Validation		
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Validation

1 Guiding Principles and Scope

1.1 Validation is the process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework 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 casework samples.

1.2 This is different from a performance check, which is a quality assurance measure to assess the functionality of laboratory instruments, equipment, and software that affect the accuracy and/or validity of forensic sample analysis. Modification to a system such as a hardware or software upgrade that does not impact interpretation or analysis of the typing results or the statistical analysis **shall require a performance check** prior to implementation.

1.3 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 Department of Forensic Biology prior to the adoption of a procedure by our laboratory. This procedure describes the requirements of the validation process.

1.4 When changes are made to a previously validated method, the influence of this change shall be evaluated by the appropriate Technical Leader, this includes the affect on associated data interpretation. A new or modified validation may be required if the change affects the original validation results.

2 Procedure

2.1 All staff members are encouraged to propose new technologies, methodologies, or procedures to be used in casework. Proposals may be forwarded to the Research and Development Team and/or the Technical Leader Team. The Director shall make a final determination on whether or not to validate any proposed new technology, methodology, or procedure.

2.2 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. The appropriate Technical Leader shall be consulted to determine which studies must be conducted to ensure efficacy and reliability for forensic casework use. If the technology, methodology, or procedure concerns DNA testing, the Technical Leader must ensure that the appropriate tests, as listed in the FBI's Quality Assurance Standards for Forensic DNA Testing, are conducted.

2.3 Validation plans may differ from the initial assessment of the Technical Leader. They may be updated as development proceeds.

2.4 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.

3 Developmental Validation

3.1 Developmental validation is the acquisition of test data and determination of conditions and limitations of a ***new or novel*** methodology for use on forensic samples.

3.2 If another laboratory's developmental validation studies are being used, appropriate documentation or citations for these studies must be available.

3.3 Developmental validation studies must include the following, where applicable:

3.3.1 Testing using case-type samples, including samples from adjudicated cases or mock samples that mimic casework samples

3.3.2 Characterization of genetic marker

3.3.3 Sensitivity, stability, and species specificity studies

3.3.4 Reproducibility studies

3.3.5 Population studies, such as allele frequency distributions and independence of the population databases

3.3.6 Mixture studies

3.3.7 Precision and accuracy studies

3.3.8 PCR-based studies, including reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and product detection studies.

3.4 All developmental validations conducted by the Department must include an executive summary, which summarizes all the studies conducted. The executive summary must include specific recommendations (such as settings, quality assurance parameters, interpretation guidelines, or mixture interpretation guidelines) and must include a statement as to whether the method is fit for the intended use. While not required, it is recommended that each study conducted have an individual summary of results.

4 Internal Validation

4.1 Internal validation is an accumulation of test data within the laboratory to demonstrate that ***established*** methods and procedures (such as forensic DNA methods or procedures that are published in peer reviewed articles) perform as expected in the laboratory.

4.2 Prior to implementing a new or revised methodology or procedure, the Department 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 body-fluid identification procedures. Internal validation studies must be sufficient to support and document the reliability of the method or procedure and must include the following, where applicable:

4.2.1 Testing using known samples

4.2.2 Testing using non-probative evidence samples or mock evidence samples

4.2.3 Reproducibility and precision

4.2.4 Sensitivity and stochastic studies

4.2.5 Mixture studies

4.2.6 Contamination assessment

4.3 As a result of the internal validation studies, quality assurance parameters, interpretation guidelines, and mixture interpretation guidelines (where applicable) shall be defined.

4.3.1 The procedure for validation of methods and interpretation guidelines should include the following:

4.3.1.1 Include the associated data analysis and interpretation.

4.3.1.2 Establish the data required to report a result, opinion, or interpretation.

4.3.1.3 Identify limitations of the method, reported results, opinions, and interpretations.

4.4 The documentation of an internal validation includes an executive summary, which summarizes all the testing conducted. The executive 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. While not required, it is recommended that each study conducted have an individual summary of results.

5 Review and Approval of Validation

5.1 Completed validation project packages are submitted to the appropriate Technical Leader for review and approval. The package includes:

5.1.1 Test records and all required summaries

5.1.2 Draft technical procedure

5.2 All validations must be reviewed and approved by the appropriate Technical Leader before the technology and/or procedure is used in casework.

5.3 **Note**: Approval of a validation does not necessarily denote that a technology or procedure is online for casework. Training needs, budgetary concerns, etc., must be taken into consideration before the technology or procedure is implemented.

5.4 At the Technical Leader's discretion, the technology or procedure may be used on select cases prior to lab-wide implementation. However, the technology or procedure is not to be used on any casework until standard operating procedures are written and have been approved by the appropriate Technical Leader.

6 Training

6.1 Training of the general laboratory commences after approval of the validation by the appropriate Technical Leader. The initial training of analysts (typically the Training Group, the Quality Assurance Group and the Implementation Team members) can be considered a "dry-run" of the procedure, and the technology, methodology, and/or procedure are not used in casework until all concerns that may be raised during the initial training have been addressed.

7 Storage of Validation Records

7.1 Records of validation studies are stored by the Quality Assurance Unit in conjunction with the Validation Group indefinitely. In general, validations that have been reviewed by an external audit team will be stored electronically, or in hardcopy on the fourth floor of the DNA Building (Records Storage), while hardcopy validations that have not been reviewed by an external audit team will be stored within the operational areas of the Validation Group or the Quality Assurance Unit. However, general convenience and spacing issues may alter the exact location of any validation study.