OSAC 2021-S-0028 Standard for Use of Serological Testing Methods Associated with Forensic Investigations

Human Forensic Biology Subcommittee
Biology SAC
Organization of Scientific Area Committees (OSAC) for Forensic Science

Draft OSAC Proposed Standard

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Prepared by
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The STRP panel will consist of an independent and diverse panel, including subject matter experts, human factors scientists, quality assurance personnel, and legal experts, which will be tasked with evaluating the proposed standard based on a comprehensive list of science-based criteria.

For more information about this important process, please visit our website at: https://www.nist.gov/topics/organization-scientific-area-committees-forensic-science/scientific-technical-review-panels.

Keywords: serology, analysis, contamination prevention

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1 Scope

This standard provides requirements for documented analytical procedures/protocols needed for the use of forensic serological methods to evaluate body fluids, stains, or residues associated with forensic investigations.
This standard includes requirements for laboratory facilities and evidence control; use and monitoring of the analytical procedures; and reagents, chemicals, and equipment used for forensic serological testing. Also, requirements for personnel and training, equipment maintenance/calibration, report writing, and reviews are covered in this standard.

2 Normative References

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.
ANSI/ASB Standard 077, First Edition 2020, *Standard for the Developmental and Internal Validation of Forensic Serological Methods*
ANSI/ASB Standard 110, *Standards for Training in Forensic Serological Methods*

3 Terms and Definitions

3.1
administrative review
An evaluation of the report and supporting documentation for consistency with laboratory policies and for editorial correctness.

3.2
analytical procedure
An orderly step-by-step process designed to provide reproducible, accurate results.

3.3
confirmatory test
A test that is specific for a biological material or substance of interest and that is used for the conclusive identification of a biological fluid; this usually refers to a serological or microscopic test for detection of a particular biological fluid (e.g., blood or semen).

3.4
contamination
Exogenous DNA or other biological material in a DNA sample, PCR reaction, or item of evidence; the exogenous DNA or biological material could be present before the sample is collected, or introduced during collection or testing of the sample.

3.5
controls
Samples of known types, run in parallel with experimental reference, or evidence samples that are used to demonstrate that a procedure is working correctly.

3.6
inconclusive
A statement provided as the conclusion when testing results are insufficient or lacking in quality and/or quality, as defined by the laboratory, for comparison purposes; the data are inadequate to draw any meaningful conclusions.

3.7
material modification
An alteration of an existing procedure that may have consequential effect(s) on results.

3.8
performance check
In general, a quality assurance measure to assess the functionality of laboratory instruments and equipment that affect the accuracy and/or validity of forensic sample analysis.

3.9
presumptive test
A screening test that indicates the presence of a material of interest although the test result does not constitute the identification of that material. A negative presumptive test indicates that the material of interest was not detected; it is not confirmation of its absence.

3.10
serology
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 (normal and enhanced lighting), biochemical assays, and/or microscopy. This definition applies to current biology laboratory practices, which may be followed by DNA testing.

3.11
standard operating procedure
A series of instructions to be followed in performing a specified task or under specific circumstances.

3.12
technical management
Personnel, as defined by the laboratory, who have serological technical responsibility of the laboratory operations.

3.13
technical review
A qualified second party's evaluation of reports, notes, data, and other documentation to ensure there is appropriate and sufficient support for the actions, results, conclusions, opinions, and interpretations.

4 Requirements

4.1 Facilities and Evidence Control

4.1.1 General

The laboratory shall have facilities designed to ensure the integrity of all evidence where the serological testing procedures are performed within the laboratory.

4.1.2 Access to Facilities

Access to the laboratory shall be controlled and limited in a manner to prevent access by unauthorized personnel. All exterior entrance/exit points require security control. The distribution of all keys, combinations, or other access control mechanism(s) shall be documented and limited to the personnel designated by laboratory management.

4.1.3 Maintenance of Facilities

The laboratory shall have and follow written analytical procedures for cleaning and decontaminating facilities to ensure the integrity of all evidence where analytical procedures are being performed by the laboratory.

4.2 Personnel

4.2.1 Technical Management

The laboratory or multi-laboratory system shall have designated personnel who is responsible for the implementation and annual review of analytical procedures for forensic serological methods performed by the laboratory. Additionally, the designated personnel shall authorize, in written form, the successful completion of training by an analyst. This documented authorization shall extend to personnel that perform technical reviews.

4.2.2 Training of Personnel

Personnel shall have the education, training, and experience commensurate with the responsibilities, duties, and skills necessary to perform the analytical procedures performed by the laboratory, as defined by the laboratory. All serology laboratory personnel shall receive training and successfully complete a competency test prior to performing any analytical procedure or following material modification(s) to an analytical procedure performed by the laboratory. All forensic laboratory personnel that will perform technical review shall meet the minimum education requirements and receive training per laboratory protocol as well as demonstrate competency as a technical reviewer prior to performing technical review of serological data and/or reports. Previously qualified serology analysts shall demonstrate competency prior to performing technical reviews.

4.2.3 Personnel records

The laboratory shall have and follow an internal document retention policy that includes, but is not limited to, documents associated with education, training, competency and proficiency testing, and continuing education for all personnel involved in the analytical testing performed by the laboratory.

4.3 Analytical Procedures

4.3.1 General

The laboratory shall have and follow written analytical procedures for each serological method used by the laboratory. The analytical procedures shall be based upon validation studies and scientific literature.

4.3.2 Content

Laboratory procedure(s) shall include the following information as they apply to the analytical procedures performed by the laboratory:

a) Classification of the testing method as either a presumptive or confirmatory test;

b) Safety measures to be taken throughout the testing process, including the use of personal protective equipment;

c) Contamination prevention measures to be taken throughout the testing process. At a minimum, decontamination/cleaning and evidence handling analytical procedures to prevent the potential indirect transfer of cellular materials onto items of evidence;

d) Equipment, materials, reagents, and chemicals used in evidence testing and sample collection;

e) Preparation, labeling, storage, and quality control testing of reagents and chemicals used in testing;

f) Testing procedures;

g) Order in which evidence within a single case is tested;

h) Requirements for rare circumstances when deviating from written analytical procedures, including technical management involvement;

i) Recording of examination notes;

j) Interpretation of test results;

k) Define/identify limitations, such as potential false positive, false negative test results, and inconclusive results;

l) Sample collection and preservation for potential DNA analysis; and

m) Reporting results.

4.3.3 Monitoring of Analytical Procedures

The laboratory shall have a documented procedure for monitoring the performance of its analytical procedures. The procedure shall define:

a) Positive and negative control samples used in monitoring;

b) The frequency at which the monitoring is performed (e.g., concurrently with testing, daily, before use);

c) Successful performance of the positive and negative controls; and

d) Actions to be taken in the event of the unsuccessful performance of a control.

4.3.4 Approval of Analytical Procedures

All analytical procedures shall be approved by the technical management, as applicable, prior to implementation by the laboratory.

4.3.5 Revisions to Analytical Procedures

Any revision to an analytical procedure shall be approved by the technical management required by laboratory policy, prior to implementation by the laboratory. Staff notification of this change shall be documented.

4.3.6 Deviation of Analytical Procedures

Any deviation made to a validated analytical procedure shall be documented. The performance of a deviation to any analytical procedure shall be evaluated prior to use on evidence. The evaluation shall be accomplished by comparison to the original analytical procedure using similar samples. The deviation shall be approved by technical management required by laboratory policy, prior to use on evidence. Staff notification, training, and competency testing of this deviation shall be documented.

4.3.7 Review of Analytical Procedures

The laboratory's standard operating procedures shall be reviewed annually by technical management and the review shall be documented.

4.3.8 Records of Testing

The laboratory shall have and follow written procedures for documenting and maintaining case notes for all serological testing performed to support the reported conclusions. The laboratory shall maintain all analytical documentation generated by personnel related to the testing. The records shall be sufficient so that another qualified individual can evaluate what was tested and interpret the test results.

4.4 Reagents and Chemicals

4.4.1 General

The laboratory's analytical procedures shall specify the reagents and chemicals that are acceptable for use in each test performed. The analytical procedures shall define, as appropriate:

a) Formulation of prepared reagents;

b) Labeling of reagents;

c) Storage conditions;

d) Expiration date to be used for reagents and chemicals;

e) Quality assurance procedures for evaluation of reagents and chemicals prior to use;

f) Documentation of reagents and chemicals used in testing; and

g) Documentation of successful performance of reagents and chemicals prior to use in testing.

4.5 Equipment Used in Testing

4.5.1 General

The laboratory shall use equipment suitable for the testing methods employed. The laboratory's analytical procedures shall specify the equipment used in testing.

4.5.2 Equipment Maintenance and Calibration

The laboratory shall have a documented program for proper maintenance and calibration for equipment. The program shall define and require the following:

a) The schedule for the maintenance and calibration of equipment used in testing;

b) That performance checks be performed prior to use in testing; and

c) Labeling of equipment that is out of service.

4.5.3 Records of Equipment Maintenance and Calibration

The laboratory shall retain records of maintenance and calibration that include repair, service, and performance checks for all equipment that would affect the outcome of the testing being performed.

4.6 Reports

4.6.1 General

The laboratory shall have documented procedures that address case notes, report writing, as well as technical and administrative review of reports. The procedure/protocol for releasing reports and supporting documentation shall be included in the procedure(s). Includes items received, but no work done.

4.6.2 Content

Casework reports shall include the following elements:

a) Case identifier;

b) Description of the evidence examined;

c) Description of the analytical testing performed;

d) Results and/or conclusions, for each evidence item tested, including the reason for an inconclusive result;

e) Date of the report;

f) Disposition of evidence; and

g) A signature and title, or equivalent identification, of the person accepting responsibility for the content of the report.

4.6.3 Technical Review of Reports and Case Records

Prior to release of the report and associated case notes, the laboratory shall conduct and document a technical review of the documents to ensure conclusions and supporting test results are reasonable and within the constraints of scientific knowledge. The review shall be performed by personnel who are proficient in the analytical procedure being reviewed or those that are only qualified to perform technical reviews (as outlined in 4.2.2). The technical review shall include:

a) A review of all records, including notes, worksheets, and photographs, that support the reported results and/or conclusions.

b) Reviewer ensures appropriate controls were tested and documented in case file.

c) A review of the case records to verify that the reported results and/or conclusions are supported by the data.

4.6.4 Administrative Review

Prior to the release of a report and associated case records, the laboratory shall conduct and document an administrative review for consistency with laboratory policies and for editorial correctness. The administrative review shall include the following elements, any or all of which may also be included within the technical review:

a) A review of the case file and final report for editorial correctness and that information specified in Standard 4.6.2 is complete and accurate;

b) A review of the chain of custody for completeness and accuracy; and

c) A review of the disposition of evidence;