

Administering Proficiency Testing

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Administering Proficiency Testing

1 INTRODUCTION

Proficiency testing is used to monitor the performance of qualified Examiners and Biologists who conduct mitochondrial DNA, nuclear DNA, and/or serology casework examinations, and/or DNA database sample processing for the FBI Laboratory DNA Units and to meet the requirements of the *Quality Assurance Standards for Forensic DNA Testing Laboratories* and *Quality Assurance Standards for DNA Databasing Laboratories* (together referred to as QAS). The DNA Units include the DNA Casework Unit (DCU), the DNA Support Unit (DSU), the Federal DNA Database Unit (FDDU), and the Scientific and Biometrics Analysis Unit (SBAU) DNA group. Proficiency testing also demonstrates that the analytical procedures are being performed properly and the laboratory's system is producing accurate results.

2 SCOPE

- These procedures apply to:
 - DNA personnel who perform laboratory activities on evidence and/or database samples, interpret serology and/or DNA results, and/or perform technical reviews of casework and/or database analysis.
 - DNA personnel who perform duties relating to the management, records, and tracking of proficiency tests and associated corrective actions.
- For these procedures:
 - an Examiner will include individuals (however titled) who perform the role of analyst (i.e., interpret data) and/or technical reviewer as defined by the QAS
 - a Biologist will include individuals (however titled) who perform the role of technician (i.e., perform testing) as defined by the QAS.
- Laboratory support personnel that perform sampling (i.e., collection, punch) will participate in proficiency testing to monitor performance in accordance with the level 1 documents.
- Laboratory support personnel whose responsibilities are limited to evidence management, accessioning, and/or other lab duties exclusive of analytical techniques on forensic or database samples will not be proficiency tested.

3 PROCEDURES

DNA personnel will comply with the FBI Laboratory level 1 documents as well as the QAS requirements for proficiency testing.

- Only external proficiency tests from providers accredited to the International Standards for proficiency testing (i.e., ISO/IEC 17043) will be used to fulfill the requirements of the QAS.
 - Accreditation certificates will be reviewed to ensure the relevant tests appear on the provider's scope of accreditation. The approval of these external service providers will be recorded in STACS and/or in the FBI Laboratory's records for externally provided products and services.

- The DSU QA/QC Group will maintain the performance monitoring plan for DNA personnel.
- Records will be generated similar to casework/databasing records. As an exception to the LAB-100 requirement, not all records will be entered into the appropriate LIMS (i.e., STACS or FA) and the evaluation and feedback are not recorded in a LIMS. DNA performance monitoring records are retained by DSU.
- A proficiency test may be used to test multiple component/parameters on the scope of accreditation and multiple technologies, methodologies, or typing test kits as required by QAS.
- A proficiency test may be assigned to multiple participants provided that one Examiner is assigned to complete the interpretation and report the results.
- The distribution date will be used to track the proficiency testing cycles.

3.1 Body Fluid Identification (Serology) Proficiency Tests

- A. Examiners and Biologists authorized to perform, interpret, and/or technically review serological casework will participate in a minimum of one open, external serology proficiency test per calendar year (January through December).
- B. Serology proficiency testing will be conducted in a manner consistent with typical casework and will involve the examination of potential biological materials for the presence or absence of blood and semen.
- C. The relevant tests routinely performed should be conducted on the items contained in the proficiency test.
 1. The relevant tests will be determined by the assigned Examiner using the case scenario provided by the PT provider for the test.
 - i. If insufficient information is provided to make an informed decision, samples will be tested for both blood and semen.
 2. Presumptive tests and confirmatory tests will be conducted as they would be in casework examinations.
 - i. All possible serology tests do not need to be performed on each sample, unless appropriate.
 - ii. Presumptive tests are not required if they would not be performed in the typical examination workflow (i.e., direct to DNA for sexual assault kits swabs).
 - iii. Confirmatory tests are not required if they would not be performed in the typical examination workflow (i.e., presumptive test is negative).

3.2 DNA Proficiency Tests

- A. In accordance with the QAS, Examiners and Biologists authorized to perform, interpret, and/or technically review DNA casework examinations or DNA database sample processing will participate in at least semi-annual open, external DNA proficiency tests per calendar year.
 1. Semi-annual requires participation in DNA proficiency testing between January 1st and June 30th and July 1st and December 31st of each year.

- i. The interval between the issuance of the two tests must be at least four months and no more than eight months.
 - ii. An individual that participates in more than two tests per year may have a shorter interval between tests.
- 2. The technology, methodology, and typing test kits used on proficiency tests in the calendar year will be in accordance with the QAS and in a manner consistent with typical casework or databasing applications.
- 3. A list of the DNA technologies and methodologies as defined by QAS are described in Appendix A.
- 4. If an individual is not administered a proficiency test and falls out of the proficiency testing cycle for a specific technology or methodology, that individual will not perform, interpret, and/or technically review casework examinations or DNA databasing using that technology or methodology until a requalification test is successfully administered. Refer to the DNA Training Manual (i.e., BIO-940).
- B. Laboratory support personnel that perform sampling (i.e., collection, punch) will perform the task on a proficiency test annually.

3.3 Review and Submission

- A. Examiners will follow the reporting procedures established by the specific test provider for recording test results for submission.
 - 1. The comments section(s) of the test provider's results forms should be used to address any pertinent results or conclusions that fall outside the reporting restrictions of the test provider's results forms.
- B. All proficiency tests will undergo the appropriate technical and administrative reviews prior to submission of the test results.
 - 1. Data quality reviews (e.g., review of capillary electrophoresis (CE) data for determining need for reinjections) are not considered a confirmation of identification or a technical review of the proficiency test and therefore may be conducted by an individual participating in the same distribution.
 - 2. Data confirmations conducted for technical review purposes (i.e., mtDNA sequence confirmations, FDDU technical review) will be conducted by an individual not participating in the same distribution or a participant who has completed his/her portion of the test.
 - 3. **For casework tests**, the elements of technical and administrative reviews listed in the applicable level 1 and DNA level 2 documents for case file reviews will be performed, as applicable.
 - i. Reviewers do not need to be recorded in a LIMS provided a record of the technical and administrative reviewers is retained with the proficiency test records.
 - 4. **For DNA databasing tests**, the technical and administrative reviews will be conducted as described below.
 - i. Technical review of the data will be performed and recorded in STACS™ Database Software (STACS-DB). The technical review may

include the use of a National DNA Indexing System (NDIS) approved expert system. A technical review of the data will include the following:

- A review of all DNA types to verify that they are supported by the raw or analyzed data
 - A review of all controls, internal lane standards, and allelic ladders to verify that the expected results were obtained.
 - A review to confirm that the reworked samples have appropriate controls
 - ii. A technical review of all notes, worksheets, and electronic data supporting the results in the PT file will be conducted. Technical review of the data and supporting records may be completed by the same person.
 - iii. An administrative review of the proficiency test records for clerical accuracy will be conducted.
 - iv. Technical and administrative reviews will be recorded in the proficiency test records.
- C. Proficiency test results will be submitted to the proficiency test provider on or before the provider's due date.
- 1. The DSU QA/QC group will submit test results for the individual test participants, unless a provider requires a participant to submit their individual test results.
 - 2. External tests not accepted by the provider do not satisfy the proficiency test requirement. If this should occur, a new external proficiency test will be ordered as soon as possible and appropriate records will be maintained.
- D. The Examiner will ensure applicable PT records are provided or made available to the DSU QA/QC group for retention.
- E. Any potential inconsistency or error, or any issue with a proficiency test that may have affected the results or evaluation of the test should be proactively communicated to the accrediting body through the Proficiency Test Program Manager (PTPM).

3.4 Evaluation of Proficiency Test Results

- A. All proficiency test results will be evaluated in accordance with the appropriate level 1 document and the QAS requirements. The *Proficiency Test Evaluation Form* (BIO-001) will be used to record the evaluation.
- B. Inconclusive or not interpretable conclusions will be reviewed by the TL for compliance with unit specific procedures. This review may be conducted prior to the evaluation of results and captured in the PT records.
- C. The DSU QA Program Manager will ensure that the *Proficiency Test Evaluation Form* is provided to the proficiency test participants following the evaluation.
- D. The TL will be informed of the results of all participants.
- E. Proficiency test records will be maintained by the DSU QA/QC Group.

3.5 Discrepancies and Errors

- A. All discrepancies and potential technical, analytical, and/or administrative errors will be evaluated by the TL and handled in accordance with the appropriate level 1 documents. The TL will initiate necessary actions in conjunction with the applicable Unit Chief(s).
- B. The TL will inform the appropriate CODIS Administrator of all non-administrative discrepancies that affect the DNA typing results and/or conclusions at the time of discovery.
- C. The DSU QA/QC Group will ensure any corrected PT records are maintained with the appropriate proficiency test records.

4 RECORDS

- A member of the DSU QA/QC Group will ensure the appropriate records as listed in the level 1 documents are retained.
 - As an exception to the LAB-100 requirements, performance monitoring records for DNA personnel that perform laboratory activities, including the evaluations and feedback, are not all entered in the appropriate LIMS. Performance monitoring records for DNA discipline personnel are retained by DSU.
- A member of the DSU QA/QC Group will ensure the following information is recorded for all external proficiency tests administered in the DNA Units and that the information is available upon request.
 - Name(s) of test participant(s).
 - Test type (position type and internal/external).
 - Test identification number.
 - Distribution date.
 - Date returned.
 - Due date.
 - Evaluation date.
 - Name of evaluator.
 - Results: satisfactory or unsatisfactory.
 - Description of a discrepancy, when applicable.

5 REFERENCES

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

Federal Bureau of Investigation, Quality Assurance Standards for DNA Databasing Laboratories, latest revision.

6 REVISION HISTORY

Revision	Issued	Changes
01	06/15/2023	Added review and approval of accreditation certificates. Changed frequency of sampler PTs to annually to align with ANAB 3125 revisions. Added Appendix A.
02	02/15/2024	Added exception for retaining records in LIMS.
03	12/16/2024	Added option to record approval of PT accreditation in lab records. Changed “PT schedule” to “performance monitoring plan”. Revised Appendix A for NGS mito methodologies.

7 APPENDIX A: QAS TECHNOLOGIES AND ASSOCIATED METHODOLOGY

A. STR/YSTR (Casework)

- Extraction
- Quantification
- Amplification
- Detection (CE)

B. STR (Databasing)

- Direct Amplification
- Detection (CE)

C. Mito

- Extraction
- Pre-Amplification Quantification
- Amplification
- Library Purification
- Post-Amplification Quantification
- Post-Pool Quantification
- Sequencing