DNA Case Files, Reports, and Reviews

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1 INTRODUCTION

These procedures supplement the FBI Laboratory level 1 documents and establish procedures for the preparation and review of *Laboratory Reports* (7-1 or 7-1 LIMS) and FBI Laboratory File records in the DNA discipline. These procedures also supplement the Level 1 and Level 2 documents, as applicable, when the DNA Casework Unit (DCU) issues an i3 product in lieu of a *Laboratory Report*.

2 SCOPE

This document applies to DNA personnel in the DCU that prepare or review DNA case notes and *Laboratory Reports* (or i3 products).

3 PROCEDURES

3.1 Technical Records

Refer to the Level 1 documents for definitions and requirements of technical records.

A. Technical records that are case notes (See LAB-100) or analytical documentation (See QAS) that support the results/conclusions in the report and/or that influence or provide evidence of decision-making for the case will be retained in the FBI Laboratory File in accordance with the appropriate level 1 documents [See Appendix A for examples].
B. Other technical records (e.g., QA/QC records, electronic data files, records not specific to a case) that are not retained in the FBI Laboratory File will be retained typically in STACS, in Laserfiche, on BASNet, or on SharePoint [See Appendix B for examples].
C. Records that meet the FBI Definition of Transitory Records will not be retained beyond 180 days in accordance with FBI policy [See Appendix C for examples].

3.1.1 Case Notes / Analytical Documentation

A. The DCU uses Sample Tracking and Control Software (STACS) in lieu of Forensic Advantage (FA) to record and/or generate many case-related records.
    1. FBI Laboratory File records are uploaded to FA and transferred to Sentinel for retention in the 1A upon completion of the DNA case record.
B. Sufficient information (i.e., barcode or other unique identifier) regarding the instruments and reagents used in the laboratory activities will be recorded as prompted by STACS or the templates used to record case notes (e.g., the mtDNA Workbook for Sanger sequencing).
C. Nuclear DNA electropherograms (EPG) retained in the FBI Laboratory File (i.e., printouts or PDFs) should be of sufficient resolution to demonstrate that all DNA types are supported by the analytical data during technical review.

D. When a single lab number has multiple FA Case Records in the DNA units, the records retained for each Case Record may be truncated to the pages of technical records that support the report for the specific Case Record.
E. A list of commonly used abbreviations/symbols in DNA records is available within the DNA QA Manual (i.e., BIO-101).
F. The Examiner will ensure they have reviewed the data and results for each laboratory activity in the FBI Laboratory File.
    1. The Examiner's initials or secure electronic equivalent on an electronic (or printed) record is the documentation of this review.
    2. If the Examiner is not the individual that generated the case notes for a laboratory activity, the Examiner will record their review typically by using available electronic tools (e.g., Adobe Acrobat Pro) to mark at least the first page of a PDF, by approving the record when uploaded to the Case Record Object Repository in FA, or by recording their review in a communication log.
    3. Procedural and interpretation notes retained in the FBI Laboratory File may contain deliberative material used by the Examiner (or reviewers) and may not reflect the final interpretation decisions. The *Laboratory Report* (or i3 product) will reflect the final results and conclusions.
        i. Case notes added to the FBI Laboratory File during the review process will be reviewed by the Examiner prior to upload to Sentinel. The Examiner's approval in Sentinel will be the documentation of this review.
G. Copies of records generated by other Laboratory units or outside entities that are not used by the examiner in the evaluation of the evidence or to support the results or conclusions do not need to be retained in the DNA case notes (e.g., Case Record Object Repository, 1A).
H. If amendments to technical records are made, DNA personnel ensure the change can be tracked to the previous versions or the original observation. Amendments must include the date of the alteration, an indication of the altered aspects, and the personnel responsible for the alteration. Nothing in the case notes may be obliterated or erased.
    1. Contemporaneous revisions are not considered amendments. Changes are considered contemporaneous if made before reaching a decision point. Decision points may include transferring samples to the next stage of processing, uploading completed records to STACS or FA, or submitting the file for technical review.
    2. If an identifier or similar addition is made to the case records (e.g., laboratory number, the "SECRET" or "copy" designation) manually or through the use of a stamp or other electronic means (e.g., page counter), this addition is not considered an amendment and does not require the date or initials of the person making the addition.
    3. The following are methods that may be used to track changes made to completed records.

- Changes to hard copy and/or handwritten records may be tracked using a single strike-out, dating and initialing the change or by retaining any pages that are replaced in the 1A.
- Changes to electronic records in STACS are tracked within STACS.
- Electronic record pages may be annotated, added, or amended when the revised or additional pages are clear. If a page is replaced, the original page will be retained but marked to indicate it was replaced.
- A new file may revise a portion of, or the entirety of, the original file, as appropriate through a version history for the file.
- Changes to electronic records not otherwise tracked may be summarized in a communication log.

3.1.2 CODIS-Eligible Profiles

For cases with CODIS-eligible profiles, the following information must be recorded and verified prior to CODIS entry. The information may be recorded and verified in STACS, as applicable. Refer to the applicable DNA procedure for CODIS entry and eligibility requirements (i.e., BIO-590).

- DNA profile and Amelogenin (if applicable) results being entered
- Specimen category (e.g., Forensic Unknown, Missing Person)
- Relevant eligibility information
- Database match and/or rarity calculator results, if applicable
- Pedigree and metadata for missing person, if applicable (Missing Persons cases only)
- Consent forms (Missing Persons cases only)

3.1.3 Case-Related Records from Non-FBI Laboratories

Relevant records generated by a non-FBI laboratory for a case assigned to the DCU will be retained in the 1A. These are typically uploaded with the administrative records to the Case Record Object Repository in FA and/or attached to the communication log.

3.2 Expedited Results

A. Any dissemination of expedited results prior to the issuance of the *Laboratory Report* (or i3 product) will be provided and recorded in accordance with the appropriate level 1 document. The communication record must include the opinions or interpretations communicated by dialog with the contributor.
B. The following results or conclusions require verification/technical review by another qualified Examiner and that verification/technical review recorded in the case notes prior to dissemination:
    - Mitochondrial DNA (mtDNA) conclusions of “cannot be excluded” or “inconclusive”
    - Comparisons to nuclear DNA (nDNA) mixture profiles evaluated with STRMix
    - Statistical results
    - Conclusions based on kinship calculation results

C. The following do not require verification/technical review prior to dissemination of expedited results:
    - Comparisons to single source nDNA profiles (if statistical results are not provided)
    - Comparisons to nDNA profiles resulting in a manual exclusion
    - mtDNA exclusions
    - Parent/offspring comparisons to full profiles (if no statistical results provided)
    - Other testing results (e.g., serology)
D. DNA profile records will not be released without a recorded technical review.

3.3 Sequence Confirmation *(Sanger sequencing data only)*

The mtDNA Sanger sequences for all samples and associated controls (HL60, NC, and RB) will be confirmed/verified by a second qualified individual. Sequence confirmation may be completed prior to completion of the *Laboratory Report* or during technical review. Refer to the appropriate DNA interpretation procedure (i.e., BIO-575).

3.4 Formatting and Content of a Laboratory Report

A. An Examiner will prepare a *Laboratory Report* in accordance with the appropriate level 1 document. The *Laboratory Report* will contain or reference the following information, as appropriate:
    - Case identifier (i.e., laboratory number(s) and/or Case ID number(s)).
    - Description of the evidence received or examined by the DNA Units and identification of the samples tested for DNA, when applicable.
    - DNA technology (e.g., STR, YSTR, mtDNA) used for analysis.
    - Identification of the loci or amplification system or region(s) for which characterization was attempted.
    - Results and/or conclusions for each forensic sample tested.
    - Qualitative interpretative statement and/or a quantitative (statistical) statement to support all inclusions or for all conclusions supported by a STRmix analysis.
    - Report date.
    - Disposition of evidence.
    - Name of the Examiner responsible for the content of the *Laboratory Report*.
B. The date on the *Laboratory Report* will be the date the technical content of the report was finalized and will reflect the date on or prior to all technical work supporting the results and/or conclusions in the *Laboratory Report* being completed.
    1. The report date will be updated, as appropriate, during the review process if revised or additional technical records are generated, unless the new records contain no additional technical content (e.g., reprint of the communication log for a new entry).

C. The Results of Examination section of the *Laboratory Report* will include, as appropriate, sampling descriptions, results and/or conclusions, statistical calculation results, information pertaining to the entry of sample(s) profiles into the CODIS or other appropriate databases, and a Methods/Limitations section.
    1. Evidence listed in the *Laboratory Report* as received but not examined may be addressed in the Listing and Description of Evidence, Results of Examination, or the Remarks sections, as appropriate.
    2. The initial entry of a profile into a DNA database will be included in the *Laboratory Report*.
    3. The extent of database searches will be communicated to the contributor and updated as needed.

D. The Remarks section of a Laboratory Report will contain the disposition of evidence and other remarks as required by level 1 documents.
    1. This section may also contain requests for additional samples (e.g., additional bones from an Unidentified Human Remains (UHR), additional relatives of a Missing Person), information pertaining to samples retained for future testing (e.g., for the National Missing Persons DNA Database (NMPDD), population databasing), and potential additional testing that may be suitable (i.e., Y-STRs).
    2. Evidence will be dispositioned as consumed when no evidence material remains for future testing (e.g., the entire swab tip is cut from the swab, an entire bone fragment is pulverized and used for extraction).

3.5 Reviewing a Laboratory Report

A. Technical and administrative reviews will be conducted in accordance with the level 1 documents.
    1. The case file records will reflect that the technical and/or administrative review(s) were conducted and who performed those review(s).
    2. The electronic signature of the technical and administrative reviewer(s) is captured in STACS and/or FA.
        - Signature of the technical reviewer will concurrently reflect the verification of the reported comparison results.
    3. Case notes (e.g., interpretation notes) generated during the technical or administrative reviews will be added to the FBI Laboratory File.

B. Technical and administrative reviewers may be self-assigned in STACS and/or FA.
    1. The technical reviewer(s) must be currently or previously qualified in the method, technology, typing test kit, platform, and interpretation software being reviewed, be authorized to conduct technical reviews, and be proficiency tested semi-annually as a Forensic Examiner (i.e., conducting interpretation and/or technical review).
    2. If a portion of the case notes are technically reviewed by a separate technical reviewer (e.g., expedited results), the review of the affected portion will be noted in the case file.

3. The technical reviewer cannot be the author of the report or review their own work, with the exception of confirmation/verification records.
    i. Sanger sequence confirmation and technical review may be completed by the same or different individuals provided neither are the primary interpreting examiner or the author of the report.
4. In addition to the UC or TL, any unit personnel may be tasked to perform administrative reviews. An administrative reviewer does not need to be currently or previously qualified in the methodology being reviewed or be semi-annually proficiency tested.

C. Disagreements will be handled in accordance with the level 1 documents with the following exception:
    1. When the reporting examiner and the technical reviewer cannot come to an agreement on the reported NOC, a qualified Supervisory Forensic Examiner (or designated SME) will facilitate a collaborative review of data pertaining to the reported NOC prior to the formation of a Scientific Review Board (SRB). The notes will reflect any change in interpretation. The *Laboratory Report* (or i3 product) will reflect the agreement of the involved parties. If agreement cannot be made after the collaborative review, an SRB will be formed as described in the level 1 documents.

3.5.1 Verification and Technical Review

Completion of the technical review signifies agreement with the examination process and technical information in the case file and *Laboratory Report*.

A. In addition to the requirements in the level 1 documents, the technical reviewer will review:
    - The casefile records (see Appendix A) and the *Laboratory Report.*
    - The *Laboratory Report* to ensure the presence and accuracy of the report elements listed above.
    - The *Laboratory Report* to verify that the results/conclusions are supported by the data for each item tested and in compliance with laboratory guidelines.
        - This will include the concurrent verification of each comparison result, when appropriate.
    - The statistical calculations, if applicable.
    - The CODIS eligibility, or eligibility for other appropriate databases, of the DNA profile/sequence(s), including the DNA types and specimen category for eligible samples, if applicable.

B. The technical reviewer will ensure that calculations and data transfers subject to human error (i.e., manual calculations or transcriptions) are checked, unless these values are checked by STACS or other electronic tools. If the technical records do not indicate a necessary check was performed, the technical reviewer will perform the check.

C. In addition, for nuclear DNA results, the technical reviewer will:
    - Review supporting electropherograms to verify that all DNA types and conclusions are supported by the analytical data, if applicable. If

electropherogram printouts or PDFs are not of sufficient resolution to verify all DNA types, the technical reviewer must request additional electropherogram printouts or PDFs or review the data electronically and record that the data was electronically reviewed.
    - Ensure all controls, internal size standards and allelic ladders meet the interpretation guidelines for reported results, if applicable.

D. For mitochondrial DNA results via Next Generation Sequencing (NGS), the technical review requirements of the data, the DNA types (i.e., sequences), and controls is done through review of the STACS notes and the documents produced using the NGS software tools, except where listed below. The technical reviewer will:
    - Review all data transfer/verification tool records
        - Ensure that the controls meet the interpretation guidelines for reported results.
        - If negative controls exceed the minimum allowed reads and % thresholds, then review the Variant Comparison Table(s) (aka the contamination matrix).
    - Review the sequence data in STACS.
        - If there is apparent heteroplasmy in a primer binding site region, review the data in GeneMarker HTS.
    - Review sequence results to ensure the appropriate sequences were compared to known phylogenetic alignments, if applicable.

E. For mitochondrial DNA results via Sanger sequencing, the sequence confirmation will fulfill the technical review requirements for the supporting electropherograms, the DNA types (i.e., sequences), and controls. The technical reviewer, if necessary, will generate the appropriate sequence confirmation records. If the sequence confirmation is done prior to the technical review, the technical reviewer will review the sequence confirmation records, to include:
    - The Sequencher™ project and profile sheets from the Examiner and confirmer to ensure they are included.
    - The case summary sheet to ensure it contains all analyzed sequences with the correct sequence ranges and profiles.
    - Sequence results to ensure the appropriate sequences were compared to known phylogenetic alignments, if applicable.
    - The review of the controls.

3.5.2 Administrative Review

Completion of the administrative review indicates that the *Laboratory Report* has been approved and is authorized for issuance.

A. In addition to the requirements in the level 1 documents, the administrative reviewer will:
    - Review the case notes and the *Laboratory Report* for clerical accuracy and ensure the presence and accuracy of the report elements listed above.
    - Review the Chain-of-Custody and disposition of evidence.

- Ensure that a technical review was completed, when applicable, and properly recorded.

3.6 Issuing a Laboratory Report

A. Upon completion of the appropriate reviews, the *Laboratory Report* and supporting records will be serialized in Sentinel in accordance with the level 1 documents.
    1. When supporting records are compiled electronically, a digital 1A will be created and uploaded to Sentinel as a digital attachment.
    2. When a physical 1A is created, a physical attachment will be added in Sentinel. At least the total number of pages and/or data discs of records retained within the 1A envelope will be accounted for on the outside of the 1A envelope.

B. The *Laboratory Report* will be considered issued when the *Laboratory Report* is uploaded to Sentinel. The issue date is the date of upload approval and is captured on the official record of the *Laboratory Report* in Sentinel.

4 RECORDS

Technical records will be generated and retained in accordance with this procedure and the appropriate level 1 documents.

5 REFERENCES

FBI Laboratory National DNA Index System (NDIS) DNA Data Accepted at NDIS (Operational Procedures), latest version.

Federal Bureau of Investigation, Quality Assurance Standards for Forensic DNA Testing Laboratories, latest version.

Federal Bureau of Investigation, Quality Assurance Standards Audit for Forensic DNA Testing Laboratories, latest version.

Federal Bureau of Investigation, Records and Information Management Policy Guide (1323PG), May 31, 2024 (or latest revision)

Federal Bureau of Investigation, FBI Policy Directive 1001D, January 8, 2018 (or latest revision)

Federal Bureau of Investigation, Information Management Division, One-Shot: Hard-Copy Records & Sentinel, July 26, 2022 (or latest revision)

6 REVISION HISTORY

Revision	Issued	Changes
00	02/04/2022	Reformatted DNA 610-12 into new template and assigned new Doc ID. Added exception for disagreements to NOC conclusions.
01	06/05/2024	Removed SBAU. Added reference to i3 products. Removed lists of Exam and Admin records. Replaced examination records with technical records/FBI Laboratory File/case notes as appropriate throughout. Clarified DNA technical records that are retained and where. Defined technical records that are not retained. Added clarification that the TR does the verification of all conclusions. Added appendices A, B and C.
02	02/10/2025	Updates for NGS and other minor edits throughout

7 APPENDIX A: DNA CASEFILE RECORDS

In support of the *Laboratory Report* (or i3 product), the records listed below, when generated, are retained in the FBI Laboratory File. The order of the records may vary, but records are generally grouped and combined into a single PDF file for each packet as listed. Additional packets or records may be added as appropriate. *Italics represent mtDNA specific records.*

7.1 Admin Packet

1. FA Case Report
2. Request (e.g., LER) for each submission
3. Additional paperwork (e.g., SAK, FD-935, relative consent forms, reports [e.g., trace, ME, anthropology, NamUs])
4. Communication Log
5. DNA applicable emails
6. FA printout(s) of evidence
7. Evidence Check-in notes (if SUS)
8. Examination Plan (if MUS)
9. Deviations

7.2 Case Notes Packet

1. Case Notes printout from STACS
2. Serology notes
2. Collection notes
3. Extraction Notes
4. Quantitation Notes
5. Amplification Notes
6. CE Notes
7. *Additional NGS Notes (e.g., Post Ligation Clean-up Notes, Normalization Notes, etc.)*
8. *Pool Volume Calculation Sheet*
7. Discontinued Sample Sheet
8. Profile Summary
9. KInCALcOrder Sheet (if kinship case)
10. Rework notes (e.g., re-amp, re-prep, concentration, dilution)
11. Amp/CE set-up/reinjection notes

7.2.1 <u>For mtDNA Sanger sequencing cases</u>

1. *Summary Sheet*

2. In order per sample: (note: K Auto samples will only have amp and sequencing grids unless reworks were necessary)

a. *qPCR results*
b. *Amp sheet*
c. *Cycle-sequencing sheet*
d. *Quant sheet(s)*
e. *Agilent printout*
f. *Sequence injection sheet(s)*

7.3 Data Packet

7.3.1 STR/YSTR Data

1. Electropherograms (EPGs)
2. Interpretation sheet
3. FBI Laboratory Elimination DNA Database Search (for non-reference single source full or partial profiles)

7.3.2 NGS Data

1. Contamination assessment
2. Consensus Statistic assessment
3. Variant Comparison Table (if needed)
4. Amplicon report and major variance report before and after trimming (if needed)
5. Documentation for nomenclature (if needed)

7.3.3 Sanger Data

1. *Sequence summary sheet*
2. *In order per sample:*
    a. *Sequencher of examiner*
    b. *Sequencher of confirmer*
    c. *Diff sheet of examiner*
    d. *Diff sheet of confirmer*
    e. *Documentation for nomenclature*
    f. *HL60*

7.4 Stats Packet

1. STRmix reports
2. COSTaR results
3. YHRD results
4. KInCALc results
5. *EMPOP/POPstats results*
6. *Haplocalc results*

7.5 Previous Exams Packet

1. Report
2. Profile*/Sequence* Summary sheet (if needed)
3. EPGs (if needed for evidence samples)
4. Interpretation sheet (if needed for evidence samples)

7.6 CODIS Packet

1. CODIS Metadata Sheet(s)

7.7 Chain of Custody and Shipping Invoice (if SUS)

7.8 Ancillary Records

In addition to the records listed above, the following records (if generated) will be retained in the FBI Laboratory File. These records may be added to one of the above packets or as a separate record, as appropriate. Handwritten notes will be scanned for retention and the original discarded in accordance with FBI policy.

- Written procedural notes, observations or data that influence or provide evidence of decision-making (e.g., sperm slide coordinates, CE set-up/reinjection notes)
- Examiner to Biologist instructions/procedural notes (e.g., extraction/combination guidance, primer guidance, re-amp/re-prep instructions, STACS Case Notes)
- Interpretation Notes (e.g., Examiner/TR/AR notes pertaining to interpretation of results and conclusions)
- Written communications that support results/conclusions and/or influence or provide evidence of decision-making.

8 APPENDIX B: TECHNICAL RECORDS RETAINED INDEPENDENT OF THE FBI LABORATORY FILE

The following are examples of records that are retained independent of the FBI Laboratory File and where they are generally retained within the DNA discipline.

Record Description	**Where retained (subject to change)**
QA/QC, reagent, and instrument records	STACS, Laserfiche, or Sharepoint
Instrument usage logs	Laserfiche
Quant import/results/data files	STACS
Amp Set-up sheets/Worklists	STACS
CE Raw data files	STACS
STRmix data files (e.g., supporting files)	STACS
NGS data files	BASNet or STACS
Logs used in troubleshooting	Laserfiche
CODIS records (e.g., no match information)	STACS

9 APPENDIX C: EXAMPLES OF TRANSITORY RECORDS/NON-TECHNICAL RECORDS

The following are examples of records that are categorized as Transitory (as defined by FBI policy) or non-technical records in the DNA discipline and therefore are not retained.

- .txt files used to transfer information to/from STACS or other computer systems. Pertinent data in these files is captured in the STACS notes or other technical records.
- To do lists (personal or group) or communications used to share status updates or task requests that do not provide any instruction or decision-making information.
- Electronic input files (e.g., KInCALc, YHRD, COSTaR) when the output record reflects the input data or the input files are retained; therefore, allowing for repetition if necessary.
- Personal work logs used for administrative metrics or personnel records.
- Task-specific reminder lists.