Validations

1. Purpose

To define what Internal Validation Developmental Validation, and Performance Check for new instruments and methods 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.
    a. The validation is intended to establish:
        i. The data analysis and interpretation associated with the method
        ii. Criteria for the expectations of the data and requirements of data suitability to report a result, opinion, or interpretation based on that data
        iii. The limitations of the method where it should not be applied to casework

2. Additional validation or performance checks are performed on new or updated procedures, methods, software, and instruments that affect the quality of the testing.

3. Each validation will have a written validation plan that includes:
    a. The method that will be used
    b. The acceptance criteria for each evaluated component, to use the method in casework

4. Individuals must be authorized or previously authorized to perform the testing and analysis in the validation
    a. DOC-327 Validation Participation Authorization form may be used to complete the authorization

5. Finalized validation summaries will be maintained as a controlled document.
    a. The validation summary and its associated support documentation will be approved by the DNA Technical Leader and will include the following elements:
        i. Procedure used in the validation
        ii. Specification of the requirements
        iii. Determination of the performance characteristics of the method
        iv. Results obtained
        v. A statement of validity, detailing its fitness for the intended use

6. Completed validation records that include supporting data will be maintained indefinitely.

7. A log summarizing validation progress and completion date will be maintained.

8. **Internal Validation** studies include, as applicable:
    a. Known and non-probative evidence samples or mock evidence samples
        i. Case-Type samples should only be comprised of mock casework samples. Actual casework samples where the customer has given permission to use the sample/extract in the validation may only be used after the sample/extract have been previously run on an equivalent, validated technology and those results have been reported to the customer. No report will be issued to the customer on the results obtained with the un-validated technology.
    b. Precision and Accuracy Studies
    c. Sensitivity and Stochastic Studies
    d. Mixture Studies
    e. Contamination Assessment Studies

9. 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
        i. Case-Type samples should only be comprised of mock casework samples. Actual casework samples where the customer has given permission to use the sample/extract in the validation may only be used after the sample/extract have been previously run on an equivalent, validated technology and those results have been reported to the customer. No report will be issued to the customer on the results obtained with the un-validated technology.
    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

10. Newly validated DNA methods, testing kit, or instrument (Amplification through Characterization) is checked against a traceable reference material.

11. 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

12. Software Validation
    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

13. A **Performance Check** is performed on new instrumentation that has been previously validated by the laboratory. 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. The scope of the Performance Check will be established by the DNA Technical Leader, based on the instrument being checked, and will be documented prior to the performance check commencing.
    b. This includes instruments, processes and chemistries that are located at satellite laboratories.
    c. This includes an instrument that is intended to be returned to service after being removed as directed by the DNA technical leader.
        i. Refer to MNT-200 General Maintenance for performance checks of instruments returning to service.

4. References

Scientific Working Group on DNA Analysis Methods - Validation Guidelines for DNA Analysis Methods

5. Definitions

N/A