Purpose

This procedure was established to outline the requirements and guidelines necessary for proficiency testing within the DNA/Biology section of the LSD&FC laboratory.

Scope

This SOP applies to all technical personnel at LSDFC.

Guidelines & Requirements

- ISO/IEC 17025: 2017 (E) Standards
- R104 - A2LA General Requirements – ISO/IEC 17025:2017 Accreditation of Field Testing and Field Calibration Laboratories
- R103 – General Requirements: Proficiency Testing For ISO/IEC 17025 Laboratories
- P113- A2LA Policy on Measurement Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies (CABs)
- P102a – A2LA Policy on Metrological Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies for all Calibrations and Verifications of Measurement and Test Equipment
- AABB's Guidelines "Guidance for Standards for Relationship Testing Laboratories", 12th Edition.

Reagents/Materials/Equipment

Proficiency Test(s) compliant with the requirements established above.

Procedure

Proficiency Tests

1. Proficiency tests are given to qualified laboratory staff to evaluate both their individual competence and the overall quality performance of the laboratory.

2. Proficiency tests must be analyzed using only approved methods and/or procedures.
3. The proficiency testing program shall meet the A2LA Proficiency Testing for ISO/IEC 17025 Testing Laboratories.
4. External DNA proficiency tests are obtained from A2LA approved proficiency test providers, for example, Collaborative Testing Service (CTS), Orchid Cellmark (IQAS), and Forensic Assurance
5. Proficiency testing samples shall be equally distributed among trained and qualified personnel.

Biological Relationship Proficiency Testing

1. The Human Identity Laboratory must participate in a proficiency testing program for each genetic system used for reporting test results.
2. Per AABB guidelines and as applicable, Proficiency testing shall be representative of the cases the laboratory performs to include standard trios, single parent (2-party) and family studies (reconstruction cases).
    a. Note: CAP does not include single parent cases within their proficiency testing program. LSD&FC shall perform a calculation of an internally created proficiency for 2-party casework.
3. The laboratory must participate in a formal graded external proficiency test program for one or more of the genetic systems used to report test results.
4. LSD&FC must participate three times a year for each genetic system analyzed in the laboratory.
5. LSD&FC may not participate in inter-laboratory communication about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider.
6. Active proficiency samples may not be referred to another laboratory nor accepted from another laboratory.

Forensic Proficiency Testing

1. The Quality Manager will administer the proficiency test within the laboratory with assistance from the DNA Technical Leader if needed.

2. All forensic qualified analysts, technical reviewers, and technicians must undergo semiannual external proficiency testing to the full extent in which they perform each technology in casework.

3. A qualified analyst who is proficiency tested in the specific DNA methodology is qualified to serve as a technical reviewer without needing to take an additional proficiency test as a technical reviewer.

   Note: Technology refers to the type of forensic DNA analysis performed (i.e. STR or YSTR). It is permissible for multiple technologies to be reported on a single proficiency test.

4. The proficiency test must occur two times during one calendar year. The first event must take place in the first six months of the calendar year and the second event in the last six months of the calendar year. The interval between the events is at least four months and not more than eight months. The due date to the manufacturer shall be used to calculate the time interval between proficiency tests.

5. An analyst whose sole responsibility is technical review must be proficiency tested in technical review.

6. The administrative reviewer is not required to be a current or former qualified DNA analyst.

7. When possible, proficiency test samples will be representative of the samples that would be analyzed in routine casework.

8. The proficiency test shall cover at least annually the following assays:

   - Human Blood Identification
   - Semen Identification
   - Routinely used DNA extraction Methods (i.e. simple organic, differential organic, SwabsSolution™ Kit, PunchSolution™ Kit)

9. Quantitation and STR system used for biannual proficiency testing shall include the following assays:

a. Powerplex® Fusion 6C Kit

b. Quantiplex Pro RGQ Kit

10. The proficiency program is administered in an open proficiency testing format.

11. Upon receipt of the proficiency test, the Quality Manager enters the appropriate information in the proficiency 4-year plan. The Quality Manager then fills out the "DNA/Biology Proficiency Test Tracking Form". This form includes the following information:
    - Name of analyst/technician receiving the test
    - Date received and date when results are due back to the Quality Manager
    - Kit Manufacturer/Vendor
    - Kit Unique Identifier
    - Date results submitted to the manufacturer/vendor
    - Staff Category (i.e. DNA analyst, technician, or technical reviewer)
    - Type of sample (e.g. relationship, forensic)
    - Type of serology testing (if applicable)
    - Type of DNA extraction
    - Type of Quantitation
    - Type of Amplification (i.e. PowerPlex Fusion 6C)
    - Type of Capillary Electrophoresis Instrument
    - Type of Analytical Software
    - Type of Interpretation (e.g. serology, DNA mixture, relationship)

    The form and the proficiency test are then hand-delivered by the Quality Manager to the analyst/technician. Both analyst/technician and Quality Manager shall sign and date the form to document the transaction.

12. Upon completion of testing, a laboratory report summarizing the results of the proficiency test is prepared by the analyst. Technicians shall prepare technical documentation corresponding to the tests performed and do not need to prepare a report. The tested DNA analyst/technician is also responsible for completing any vendor paperwork for documentation of the results. The DNA analyst must ensure that the data transcribed to the vendor's paperwork is accurate. The proficiency

test file is then forwarded for full technical and administrative reviews. An analyst working on the same proficiency test shall not participate in the technical and administrative review of the proficiency test.

13. After the proficiency test has been completed and reviewed, the analyst/technician assigned to the proficiency test is responsible for delivering the test results to the Quality Manager.

14. The Quality Manager will deliver the results on or prior the due date to the test provider. The delivery method may vary from vendor to vendor, but is typically either by mail, fax, e-mail or electronic submission through the test provider's website.

15. The Quality Manager will arrange for the direct submittal of the final proficiency test results by the proficiency test provider to A2LA, followed by subsequent analysis of all relevant proficiency testing participation to A2LA within 30 days upon receipt.

16. In the event that an external test is not available for a subdiscipline (e.g. body fluid identification), an internal proficiency test may be used. An internal proficiency test may be any of the following:
    - A sample prepared in-house either by the section technical leader or director;
    - An expired (i.e. non-current) test from an external proficiency test provider:
    - A previously analyzed case material.

The process for distribution, recording, testing, and documentation of tests results shall follow the same procedure as an external test. The evaluation of the tests results for tests prepared in-house shall be performed by the Quality Manager and technical personnel who participated in the preparation of the test. Evaluation of the other types of tests as listed above shall be performed by the Quality Manager with assistance of technical personnel not involved in the testing, if needed. The LSDFC Proficiency Test Review Form shall be prepared (see Section 17 for further information). The Quality Manager shall provide evaluation of this proficiency test within 30 days of completion to A2LA and provide a note why an external proficiency test was not used. If feasible, the Quality Manager shall procure an

external test for the subdiscipline prior to the due date for the next proficiency test cycle.

17. LSD&FC will maintain the following records for each proficiency tests:
    a. Test set identifier
    b. Identity of analyst/technician
    c. Date of analysis and completion
    d. Completed case file with all photos, worksheets, case notes, data, conclusion, statistics and report
    e. Proficiency test results
    f. Any discrepancies noted
    g. Any corrective actions taken

18. These records will be retained by the Quality Manager according to the Retention Procedure in a secure location, and accessible upon request.

19. After the official results have been returned by the proficiency test provider, the Quality Manager will compare the official results to the results provided by each qualified staff member of LSD&FC and prepare the LSDFC Proficiency Test Review Form. This form captures the evaluation criteria listed under Section 19. Upon review of the evaluation with the Quality Manager, the analyst/technician shall document this review by signing and dating the form.

20. After review of the evaluation by the analyst/technician, signature of the form by both analyst/technician and quality manager, the form is then routed to the section director and center director for his/her signature.

21. The following proficiency test criteria will be evaluated:

Results:	All reported results of analysis are correct according to consensus results provided by the PT Provider or by the internal test preparer
Conclusions:	• All reported inclusions are correct. • All reported exclusions are correct. • All results reported inconclusive or uninterpretable results are within

	laboratory guidelines.
Reports:	• All final reports will be graded as Satisfactory or Unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the results reported. • Administrative errors must be documented and corrective actions taken and documented.
Discrepancies:	• All discrepancies and subsequent corrective actions taken will be documented.

22. If a discrepancy is identified in a proficiency test:

h. If an ***Administrative Error*** is detected (i.e., error on documentation, clerical), immediate action will be taken to correct the error (e.g., submit a corrected report). The Section Director and Center Director will be notified. Further incidents may result in retraining or disciplinary action. The issue shall be documented on the Incident Report Form.

i. If a ***System Error*** is detected (i.e., error due to equipment or reagents), immediate action will be taken by the laboratory to determine the cause of the error and correct it. A review of all casework performed since the last proficiency test will be conducted. All laboratory personnel will be notified including the Section Director and Center Director. If necessary, modifications to the standard operating procedure or acquisition of new equipment or change in reagent supplier will be made to eliminate the possibility of future error. These changes will be performed following the SOP writing and revision procedure. The issue shall be documented in a Corrective Action Report.

j. If an ***Analytical Error*** is detected (i.e., discrepancy due to analytical or interpretive mistake) the analyst/technician involved will be removed from casework until the source of the error is determined. The Section Director and Center Director must be notified immediately. The Quality Manager will initiate a Corrective Action Report. The DNA Technical Leader will assist the quality manager for the determination of the root cause. The CAR Form will be completed according to the Quality Assurance

Guidelines; the analyst/technician involved may require retraining; disciplinary action may be indicated.

- The Center Director and the Section Director, Section Technical Leader and Quality Manager will conduct a thorough review of procedures and techniques used by the analyst with the discrepancy.
- The procedures involved will be reviewed to determine if the cause of the error lies within the SOPs. If it is determined that the discrepancy was within the procedure, the procedure will be modified to correct the problem.
- If it is determined that the discrepancy was an analyst/technician's technical error, the individual will be re-trained in the area in question. All cases since the analyst/technician last proficiency will be reviewed to determine if similar discrepancies were noted. Once it has been determined by the Quality Manager and Technical Leader that the analyst/technician has corrected the problem he/she may, depending on the nature of the discrepancy, be allowed to perform a competency test to determine if he/she should be allowed to resume casework.
- Per A2LA Requirements on proficiency testing for ISO/IEC 17025 Requirements, the Quality Manager shall enroll the analyst/technician in the next available PT round to demonstrate acceptable performance.

d. Upon close-out of the corrective action report, the CAR and all supporting documentation shall be forwarded to A2LA within 30 days of the close-out date.

e. AABB guidelines require the laboratory to evaluate and take action on nonconforming proficiency test results in response to unacceptable grades or deviations from nongraded challenges with known answers or that have reached 80% consensus. If the laboratory fails an overall conclusion regarding alleged genetic relationship, the corrective action plan shall include communicating to the AABB's Accreditation and Quality Department within 30 days with the following items:
   i. The nonconformance(s)
   ii. The corrective action(s) taken
   iii. The plan to monitor the effectiveness of the corrective action plan

k. Refer to the procedure on Non-conformities and Corrective Actions for

further guidance.

l. A copy of the corrective action report will be stored in the affected case file.

m. The Quality Manager will review and sign off on all Corrective Action reports.

Procedure History

Procedure History		
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Author		**Date**
Shelley Johnson		September 1, 2017
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Review & Approval History		
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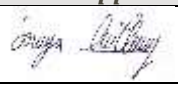
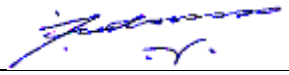
11/28/2018		***Soraya McClung, MFS*** ***Director, DNA Technical Leader***
11/28/2018		***Richard I. Somiari, PhD*** ***Center Director***
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11/28/2018	Added A2LA Requirements (R103) Updated Footer	Soraya McClung	v1.0
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