

FORENSIC BIOLOGY QUALITY ASSURANCE/QUALITY CONTROL MANUAL

Proficiency Testing Program		
Status: Published		Document ID: 1186
DATE EFFECTIVE 03/07/2017	APPROVED BY Quality Assurance Manager	PAGE 1 OF 4

Proficiency Testing Program

1 Guiding Principles and Scope

- 1.1 Proficiency tests are given to qualified analysts to evaluate both their individual competence and the quality performance of the laboratory. Proficiency tests must be analyzed using only approved methods and/or procedures. While there are several types of proficiency tests, the Department of Forensic Biology utilizes open-external proficiency testing and blind-reanalysis proficiency testing.
- 1.2 The proficiency testing program is designed to meet the requirements of ASCLD/LAB and the Quality Assurance Standards for Forensic DNA Testing Laboratories. The external proficiency testing program is not just a requirement; it is also a quality assurance measure used to monitor performance and identify areas in which improvement may be needed.
- 1.3 External DNA proficiency tests are obtained from New York State and ASCLD/LAB approved proficiency test providers, for example, Collaborative Testing Service (CTS), Orchid Cellmark (IQAS), and the College of American Pathologists (CAP).
- 1.4 Serology results are reported on DNA tests obtained from CTS.

2 DNA Open-External Proficiency Testing Program

- 2.1 All analysts, technical reviewers, and technicians undergo semiannual external proficiency testing to the full extent in which they perform each technology in casework. Technology refers to the type of forensic DNA analysis performed (i.e. STR, YSTR, mtDNA.) The program is administered in an open proficiency-testing format and in accordance with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.
- 2.2 One test is assigned to each participant in the first six months of the calendar year and the second test is assigned in the last six months of the calendar year.
 - 2.2.1 The interval between consecutive tests must be at least four months and cannot exceed eight months.
 - 2.2.2 **The laboratory uses the assigned date/start date to calculate the interval between tests.**
 - 2.2.3 Newly qualified individuals enter the external proficiency testing program within six months of the date of their qualification.

Controlled versions of Department of Forensic Biology Manuals only exist in the Forensic Biology Qualtrax software. All printed versions are non-controlled copies.

FORENSIC BIOLOGY QUALITY ASSURANCE/QUALITY CONTROL MANUAL

Proficiency Testing Program		
Status:Published		Document ID: 1186
DATE EFFECTIVE 03/07/2017	APPROVED BY Quality Assurance Manager	PAGE 2 OF 4

- 2.3 The scheduling of external proficiency tests is completed by a member of the Quality Assurance Unit prior to the start of each calendar year. While minor changes may be made during the year (test vendor, paired analyst, addition/removal of personnel, etc.), the schedule of each analyst/technician is not changed unless a change is necessary due to an extended leave of absence.
- 2.4 All specimens of an external proficiency test are analyzed according to current standard operating procedures. However, some exceptions are made in order to comply with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories. For example, the following sample types, which during normal casework analysis might only be tested in one or two multiplex reactions, must be amplified at all CODIS core loci or CODIS core sequences and tested in all applicable technologies (Autosomal STR, Y-STR, and/or Mitochondrial DNA) to the full extent that the analyst participates in casework:
- 2.4.1 Excluded suspects
 - 2.4.2 Mixtures, even if there are other clean profiles
 - 2.4.3 Epithelial cell fractions from an unknown stain or from a body orifice swab, even if the results match the victim type.
- 2.5 The laboratory utilizes a team approach for casework testing. Therefore, proficiency tests are conducted in the same manner. However, each individual is proficiency tested at least once per year in each methodology to the full extent of his or her participation in casework.
- 2.6 Methodology refers to analytical procedures used to support a DNA-typing technology [i.e. extraction methods (manual v. automated,) quantification methods, typing test kits and instrument platforms]. The extent in which each individual participates in casework may be team dependent.
- 2.7 Individuals who perform STR, YSTR, and/or mtDNA amplification, analysis and/or review must perform these skills twice per year per technology.
- 2.7.1 Unlike other titles, Criminalist Level I's are competent only in selected areas of the analytical process and their competency differs between the different teams within the laboratory. Criminalist I's cannot interpret the final DNA typing data or prepare an associated written scientific report. Thus, their participation in proficiency tests is limited to the methodologies that they are competent in and they are paired with a DNA Analyst on proficiency tests.
 - 2.7.2 Individuals using both manual and automated methods are proficiency-tested in each at least once per year.
- 2.8 A laboratory report to summarize the results of the Proficiency Test is written by the DNA interpreting analyst. The DNA interpreting analyst is also responsible for completing any vendor paperwork to document the results. The DNA interpreting analyst must ensure that the data

Controlled versions of Department of Forensic Biology Manuals only exist in the Forensic Biology Qualtrax software. All printed versions are non-controlled copies.

FORENSIC BIOLOGY QUALITY ASSURANCE/QUALITY CONTROL MANUAL

Proficiency Testing Program		
Status:Published		Document ID: 1186
DATE EFFECTIVE 03/07/2017	APPROVED BY Quality Assurance Manager	PAGE 3 OF 4

transcribed to the vendor's paperwork is accurate. The proficiency test file is then forwarded to the analyst's supervisor, manager, and/or designee for a full technical review.

- 2.9 In addition to conducting a full technical review of the proficiency test file, the reviewer(s) must also review the completed vendor's paperwork to ensure that data has been transcribed correctly.
- 2.10 After the proficiency test has been completed (including a full administrative review), the DNA interpreting analyst assigned to the proficiency test is responsible for delivering the test results to the test vendor. The delivery method may vary from vendor to vendor, but is typically either by fax or e-mail.
- 2.11 After official results have been received by the proficiency test provider, a designated Quality Assurance Unit member grades the tests.
 - 2.11.1 Non-administrative discrepancies on proficiency tests that affect typing results and/or conclusions should be reported to the appropriate Technical Leader at the time of discovery. If confirmed, the Technical Leader must inform the CODIS Custodian/Supervisor so that appropriate follow-up action can be initiated. A formal [QUALITY INCIDENT REVIEW](#) may be required.
- 2.12 All proficiency-test participants are informed of their final test results. Participants are required to sign the appropriate area on the Proficiency Test Evaluation Form to document that they have received and have been informed of the final test results.
- 2.13 After the grading of all proficiency tests within the series, the designee informs the appropriate Technical Leader of the results of all participants.

3 Serology Open-External Proficiency Testing Program

- 3.1 Serology is a sub-discipline of the Biology discipline (as per ASCLD/LAB). The laboratory will endeavor to arrange for each employee to annually complete a serology proficiency test, but it is not required to do so.
- 3.2 Forensic Biology proficiency tests purchased from CTS allows the participant to report results for serology tests as well as for DNA testing. Therefore, serology proficiency testing is satisfied in this manner. The management of this test is identical to the management of DNA external proficiency tests – tests are reported, reviewed, and participants are evaluated in the same manner.

4 Blind Re-analysis Proficiency Testing Program

- 4.1 The Blind Re-analysis Proficiency Testing Program is a quality assurance program where a previously examined sample is re-examined by a different analyst to check for correctness of the initial examination and results.

Controlled versions of Department of Forensic Biology Manuals only exist in the Forensic Biology Qualtrax software. All printed versions are non-controlled copies.

FORENSIC BIOLOGY QUALITY ASSURANCE/QUALITY CONTROL MANUAL

Proficiency Testing Program		
Status:Published		Document ID: 1186
DATE EFFECTIVE 03/07/2017	APPROVED BY Quality Assurance Manager	PAGE 4 OF 4

- 4.2 **DNA Blind Reanalysis Program.** The Quality Assurance Unit is responsible for reanalyzing DNA samples, reviewing the results, and comparing them to the original analyses.
- 4.2.1 Each month, a minimum of two (2) exemplar samples are selected from cases completed within the previous year.
 - 4.2.2 Each sample is submitted for extraction, quantitation, amplification (in at least one casework multiplex system), analyzed for STR results, and the results compared to the original results. Re-examined results are documented separate from the case file and maintained as a record by the Quality Assurance Unit.
 - 4.2.3 A second reanalysis must be performed if the results are not concordant. All follow-up actions must be documented and maintained.
- 4.3 **Serology Blind Reanalysis Program.** The laboratory has a blind serology re-analysis program for negative cases. The purpose of this program is to ensure that negative serology results are accurate.
- 4.3.1 Approximately 25% of negative sexual assault kits are selected by a Quality Assurance member for re-analysis. The re-analysis must occur prior to the release of any report.
 - 4.3.2 Re-analysis of negative serology cases is conducted by casework analysts that are not involved in the original analysis. Each sample within the case that was previously analyzed is re-analyzed to ensure consistent results and checked for correct itemization. Examination notes and confirmatory-test results are compared. Original and re-examined results are retained in the case file.
 - 4.3.3 If discrepancies between results occur, the Quality Assurance Manager and/or the Quality Assurance Supervisors must be contacted to determine what follow-up action is necessary. All follow-up actions must be documented and maintained.