

OSAC PROPOSED STANDARD

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Standard for Use of Serological Testing Methods Associated with Forensic Investigations

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



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

Prepared by
Human Forensic Biology Subcommittee
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Standard for Use of Serological Testing Methods Associated with Forensic Investigations

1 Scope

This standard provides quality assurance requirements for documenting analytical procedures/protocols needed for the use of forensic serological methods to evaluate body fluids associated with forensic investigations.

This standard includes requirements for laboratory facilities and evidence control; use and monitoring of the analytical procedures; reagents, chemicals, and equipment used for forensic serological testing. Also covered in this standard are the requirements for personnel performing serological testing, equipment maintenance/calibration, reports, records of testing, technical reviews, and administrative reviews. This document does not address details of validation, training, evidence handling, sample collection and preservation, reporting of analyses, testimony, and safety.

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, *Standard for the Developmental and Internal Validation of Forensic Serological Methods*. 2020. 1st. Ed.

ANSI/ASB Standard 110, *Standards for Training in Forensic Serological Methods*. 2020. 1st. Ed.

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

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competency testing

An evaluation of a person's knowledge and ability before performing independent forensic science casework. This may include a written, oral and/or practical test or series of tests designed to establish that an individual has demonstrated achievement of technical skills and met minimum standards of knowledge, procedures, documentation, and verbal acuity necessary to perform forensic analysis, reporting, and testimony.

3.4**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).

3.5**contamination**

The unintentional introduction of exogenous material or substance into a test sample

3.6**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.

3.7**inconclusive**

A statement provided as the reported interpretation when testing results are insufficient or lacking in quality and/or quantity, as defined by the laboratory, for comparison purposes; the data are inadequate to draw any meaningful interpretations.

3.8**material modification**

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

3.9**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.

3.10**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.

3.11

proficiency testing

A quality assurance measure used to monitor performance and identify areas in which improvement may be needed.

3.12

serology

The detection, characterization, identification, and/or typing of body tissues and fluids, either in native form or as stains 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.

3.13

standard operating procedure

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

3.14

technical management

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

3.15

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

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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 and Environmental Monitoring

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

4.2 Personnel

4.2.1 Technical Equipment

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. 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 laboratory-defined minimum education requirements and receive training (to cover the range of testing performed in the laboratory) 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 Performance Monitoring

Analysts must complete proficiency testing at least one per calendar year. The laboratory shall use an external proficiency test provider that is accredited to the current applicable standard of the International Organization for Standardization and the applicable test is included on the proficiency test provider's scope of accreditation. External proficiency testing shall be an open proficiency testing program and shall be submitted to the proficiency testing provider in order to be included in the provider's published external summary report.

4.2.4 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 that is readily available to all laboratory personnel. 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 procedures to prevent the potential transfer of biological 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) Guidance on evaluating evidence items based on case-related information to determine the appropriate test(s) to be performed;

- h) Requirements for rare circumstances when deviating from written analytical procedures, including technical management involvement;
- i) Recording of examination notes at the time they are made. Examination notes may include, but not be limited to: written notes, photography, drawing, photocopying, or scanning;
- j) Interpretations that can be drawn based on the results of a test or combination of tests, including the acceptance criteria for all controls,
- k) Define/identify limitations of the testing procedure, such as potential false positive test result(s), false negative test result(s), and inconclusive results;
- l) Sample collection, preservation, and evidence consumption for potential DNA analysis; and
- m) Reporting positive, negative, and inconclusive 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 and documented by the technical management prior to implementation by the laboratory.

4.3.5 Annual Review of Analytical Procedures

Analytical procedures shall be reviewed annually by technical management. Any revision made during the review shall be approved and documented by the technical management required by laboratory policy, prior to implementation by the laboratory. Staff review and/or staff notification of change(s) shall be documented.

4.3.6 Material Modification of Analytical Procedures

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

4.3.7 Records of Testing

The laboratory shall have and follow written procedures for taking and maintaining case notes to support the reported interpretations of serological testing. The laboratory shall maintain all analytical documentation generated by personnel related to the testing. Records shall include at a minimum: date(s) of testing, individual(s) performing the testing, description of item(s), and results of 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 approved for use in each test performed. The analytical procedures shall define, as appropriate:

- a) Formulation of prepared reagents;
- b) Labeling of reagents;
- c) Storage and handling conditions, as appropriate;
- d) Expiration date to be used for reagents and chemicals;
- e) Documentation of reagents and chemicals used in testing;
- f) Quality assurance procedures for evaluation of reagents and chemicals prior to use; and
- g) Documentation of performance of reagents and chemicals prior to use in testing.

4.5 Equipment Used in Testing

4.5.1 General

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 handling, maintenance and calibration for equipment. The program shall require the following:

- a) Identification of critical equipment used in testing;
- b) The schedule for the maintenance and calibration of equipment used in testing;
- c) Procedures for conducting performance checks and evaluating results of critical equipment;
- d) Labeling of in-use equipment in such a way as to allow the user to readily identify the status of the calibration or period of validity; and
- e) 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. Records shall be accessible to laboratory staff.

4.6 Reports

4.6.1 General

The laboratory shall have documented procedures that address case notes, report writing, technical and administrative review of reports, as well as the procedure/protocol for releasing reports and supporting documentation shall be included in the procedure(s).

4.6.2 Content

Casework reports shall include, at a minimum, the following elements:

- a) Case identifier;
- b) Description of the evidence examined;

- c) Description of the analytical testing performed;
- d) Results and/or interpretations, for each evidence item tested, including the reason for a result being interpreted as inconclusive;
- 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 an independent technical review of the documents, in accordance with laboratory procedures, to ensure conclusions and supporting test results are reasonable and within the constraints of scientific knowledge. The technical reviewer shall not be the author of the applicable report and its contents. 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) A review of the records to ensure that appropriate controls were tested and documented in case file; and
- 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 of the records for consistency with laboratory procedures and reporting 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 completeness, accuracy, and editorial correctness;

- b) A review of the report for compliance with the elements described in 4.6.2;
- c) A review of the chain of custody for completeness and accuracy; and
- d) A review of the disposition of evidence.

4.6.5 Discrepant Conclusions During Review

The laboratory shall and follow a policy and/or procedure to address unresolved discrepant conclusion(s) between analyst and reviewer(s).