2 Quality Assurance

The Quality Manual prescribes general requirements for the quality assurance program. These requirements are based on ASCLD/LAB standards. In addition to ASCLD/LAB standards, the DNA section adheres to the FBI DNA Quality Assurance Standards for DNA Testing Laboratories (based upon the DAB standards). In order to participate in the National DNA Index System (NDIS); the DNA section complies with these DAB standards, the FBI's *NDIS Standards for Acceptance of DNA Data*, and the FBI's prescribed NDIS procedures.

2.1 Quality Control

Examiners keep quality control records as required in the quality manual and DNA SOP. The following controls will be used in DNA analysis:
For the monitoring of analytical procedures throughout DNA analysis, the following controls and standards are used:

- An extraction reagent blank is an analytical control sample with each extraction set that contains all reagents used in that extraction process but no template DNA and is used to monitor contamination from extraction to final fragment analysis
  - Must be extracted concurrently with its associated forensic samples
  - Must be subjected to the same concentration conditions as required by its associated forensic sample(s) containing the least amount of DNA
  - Must be amplified using the same primers and the same instrument model as its associated forensic samples
  - Must be amplified using the same concentration conditions as required by the associated forensic sample(s) containing the least amount of DNA
  - Must be amplified concurrently with its associated forensic sample(s) if it is not quantified prior to amplification
  - Must be typed using the same instrument model
  - Must be typed using the same injection conditions as required by its associated forensic sample(s) containing the least amount of DNA
- A hair shaft negative control will be analyzed for each hair root analyzed.
- Quantification standards
- Quantification negative control
  - A quantification negative control is an analytical control sample that is used to detect DNA contamination of the quantification reagents
  - Must have an IPC value and less than 5×10^{-3} ng/µl of detectable DNA present.
- Amplification positive controls
  - An amplification positive control is an analytical control sample that is used to determine if the PCR was successful
  - Must be amplified and typed concurrently in the same instrument with the associated forensic samples, at all loci using the same primers
- Amplification negative controls
  - An amplification negative control is an analytical control sample that is used to detect DNA contamination of the amplification reagents

  - Must be amplified and typed concurrently in the same instrument with the associated forensic samples, at all loci using the same primers
  - Must be subjected to the same injection conditions as required by its associated forensic sample(s) containing the least amount of DNA
- Allelic ladders and internal size markers

Critical reagents

Critical reagents are those that require testing prior to use on evidentiary samples in order to prevent unnecessary loss of sample and must include commercial DNA typing kits. These are itemized in Critical Reagents Section (Section 5), and are quality control tested using the forms in Forms Section. The human DNA controls, primer sets, and DNA polymerase contained within these kits must be quality control tested as part of the kit testing.

The critical reagent quality control log will contain reagent quality control worksheets as well as any necessary corrective action records pertaining to critical reagent testing. The quality control worksheet will show reagent name(s), lot number(s), expiration date(s), quality control test instructions and evaluation criteria. If a reagent does not meet those criteria, the documentation will be marked accordingly.

Reagents and supplies that have passed their expiration dates may not be used on casework samples. Outdated reagents may be used for training purposes only, but must be designated as such.

Validation

The DNA section will not generally develop a novel methodology; but if it does, the methodology will undergo full developmental validation in compliance with all relevant standards prior to use in casework. Methodology that has undergone developmental validation elsewhere will be internally validated in compliance with all relevant standards prior to use in casework. Substantial changes in an existing protocol will also be subjected to an appropriate internal validation evaluation, comparing it to the original procedure, to demonstrate, at a minimum, no loss of reliability, reproducibility, precision, or sensitivity.

No new or modified method, i.e., any method not already described in the SOP, is to be used without the documented approval of the Technical Leader, Quality Manager, and Crime Laboratory Director.

New software, or software with significant modifications, must be subjected to validation testing prior to its use in casework.

Analysis Training

Please refer to the DNA Training Manual.

Continuing education training

Continuing education training will be conducted for enhancement of an examiner's skills. The supervisor will recommend to management and coordinate training activities for personnel. As part of their continuing education, each examiner approved to perform DNA analyses will attempt to read at least one article per month of current scientific literature. Each examiner will keep an updated log documenting any scientific literature read. In addition, the technical leader, CODIS Administrator, and DNA analysts will complete a minimum of eight hours of continuing education annually.

The Technical Leader and the Quality Manager may identify areas for which remedial training is necessary based on the results of proficiency or competency test results, laboratory audits, or peer review activities.

Unusual samples

An approved examiner may use a valid procedure for analysis of a body fluid or tissue not encountered during training providing the analyst has previously demonstrated competence in that procedure. Examiners must undergo training and competency testing for extraction of bone and teeth prior to analyzing these samples.

Review of casework

All case files and laboratory reports will be administratively and technically reviewed prior to release from the laboratory. Reviews should follow the reviewer checklist, and a copy of the completed reviewer checklist should be included in each case file.

Technical reviews shall be conducted by a second analyst qualified (or previously qualified) and proficient in the DNA platform currently in use in the DNA section. All reviews of DNA case folders shall include a review of the following:

1. All case notes, worksheets, and printed electropherograms
2. Raw data for the samples being used for interpretation (this includes the creation of a new GeneMapper project on the computer using the original raw data from the case; all electropherogram plots in the case file should match the electropherogram plots generated during the reviewer's second read; the reviewer shall indicate agreement with the second read by signing and initialing the GeneMapper project table for each run reviewed in the case folder)
3. DNA types to verify they are supported by the raw or analyzed data
4. Profiles to verify correct inclusions and exclusions, as well as the appropriate use of "inconclusive"
5. All controls, internal lane standards, and allelic ladders to verify that the expected results were obtained
6. Statistical analysis, if applicable
7. The final report to verify that the results/conclusions are supported by the data, as well as to verify that each tested item is addressed

8. CODIS profiles should be reviewed for:
    a. Eligibility
    b. Correct type
    c. Correct specimen category

The analyst who worked the case may not perform the administrative review. The analyst who performs the technical review may also perform the administrative review; however, it is recommended that another analyst or supervisor perform the administrative review when possible. Administrative reviews must include, at a minimum, a review of the following:

1. The final report for clerical errors
2. The final report for the presence and accuracy of the following elements:
    a. Case identifier
    b. Description of the evidence examined
    c. Description of the technology used
    d. Inclusion of loci used for analysis
    e. Results and/or conclusions
    f. A qualitative or quantitative interpretive statement
    g. Date issued
    h. Disposition of evidence
    i. Signature and title of the person accepting responsibility for the content of the report
3. Chain of custody
4. Disposition of evidence

The analysts and reviewers should typically be able to come to agreement on all issues of substance in the laboratory report after sufficient discussion; disagreements of substance should be brought to the attention of the Technical Leader, whether or not they are resolved at the analyst level. If disagreements of substance between the analysts and a reviewer cannot be resolved, the technical leader shall make the final determination.

Technical and Administrative Reviews are required for data generated by non-NDIS-participating outsource labs that do not submit data for upload into CODIS. However, if the lab that has generated the data is NDIS-participating and will routinely submit data for upload into CODIS, Technical and Administrative Reviews will not be required by HPD personnel when that data is returned to HPD.

Proficiency testing

Proficiency testing and review will follow the requirements of the quality manual. In addition, the Quality Manager will maintain a copy of the analysis documentation for each proficiency test. Proficiency tests will be analyzed and interpreted according to standard operating procedures including technical review. Administrative review may or may not be appropriate to a given test format and is to be performed at the discretion of the DNA section. Proficiency test participants will be notified of their final test results.

Analysts will enter into a proficiency test program within 6 months of being deemed competent on any portion of casework analysis. Proficiency testing should include each technology to the full extent to which analysts and technicians participate in casework. It is required that if both manual and automated methods are used, the analyst must be proficiency-tested in each, at least once per year. However, it is recommended that the analyst performs both method types semi-annually. It is required that each technology (STRs, Y-STRs) be proficiency-tested semi-annually.

Proficiency work is to follow as closely as possible that of normal casework. In doing so, DNA results reported to CTS (or other ASCLD/LAB approved external proficiency test provider) should not vary from DNA results included within the case file, as established by the HPD DNA SOPs. For example, asterisks indicating possible allelic data below the interpretation threshold and notations to distinguish major and minor components in a mixture should be included in results submitted to the test provider, if applicable.

Per QAS, analysts must be externally proficiency-tested semiannually in each DNA technology performed to the full extent in which you perform casework examinations. However, not all proficiency tests include a semen-containing sample that would ordinarily be subjected to a differential extraction method. If all proficiency tests did contain a semen-containing sample, the ability to monitor the analysts' ability to correctly identify semen in a body fluid identification test would be compromised.

If the only extraction method for which an analyst is competent in is the differential extraction method, he/she must perform this extraction method in both proficiency tests in a given year, regardless of whether or not one of the evidence samples is found to be semen-containing. This will permit him/her to be proficiency-tested in the differential extraction method semi-annually.

If the analyst is competent in other extraction methods, he/she may perform the appropriate extraction method, given the screening results of the proficiency samples, as long as at least one differential is performed in a given year.

If performing quantification for proficiency samples, the analyst should create his/her own DNA standards.

Audits

The Quality Manager will plan, arrange, and direct audits according to ASCLD/LAB and QAS requirements. This audit will be completed once each calendar year, with the intervals between FBI Quality Assurance Audits being no less than 6 months and no more than 18 months. The auditor(s) will use both the ASCLD/LAB and FBI Quality Assurance Audit Documents as a checklist for compliance.

Personnel records

The Quality Manager will maintain a transcript, approval memos, complete proficiency records, continuing education records, and testimony monitoring records for each examiner. The laboratory must maintain the competency notebook, original or copies of training records, and proficiency test files for each examiner. Original training records must be replaced with complete copies prior to separation of an examiner from HPD Crime Lab. The laboratory shall maintain a transcript, approval memos, and testimony monitoring reports for each examiner.

Chemical and reagent labels

Purchased chemicals and reagents will be marked on the container with the date received and/or date opened. An expiration date will be placed on the outer container. In general, the manufacturer's labeling will be followed to determine expiration dates of purchased chemicals and reagents. If no manufacturer information exists for a purchased reagent, it will be considered expired 5 years from the received date.

The prepared reagent label will include the reagent name, lot number (consisting of preparation date and preparer's initials), and date of expiration. In general, most solutions prepared in the DNA section shall expire 1 year from the date of preparation. However, the expiration date of the overall reagent will be no later than the expiration date of the individual reagent with the nearest expiration date. Additional information may be documented in a reagent log.

Reagents that are subjected to quality control testing prior to use should also be marked with the "QC date".

Equipment

Equipment operation manuals will be readily available to each examiner approved to use the equipment. Calibration, maintenance, and repair activities will be recorded in an equipment calibration and maintenance log, or in a logbook dedicated to that specific piece of equipment. The equipment calibration and maintenance log will include at a minimum the date, activity, laboratory personnel performing or overseeing the activity, non-HPD technician(s) performing or overseeing the activity, and a record of quality control checks performed to verify operation prior to returning a piece of equipment to casework use.

Contamination log

Any and all contamination events will be summarized in a contamination log that will document the date detected, first date evident in analysis records, case numbers of affected cases, and location of documents detailing contamination source and corrective action. A copy of this documentation should be provided to the Quality Manager and the Laboratory Director. The section defines two types of contamination events. Both types are required to be documented in the contamination log and are as follows:

- Type 1: A contamination event that affects the DNA extract and requires a re-extraction of DNA from the sample.
- Type 2: A contamination event that does not affect the DNA extract (i.e. one involving contamination in the amplified product OR contamination in the formamide set-up) and does not require a re-extraction of DNA from the sample.