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 ANAB and the FBI 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 ANAB approved proficiency test providers, for example, Collaborative Testing Service (CTS), Bode Cellmark Forensics (IQAS), the College of American Pathologists (CAP) and Forensic Assurance (FA).

1.4 Serology results are reported on DNA tests obtained from CTS and FA.

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 <u>assigned date/start date</u> 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.

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 single source 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 The DNA interpreting analyst uses CODIS software to check the Lab Types database contained within LDIS as a quality control measure. The results of this search are placed in the proficiency test case file and/or attached to the LIMS case record page.

2.9 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 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.

2.10 In addition to conducting a full technical review of the proficiency test file, the reviewer(s) must also review the completed vendor's hardcopy paperwork to ensure that data has been transcribed correctly prior to being issued to the vendor. If the data is being solely sent electronically to the vendor, the analyst must print the vendor paperwork for technical review. This review is documented by the technical reviewer's electronic signature of the case report in the LIMS.

2.11 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, e-mail or vendor portal.

2.12 After official results have been received by the proficiency test provider, a designated Quality Assurance Unit member grades the tests.

2.12.1 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. The Control of Non-Conforming Work procedure and/or the Quality Incident Review procedure may be followed in such instances.

2.13 All proficiency-test participants are informed of their final test results. Participants are required to sign the appropriate area on the hardcopy Proficiency Test Evaluation Form, or electronically sign the Proficiency Test Grading workflow in Qualtrax, to document that they have received and have been informed of the final test results.

2.14 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 ANAB). 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 and FA allow 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.

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 **Blind Reanalysis Program.** The laboratory has a blind re-analysis program for sexual assault kits containing clothing items that are negative for the presence of male DNA. The purpose of this program is to ensure that negative results are accurate.

4.3.1 Approximately 25% of sexual assault kits which are negative for the presence of male DNA, as well as containing clothing items that were negative for the presence of biological stains, 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 sexual assault cases is conducted by Quality Assurance Group analysts that were not involved in the original analysis. The sexual assault kit is re-inventoried to ensure all items that should have been tested were tested and the clothing present in the kits are re-examined to ensure that no potential biological stains were missed. Examination notes and 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.