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, observation based 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 In keeping with the spirit of the standards, participants assigned to the same test should not discuss their results during the testing period or prior to the vendor due date unless they are paired together. A participant should not perform technical reviews for others participating on the same test they are assigned unless technical reviews are the individual's sole responsibility.

1.4 External proficiency tests are obtained from New York State and ANAB approved proficiency test providers, for example, Collaborative Testing Service (CTS), Bode Cellmark Forensics (IQAS)and Forensic Assurance (FA).

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

2 DNA Open-External Proficiency Testing Program

2.1 All DNA analysts, technical reviewers, and technicians undergo semiannual external proficiency testing. 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 eight 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. The Proficiency Testing schedule is reviewed and approved by the Quality Assurance Manager and the Technical Leader. 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 If the laboratory participates in a proficiency test provider's pre-distribution program, that test may count as one of the two external proficiency tests for the analyst performing the test for that calendar year. The laboratory must resubmit the pre-distribution test results during the general distribution testing phase for that specific test in order to be included in the provider's published external summary report. The pre-distribution test will be considered assigned with the general distribution testing phase of the proficiency test when the general distribution testing phase commences.

2.5 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):

2.5.1 Excluded suspects

2.5.2 Mixtures, even if there are other single source profiles

2.5.3 Epithelial cell fractions from an unknown stain or from a body orifice swab, even if the results match the victim type.

2.6 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.

2.7 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.

2.7.1 Individuals using both manual and automated methods are proficiency-tested in one method at least once per year.

2.8 Individuals who perform STR, YSTR, and/or mtDNA amplification, analysis and/or review must perform these skills at least once per year per technology. Technology refers to the type of forensic DNA analysis performed (i.e. STR, YSTR, mtDNA.)

2.8.1 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.

2.9 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.

2.10 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 form (hardcopy or electronic) to document the results. The DNA interpreting analyst must ensure that the data transcribed to the vendor's form is accurate. The proficiency test file is then sent for a full technical review.

2.11 In addition to conducting a full technical review of the proficiency test file, the reviewer(s) must also review the completed vendor's form 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.

2.12 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 e-mail or vendor portal.

2.12.1 Circumstances may arise when an individual may not be able to meet the vendor submission due date. On rare occasions, requests may be made to the vendor to extend their due date. The granting of an extension is at the discretion of the vendor.

2.13 Participants should fill out the PT Requirements Tracking log as a tool for them to keep track of their annual requirements and assist the grading process.

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

2.14.1 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.

2.14.2 (ANAB AR 3125 7.7.5 f) When the expected result is not attained during a proficiency test, ANAB will be notified within approximately 30 days from when the result is reviewed by the QA designee.

2.15 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.

2.16 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 (Body Fluid Identification) 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.

3.1.1 This test covers non-instrumental serology testing

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 Molecular Serology (Proteomics) External Proficiency Testing Program

4.1 All trained analysts, technical reviewers, and technicians undergo annual external proficiency testing to full extent in which they perform each technology in casework. Technology refers to the type of forensic serology analysis performed (MRM LCMS).

4.2 External Molecular Serology proficiency tests are purchased from CTS.

4.3 All specimens of an external proficiency test are analyzed according to current standard operating procedures.

4.4 The laboratory utilizes a team approach for casework testing. Therefore, proficiency tests are conducted in the same manner. However, each individual is proficiency tested to the full extent of his or her participation in casework.

4.5 The laboratory report summarizing the results of the Proficiency Test and the vendor form documenting results is written by the analyst. The analyst must ensure that the data transcribed to the vendor's form is accurate. The proficiency test file is then sent for full technical review.

4.6 The test is reviewed by an assigned Technical Reviewer. The reviewer must conduct a full technical review and ensure vendor form data has been transcribed correctly prior to being issued to the vendor. The review is documented by the technical reviewer's electronic signature of the case report in LIMS.

4.7 After the proficiency test has been completed and a full administrative review has concluded, the Interpreting Analyst 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 e-mail, or vendor portal.

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

4.8.1 Non-administrative discrepancies on proficiency tests that affect results and/or conclusions should be reported to the appropriate Technical Leader at the time of discovery. The Control of Non-Conforming Work procedure and/or the Quality Incident Review procedure may be followed in such instances.

4.8.2 (ANAB AR 3125 7.7.5 f) When the expected result is not attained during a proficiency test, ANAB will be notified within approximately 30 days.

4.9 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.

4.10 After the grading of all proficiency tests within the series, the Quality Assurance designee informs the appropriate Technical Leader of the results of all participants.

5 Observation-based Proficiency Testing for Rapid DNA

5.1 The laboratory does not utilize external proficiency tests that include Rapid DNA sample processing and interpretation. Therefore, observation-based proficiency tests are employed to demonstrate the analyst's technical skills and interpretation.

5.1.1 Analysts trained in Rapid DNA testing will be internally proficiency tested once per year.

5.2 Observation-based proficiency tests include the testing of an unknown sample prepared by the Quality Assurance Unit. Testing is documented using an internal proficiency test case file.

5.2.1 A buccal swab of a lab staff member will be collected on an ANDE collection swab as described in the ANDE Rapid DNA manual.

5.3 Participants must process the sample in accordance with the current manual procedure, make comparison to the appropriate databases, and report their conclusions.

5.4 The test is reviewed by the assigned Technical Reviewer and submitted to the Quality Assurance Unit to grade. A member of the Quality Assurance Unit confirms the analysts have correctly completed all the aspects of testing and the correct results were obtained.

5.4.1 Non-administrative discrepancies on proficiency tests that affect results and/or conclusions should be reported to the appropriate Technical Leader at the time of discovery. The Control of Non-Conforming Work procedure and/or the Quality Incident Review procedure may be followed in such instances.

5.4.2 (ANAB AR 3125 7.7.5 f) When the expected result is not attained during a proficiency test, ANAB will be notified within approximately 30 days from when the result is reviewed by the QA designee.

5.5 Participants are notified of the final test result after grading is complete in the same manner as external proficiency tests. The appropriate Technical Leader is informed of the test results of all participants.

6 Blind Re-analysis Proficiency Testing Program

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

6.2 **DNA Blind Reanalysis Program.** The Quality Assurance Unit is responsible for reanalyzing DNA samples, reviewing the results, and comparing them to the original analyses.

6.2.1 Each month, a minimum of two (2) exemplar samples are selected from cases completed within the previous year.

6.2.2 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.

6.2.3 A second reanalysis must be performed if the results are not concordant. All follow-up actions must be documented and maintained.

6.3 **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.

6.3.1 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.

6.3.2 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.

6.3.3 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.

6.4 **Molecular Serology Blind Reanalysis Program.** Molecular serology samples will be re-analyzed, results will be reviewed and compared to the original analyses. The purpose of this program is to ensure that results are concordant.

6.4.1 Each month, a minimum of two (2) protein extracts are selected from completed cases that have had samples processed with in the past 4 months.

6.4.2 Each sample is submitted for, digestion and LCMS, 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 Molecular Serology group.

6.4.3 A second reanalysis must be performed if the results are not concordant. All follow-up actions must be documented and maintained.

6.4.4 If an instrument is down for a month, reanalysis is not required for that month.

7 Quality Control Monitoring Program

7.1 The Quality Control (QC) Monitoring Program is a quality assurance program where cases examined by an analyst during a specified time-period are reviewed prior to distribution to ensure that no cross-contamination has occurred during evidence exam.

7.2 Each week, cases examined by one or more analysts from the previous week are selected for review via the QC Monitoring Program. Approximately 5-10% of cases examined each week will be selected for the QC Monitoring Process. This selection is done by Management. Management queries the cases examined and samples cut by the analyst over a 3-day period and assigns a QC Monitor to the set of cases.

7.3 Testing is performed on the set of cases and the results are technically reviewed as per normal course of business. Prior to the cases being finalized, the QC Monitor evaluates the cases for cross-contamination via the QC Monitoring Process.

7.3.1 The QC monitor sets up a STRmix™ database search utilizing the relevant profiles in the set of selected cases as part of the QC Monitoring Process. The QC monitor reviews the results and if necessary, consults with the Technical Leader and the Quality Assurance Manager. Additional STRmix™ runs may be performed if needed.

7.3.1.1 Comparisons made during the QC monitoring process are for Quality Control purposes only, in order to evaluate for cross-contamination.

7.3.2 The QC monitoring process is reviewed by the designated QC Reviewer to ensure the correct data was entered into the profile lists, and that the results were evaluated properly. Once the QC Review is completed, the Technical Reviewer(s) finalizes all cases in the set unless additional testing or consultation is needed.

7.4 All actions are documented and maintained in a Qualtrax workflow.

8 Competency for Reinterpretation of Legacy Data

8.1 The laboratory does not utilize external proficiency tests that include interpretation of legacy technology, typing test kits or platforms for which they were previously qualified. Therefore, the laboratory employs an interpretation competency test to demonstrate that analysts have maintained or have reestablished the technical skills and knowledge needed in the reinterpretation of legacy data.

8.2 Legacy interpretation competencies contain case scenario(s), exemplar and evidentiary DNA profiles previously run using legacy DNA typing systems for interpretation and comparison as well as references to manual sections of data interpretation in use at the time the samples were typed. Analysts must interpret sample results, make appropriate comparisons, and perform relevant statistical analyses as applicable to the interpretation guidelines in place at the time the samples were typed.

8.3 A member of the Technical Leader Team (s) reviews the documentation associated with an analyst's legacy interpretation competency and confirms that they have correctly completed the elements of the competency. The analyst is then authorized (via email) to reinterpret legacy data for no more than a two-year period. The documentation of this authorization is retained by the Training Group.