Purpose

Validation is the process by which a procedure is evaluated to determine its efficacy and reliability for Biology/DNA analysis. It is the accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected. Only validated methods and procedures may be used with processing of DNA/Biology casework samples.

The validation process identifies the critical aspects of a procedure which must be carefully controlled and monitored. Validation studies must have been conducted by the LSD&FC prior to the adoption of a procedure by the Center. This procedure describes the requirements of the validation process.

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

Method(s) for Validation

Procedure

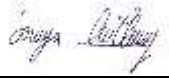
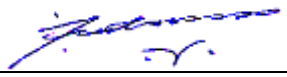
1. All staff members are encouraged to propose new technologies, methodologies, or procedures to be used in casework.
2. Proposals may be forwarded to the Section Director and/or the Center Director.
3. The Management shall make a final determination on whether or not to validate any proposed new technology, methodology, or procedure.
4. ***Validations*** are a planned activity, and the exact tests of one validation may differ from another depending on the new technology, methodology, or procedure being tested.
5. Management shall be consulted to determine which studies must be conducted to ensure efficacy and reliability for Biology/DNA casework use.
6. A validation plan shall be prepared by the Technical Leader and reviewed by the section director prior to execution. The plan shall include a description of the samples to be used for the study. Known and/or previously characterized samples shall be used for the study. The plan should include the acceptance criteria.
7. If the technology, methodology, or procedure is to be used for forensic DNA testing, the Quality Manager must ensure that the appropriate requirements, as listed in the ISO/IEC 17025: 2017 Standards Document and the A2LA R104 Requirements for "Selection, Verification and Validation of methods" are met. The Uncertainty of Measurement requirement is not applicable to the DNA/Forensic Biology Section and therefore will not be included in the validation plan.
8. The Quality Manager shall ensure that the appropriate tests are used to comply with the Standards for Relationship Testing Laboratories set forth by the AABB for Relationship Testing.
    a. Before a change in a process for a test method or adds a new process or test method it shall be validated.
    b. For new or novel test methods, part of the validation process shall require the analysis of at least 20 biological relationship test samples with consistency of test results within the laboratory (precision) and between the laboratory or other laboratories (accuracy).
    c. The complete validation process shall identify thresholds and acceptability criteria and include evaluations of persons whose phenotypes are unknown, but whose relationships are well established.
    d. Validation studies shall be reviewed and accepted by the Relationship Testing Standards Program Unit known as (RT SPU) of the AABB.

e. For loci (or locus) added to the existing test methods, the validation process shall require the analysis of at least 20 biological test samples with consistency of test results within the laboratory. If the laboratory establishes its own frequency database for the loci (or locus), the power of exclusion shall be determined and compared with published values, if available, as part of the validation process.

9. Validation plans may differ from the initial assessment and may be updated as the validation study development proceeds.
10. While not required, prior to starting any validation, a preliminary assessment may be done to ensure the time and effort that will be dedicated to the validation will be worthwhile.
11. An ***internal validation*** is an accumulation of test data within the laboratory to demonstrate that established methods and procedures (such as forensic DNA methods or relationship procedures that are published in peer reviewed articles) perform as expected in the laboratory.
12. Prior to implementing a new methodology or procedure, LSD&FC must first demonstrate the reliability of the method or procedure internally. This includes changes in detection platform, changes in DNA test kits, or the implementation of new identification procedures.
13. Internal validation studies must be sufficient to support and document the reliability of the method or procedure and must include the following, where applicable:
    a) Testing of mock samples
    b) Precision using reference standards or reference materials
    c) Reproducibility
    d) Repeatability
    e) Sensitivity
    f) Specificity
    g) Stochastic studies (i.e. Limit of Detection, Limit of Quantitation, linearity, variance)
    h) Mixture studies
    i) Specificity
    j) Contamination assessment
14. As a result of the internal validation studies, quality assurance parameters, interpretation guidelines, and mixture interpretation guidelines (where applicable) shall be defined.

15. The documentation of an internal validation includes the validation summary, which summarizes all testing conducted. The validation summary must include specific recommendations (such as settings, quality assurance parameters, interpretation guidelines, or mixture interpretation guidelines) and a statement as to whether or not the method is fit for the intended use.
16. The validation study should include:
    a) Data and all required summaries
    b) Draft technical procedure
17. New procedures validated to replace existing ones shall generate comparable or better results to the previously used method.
18. All validations must be reviewed and approved by the DNA/Forensic Biology Section Director, the DNA Technical Leader, the Quality Manager, and the Center Director before a procedure is used in the Biology/DNA casework.
19. All appropriate staff will receive training on the newly validated methodologies prior to use with Biology/DNA casework. Training is not required for staff who participated in the validation study.
20. Validation study documentation are retained by the Quality Manager for a period of five years or one full accreditation cycle.

Procedure History

Procedure History		
Initial Version Created		
Author		**Date**
Shelley Johnson		September 1, 2017
Current Version		**Effective Date**
v2.0		November 28, 2018
Review & Approval History		
Date	**Reviewed & Approved by**	**Title**
11/28/2018		**Soraya McClung, MFS Director, DNA Technical Leader**
11/28/2018		**Richard I. Somiari, PhD Center Director**

Revision History			
Date	**Reason for Revision**	**Reviser**	**Version being changed**
11/28/2018	Removed FBI QAS Requirements Updated Guidelines & Requirements Updated Footer	Soraya McClung	v1.0

Review History		
Reviewed By	**Date**	**Version**