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Standard for Internal Validation of Forensic DNA Analysis Methods

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Foreword

Internal validation is an integral step in the development and implementation of DNA methodologies for use in forensic testing. Internal validation provides opportunity to characterize the strengths and limitations of a methodology prior to laboratory implementation. The purpose of this document is to provide general requirements for the internal validation of all forensic DNA analysis methods.

This document is intended to be an umbrella document to subsequent validation standards, each of which will cover more detailed term definitions, specific methodologies, and their corresponding technical specifications.

This standard was revised, prepared, and finalized by the DNA Consensus Body of the AAFS Standards Board. The draft of this standard was developed by the Biology/DNA Biological Data Interpretation and Reporting Subcommittee of the Organization of Scientific Area Committees. All hyperlinks and web addresses shown in this document are current as of the publication date of this standard.

Keywords: *internal validation, DNA, forensic DNA analysis methods*

Table of Contents

Standard for Internal Validation of Forensic DNA Analysis Methods

1 Scope

This document details general requirements for performing an internal validation of all forensic DNA analysis methods within a forensic DNA laboratory.

2 Normative References

There are no normative references for this standard. Annex A, Bibliography contains informative references.

3 Terms and Definitions

3.1
developmental validation
The acquisition of test data and determination of conditions and limitations of a new methodology. This generally occurs while the conditions and parameters are being worked out prior to the establishment of a defined assay, procedure or product. Internal validation studies typically follow developmental validation studies.

3.2
forensic DNA analysis
The use of DNA technologies for the evaluation of biological evidence that may be involved in legal matters.

3.3
internal validation
The accumulation of test data within the laboratory for developing the laboratory standard operating procedures and demonstrating that the established protocols for the technical steps of the test and for data interpretation perform as expected in the laboratory.

3.4
interpretation
The process of evaluating DNA data for purposes including, but not limited to, defining assumptions related to mixtures and single source profiles, distinguishing between alleles and artifacts, assessing the possibility of degradation, inhibition, and stochastic effects, and determining whether the data are suitable for comparison.

3.5
methodology
Methodology is used to describe the analytical processes and procedures used to support a DNA-typing technology: for example, extraction methods (manual vs. automated), quantitation methods (slot blot, fluorometry, real-time), typing test kit, and platform (capillary electrophoresis, real-time gel and end-point gel systems, next generation sequencing).

3.6
validation
The process of performing and evaluating a set of experiments that establish the efficacy, reliability, and limitations of a method, procedure or modification thereof; establishing recorded

documentation that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.

4 Requirements

4.1 The laboratory shall conduct internal validation studies on all forensic DNA analysis methodologies prior to use on casework or database samples.

4.2 The laboratory shall conduct additional internal validation studies if an alteration that has the potential to influence results is made to a validated forensic DNA analysis methodology.

4.3 Internal validation studies shall be documented to include, at a minimum, a summary of all testing results and conclusions, raw data, and statistical calculations (if applicable) used to support conclusions.

4.4 Quality assurance parameters, interpretation guidelines, and analytical procedures shall be derived from internal validation studies.

In addition to the internal validation, information from developmental validation studies and internal validation studies from other forensic laboratories may be utilized, if made available for review.

4.5 Developmental validation studies may be used to satisfy applicable elements of the internal validation requirements if the laboratory conducted or participated in developmental validation of the methodology.

4.6 Results from internal validation studies that contradict developmental validation shall be investigated. A statement of explanation for the contradiction shall be included in the final internal validation document if the data are acceptable for analytical procedure development.

4.7 Results from internal validation studies that fall outside the scope of developmental validation shall be included in the final internal validation document if the data are utilized for analytical procedure development.

4.8 Where methodology-specific internal validation requirements exist, if a required study is determined to be not applicable, an explanation shall be provided in the final internal validation document.

4.9 Each laboratory within a multi-laboratory system shall conduct applicable internal validation studies.

Internal validation studies that are transferable across the entire lab system may be shared among laboratories within the system, if made available for review.

4.10 Internal validation studies shall be approved by the DNA Technical Leader or other appropriate personnel prior to implementation of the methodology for casework or database applications. Approval shall be documented by the DNA Technical Leader or other appropriate personnel, at a minimum, with initials and the date of review.

5 Conformance

5.1 In order to demonstrate conformance with these requirements, the laboratory shall have the following.

5.2 Documented internal validation studies and modifications to forensic DNA analysis methodologies intended for forensic casework or database applications prior to implementation.

5.3 Quality assurance parameters, interpretation guidelines, and analytical procedures derived from internal validation studies.

5.4 Documented approval by the DNA Technical Leader or other appropriate personnel prior to implementation.

Annex A
(informative)

Bibliography

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