Validation

1 Guiding Principles and Scope

1.1 Validation is the process by which a method 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 and equipment. Each additional critical instrument, of the same instrument model validated for use in the laboratory, shall require a performance check prior to use in casework analysis.

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 effect on associated data interpretation. If the change to the method alters the validated steps, reagents, or critical instruments, the modified procedure must be evaluated by comparing the original procedure to the modified procedure using similar DNA samples. This evaluation must be documented, reviewed, and approved by the Technical Leader prior to implementation of the modified procedure into casework. A new or modified internal validation may be required if the change affects the original validation results or the modification has an impact on the efficacy or reliability of casework analysis.

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 management, the Technical Lead Team, and/or the Validation supervisor. 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.

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

2.5 The Technical Leader will authorize personnel to perform specific validations and testing. This will be documented as necessary, including but not limited to the management meeting power point.

2.6 For samples collected for validation studies, the FBiology Consent Template should be used.

3 Developmental Validation of Methods

3.1 Developmental validation is the acquisition of test data and determination of conditions and limitations of a ***new or novel*** method 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:

- Testing using case-type samples, including samples from adjudicated cases or mock samples that mimic casework samples
- Characterization of genetic marker
- Sensitivity, stability, and species specificity studies
- Reproducibility studies
- Population studies, such as allele frequency distributions and independence of the population databases
- Mixture studies
- Precision and accuracy studies
- 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.

3.5 Developmental validation shall precede the implementation of any new methods used for forensic DNA analysis. Peer-reviewed publication of the underlying scientific principle(s) of a method shall be required.

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4 Internal Validation of Methods

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 all manual and robotic methods used to perform any stage of DNA typing technology, 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 data analysis and interpretation and the following, where applicable:

- Testing using known samples
- Testing using non-probative evidence samples or mock evidence samples
- Reproducibility and precision
- Sensitivity and stochastic studies
- Mixture studies
- Contamination assessment

4.2.1 Mixture interpretation studies must include samples with a range of the number of contributors, template amounts, and mixture ratios expected to be interpreted in casework.

4.3 As a result of the internal validation studies, the following shall be defined:

4.3.1 quality assurance parameters

4.3.2 interpretation guidelines

4.3.3 mixture interpretation guidelines (where applicable)

4.3.4 the application of appropriate statistical calculations and any statistical thresholds used to make conclusions (where applicable)

4.3.5 establish the data required to report a result, opinion, or interpretation

4.3.6 identify limitations of the method, reported results, opinions, and interpretations, including the criteria for uninterpretable data

4.4 Newly validated DNA methods, typing test kits, or platform instrument models shall be checked against an appropriate and available certified reference material (or sample made traceable to the certified reference material) prior to the implementation of the method for forensic analysis.

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4.4.1 The check against an appropriate and available certified reference material prior to the implementation is not required for an NDIS approved Rapid DNA System for use on database, known or casework reference samples that has been performance checked or for a Rapid DNA instrument used for modified Rapid DNA analysis on database, known or casework reference samples that has been internally validated.

4.5 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 Software Validation

5.1 Software used by the laboratory must be evaluated to assess its suitability for intended purpose. The evaluation will also determine the necessity of validation studies and/or software testing required before implementation.

5.2 Developmental validation of software that is used as a component of instrumentation for the analysis and/or interpretation of DNA data, or for statistical calculations, shall be performed prior to implementation in forensic DNA analysis. The underlying scientific principle(s) utilized by the software shall be publicly available for review or published in a peer-reviewed scientific journal.

5.2.1 Developmental software validation studies for new software or new modules of existing software used as a component of instrumentation shall include at a minimum, functional testing and reliability testing.

5.2.2 Developmental software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data shall include at a minimum, functional testing, reliability testing, and as applicable, accuracy, precision, sensitivity, and specificity studies.

5.2.3 Developmental software validation studies for new software or new modules of existing software for statistical calculations shall include at a minimum, functional testing, reliability testing, and as applicable, accuracy, and precision studies.

5.3 New software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations shall be subject to internal validation specific to the laboratory's intended use prior to implementation.

5.3.1 Internal software validation studies for new software or new modules for existing software used as a component of instrumentation shall include functional testing and reliability testing.

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5.3.2 Internal software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data shall include functional testing, reliability testing, and, as applicable, precision and accuracy studies, sensitivity, and specificity studies.

5.3.3 Internal software validation studies for new software or new modules of existing software for statistical calculations shall include functional testing, reliability testing, and, as applicable, precision and accuracy studies.

5.3.4 Software that does not impact the analytical process, interpretation, or statistical calculations shall require at a minimum, a functional test.

5.4 Modifications to software used by the laboratory as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations, shall be evaluated to determine if the modifications result in major or minor revisions to the software.

5.4.1 Any major revisions to software shall require regression testing, in addition to any requirements in section 5.3, before implementation. Examples of a major revision can include, but are not limited to, modifications of any algorithm, any statistical and/or calculation equation, sequence alignment strategy, data reports, and/or export of results.

5.4.2 Minor revisions to software shall require at a minimum, a functional test. Examples of a minor revision can include, but are not limited to, cosmetic modifications, improved printing or viewing features, or fixing invalid error messages.

5.5 The Qualtrax workflow, Fbio_Software Evaluation, should be used to facilitate documentation of software evaluation, validation and testing requirements, and approval.

6 Review and Approval of Validation

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

- Test records and all required summaries
- Draft technical procedure

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

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

6.4 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

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casework until standard operating procedures are written and have been approved by the appropriate Technical Leader.

6.5 Once their approval is documented, the Technical Leader is authorized to perform that technique in casework..

7 Training

7.1 The Technical Leader may authorize staff to perform techniques in casework if they worked extensively on the validation of such methods. A letter of authorization will be kept in the analyst's training folder.

7.2 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.

8 Storage of Validation Records

8.1 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 space issues may alter the exact location of any validation study.

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