the CODIS user to change the password upon first login.

7.2.4.1.2.2 CODIS users shall not release their password to any other individual, including the CODIS administrator; however, the CODIS administrator, or designee, can reset passwords, when necessary.

7.2.4.1.2.3 CODIS network passwords will expire every 90 days.

7.2.4.1.3 Each CODIS user shall use his/her individual user name and password to login to the CODIS terminal and/or server containing the CODIS software. CODIS users are not permitted to share user names or passwords.

7.2.4.1.4 For CODIS users not authorized to access CODIS software applications, but still requiring access to the Criminal Justice Information Services Shared Enterprise Network (CJIS SEN), their individual account permissions will be set to prevent them access to modify CODIS data.

7.2.4.1.5 When logged onto the CODIS terminal and/or server, the CODIS user shall lock their screen or log off before moving to an area in which the user can no longer visually observe the CODIS terminal/server. All CODIS terminals and/or servers shall be set to lock the screen after ten minutes or sooner of non-use and require the CODIS user's password to unlock the screen.

7.2.4.1.6 Concurrent logins (i.e., logging onto two separate terminals or a server and a terminal with the same user name and password simultaneously) shall be prohibited.

7.2.4.1.6.1 For administrative purposes, the CODIS administrator, or backup CODIS administrator, shall be permitted to log onto multiple computers concurrently if the computer(s) not directly in use is locked and requires a password for use.

7.2.4.1.7 The CODIS software shall be installed on a computer that does not have internet access unless prior written approval for the use of a firewall has been obtained from the FBI.

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- 7.2.4.1.8 CODIS software enhancements provided by the FBI will be implemented in accordance with NDIS) Operational Procedures Manual.
- 7.2.4.1.9 The CODIS Unit shall conduct backups of the CODIS data on a routine schedule but not less than once per week.
- 7.2.4.1.10 On a routine schedule, but not less than once per month, the backup media shall be stored at a secure physical location other than the OSBI Forensic Science Center. This may include another NDIS participating laboratory, another building within the OSBI that is subject to the same security requirements, or a bank safety deposit box.
  - 7.2.4.1.10.1 Electronic media on which CODIS data is stored shall be maintained in a lockable container.
- 7.2.4.1.11 It is also recommended that anti-virus definitions be updated regularly (weekly or monthly, depending on upload frequency) to prevent corruption of critical CODIS data.

### 7.2.5 Removal/Expungement

- 7.2.5.1 The OSBI recognizes the need to remove from the CODIS database all DNA profiles for which the authority to collect the samples has either been removed or if the sample was improperly included in the database. The following procedures are designed to ensure the rights of individuals are protected by allowing for removal of any DNA profile that does not meet the Oklahoma statutory requirements for inclusion in the CODIS database.

#### 7.2.5.2 Criteria for Removal/Expungement

##### 7.2.5.2.1 Removal of Non-Qualifying Convicted Offender Samples

- 7.2.5.2.1.1 Any known DNA profile from an individual included in the database through erroneous collection by an authorized collection facility may be administratively removed from the CODIS database by:
  - 7.2.5.2.1.1.1 A letter from the authorized collection facility, signed by the appropriate official, stating a blood or buccal sample was erroneously collected from the individual in question and sent to the OSBI for inclusion in the database.
  - 7.2.5.2.1.1.2 The OSBI CSD director, or designee, can order removal of a DNA profile from the database, if, after review by an OSBI CODIS analyst, it is determined no qualifying offense exists to justify inclusion in CODIS.
- 7.2.5.2.1.2 Any individual wishing to petition the OSBI for removal of their DNA profile from CODIS must provide such a request in writing to the OSBI. An OSBI CODIS analyst will make a determination as to the requestor's status in CODIS and provide the OSBI CSD director, CODIS administrator, or

## Standard Operating Procedures

designee, a recommended course of action to assure the OSBI and CODIS are in compliance with applicable statutes.

### 7.2.5.2.2 Court Reversal of a Qualifying Conviction

7.2.5.2.2.1 In accordance with the DNA Analysis Backlog Elimination Act of 2000 (42 U.S.C. Section 14132(d)(2)), in the event the courts overturn the qualifying offense of a convicted individual whose DNA profile is included in CODIS, the DNA profile may be expunged from CODIS.

7.2.5.2.2.2 The OSBI must be notified, in writing, of the reversal and the subsequent need to expunge for each conviction of the person. This may be accomplished in writing from:

7.2.5.2.2.2.1 The District Attorney prosecuting the case stating that the qualifying offense has been removed. A certified copy of the final court order overturning the conviction must be provided to the OSBI.

7.2.5.2.2.2.2 An individual (or legal counsel thereof) whose conviction has been overturned may request the DNA profile be expunged. Such a request must be in writing. A certified copy of the final court order overturning the qualifying offense must accompany the request.

7.2.5.2.2.2.3 For these purposes, a court order is not considered “final” if time remains for an appeal or application for discretionary review with respect to the order.

### 7.2.5.2.3 Removal of Non-Conviction Sample Collected Under Federal Immigration Changes

7.2.5.2.3.1 In accordance with the amendments made by the DNA Fingerprint Act of 2005 (P.L. 109-162 (see 42 U.S.C. Section 14132(d)(2)(A)(ii)), individuals whose DNA sample was collected as the result of arrest, indictment, or other legal authority (such as suspect samples) may have their DNA profile expunged from CODIS in the event no charges were filed within the applicable time period, or the charge is dismissed or results in an acquittal.

7.2.5.2.3.2 The OSBI must be notified, in writing, of the subsequent need to expunge for each charge against the person. This may be accomplished in writing from:

7.2.5.2.3.2.1 The District Attorney prosecuting the case stating that the qualifying offense has been removed. A certified copy of the final court order establishing that no charge was filed within the applicable time period, or that such charge has been dismissed or has

## Standard Operating Procedures

resulted in an acquittal, must be provided to the OSBI.

7.2.5.2.3.2.2 An individual (or legal counsel thereof) whose sample was collected may request the DNA profile be expunged. Such a request must be in writing. A certified copy of the final court order establishing that no charge was filed within the applicable time period, or that such charge has been dismissed or has resulted in an acquittal, must accompany the request.

7.2.5.2.3.2.3 For these purposes, a court order is not considered “final” if time remains for an appeal or application for discretionary review with respect to the order.

### 7.2.5.2.4 Removal of Felony Arrestee Samples

7.2.5.2.4.1 In accordance with Oklahoma Statute Title 22 Chapter 3 Section 210, all DNA samples, records and identifiable information generated pursuant to the provisions of this section shall be automatically expunged from the OSBI CODIS Database under the following circumstances:

7.2.5.2.4.1.1 The felony offense for which the person was arrested does not result in charges either by information or indictment and the statute of limitations has expired,

7.2.5.2.4.1.2 The state voluntarily dismissed the felony charge filed against the person,

7.2.5.2.4.1.3 The individual is found not guilty of the felony charges by a court of law, or

7.2.5.2.4.1.4 The court dismissed the felony charge filed against the person.

7.2.5.2.4.2 If the state has voluntarily dismissed the felony charge filed against the person, it shall be the responsibility of the appropriate district attorney’s office to notify the OSBI CODIS Unit as to the decision. There is no way for laboratory personnel to monitor the status of unfiled charges.

7.2.5.2.4.3 If the court has dismissed the felony charges the court clerk or designee will notify the OSBI CODIS Unit as to the status of those charges.

7.2.5.2.4.4 If the OSBI CODIS Unit is unaware of any dismissed charges, the records for each felony arrestee sample will be evaluated by CODIS personnel 1 year after the received date of the sample.

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- 7.2.5.2.4.4.1 If there is no record available indicating that charges have been dismissed, reduced to a misdemeanor, or that the individual was found not guilty, the sample will not be expunged and will be reevaluated annually until the statute of limitations for the arrest offense has passed.
- 7.2.5.2.4.4.2 If there is evidence in the criminal record that the person for which the sample was collected was convicted of a qualifying felony or misdemeanor charge as the result of the arrest, or of any charge since the arrest, the "Sample Type" in the CoDNA record for the individual will be converted from A1, A2 or A3 to FC (Felony Conviction) or MC (Misdemeanor Conviction).
- 7.2.5.2.4.4.3 If, in evaluating the criminal history of Felony Arrestees, it is determined that there was a qualifying felony conviction prior to the felony arrest for the individual, the Offense Type in the CoDNA record for the individual will be converted from A1, A2 or A3 to PF (Prior Felony). Alternatively, if a previous qualifying misdemeanor conviction, the "Offense Type" will be converted to PM (Prior Misdemeanor).
- 7.2.5.2.4.4.4 If there is evidence that the charges were dismissed, that the individual was found not guilty, that the charges were reduced to a misdemeanor, or the statute of limitations has expired for the felony arrest charges, the sample will be expunged.
- 7.2.5.2.4.4.5 If the only listed charges in the criminal history are misdemeanors or there are no listed charges, the sample will be expunged.

### 7.2.5.3 Laboratory Removal/Expungement Procedures

- 7.2.5.3.1 If any sample warrants expungement the following procedures will be followed:
  - 7.2.5.3.1.1 The sample record will be deleted from the CODIS Database.
  - 7.2.5.3.1.2 The sample itself will be pulled from storage and destroyed. An index card or equivalent with the sample number and the word "expunged" will be filed in the storage location instead of the sample. There will be no personally identifying information on this index card relating to the destroyed sample; the index card will simply act as a placeholder and allow the CODIS Unit to perform any necessary inventories.

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7.2.5.3.1.3 The CoDNA record in the LIMS system will be updated in the following manner:

7.2.5.3.1.3.1 The “Offense Type” will be converted to “E” (Expunged).

7.2.5.3.1.3.2 The “Profile in CODIS” field will be updated to “No.”

7.2.5.3.1.3.3 The “Status of Sample” field will be updated to “Closed.”

7.2.5.3.1.3.4 Personally identifying information will be removed from the record. Related charges may be kept for statistical purposes.

7.2.5.3.1.4 Either the DNA Profile Administrative Removal/Expungement Form (CODIS\_Admin\_Removal\_Expunge) will be completed or the expungement will be documented in the OSBI CODIS EXPUNGEMENTS Database.

7.2.5.3.2 **Notification:** For requested expungements of convicted offender samples, notification of administrative removal or expungement will be in writing from the CODIS administrator, or designee, to the requestor on official OSBI letterhead.

7.2.5.3.2.1 In the event the DNA profile being expunged has generated a match with another laboratory through the CODIS database, the CODIS administrator, or designee, will notify the CODIS administrator from the other laboratory involved in the match, and inform them that an expungement is being performed.

7.2.5.3.3 **Documentation:** The OSBI CODIS Unit will retain a copy of all appropriate documents relating to the removal or expungement including, but not limited to:

7.2.5.3.3.1 All correspondence and associated documentation, such as court orders, removal and/or expungement requests, criminal history, letters from NDIS, etc.,

7.2.5.3.3.2 Completed DNA Profile Administrative Removal/Expungement Form (CODIS\_Admin\_Removal\_Expunge), and

7.2.5.3.3.3 Letter(s) of notification to the requestor(s).

### 7.2.6 Removal of Casework Profiles

7.2.6.1 A casework or database analyst shall request that a forensic casework profile that is found to be improperly included in the database be removed from the CODIS database by forwarding a completed CODIS Request for Profile Removal Form (CODIS\_Profile\_Removal\_Request) to the CODIS Unit, as specified in [CODIS\\_1 \(Data Entry & Search Procedures\)](#) of this policy manual.

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7.2.6.2 A copy of all documents relating to the removal of the forensic casework profile including, but not limited to, the CODIS Request for Profile Removal Form and the Delete Specimen Report will be retained in the casefile for the forensic sample.

### 7.3 Notes

- 7.3.1 For the purposes of this policy, a known DNA profile can be from any legally obtained known reference sample, including convicted offender samples, arrestee samples, and/or legal samples.
- 7.3.2 An arrestee sample which has a previous qualifying conviction, or which results in a qualifying conviction, may be converted to the appropriate offense type code in CoDNA at any time.
- 7.3.3 A sample that has been collected having a suspended sentence may be kept indefinitely.
- 7.3.4 A sample that has been collected having a delayed or deferred sentence can be legally kept until the end of the deferment. If a sex offender registration has a deferred or delayed sentence, however, the sample may be kept indefinitely.

#### **Attachment(s):**

OSBI CODIS Unit Policy Manual **CODIS\_Admin\_Removal\_Expunge**

OSBI CODIS Unit Policy Manual **CODIS\_Profile\_Removal\_Request**

#### **Reference(s):**

FBI National DNA Index System (NDIS) Operational Procedures Manual

FBI National DNA Index System (NDIS) Operational Procedures NDIS Security Requirements

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories



# Quality Control Procedures

## QC\_1 CLEANING, DECONTAMINATION & STERILIZATION ([↑ Table of Contents](#))

### Quick links:

[DBQM\\_9 \(Analytical Procedures\)](#)

### 1.1 Scope

Quality control for cleaning and decontamination in the CODIS Unit laboratory.

### 1.2 Reagents & Supplies

1.2.1 1:10 bleach, alcohol and/or cleaner labeled as tuberculocidal

1.2.2 Detergent

### 1.3 Equipment

1.3.1 UV crosslinker

1.3.2 Autoclave

1.3.3 Dishwasher, if available

### 1.4 Individual Steps of Protocol

#### 1.4.1 General Decontamination

##### 1.4.1.1 Instruments

1.4.1.1.1 Instruments used to process biological samples (e.g., forceps, scissors, etc.) shall be cleaned with an approximate 1:10 bleach solution or alcohol before and after each sample is handled.

1.4.1.1.2 Exposure to ultraviolet light for a minimum of 15 minutes in a UV crosslinker should be used to decontaminate articles that are small enough to fit into the unit and that will not be damaged by the ultraviolet light.

##### 1.4.1.2 Equipment

1.4.1.2.1 Equipment shall be decontaminated with an approximate 1:10 bleach solution or alcohol (based on manufacturer recommendations and/or equipment type, e.g., use alcohol on stainless steel), periodically, as needed.

1.4.1.2.2 This shall be documented on the Decontamination Log ([QC\\_Decontamination\\_Log](#)) associated with the equipment.

##### 1.4.1.3 Floors

1.4.1.3.1 Use an approximate 1:10 bleach solution for decontamination of floors, as necessary.

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### 1.4.1.4 Work Surfaces

- 1.4.1.4.1 Work surfaces shall be cleaned with an approximate 1:10 bleach solution both before **and** after each use.
- 1.4.1.4.2 Biological samples shall be handled on a clean sheet of paper or benchkote-like material to minimize the potential for work surface contamination.

### 1.4.1.5 General Laboratory Glassware & Plasticware

- 1.4.1.5.1 Glassware and plastic containers can be cleaned with detergent and completely rinsed with tap water, and then distilled water, by hand, immediately after use.
- 1.4.1.5.2 An automatic dishwasher may be used instead of handwashing.
  - 1.4.1.5.2.1 If a dishwasher is used, glassware must be rinsed with distilled water either after washing or before use.

### 1.4.1.6 Glassware & Plasticware Used to Handle Biohazards

- 1.4.1.6.1 Clean and sterilize any glassware and/or plasticware used to handle biological samples following such a procedure:
  - 1.4.1.6.1.1 Rinse item with an approximate 1:10 bleach solution or a cleaner labeled as tuberculocidal and then wash as above with detergent.
  - 1.4.1.6.1.2 In addition to above, ultraviolet light exposure for ~15-30 minutes can be used for sterilization.
  - 1.4.1.6.1.3 In addition to above, steam and/or heat sterilization in an autoclave can be used for items that will not melt.

### 1.4.1.7 Solutions, Utensils & Tubes Necessary for DNA Analysis

- 1.4.1.7.1 Sterilized by exposure to UV light for a minimum of 15 minutes in a UV crosslinker prior to use.
- 1.4.1.7.2 Only small aliquots of solutions should be used during analysis.

## 1.4.2 Solutions & Supplies Requiring Sterilization

### 1.4.2.1 Autoclaving

- 1.4.2.1.1 Autoclaving (sterilization) of solutions, if required, should be performed at the time of preparation. Each respective reagent preparation procedure shall indicate if the solution requires sterilization by autoclaving.
- 1.4.2.1.2 Steam autoclaving of solutions should be performed at ~120°C for ~20 minutes following the instructions from the autoclave operations manual.
- 1.4.2.1.3 Use autoclave indicator tape on the containers.

## Quality Control Procedures

1.4.2.1.4 After autoclaving is complete, check the indicator tape to make sure sterilization has taken place. If tape has not turned black, repeat procedure.

### 1.4.2.2 Ultraviolet Crosslinker

1.4.2.2.1 If crosslinking is required, items will be exposed to UV light (short wave: 254nm) for a minimum of 15 minutes following instructions within the operator's manual for use of the crosslinker.

1.4.2.2.2 The crosslinker should be equipped with short wave (254 nm) tubes in order to ensure decontamination.

### 1.4.3 Decontamination Following a Contamination Event

1.4.3.1 Following any contamination event, the CODIS Unit should perform a standardized decontamination procedure after the remediation method has been determined. The following may be utilized:

1.4.3.1.1 Discard facemask(s) and obtain a new facemask, if applicable.

1.4.3.1.2 Remove laboratory coat(s) from the laboratory and have it/them cleaned or obtain a new disposable lab coat.

1.4.3.1.3 Dispose of aliquots of reagents, such as any kit(s)/reagent(s) that have been tested and shown to be contaminated.

1.4.3.1.4 Decontaminate all supplies (e.g. pipettors, racks, decappers, etc.) and equipment (e.g. centrifuges, hoods, etc.) used throughout the analysis process with an approximate 1:10 bleach solution or alcohol (based on manufacturer recommendations and/or equipment type, e.g. use alcohol on stainless steel).

1.4.3.1.5 Decontaminate all work areas, including common areas, potentially used throughout the analysis process with an approximate 1:10 bleach solution.

1.4.3.1.6 UV crosslink all small supplies and reagents associated with the analysis process.

#### **Attachment(s):**

OSBI CODIS Unit Policy Manual **QC\_Decontamination\_Log**

#### **Reference(s):**

Systemc DX/DE Series Operating Manual (autoclave user guide)

Spectroline Microprocessor-Controlled UV Crosslinkers Operator's Manual

SWGDM Contamination Prevention and Detection Guidelines for Forensic DNA Laboratories

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

OSBI Forensic Biology Units' Training Manual

# Quality Control Procedures

## QC\_2 CROSSLINKERS ([↑ Table of Contents](#))

### 2.1 Scope

Quality control for crosslinker to ensure optimal operation.

### 2.2 Reagents & Supplies

2.2.1 Crosslinker bulb (short wave, 254 nm)

### 2.3 Equipment

2.3.1 Crosslinker

### 2.4 Individual Steps of the Procedure

#### 2.4.1 Performance Check

2.4.1.1 At a minimum, the CODIS Unit shall perform an annual performance check for each crosslinker.

2.4.1.2 The procedure listed in the operator's manual shall be used to check the intensity of the bulbs.

2.4.1.3 If the performance check is not completed within the anniversary month of the last performance check, the crosslinker shall be removed from service until a performance check is successfully completed.

2.4.1.4 Document the results on the general Equipment Maintenance Log (**QC\_Equip\_Maint\_Log**).

#### **Attachment(s):**

OSBI CODIS Unit Policy Manual **QC\_Equip\_Maint\_Log**

#### **Reference(s):**

Spectroline Microprocessor-Controlled UV Crosslinkers Operator's Manual

# Quality Control Procedures

## QC\_3 NIST CERTIFIED EQUIPMENT (↑ [Table of Contents](#))

### 3.1 Scope

Quality control for NIST certified equipment to ensure optimum operation.

### 3.2 Equipment

3.2.1 Any NIST certified equipment, such as weights, timers, tachometers, temperature verification systems, thermometers, etc.

### 3.3 Individual Steps of the Procedure

3.3.1 The calibration for weights, timers, tachometers, and delegated temperature verification systems is to be performed annually or prior to the expiration date of the current NIST certificate, whichever is longer. Thermometers must be calibrated annually.

3.3.2 Contact a company/business that is an authorized NIST certifying body and meets the accreditation requirements for an external service provider, such as Probata Corporation at (405) 607-4813, or the NIST Calibration Program at (301) 975-2092 or [calibrations@nist.gov](mailto:calibrations@nist.gov) to arrange for the calibration.

3.3.3 Once an IPR is approved, deliver to the agency directed by the NIST representative for the calibration.

3.3.4 The vendor shall ascertain and certify that the equipment is functioning appropriately. Notification should be given if repairs or replacement are required before service is performed and before instrument is returned for use.

3.3.5 Calibration and maintenance records for NIST certified equipment will be maintained accordingly.

### 3.4 Notes

3.4.1 It may be more cost effective to replace NIST certified timers at the end of their current certificate rather than to send for recalibration.

#### Attachment(s):

None

#### Reference(s):

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

International Standard ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories

ANAB ISO/IEC 17025:2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125)

# Quality Control Procedures

## QC\_4 REFRIGERATORS & FREEZERS ([↑ Table of Contents](#))

### 4.1 Scope

Quality control for refrigerators and freezers to ensure optimum operation.

### 4.2 Equipment

4.2.1 Refrigerator/freezer (with thermometer to measure temperature)

### 4.3 Individual Steps of Procedure

4.3.1 At least once a week, refrigerator and freezer temperatures shall be checked and recorded on the Temperature Log (**QC\_Temp\_Log**) and maintained in the appropriate location on the network.

4.3.1.1 The weekly temperature should not be recorded when the unit is in defrost mode.

4.3.1.2 The individual recording the temperature shall check the records for any variances from the expected value that may show the performance of the unit over several measurements is unsatisfactory.

4.3.1.3 If the weekly check results in a temperature outside of the expected temperature range, the individual performing the temperature check shall check again in 15 to 30 minutes or make an adjustment to the temperature setting and repeat the check in 30 minutes.

4.3.1.4 If the temperature remains outside the acceptable range, the individual performing the check shall notify the unit supervisor immediately and take the action described below for unsatisfactory unit performance.

4.3.1.5 Equipment can be inspected at this time for mold, mildew, excess frost/ice buildup or any other possible deleterious condition that may require maintenance. Any maintenance shall be recorded on the equipment maintenance log.

### 4.4 Interpretation of Results (Refrigerator/Freezer Performance)

4.4.1 For unsatisfactory unit performance (i.e., temperature outside of expected):

4.4.1.1 The unit shall be inspected and the cause of any variance determined and corrected.

4.4.1.2 If the cause cannot easily be determined or corrected by in-house personnel, the unit shall be emptied and placed "out of service" until function is restored or the unit replaced.

4.4.1.2.1 The contents shall be transferred to a working unit (if possible) or to a temporary storage container until expedient arrangement can be made for proper storage.

4.4.1.2.2 The date the unit is placed out of service shall be recorded on the Temperature Log (**QC\_Temp\_Log**) and maintained in the appropriate location on the network.

4.4.1.2.3 The unit supervisor or designee shall arrange to have the unit repaired or replaced.

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- 4.4.2 If a unit sets off an alarm, the alarm monitoring company, as per contract, should contact the designated contact person for that laboratory in a timely manner. The contact person shall notify, if necessary, the appropriate unit supervisor or his/her designee in a timely manner. The supervisor/designee shall take the action described above.

### 4.5 Notes

- 4.5.1 Standard refrigerators should generally maintain a temperature range of approximately 1°C to 10°C. Standard freezers should generally maintain a temperature range of approximately -30°C to 0°C. Specific protocols that specify a temperature range shall supersede the aforementioned ranges.
- 4.5.2 Refrigerator/freezer units with frost-free functions have short duration defrost cycles. The monitoring probes should be placed such that they are not in an area where the temperature fluctuates enough to set off the alarm during defrost cycles, and the alarm monitoring pad should be set to take the variance into account.
- 4.5.3 Each thermometer should be placed in an easily visible location. The bulb, sensor, or probe portion should be free from contact with any other item or material.
- 4.5.4 Unless otherwise specified in superseding protocols, thermometers do not need to be NIST traceable or require any calibration.
- 4.5.5 The contents of each refrigerator/freezer unit should be arranged and reasonably limited so that the proper circulation of air within the unit is maintained.

### Attachment(s):

OSBI CODIS Unit Policy Manual **QC\_Temp\_Log**

### Reference(s):

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

# Quality Control Procedures

## QC\_5 BALANCE ([↑ Table of Contents](#))

### 5.1 Scope

Quality control for balance to ensure optimum operation.

### 5.2 Equipment

#### 5.2.1 Balance

### 5.3 Individual Steps of the Procedure

#### 5.3.1 Routine Maintenance

To keep the balances operating properly, the housing, chamber and pan should be kept clean and free from foreign material. If necessary, a cloth dampened with a mild detergent may be used for cleaning.

#### 5.3.2 Performance Check

5.3.2.1 At a minimum, the CODIS Unit shall perform an annual performance check on each balance. The performance check will be performed by an external vendor in accordance with OSBI CSD QM 6.5 (Metrological Traceability) and QP 24 (Calibration and Handling of Equipment).

5.3.2.2 If the performance check is not completed within the anniversary month of the last performance check, the balance shall be removed from service until a performance check is successfully completed.

#### 5.3.3 Required Documentation

5.3.3.1 Archive the certification from the external vendor in the appropriate network folder as documentation of the successful completion of the performance check.

5.3.3.2 If no certificate is available, the performance check will be documented using the general Equipment Maintenance Log (**QC\_Equip\_Maint\_Log**) and maintained in the appropriate location on the network.

### 5.4 Interpretation of Results (Balance Performance)

5.4.1 If any balance fails to perform within the accepted range, troubleshooting procedures provided in that individual model's instructions and operator's manual should be followed.

5.4.2 If problems persist that cannot be corrected in the laboratory, the balance shall be serviced by an authorized service center.

5.4.3 Certification from the external vendor shall serve as the successful completion of the performance check.

#### Attachment(s):

OSBI CODIS Unit Policy Manual **QC\_Equip\_Maint\_Log**

#### Reference(s):

Mettler Toledo Excellence Analytical Balances XSE Models Operating Instructions

OSBI Criminalistics Services Division Quality Manual and Quality Procedures



## **Quality Control Procedures**

FBI Quality Assurance Standards for DNA Databasing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

# Quality Control Procedures

## QC\_6 PIPETTORS ([↑ Table of Contents](#))

### Quick link:

[DBQM\\_10 \(Equipment\)](#)

### 6.1 Scope

Quality control for pipettors (mechanical pipettes) to ensure optimum operation.

### 6.2 Reagents & Supplies

6.2.1 Weighing receptacle (e.g., water trap or weigh boat)

6.2.2 Deionized water

### 6.3 Equipment

6.3.1 Mechanical pipet

6.3.2 Balance (calibrated)

6.3.3 Calibri software, if available

### 6.4 Individual Steps of the Procedure

#### 6.4.1 Performance Check

6.4.1.1 At a minimum, the CODIS Unit shall perform an annual performance check on all pipettors. The annual performance check may be completed in-house or by an external vendor.

6.4.1.2 If the performance check is not completed within the anniversary month of the last performance check, the pipettor shall be removed from service until a performance check is successfully completed.

#### 6.4.2 Pipettor Type Requirements

6.4.2.1 Adjustable pipettors shall be checked at the minimum and maximum values, with the exception of the 2 $\mu$ L and 10 $\mu$ L pipettors, which will be checked using 1 $\mu$ L for the minimum value. For Rainin pipettors, the range for P-2 is 0.1 to 2 $\mu$ L, P-10 is 0.5 to 10 $\mu$ L, P100 is 10 to 100 $\mu$ L, P-200 is 50 to 200 $\mu$ L and P-1000 is 100 to 1000 $\mu$ L.

6.4.2.2 Repeat pipettors shall be checked at the minimum and maximum values based on the dispensing volume range associated with the attached tip, and they shall be labeled with the approved volume range.

6.4.2.3 Multichannel pipettors shall be checked at the minimum and maximum values with the exception of 10 $\mu$ l multichannel pipettors which will be checked using 1 $\mu$ l for the minimum. Each channel being checked individually and the set of channels being checked collectively.

#### 6.4.3 Performing an In-House Performance Check

6.4.3.1 Using a calibrated balance, place a weighing receptacle on the balance and tare.

## Quality Control Procedures

6.4.3.2 Deliver the desired volume of water to the weighing receptacle and record the registered weight. This may be accomplished by using the Calibri software recording the measured volume.

6.4.3.3 If taking measurements by hand, calculate % error for each measurement using the formula:

$$(\text{Delivered Weight} - \text{Expected Weight}) / \text{Expected Weight} \times 100\%$$

### 6.4.4 Required Documentation

6.4.4.1 Document results of the in-house performance check for each pipettor using the Pipettor Performance Check Log (**QC\_Pipet\_PC\_Log**) and/or the Pipettor Performance Check Reproducibility Log (**QC\_Pipet\_PC\_Reproducibility\_Log**) and maintained on the network or archive the "Calibration Report" from the Calibri software in the appropriate QC folder on the network.

6.4.4.2 Certification from the external vendor shall serve as the successful completion of the performance check, including for any pipet sent to an external vendor for adjustment/maintenance. The calibration certificates issued by these competent calibrating laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

6.4.4.2.1 Calibration labs fulfilling the requirements of ISO 17025 are considered competent. Copies of ISO 17025 certificates shall be maintained with the calibration/test report as sufficient evidence of traceability of the calibration data reported. A review of the certificate(s) by the technical manager (or designee) and/or Lead Analyst shall serve as documentation of this check of compliance regarding function and calibration.

### 6.5 Interpretation of Results (Pipettor Performance)

6.5.1 Determine whether the pipettor passed or failed the performance check. The tolerance for pipettor volumes greater than or equal to 10µL is 3%. The tolerance range for volumes less than 10µL is 10%.

6.5.2 If the percent error is greater than the stated above, repeat measurement four more times. Average the volume of the five measurements and calculate the percent error using the Pipettor Calibration Reproducibility Log (**QC\_Pipet\_PC\_Reproducibility\_Log**). If the percent error is within the established tolerance, the pipettor is accepted as meeting criteria.

6.5.3 If the pipettor fails after five tries, adjustment/maintenance is necessary. This can be done in-house or at an authorized service center (external vendor).

#### Attachment(s):

OSBI CODIS Unit Policy Manual **QC\_Pipet\_PC\_Log**

OSBI CODIS Unit Policy Manual **QC\_Pipet\_PC\_Reproducibility\_Log**

OSBI CODIS Unit Policy Manual **QC\_Robotic\_Sys\_Pipet\_Tools\_PC\_Log** (reference QC\_12)

#### Reference(s):

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

## **Quality Control Procedures**

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

OSBI CODIS Unit Training Manual

# Quality Control Procedures

## QC\_7 THERMOMETERS ([↑ Table of Contents](#))

### Quick link:

[DBQM\\_10 \(Equipment\)](#)

### 7.1 Scope

Quality control for thermometers to ensure optimum operation.

### 7.2 Equipment

- 7.2.1 Thermometer
- 7.2.2 Water bath
- 7.2.3 NIST certified thermometer

### 7.3 Individual Steps of the Procedure

#### 7.3.1 Performance Check

- 7.3.1.1 At a minimum, the CODIS Unit shall perform an annual performance check on each NIST traceable thermometer used for conducting performance checks. The annual performance check can be accomplished either through certification by an external vendor or through verification in-house.
- 7.3.1.2 If the performance check is not completed within the anniversary month of the last performance check, the thermometer shall be removed from service until a performance check is successfully completed.
- 7.3.1.3 Perform an in-house performance check as follows:
  - 7.3.1.3.1 Set a water bath to the desired temperature.
  - 7.3.1.3.2 Allow water to heat for at least 30 minutes.
  - 7.3.1.3.3 Place bulb of each thermometer to be checked into the water bath along with the NIST certified thermometer.
  - 7.3.1.3.4 Wait several minutes and record the temperature on the Thermometer Performance Check Log (**QC\_Thermometer\_PC\_Log**).
  - 7.3.1.3.5 Wait 15 minutes and record the temperature again.
  - 7.3.1.3.6 Alternatively, the calibrating digital thermometer can be placed into the same equipment as the thermometer, be allowed to equilibrate, and the reading documented.

#### 7.3.2 Required Documentation

- 7.3.2.1 Archive the certification from the external vendor in the appropriate network folder as documentation of the successful completion of the performance check. If no certificate is available, the performance check will be documented on the Thermometer Performance Check Log (**QC\_Thermometer\_PC\_Log**) and maintained in the appropriate location on the network.

## Quality Control Procedures

7.3.2.2 In-house performance checks will be documented on the Thermometer Performance Check Log (**QC\_Thermometer\_PC\_Log**) maintained in the appropriate location on the network.

### 7.4 Interpretation of Results (Thermometer Performance)

- 7.4.1 If thermometer readings equal the NIST calibrated reading, no action is needed.
- 7.4.2 If the NIST thermometer measurement is within  $\pm 1$  degree of the thermometer being tested, then the amount of deviation shall be noted, and all other readings adjusted by the same amount, and in the same direction.
- 7.4.3 If the NIST thermometer measurement is more than  $\pm 1$  degree of the thermometer being tested, the thermometer shall be replaced or taken out of service.
- 7.4.4 Certification from the external vendor shall serve as the successful completion of the performance check.

#### **Attachment(s):**

OSBI CODIS Unit Policy Manual **QC\_Thermometer\_PC\_Log**

#### **Reference(s):**

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

# Quality Control Procedures

## QC\_8 TEMPERATURE VERIFICATION SYSTEM (TVS) ([↑ Table of Contents](#))

### Quick link:

[DBQM\\_10 \(Equipment\)](#)

### 8.1 Scope

Quality control for temperature verification system (TVS) (or temperature verification kit [TVK]) to ensure optimal operation.

### 8.2 Equipment

8.2.1 Temperature verification system (TVS)

### 8.3 Individual Steps of the Procedure

#### 8.3.1 Performance Check

8.3.1.1 The CODIS Unit shall perform an annual performance check consisting of obtaining an external vendor certification for each TVS used to complete the performance checks for the thermomixers and thermal cyclers (when performed in-house).

8.3.1.2 If the performance check is not completed within the anniversary month of the last performance check, the TVS shall be removed from service until a performance check is successfully completed.

#### 8.3.2 Required Documentation

8.3.2.1 Archive the certification from the external vendor in the appropriate network folder as documentation of the successful completion of the performance check.

### 8.4 Interpretation of Results (TVS Performance)

8.4.1 Certification from the external vendor shall serve as the successful completion of the performance check.

### Attachment(s):

None

### Reference(s):

OSBI Criminalistics Services Division Quality Manual and Quality Procedures

FBI Quality Assurance Standards for DNA Databasing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

# Quality Control Procedures

## QC\_9 THERMOMIXERS ([↑ Table of Contents](#))

### Quick link:

[DBQM\\_10 \(Equipment\)](#)

### 9.1 Scope

Quality control for thermomixers to ensure optimum operation.

### 9.2 Reagents & Supplies

9.2.1 Neutral cleaning agent

### 9.3 Equipment

9.3.1 Eppendorf ThermoMixer® C

9.3.2 Temperature Verification System (TVS) (certified)

9.3.3 Stopwatch or other certified timer

### 9.4 Individual Steps of the Procedure

#### 9.4.1 Cleaning

9.4.1.1 Use neutral cleaning agents to clean the ThermoMixer® housing and thermoblocks, as needed.

9.4.1.2 Ensure that all parts are dried thoroughly before use.

#### 9.4.2 Performance Check

9.4.2.1 At a minimum, the CODIS Unit shall perform an annual performance check for each ThermoMixer® consisting of both a temperature and timer verification.

9.4.2.2 If the performance check is not completed within the anniversary month of the last performance check, the ThermoMixer® shall be removed from service until a performance check is successfully completed.

#### 9.4.2.3 Temperature Verification

9.4.2.3.1 Remove the 0.02mL well cover located in the middle of the smart block (if present).

9.4.2.3.2 Verify the appropriate temperatures used in policy (see [CODIS\\_3 \[Direct Amplification of DNA Using GlobalFiler\]](#)) with a Temperature Verification System (TVS).

9.4.2.3.3 Document the results on the ThermoMixer® Performance Check Log ([QC\\_Thermomixer\\_PC\\_Log](#)).

#### 9.4.2.4 Timer Verification

9.4.2.4.1 Measure the timer against a stopwatch or other calibrated timer set for the same time interval.



## Quality Control Procedures

- 9.4.2.4.2 Document the results on the ThermoMixer® Performance Check Log (QC\_Thermomixer\_PC\_Log).

### 9.5 Interpretation of Results (ThermoMixer® Performance)

#### 9.5.1 Temperature

9.5.1.1 If the temperature is more than 1.0°C above or below the desired temperature, the test is to be run two more times.

9.5.1.2 If the temperature verification fails two of the three times, the ThermoMixer® shall be removed from service and a qualified service technician shall be contacted.

#### 9.5.2 Timer

9.5.2.1 If the timer varies more than 30 seconds in five minutes, the instrument shall be removed from service and a qualified service technician shall be contacted.

#### **Attachment(s):**

OSBI CODIS Unit Policy Manual **QC\_Thermomixer\_PC\_Log**

#### **Reference(s):**

Eppendorf ThermoMixer® C Operating Manual

FBI Quality Assurance Standards for DNA Databasing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

# Quality Control Procedures

## QC\_10 PROFLEX™ PCR SYSTEMS ([↑ Table of Contents](#))

### Quick link:

[DBQM\\_10 \(Equipment\)](#)

### 10.1 Scope

Quality control for Applied Biosystems™ ProFlex™ PCR Systems to ensure optimum thermal cyclers operation.

### 10.2 Equipment

10.2.1 Applied Biosystems™ ProFlex™ PCR System

10.2.2 Temperature Verification Kit (TVK) (certified)

### 10.3 Individual Steps of the Procedure

#### 10.3.1 Maintenance Schedule

##### 10.3.1.1 Monthly

10.3.1.1.1 Perform the Self-Verification Test (SVT):

10.3.1.1.1.1 In the Home Screen, select **Settings**, then **Maintenance & Services**, then **Self Verification Test**.

10.3.1.1.1.2 In the Self Verification Test screen, select **Start Test** (test take about 10 minutes and the results are displayed in the form of a report).

10.3.1.1.1.3 Save the test report to the USB drive by selecting **Export**.

10.3.1.1.1.4 Record completion of test and results.

10.3.1.1.2 Clean sample block/wells.

10.3.1.1.3 Clean heated cover.

##### 10.3.1.2 Annually

10.3.1.2.1 Performance check (see below).

##### 10.3.1.3 As Needed

10.3.1.3.1 Replace fuses.

10.3.1.3.2 Upgrade system firmware (in consultation with technical manager and/or lead analyst).

10.3.1.3.3 Decontaminate sample block/wells.

10.3.1.3.4 Decontaminate heated cover.

## Quality Control Procedures

### 10.3.2 Annual Performance Check (Planned/Preventative Maintenance)

10.3.2.1 At a minimum, the CODIS Unit shall perform an annual performance check on each ProFlex™ PCR System. The annual performance check can be achieved by the planned/preventative maintenance (PM) of the instrument when performed by a qualified service technician from an external vendor (e.g., manufacturer), or, if a PM is not performed, a performance check will be completed using a Temperature Verification Kit (TVK).

10.3.2.2 If the performance check is not completed within the anniversary month of the last performance check, the ProFlex™ PCR System shall be removed from service until a performance check is successfully completed.

### 10.3.3 Performance Check Following Repair, Service or Calibration

10.3.3.1 Each ProFlex™ PCR System shall undergo a performance check after any repair, service or calibration and before use in databasing. The performance check will be completed in-house using either the Self-Verification Test (SVT) and/or the Temperature Verification Kit (TVK), as indicated by the technical manager and/or Lead Analyst, or alternatively, certification from an external vendor may also serve as the successful completion of the performance check.

### 10.3.4 Required Documentation

10.3.4.1 Record all maintenance tasks and performance checks performed on the on the ProFlex™ PCR System Maintenance Log (**QC\_ProFlex\_Maint\_Log**) and/or ProFlex™ PCR System Performance Check Log (**QC\_ProFlex\_PC\_Log**) and maintain in the appropriate network folder.

10.3.4.2 Record completion of the Self-Verification Test (SVT) on the ProFlex™ PCR System Maintenance Log (**QC\_ProFlex\_Maint\_Log**). Results must either be documented on the ProFlex™ PCR System Performance Check Log (**QC\_ProFlex\_PC\_Log**), or the instrument logs may be exported and stored digitally in the appropriate quality record folder. If a SVT is performed by a qualified service technician, the instrument logs and service call forms will be stored in the appropriate quality record folder

10.3.4.3 Archive the certification from the external vendor, such as field service reports, in the appropriate network folder as documentation of the successful completion of the performance check.

### 10.4 Interpretation of Results (ProFlex™ PCR System Performance)

10.4.1 If a ProFlex™ PCR System fails to perform correctly, the self-verification test may be repeated and the technical manager, Lead Analyst, and supervisor will be notified.

10.4.2 If continued attempts fail, the instrument shall be removed from service and a qualified service technician shall be contacted.

10.4.3 Certification from the external vendor shall serve as the successful completion of the performance check.

#### Attachment(s):

OSBI CODIS Unit Policy Manual **QC\_ProFlex\_Maint\_Log**

OSBI CODIS Unit Policy Manual **QC\_ProFlex\_PC\_Log**

## Quality Control Procedures

**Reference(s):**

Life Technologies™ ProFlex™ PCR System User Guide

FBI Quality Assurance Standards for DNA Databasing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

# Quality Control Procedures

## QC\_11 3500xL GENETIC ANALYZER ([↑ Table of Contents](#))

### Quick link:

[DBQM\\_10 \(Equipment\)](#)

### 11.1 Scope

Quality control for the 3500xL Genetic Analyzer. This protocol summarizes common tasks required to properly maintain and calibrate the 3500xL Genetic Analyzer under normal conditions. Other service work must be referred to a qualified service technician.

### 11.2 Reagents & Supplies

- 11.2.1 Capillary array
- 11.2.2 Anode Buffer Container (ABC)
- 11.2.3 Cathode Buffer Container (CBC)
- 11.2.4 Performance Optimized Polymer 4 (POP-4™)
- 11.2.5 Conditioning Reagent
- 11.2.6 HID Install Standard
- 11.2.7 Hi-Di™ Formamide
- 11.2.8 Genescan™ LIZ® Internal Lane Standard 600 (LIZ ILS 600)
- 11.2.9 Applied Biosystems™ J6 Matrix Standards (DS36)
- 11.2.10 Deionized water
- 11.2.11 Syringe
- 11.2.12 Kimwipe or equivalent lint-free cloth
- 11.2.13 96-well optical reaction plate
- 11.2.14 96-well septa mat
- 11.2.15 Plate base and retainer

### 11.3 Equipment

- 11.3.1 Applied Biosystems™ 3500xL Genetic Analyzer
- 11.3.2 Mechanical pipettors
- 11.3.3 Vortex
- 11.3.4 MiniSpin
- 11.3.5 Centrifuge

## Quality Control Procedures

- 11.3.6 Available equipment for performing heat denature/snap cool (e.g., thermal cycler/freezer, ice or cold block)

### 11.4 Individual Steps of the Procedure

#### 11.4.1 Maintenance Schedule

The following outlines the schedule for the specific maintenance tasks needed to ensure optimal performance of the 3500xL Genetic Analyzer and computer. Tasks can be performed less often if the instrument is not in use, as long as the tasks are performed before the next use.

##### 11.4.1.1 Daily (or before each run when instrument is not used daily)

11.4.1.1.1 Check Dashboard.

11.4.1.1.2 Visually inspect the fluid level in the buffer containers.

##### 11.4.1.2 Weekly (every 7 days when instrument is in use)

11.4.1.2.1 Check storage condition of used array to ensure array tip is covered in the reservoir.

11.4.1.2.2 Record number of runs.

11.4.1.2.3 Run Wash Pump and Channels Wizard (i.e. water wash).

##### 11.4.1.3 Bi-Weekly

11.4.1.3.1 Replace anode and cathode buffers.

11.4.1.3.2 Replace septa on reservoirs.

11.4.1.3.3 Replace POP-4™ pouch.

##### 11.4.1.4 Monthly

11.4.1.4.1 Flush pump trap.

11.4.1.4.2 Empty condensation container and water trap waste container.

11.4.1.4.3 Examine instrument for any residue and, if present, wipe with deionized water and a lint-free cloth.

##### 11.4.1.5 Annually

11.4.1.5.1 Performance check (see below).

##### 11.4.1.6 As Needed

11.4.1.6.1 Restart the computer.

11.4.1.6.2 Install new capillary array. Capillary arrays can be used until undesirable data such as poor sizing precision, poor allele calling, poor resolution, or decreased signal intensity is consistently observed.

## Quality Control Procedures

- 11.4.1.6.3 Perform spatial calibration after replacing a capillary array; when a service engineer performs an optical service procedure, such as realigning or replacing the laser, CCD cameras or mirrors; when the detector door is opened or the detection cell is moved; or when the instrument is moved.
- 11.4.1.6.4 Perform spectral calibration after replacing a capillary array; if there is a change to the dye set or polymer type; when a service technician performs an optical service procedure, such as realigning or replacing the laser, CCD cameras or mirrors; or when an increase of spectral separation (pull-up/pull-down peaks) is observed in the raw or analyzed data.
  - 11.4.1.6.4.1 Place a copy of the Spectral Report in the QC folder on the instrument computer desktop.
  - 11.4.1.6.4.2 If using the OSR (Off-Scale Reduction) function of the collection software, the dye set chosen for the spectral calibration needs to have the OSR extension.
- 11.4.1.6.5 Defragment the computer hard drive. The fragmentation of files decreases the performance of the Data Collection Software and the computer operating system; programs take a longer time to access files by performing multiple search operations of the fragments.
  - 11.4.1.6.5.1 In the Windows desktop, select **Start > Programs > Accessories > System Tools > Disk Defragmenter** and follow the prompts. (Note: You can click **Analyze** to see if you should defragment or not.)
    - 11.4.1.6.5.1.1 Do not manually delete spectral plate records or spectral information from the database. Doing so will permanently delete spectral information.
    - 11.4.1.6.5.2 Once complete, a dialog box will appear and allow you to view a report or close.
- 11.4.1.6.6 Archive the Library to the appropriate location on the network.
- 11.4.1.6.7 Run the HID Install Standard.

### 11.4.2 Annual Performance Check (Planned/Preventative Maintenance)

- 11.4.2.1 At a minimum, the CODIS Unit shall perform an annual performance check on the 3500xL Genetic Analyzer. The performance check performed after the annual planned/preventative maintenance (PM) from an external vendor (e.g. manufacturer) will serve as the annual performance check.
- 11.4.2.2 The annual PM will be performed by a qualified service technician.
- 11.4.2.3 Following the completion of the annual PM, a performance check will be performed for the 3500xL Genetic Analyzer to verify the instrument conforms to analysis sizing precision, sizing range, and peak height specifications.

## Quality Control Procedures

11.4.2.3.1 The performance check will consist of the evaluation of the first successful positive control, negative control, and ladder ran on the instrument. This performance check is required prior to the acceptance of data. These controls may be run concurrently with database samples, but if the controls fail, no data from the plate will be accepted.

11.4.2.3.2 If instrument sensitivity concerns are present, the technical manager and/or lead analyst will be notified and a dilution series shall be analyzed at the instruction of the technical manager.

11.4.2.4 If the PM and performance check are not completed within the anniversary month of the last performance check, the 3500xL Genetic Analyzer shall be removed from service until they have been successfully completed.

### 11.4.3 Performance Check Following Installation of Capillary Array or Repair, Service or Calibration

11.4.3.1 A performance check will be performed for the 3500xL Genetic Analyzer to verify the instrument conforms to analysis sizing precision, sizing range, and peak height specifications after the replacement of the capillary array (including reinstallation of one that has been stored) or following any repair, service or calibration, including when alterations to the optics of the instrument (i.e. laser or other optical components) have been performed.

11.4.3.2 The performance check will consist of the evaluation of the first successful positive control, negative control, and ladder ran on the instrument and is required prior to the acceptance of data. This performance check is required prior to the acceptance of data. These controls may be run concurrently with database samples, but if the controls fail, no data from the plate will be accepted.

11.4.3.3 If instrument sensitivity concerns are present, the technical manager and/or lead analyst will be notified and a dilution series shall be analyzed at the instruction of the technical manager or lead analyst.

### 11.4.4 Required Documentation

11.4.4.1 Place a copy of the Spectral Report in the QC folder on the instrument computer desktop.

11.4.4.2 Record all maintenance tasks performed on the 3500xL Genetic Analyzer Maintenance and Performance Check Log (**QC\_3500xL\_Maint\_&\_PC\_Log**) on the network.

11.4.4.3 Record all performance checks performed on the 3500xL Genetic Analyzer Maintenance and Performance Check Log (**QC\_3500xL\_Maint\_&\_PC\_Log**) on the network. In addition, document the results of the performance check by saving them to the appropriate network folder, including the electropherograms of the controls.

11.4.4.4 Archive the certification from the external vendor, such as field service reports, in the appropriate network folder.

### 11.5 Interpretation of Results (3500xL Genetic Analyzer Performance)

11.5.1 If the 3500xL Genetic Analyzer fails to perform correctly, the instrument shall undergo troubleshooting to the extent of the technical skills of the laboratory personnel in an attempt to re-establish satisfactory performance.



## Quality Control Procedures

11.5.2 If the 3500xL Genetic Analyzer continues to yield unsatisfactory performance, the instrument shall be removed from service and a qualified service technician shall be contacted.

**Attachment(s):**

OSBI CODIS Unit Policy Manual **QC\_3500xL\_Maint\_&\_PC\_Log**

**Reference(s):**

Applied Biosystems™ 3500/3500xL Genetic Analyzer User Guide

Applied Biosystems™ 3500/3500xL Genetic Analyzer with 3500 Series Data Collection Software 4.0.1 User Guide

FBI Quality Assurance Standards for DNA Databasing Laboratories

SWGDM Guidance Document for the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories

## Approval

Per OSBI CSD QP 2 (Document Control), technical protocols/procedures, discipline quality manuals, and related attachments and references will be approved by the appropriate technical manager and the OSBI CSD director, or designee.

**Joseph Orcutt,  
Technical Manager,  
Forensic Biology Discipline**

  
\_\_\_\_\_  
Signature

7/31/23  
Date

**Janice Joslin,  
Laboratory Director,  
OSBI CSD**

\_\_\_\_\_  
Signature

07/31/2023  
Date

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