



Intermountain Forensics

SOP #	ADM-105
Revision #	01

Forensic DNA Technical Leader Approval

Issue Date

6/3/20

Validations

1. Purpose

To define what Internal Validation, Developmental Validation, and Performance Check are and when to perform them.

2. Summary

Validation studies are performed to determine the suitability and reliability of a testing method, technology, software and/or instrument. Validation data may be shared in a multi-laboratory system.

3. Procedure

1. All methods, technologies, software, and instruments used to generate forensic genetic data for analysis are internally validated as extensive as is necessary to determine functionality and limitations before they are used on casework.
2. Validation results obtained and a statement as to whether the method is suitable for the intended use is documented and summarized as well as reviewed and approved by the DNA Technical Leader.
3. Additional validation or performance checks are performed on new or updated procedures, methods, software, and instruments that affect the quality of the testing.
4. **Internal Validation** studies include, as applicable:
 - a. Known and non-probative evidence samples or mock evidence samples
 - b. Precision and Accuracy Studies
 - c. Sensitivity and Stochastic Studies
 - d. Mixture Studies
 - e. Contamination Assessment Studies
5. Any novel method developed by Intermountain Forensics will have a **Developmental Validation** performed before use on casework to include, as applicable:
 - a. Characterization of the genetic marker
 - b. Species Specificity
 - c. Sensitivity Studies
 - d. Stability Studies
 - e. Case-Type Samples
 - f. Population Studies
 - g. Mixture Studies
 - h. Precision and Accuracy Studies
 - i. PCR Studies
 - i. Reaction Conditions
 - ii. Assessment of Differential and Preferential Amplification
 - iii. Effects of Multiplexing
 - iv. Assessment of Appropriate Controls
 - v. Product Detection Studies
 - j. Peer-reviewed publication
6. Newly validated DNA methods, testing kit, or instrument (Amplification through Characterization) is checked against a traceable reference material.
7. Validation data may be used to:
 - a. Show a method, technology, and any associated instruments consistently function as intended
 - b. Determine interpretation guidelines
 - c. Determine interpretation thresholds (Analytical, Stochastic, etc.)
 - d. Determine upper and lower limits of the method, technology, and/or instruments
 - e. Share in a multi-laboratory system, provided:
 - i. The shared validation data is available at each site
 - ii. Each laboratory completes site specific:
 1. Precision Studies
 2. Accuracy Studies
 3. Contamination Assessment Studies



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8. Software
 - a. For Instruments – New or Major Modification
 - i. Functionality Testing
 - ii. Reliability Testing
 - b. Analysis and/or interpretation of DNA data - New or Major Modification
 - i. Functionality Testing
 - ii. Reliability Testing
 - iii. Precision and Accuracy Studies (if applicable)
 - iv. Sensitivity Studies (if applicable)
 - v. Specificity Studies (if applicable)
 - c. Statistical Calculations - New or Major Modification
 - i. Functional Testing
 - ii. Reliability Testing
 - iii. Precision and Accuracy Studies (if applicable)
 - d. Does not impact the analytical process, interpretation, or statistical calculations, or minor modification
 - i. Functional Testing
9. A **Performance Check** is performed by testing a known DNA source and a blank to determine expected functionality.
 - a. Additional samples may be required by the DNA TL as needed
10. When additional instruments, processes and/or chemistries are implemented that have been previously validated, a performance check shall be performed to demonstrate that the instrument meets the same standards.
 - a. This includes instruments, processes and chemistries that are located and satellite laboratories
11. Finalized validation summaries will be maintained as a controlled document.
12. A log summarizing validation progress and completion date will be maintained
13. Completed validation records that include supporting data will be maintained indefinitely.

4. **References**

[SWGDM Working Group on DNA Analysis Methods Validation Guidelines for DNA Analysis Methods](#)

5. **Definitions**

N/A