Standard for the Development and Internal Validation of Forensic Serological Methods

Biological Methods Subcommittee
Biology/DNA Scientific Area Committee
Organization of Scientific Area Committees (OSAC) for Forensic Science

OSAC Proposed Standard

Standard for the Development and Internal Validation of Forensic Serological Methods

Prepared by
Biological Methods Subcommittee
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This document has not been published by an SDO. Its contents are subject to change during the standards development process. All interested groups or individuals are strongly encouraged to submit comments on this proposed document during the open comment period administered by the Academy Standards Board (www.asbstandardsboard.org).

Foreword

This standard was revised, prepared and finalized as a standard by the DNA Consensus Body of the AAFS Standards Board (ASB). The initial draft document was developed by the Biological Methods Subcommittee of the Organization of Scientific Area Committees for Forensic Science.

This standard provides requirements ~~on how a laboratory validates new forensic serological~~for the validation of methods that will be used to evaluate body fluids, stains, or residues related to forensic investigations. A validation should include ~~studies~~characterization of the ~~performance characteristics of a technique~~test procedure, limitations of the ~~technique~~method, and the identification and documentation of influences that may change performance ~~characteristics~~.

In this document the industry standard definition for serology as it relates to forensic science is used instead of the traditional scientific definition.

All hyperlinks and web addresses shown in this document are current as the publication date of this standard.

Keywords: *forensic serology, validation, internal validation, developmental validation, forensic biology*

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Standard for the Developmental and Internal Validation of Forensic Serological Methods

1 Scope

This standard provides requirements for developmental and internal validations of forensic serological methods to evaluate body fluids, stains, or residues related to forensic investigations.

This standard does not address validation of forensic DNA analysis procedures.

2 Normative References

The document contains no normative references. See Annex A, Bibliography for other references.

3 Terms and Definitions

~~3.1~~

characterization of the test procedure

~~Includes~~Comprises the components of the test, the procedure used, limitations of the test, and the methods for detection and analysis~~.~~

3.1

including whether the test is presumptive or confirmatory ~~**tests**~~and the type of body fluid, stain, or residue being targeted.

3.2

confirmatory test

A test that is specific for the presence of a ~~particular biological material. Confirmatory tests are specific for the biological material~~body fluid, stain, or residue of interest, and ~~reduce~~reduces or ~~eliminate~~eliminates false positive results.

3.3

contamination

The unintentional introduction of exogenous materials or ~~substance~~substances into a test sample.

3.4

contamination studies

~~Verify~~Experiments performed to assess the risk that ~~the~~unintended material may be introduced into a sample from test assay components, instrumentation, the operator, ~~and test procedure are not introducing material into the sample~~or test procedures.

3.5

controls

Samples of known type, run in parallel with experimental, reference, or evidence samples that are used to demonstrate that a procedure is working correctly.

3.6

control studies

~~Studies~~Experiments performed to establish the necessary controls for each procedure, the frequency with which the controls should be performed (e.g., concurrently, daily, before use, etc.) and the performance expectations for each control.

3.7
developmental validation
The acquisition of test data and determination of conditions and limitations of a new methodology; ~~This~~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.

3.8
forensic serology
~~In general, the~~The detection, characterization, identification, and/or typing of body tissues and fluids, either in native form or as stains or residues left at a crime scene using physical methods (e.g. normal and enhanced lighting), biochemical assays, reactions and/or microscopy~~; this definition applies to current crime biology laboratory practices which may be followed by DNA testing.~~ .

3.9
internal validation
The accumulation of test data within the laboratory for developing the laboratory standard operating procedures and determining the limits of the method(s). Internal validation demonstrates that the established protocols for the technical steps of the test and for data interpretation perform as expected in the laboratory.

3.10
interference studies
~~Determine~~Experiments performed to determine substances that inhibit or ~~effect~~affect the intensity of the assay signal.

~~**3.11**~~
~~**material modification**~~
~~An alteration of an existing analytical procedure that may affect analytical results.~~

3.11
mixture studies
~~Studies of~~Experiments performed to evaluate the ~~effect of~~performance of the test method when samples containing mixtures of similar or different body fluids~~/~~ and/or cell types ~~on the capability of the test~~are assayed.

3.12
mock casework samples
Samples of known origin that mimic or simulate a range of casework sample types that may include laboratory created samples or proficiency test samples.

3.13
performance check
A quality assurance measure to assess the functionality of laboratory instruments, reagents and equipment that affect the accuracy and/or validity of forensic sample analysis.

3.14
population studies
~~Determine~~Experiments performed to determine the ~~variation in response~~effectiveness of the test when utilized with representative samples ~~originating~~ from the ~~general~~ population.

3.15
presumptive ~~tests~~test
A screening test which may be positive in the presence of a biological material of interest. ~~Presumptive~~Some presumptive tests are sensitive~~,~~ but not specific. A positive result indicates that further testing could be informative.

3.16
repeatability studies
~~Verify~~Experiments performed to verify the results of the assay by the same personnel and/or applicable instrumentation.

3.17
reproducibility studies
~~Test the assay's ability~~Experiments performed to assess the capability to obtain the same test results when an experiment is repeated between different operators and/or detection instruments.

3.18
robustness studies
~~Test~~Experiments performed to measure the ~~ability~~capability of ~~the~~a procedure to ~~produce an outcome that will be relatively~~remain unaffected by ~~the presence of a~~ small ~~number of unusual or incorrect data values~~but deliberate variations in method parameters and provide an indication of reliability during normal usage.

3.19
sensitivity studies
~~A set of critical studies to~~Experiments performed to define the lower and upper limits/bounds of an assay to accurately detect an analyte. Experiments include a serial dilution performed during developmental and/or internal validation of methods ~~designed to define the lower and upper limits/bounds of an assay to accurately detect an analyte~~.

3.20
specificity studies
~~Tests~~Experiments performed to evaluate the ability of the system to provide reliable results for targeted analytes in the presence of cross-reactive substances.

3.21
stability studies
~~Test~~Experiments performed to test the assay with various substrates that were subjected to different environmental and chemical insults including storage, handling conditions, and time interval studies.

3.22
technical designee
The designated individual in the laboratory who has technical responsibility.

4 Validation Requirements

4.1 General

4.1.1 The laboratory shall use validated methods for all presumptive and confirmatory tests. Developmental and internal validation shall precede the implementation of any new methods used for forensic serological analysis.

4.1.2 The laboratory shall use different samples for developmental validation studies and internal validation studies.

~~4.1.2~~4.1.3 The technical designee shall determine ~~if~~ the number, types and range of sample types to be used in each of the validation ~~samples is~~studies to ensure the generation of sufficient data to establish a standard operating procedure.

4.1.4 ~~Material modifications made~~The internal validation shall not exceed the scope of the conditions tested in the developmental validation. Samples that fall outside the range of conditions used in developmental validation shall require additional developmental validation studies.

~~4.1.3~~4.1.5 Any change to a validated ~~procedures~~procedure shall be ~~documented~~evaluated to determine if analytical results are affected. If a modification ~~has the potential to affect~~affects the analytical result, the ~~performance of a modified procedure or additional instrumentation shall be evaluated prior to use on evidence. If the analytical results are affected, the~~ procedure shall require an additional validation prior to implementation. ~~The validation or evaluation of the material~~ If the analytical results are not affected, the modification shall ~~conform to the requirements in this standard and shall~~ include a comparison of the modified method to the original method ~~which was modified. Material modification and evaluation documentation shall be included with the validation.~~. The evaluation of changes to validated procedures shall conform to requirements of this standard and all comparisons, evaluations, modifications, and validations shall be documented.

~~4.1.4~~4.1.6 For laboratory systems that consist of more than one laboratory, validation studies may be shared; however, performance checks shall be conducted and documented at each site.

4.2 Developmental Validation

A developmental validation study shall include the following:

— characterization of the test procedure,

— control studies;

— interference studies,

— population studies,

— reproducibility studies,

— robustness studies,

— sensitivity studies,

— specificity studies,

— stability studies,

— mixture studies,

— the analysis of mock ~~or adjudicated~~ casework samples~~.~~

4.3 Internal Validation

An internal validation study shall include the following:

— contamination studies;

— control studies;

— repeatability studies;

— reproducibility studies;

— sensitivity studies;

— specificity studies;

— mixture studies;

— the analysis of mock ~~or adjudicated~~ casework samples~~.~~

4.4 Validation Documentation

4.4.1 The laboratory shall identify and maintain a list of the scientific literature describing the test, its limitations, and~~/or~~ the scientific principles that serve as ~~its~~a foundation.

4.4.2 The laboratory shall have at a minimum a summary of data from the developmental validation ~~to support any internal~~.

~~4.4.2~~4.4.3 Developmental validation ~~study~~documentation shall include any limitations of the method.

~~4.4.3~~4.4.4 If a required component is not performed as part of a developmental or internal validation, documentation must be included to warrant the omission.

~~4.4.4~~4.4.5 The technical designee shall document the review and approval of all validations, modifications to procedures or equipment, and performance checks. Other approvals may be necessary according to laboratory policy.

~~4.4.5~~4.4.6 The technical designee shall review and approve any new or revised standard operating procedures as a result of internal validation or procedure modifications. Other approvals may be necessary according to laboratory policy.

~~4.4.6~~4.4.7 The laboratory shall have a policy for retention of the summary and data correlating to developmental validations, internal validations, ~~modifications~~modification to the procedures, and performance checks.

5 Conformance

In order to demonstrate conformance with this standard, the laboratory shall have the following:

a) documentation of the developmental validation which can be internal, external, or documented in ~~the~~ peer reviewed literature;

b) documentation of all internal validation~~;~~ studies, data, and outcomes;

c) documentation of any modification to the procedures, if applicable; and

~~c)~~ documentation of performance checks~~.~~

d) ~~Studies to establish the necessary controls for each procedure, the frequency with which the controls should be performed (e.g., concurrently, daily, before use, etc.) and the performance expectations for each control~~, if applicable.

Annex A
(informative)

Bibliography

1) Scientific Working Group on DNA Analysis Methods (~~SWIGDAM~~SWGDAM): *Guidelines for the Collection and Serological Examination of Biological Evidence*, issue date 01/15/2015: http://media.wix.com/ugd/4344b0_bce915901bb14b9cb36049df6a8441e2.pdf