SCIENTIFIC WORKING GROUP ON DNA ANALYSIS METHODS[1]

SWGDAM Validation Guidelines for DNA Analysis Methods: Overview Document

Short Title: *Validation Overview Document*

Effective XXXXXXX, XX, XXXX

Scope

The SWGDAM Validation Guidelines for DNA Analysis Methods: Overview Document provides guidelines for the validation of DNA analysis methods and supersedes the Scientific Working Group on DNA Analysis Methods (SWGDAM) Validation Guidelines for Forensic DNA Analysis Methods (2016). These guidelines are intended to serve as instructions for laboratories in validating procedures consistent with the *FBI Director's Quality Assurance Standards for Forensic DNA Testing and DNA Databasing Laboratories* (QAS). Each laboratory seeking to evaluate a new method shall determine which validation studies are relevant to the methodology, in the context of its application, and determine the experiments required to satisfy each study.

[1] The Scientific Working Group on DNA Analysis (SWGDAM; see SWGDAM.org) is comprised of forensic science practitioners and other experts who represent government laboratories within the U.S and Canada, as well as intra- and international professional groups and academia. SWGDAM recommends to the FBI Director revisions to the *Quality Assurance Standards for Forensic DNA Testing Laboratories* and the *Quality Assurance Standards for DNA Databasing Laboratories (QAS)*. SWGDAM provides a forum for its members and invited guests to discuss research, technologies, techniques, and training; and conduct or recommend studies to develop, test, and validate methods for use by forensic laboratories. SWGDAM's Guidelines and Recommendations represent best practices within the discipline. The term "should" is used herein to indicate good practices identified by SWGDAM. "Shall" distinguishes mandatory elements, which may be specified in the Quality Assurance Standards for Forensic DNA Testing Laboratories and/or Quality Assurance Standards for DNA Databasing Laboratories.

Table of Contents

Key Concepts:

- Each laboratory or laboratory system seeking to evaluate a new methodology shall determine which validation studies are relevant, in the context of its application, and determine the experiments required to satisfy each study.
- Validation shall precede the implementation of any new methods used for forensic DNA analysis.
- Developmental validation shall use case-type samples and include, as applicable, the following studies: characterization of genetic markers, species specificity, sensitivity, stability, precision and accuracy, population, mixture and PCR-based.
- Internal validation studies are used to supplement developmental validation and shall include the following studies, as applicable: known and non-probative evidence samples or mock evidence samples, sensitivity and stochastic, precision and accuracy, mixture and contamination.

1. Introduction

In the forensic context, the term "validation" refers to the process by which a procedure is evaluated to determine its efficacy and reliability for forensic application. This document

and subsequent modules provide guidelines for the validation of DNA analysis methods and supersedes the Scientific Working Group on DNA Analysis Methods (SWGDAM) Validation Guidelines for Forensic DNA Analysis Methods (2016). Terms used in this document and subsequent modules are intended to be consistent with definitions provided in the QAS.

Because these are guidelines and not minimum standards, in the event of a conflict between the QAS and these guidelines, the QAS and the QAS Audit Documents have precedence. Additionally, to avoid any such conflict, the mandatory term 'shall' has been used when that term is similarly used in the QAS although the use of the term 'shall' is not intended to transform these guidelines into standards. Laboratories are encouraged to evaluate and update their standard operating procedures and validation approach as needed, in light of these guidelines.

Methodology refers to the categories of methods used to perform a stage of DNA typing technology or technologies (e.g., methodologies for STR technology can include extraction, quantification, amplification, and detection,). Each laboratory seeking to evaluate a new method shall determine which validation studies are relevant to the methodology, in the context of its application, and determine the experiments required to satisfy each study. These guidelines are applicable to most methods used in DNA analysis. Some studies described herein may also assist in conducting evaluations of procedural modifications to existing validated methods.

Performing internal validation studies can be a time consuming and laborious process. Laboratories are encouraged to communicate and discuss plans and experiences regarding validation workflows which may save time and resources.

Laboratories validating new methods are encouraged to publish validation studies in a peer-reviewed journal or other means of dissemination to the forensic community. Publication provides access to information that other laboratories can use to guide their internal validation efforts. Utilization of published validation data from laboratories can increase efficiency, provide a valuable crosscheck between laboratories and enable ongoing improvements, and as a result, is strongly encouraged to promote consistency and demonstrate concordance among laboratories.

These Validation Guidelines have been organized such that recommended elements of validation studies are contained herein (referred to as the "Overview" document). The Overview document will be supplemented by modules intended to provide technology or methodology specific guidance. These modules will be continually added or edited as necessary and will be posted to the SWGDAM website: SWGDAM.org/publications. The studies in each module are not synchronized to the QAS; instead, they are presented in a suggested order to conserve resources such as time, reagents, samples and consumables and streamline required testing.

The study examples provided in the module appendices are informational and are not intended to dictate the types and numbers of samples every laboratory must use to satisfy

each study. Validation studies cannot account for all scenarios that may arise during casework examinations; however, laboratories should attempt to cover the range of variation expected to be encountered with forensic samples. Following implementation, laboratories should review results and, if necessary, conduct supplemental studies to improve workflow, analysis criteria, and/or interpretation.

2. General Considerations

The purpose of validation is to demonstrate the reliability and potential limitations of a method. There are two types of validations required for method implementation for forensic DNA analysis – developmental and internal. The application of existing technology to the analysis of forensic samples does not necessarily create a new methodology. Published developmental validation studies in other fields may sufficiently address forensic applications.

2.1 Developmental validation shall precede the implementation of any new methods used for forensic DNA analysis.

2.1.1 Peer-reviewed publication of developmental validation studies is strongly encouraged; however, validated methods may be implemented without such publication provided the underlying scientific principle(s) has been published.

2.1.2 A DNA laboratory may rely upon another laboratory's published developmental validation studies. The citations and/or publications referencing that validation must be available and accessible to support the underlying scientific basis.

2.2 Prior to using a method or procedure for forensic applications, a laboratory shall conduct internal validation studies on samples representative of those typically encountered by the end-user laboratory to demonstrate the reliability and potential limitations of the method.

2.2.1 Standard operating procedures, quality assurance parameters, guidelines for the evaluation and interpretation of analytical controls and DNA typing results, and as applicable statistical calculations, shall be derived from internal validation studies.

2.2.1.1 For example, lower template DNA may cause extreme heterozygote imbalance; as such, empirical heterozygote peak-height ratio data could be used to formulate mixture interpretation guidelines and determine the appropriate ratio by which two peaks are determined to be heterozygotes.

2.2.1.2 In addition to establishing an analytical threshold, results from sensitivity studies could be used to determine the extent and parameters of quality control tests that reagents or instruments require prior to their being used in actual casework.

2.2.2 For laboratory systems that consist of more than one laboratory, each of the laboratories shall complete, document, and maintain studies which may be impacted by site-specific factors (e.g. precision, sensitivity, and contamination). Studies that are not location-specific may be shared among locations and the summary of the shared validation data shall be available at each site.

2.2.3 It is important to utilize DNA samples extracted using the laboratory's validated methods as part of the internal validation studies.

2.2.3.1 Control samples (e.g., HL60, 2800M, 9947A, SRM, 007, and others) are expected to behave differently than samples extracted using laboratory processes, therefore, the known samples included in a validation should not be exclusively control samples. Control samples can be used to supplement samples extracted using the laboratory's processes.

3. Developmental Validation

The developmental validation process shall include, where applicable, the following studies using samples that are representative of those typically encountered by the end user laboratory:

3.1 **Characterization of genetic markers:** The basic characteristics (described below) of a genetic marker shall be determined and documented.

3.1.1 Inheritance: The mode of inheritance of DNA markers demonstrated through family studies.

3.1.2 Mapping: The genomic location of the genetic marker.

3.1.3 Detection: Technological basis for identifying the genetic marker (e.g., capillary electrophoresis, DNA sequencing, hybridization assays).

3.1.4 Polymorphism: Type of variation (e.g., sequence and/or length variants).

3.2 **Species specificity:** The ability to detect genetic information from non-human or non-targeted species (e.g., detection of microbial DNA in a human assay) shall be

determined through laboratory studies and/or sequence homology searches against genomic databases (e.g., a BLAST search). The detection of genetic information from non-human or non-targeted species does not necessarily invalidate the use of the assay but may help define the limits of the assay.

3.3 **Sensitivity studies:** The ability to obtain reliable results from a range of DNA quantities, to include the upper and lower limits of the assay, shall be evaluated.

3.4 **Stability studies:** The ability to obtain results from DNA recovered from biological samples deposited on various substrates and subjected to various environmental and chemical insults should be evaluated. If substrates and/or environmental and/or chemical insults could potentially affect the method, then the method shall be evaluated to determine the effects of such factors.

3.4.1 For database samples, stability studies may include samples on various substrates and subjected to potential PCR inhibitors or various storage conditions.

3.5 **Precision and accuracy studies:** The ability of the assay to obtain repeatable and/or reproducible results must be determined, when practicable.

3.5.1 The measure of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results while the measure of accuracy can be accomplished by checking results against an appropriate and available certified reference material.

3.6 **Case-type samples:** The ability to obtain reliable results should be evaluated using samples that are representative of those typically encountered by the end-user laboratory. Where appropriate, consistency of typing results should be demonstrated by comparing results from the previous procedures to those obtained using the new procedure.

3.7 **Population studies:** The distribution of genetic markers in populations (i.e., frequencies) must be determined in relevant population groups. Databases must be tested for independence expectations (e.g., Hardy Weinberg Equilibrium and Linkage Equilibrium).

3.8 **Mixture studies:** The ability to obtain reliable results from mixed-source samples shall be determined.

3.8.1 Studies should use mixture samples representing the number of contributors and the range of general mixture types expected to be encountered by the end-user laboratory.

3.8.1.1 These are best achieved by varying the number of contributors, mixture ratios, and overall template amounts.

3.8.2 These studies will assist the laboratory in establishing guidelines for mixture interpretation, which may include estimation of the number of contributors, determination of the major and minor contributor profiles, and contributor ratios or proportions in addition to correlating male:autosomal or male:female DNA quantification determination with the expected STR results.

3.9 **PCR-based studies:**

PCR-based studies should include:

3.9.1 The reaction conditions needed to provide the required degree of specificity and robustness shall be determined. These include, but are not limited to, thermal cycling parameters, the concentration of primers, buffers, magnesium chloride, dNTPs and DNA polymerase.

3.9.2 The potential for differential amplification among loci, preferential amplification of alleles within a locus, and stochastic amplification should be assessed to measure the specificity and robustness of the PCR reaction and the impact on peak height balance between and within a genetic marker.

3.9.3 The effects of multiplexing should be assessed to measure the specificity and robustness of the PCR reaction.

3.9.4 Appropriate controls should be assessed to ensure that the method works correctly and ensure the data are valid.

3.9.5 Criteria for detection of amplified product should be determined based on the platform and/or method used and instrument baseline noise should be defined for quantitative and capillary electrophoresis typing methods.

3.9.6 Appropriate measurement standards (qualitative and/or quantitative) for characterizing the alleles or resulting DNA product should be established.

3.9.7 Publication of the sequence of individual primers is not required to appropriately demonstrate the reliability and limitations of PCR-based technologies. However, availability of the primer sequences is encouraged to aid in the identification of potential primer binding site variants and troubleshooting.

4. Internal Validation

The internal validation process shall include the applicable studies detailed below and outlined in the relevant module(s).

4.1 Known and non-probative evidence samples or mock evidence samples:

4.1.1 Methods intended for casework samples shall be evaluated and tested using known samples (e.g., reference blood or buccal samples) and case-type samples. Mock evidence samples should be reflective of the range of types, quantity, and quality expected to be encountered in casework (e.g., various substrates, various concentrations, and degraded samples).

4.1.1.1 Methods intended for database samples shall be evaluated and tested using known samples, available database samples, or mock samples collected on the substrates routinely encountered by the laboratory. Mock samples should be reflective of the types and quality expected to be encountered in databasing.

4.1.2 The known samples selected for the studies should exhibit a high level of heterozygosity. The use of heterozygous samples will help establish intra-locus balance metrics and aid in the determination of appropriate interpretation thresholds.

4.1.3 Known and non-probative sample studies may be used to:

- assess the concordance of a method and therefore the degree of accuracy of the system.
- help establish appropriate stutter filters
- supplement the noise and threshold calculations
- assess potential contamination events associated with the method

4.1.4 Case-type samples may include non-human DNA at template levels similar to those expected to be routinely encountered during casework analysis (e.g., mold, bacteria). Results of these studies can be used to determine how non-human artifacts can be recognized and how their presence will affect the interpretation of the DNA profile.

4.1.5 Results of these studies should be compared to previous results, where possible, to ensure concordance. Observed discordances should be documented, and where possible, an explanation should be provided.

4.2 **Sensitivity and Stochastic Studies:**

4.2.1 The laboratory shall determine the sensitivity levels of the assay or procedure.

4.2.1.1 The known samples selected for the studies should exhibit a high level of heterozygosity. The use of heterozygous samples will help establish intra-locus balance metrics.

4.2.1.2 Sensitivity studies can be used to:

- assess the ability to obtain reliable results from a range of DNA quantities, including the upper and lower limits of the assay
- determine the dynamic range, ideal target range, limit of detection, heterozygote balance (e.g., peak height ratio), and the signal-to-noise ratio associated with the assay
- evaluate excessive random (stochastic) effects generally resulting from low quantity and/or low-quality samples

4.3 **Precision and Accuracy Studies:**

4.3.1 Precision and accuracy of the assay/instrument shall demonstrate that it is generating the expected results. These studies should also address repeatability and/or reproducibility when practicable.

4.3.1.1 **Repeatability:** Precision and accuracy of results (e.g., quantitative and/or qualitative) produced by the same operator and/or detection instrument should be evaluated.

4.3.1.2 **Reproducibility:** Precision and accuracy of results (e.g., quantitative and/or qualitative) produced by different operators and/or detection instruments should be evaluated.

4.3.2 Precision depends only on the distribution of random errors and does not relate to the true value or specified value. The measure of precision is usually expressed in terms of imprecision and reported as the standard deviation of the test results.

4.3.3 Accuracy of a measuring instrument is the ability of the instrument to give responses close to a true value. This can be accomplished by comparing the results against an appropriate and available certified reference material.

4.4 **Mixture Studies:**

4.4.1 Mixture studies consisting of samples that are representative of those typically encountered by the laboratory shall be performed. For example, forensic DNA mixture studies should use samples that represent the number of contributors and the range of general mixture types for which the procedure will be used in casework (e.g., mixture proportions and template quantities).

4.4.1.1 These studies must be used to establish interpretation guidelines to include estimation of the number of contributors to the mixture, determination of the major and minor contributor profiles, when appropriate, and for instituting criteria to deduce potential contributors.

4.4.1.2 As an additional example, laboratories validating a new extraction method should include in the mixture studies the body fluids, and combinations thereof, that they typically encounter.

4.5 **Contamination Assessment:**

4.5.1 Contamination studies shall be performed to evaluate and measure the potential for the introduction of exogenous DNA at any point during sample processing. Based on these studies, the laboratory should determine quality control procedures to mitigate contamination and/or develop a policy for data interpretation when contamination has been identified.

4.5.2 These studies also serve to assess the presence of potential contaminants in the reagents used throughout the various sample processes in the laboratory as well as the efficacy of personal protective equipment and cleaning protocols.

4.5.2.1 The laboratory shall evaluate, using negative controls and known samples, the detection of exogenous DNA originating from reagents, consumables, other samples, operator(s) and/or the laboratory environment.

4.5.3 Should contamination be encountered, the origin of the event must be explored and should be characterized when possible.

4.5.3.1 The validation should establish procedures that will minimize the occurrence of contamination events. Standard operating procedures should detail how to address contamination should it occur in casework analyses.

4.6 If conducted within the same laboratory, developmental validation studies may satisfy some elements of the internal validation. In these cases, a laboratory's

internal validation can be used to supplement any elements in which the developmental validation is insufficient.

4.7 The laboratory should evaluate the suitability of each study based on the methodology and/or application. If the laboratory determines that a study is not applicable, the reason(s) shall be documented in the validation summary. Using the specific module(s) as guidance, the laboratory should determine the appropriate number of samples, and the types of samples required for each study to demonstrate the potential limitations and reliability of the method.

4.7.1 A validation study cannot account for all potential casework scenarios; however, samples representing the range of forensic sample types expected to be routinely encountered by the laboratory should be selected for evaluation.

4.8 At the time of validating new DNA methods (from amplification through characterization), typing test kit, or platform instrument model, the laboratory shall check results from the new method/kit/platform for concordance with 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.

4.9 Internal validation data may be shared by all locations in a multi-laboratory system. The summary of the shared validation data shall be available at each site. At a minimum, each laboratory in a multi-laboratory system shall complete, document, and maintain applicable site-specific precision and accuracy, sensitivity and stochastic, and contamination assessment studies.

4.10 Internal validation studies shall be documented and summarized. Internal validation studies shall be reviewed by the technical leader and the approval documented prior to implementing a procedure for forensic applications. Documentation, at a minimum, should include:

4.10.1 Summary of each study conducted.

4.10.2 Results of each study, including generated data.

4.10.3 Approval of the technical leader for implementation.

5. Procedure Modification

Procedure modification is an alteration of an existing and previously validated analytical procedure that may have a consequential effect(s) on analytical results. Examples of a

procedure modification include: a decrease in reaction volume of an amplification kit or an increase in injection time for a genetic analyzer.

5.1. A procedure modification must be evaluated prior to use with forensic samples. The modified procedure must be evaluated by comparing it to the original procedure using similar samples to ensure concordance and ascertain the potential benefits.

5.2 The laboratory should define the appropriate sample number, sample type, and the studies necessary to evaluate the modification. The evaluation shall be documented, reviewed by the technical leader and the approval documented prior to implementation.

5.2.1 If the procedure modification is determined to have an impact on the efficacy or reliability of the forensic analysis (such as modifications that impact the efficacy of the PCR process or the detection of DNA types), additional internal validation studies (such as sensitivity and stochastic studies) may be necessary to demonstrate the continued reliability and potential limitations of the method.

6. Performance Check

A performance check is a quality assurance measure to assess the functionality of laboratory critical equipment and instruments that affect the accuracy and/or validity of forensic sample analysis.

6.1 A laboratory shall have and follow a documented program for conducting performance checks of critical instruments and equipment.

6.1.1 This program will document the laboratory protocol, the performance characteristics and acceptance limits.

6.1.2 The laboratory should evaluate the appropriate sample number and type to demonstrate the reliability of the instrument or equipment.

6.1.3 If the laboratory determines that a performance check study is not necessary, the justification should be documented.

6.1.4 A laboratory's evaluation may also determine that additional performance check studies are necessary due to unacceptable data.

6.1.5 The completion and subsequent approval/rejection of the performance check must be documented.

6.2 At a minimum, critical instruments or equipment shall require annual performance checks.

6.3 If service is performed on a critical instrument or equipment, a performance check is required before returning it to use for forensic analysis.

6.4 If the physical location or the environment of the instrument has been changed (e.g., instrument moved to another room, significant remodeling of the room), a performance check should be completed before returning it to use for casework analysis.

6.5 After an internal validation has been performed on a critical instrument, each additional critical instrument of the same make and model shall require, at a minimum, a performance check.

6.5.1 The performance check should demonstrate that results are reproducible on the new critical instrument and that testing results associated with new critical instrumentation are comparable to testing results generated during the internal validation and acceptable for use within the laboratory.

6.5.2 If the laboratory determines that the new critical instrument is not within acceptable parameters, then the laboratory must address the instrument and/or procedure to minimize or mitigate the difference.

7. Software

7.1 Software or software tools used in a forensic laboratory that may have an impact on the analytical process, interpretation, or statistical calculations shall be validated to ensure the software fulfills its intended purpose and is suitable for use in the laboratory. This includes software used as a component of instrumentation, software used for the analysis and/or interpretation of DNA data, software used for statistical calculations and software tools (e.g., macros, workbooks, LIMS) used for analytical workflows. Additional functions and/or features of software not intended for use by the laboratory do not require validation.

7.1.1 Software shall be evaluated to assess its suitability for its intended use in the laboratory and to determine the necessity of validation studies and/or software testing. This evaluation shall be documented to include the determination of which studies will be conducted.

7.1.2 Developmental validation shall be required for any software or new software modules used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations prior to implementation. At a minimum, the validation must include functional

and reliability testing, and as applicable, accuracy, precision, sensitivity, and specificity studies.

7.1.3 Internal validation studies may include:

7.1.3.1 **Functional testing** to confirm that a software performs the tasks as expected.

7.1.3.2 **Reliability testing** to establish that the software can run in the laboratory's environment.

7.1.3.3 **Accuracy and precision studies** to ensure the software is making accurate measurements and/or correct calculations.

7.1.3.4 **Sensitivity studies** to evaluate the upper and lower limits of the software.

7.1.3.5 **Specificity studies** to evaluate the ability of the system to provide reliable results over a broad variety of typing results.

7.1.4 Software validations including the summary and results shall be reviewed by the laboratory's technical leader and approval documented prior to implementation.

7.2 Modifications to software, or a software upgrade, used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or statistical calculations shall be evaluated to determine if the modifications result in major or minor revisions to the software. For software upgrades or modifications, the laboratory should require a software developer to provide written documentation, such as release notes, to explain the purpose and scope of the modification.

7.2.1 The requirement for validation and/or software testing is determined by the type of software change and the impact of the change on the operation of the software.

7.2.1.1 A *major* revision to software or software tools that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or statistical calculations shall require validation prior to implementation. These validation studies shall include functional testing, reliability testing, regression testing, and, as applicable, precision and accuracy, sensitivity and specificity studies.

7.2.1.2 A *minor* revision to software or software tools that does not impact the analytical process, interpretation, or statistical calculations shall require

at a minimum, a functional test prior to implementation to confirm that the software performs the tasks as expected.

7.2.1.2.1 Operating system or security patches that are compatible with the system requirements of the software do not fall into the scope of these guidelines.

7.3 Software validation studies may be shared by all locations in a multi-laboratory system. The summary of the shared validation data shall be available at each site. At a minimum, each laboratory in a multi-laboratory system shall complete, document, and maintain applicable site-specific reliability testing.

Appendix A

References and Suggested Readings

Butler, J.M., (2011) *Quality Assurance and Validation*. Advanced Topics in Forensic DNA Typing: Methodology. Elsevier.

Federal Bureau of Investigation. (2020) *Quality Assurance Standards for Forensic DNA Testing Laboratories;* available at https://www.fbi.gov/about-us/lab/codis/qas-standards-for-forensic-dna-testing-laboratories-effective-07-01-2020.

Federal Bureau of Investigation. (2020) *Quality Assurance Standards for Forensic DNA Databasing Laboratories;* available at https://ucr.fbi.gov/lab/biometric-analysis/codis/quality-assurance-standards-for-forensic-dna-testing-laboratories

Scientific Working Group on DNA Analysis Methods. (2017) *SWGDAM Interpretation Guidelines for Autosomal STR Typing by Forensic DNA Testing Laboratories;* available at https://1ecb9588-ea6f-4feb-971a-73265dbf079c.filesusr.com/ugd/4344b0_50e2749756a242528e6285a5bb478f4c.pdf.

Informational Web Site: Additional information may be obtained from the following web site: https://strbase.nist.gov/

Appendix B

SWGDAM Internal Validation Guideline Modules

The Validation Guidelines for DNA Analysis Methods have been organized such that recommended elements of validation studies are contained in the "Overview" document. This Overview document is supplemented by modules intended to provide technology or methodology specific guidance. The study examples in each module are not synchronized to the FBI QAS nor are they intended to be prescriptive. Instead, they are presented in a suggested order to conserve resources such as time, reagents, samples, and consumables and to streamline required testing.

Internal Validation Module for an Autosomal Multiplex Kit (xxxx, 2025)
This module describes the recommended studies for validating an autosomal multiplex amplification/typing kit. Study purpose, considerations, examples, and outcomes are presented in a suggested order.

Internal Validation Module for a Fully Continuous Probabilistic Genotyping Systems (xxx, 2025)
This module describes the recommended studies for validating the use of fully continuous probabilistic genotyping systems (PGS) for analyzing DNA single source and mixture profiles by inferring genotype weights using algorithms and assigning likelihood ratios (LR(s)) to the comparison of known reference samples to a forensic sample. Study purpose, design/considerations and outcomes are presented in a suggested order.

Internal Validation Module for Quantitation Module (in progress)

Internal Validation Module for Modified Rapid DNA for Analysis of Database, Known or Casework Reference Samples (in progress)

Internal Validation Module for Next Generation Sequencing (in progress)

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Document Version	Revision History
July 2003	Original. (Published in Forensic Science Communications in July 2004; available at http://www.fbi.gov/about-us/lab/forensic-science-communications/fsc/july2004/index.htm/standards/2004_03_standards02.htm)
November 2012	The document was revised to update the guidelines to incorporate changes to the FBI Director's Quality Assurance Standards (QAS). The revisions include: addition of a preface that describes the QAS have precedence over these guidelines; definitions added to Section 1 for critical instrument, methodology, precision and technology; revised description of developmental and internal validation in Section 2; added Table of recommended studies for internal validation in Section 4; and References and Suggested Reading added in a new Section 8.
November 2012	Approved by the SWGDAM membership.
December 2012	Approved by the SWGDAM Executive Board, with minor revisions, for posting on swgdam.org.
November 2016	The document was revised to address Next Generation Sequencing (NGS) technologies. Revisions include: new definitions in Section 1 for bioinformatics, index, library and next generation sequencing; revisions to the definitions in Section 1 for methodology and technology; the addition of NGS-specific studies to both Sections 3 and 4; and revisions to Section 7.
December 2016	Approved by the SWGDAM Executive Board, with minor revisions, for posting on www.swgdam.org.
December 2024	This document was reformatted to a Validation Overview document with general information about validation testing. The glossary was removed. References and Suggested Readings – formerly section 8 – has become the new Appendix A. Specific technology or methodology validation information has been moved to a separate Module format for each topic, reflected in the new Appendix B.

668