This document has been accepted by the Academy Standards Board (ASB) for development as an American National Standard (ANS). For information about ASB and their process please refer to asb.aafs.org. This document is being made available at this stage of the process so that the forensic science community and interested stakeholders can be more fully aware of the efforts and work products of the Organization of Scientific Area Committees for Forensic Science (OSAC). The documents were prepared with input from OSAC Legal Resource Committee, Quality Infrastructure Committee, and Human Factors Committees, as well as the relevant Scientific Area Committee. The content of the documents listed below is subject to change during the standards development process within ASB, and may not represent the contents of the final published standard. All stakeholder groups or individuals, are strongly encouraged to submit technical comments on this draft document during the ASB's open comment period. Technical comments will not be accepted if submitted to the OSAC Scientific Area Committee or Subcommittees.

Standards for the Analytical Procedures and Report Writing of Forensic Serological Methods

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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.

This standard provides requirements for analytical procedures and report writing of forensic serological methods that will be used to evaluate body fluids, stains, or residues related to forensic investigations.

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

Keywords: serology, analysis, contamination prevention, forensic biology

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1. Scope

This standard provides requirements for analytical procedures and report writing of forensic serological methods to evaluate body fluids, stains, or residues related to forensic investigations.

This document does not contain specific serological testing methods or does not require separate serology policies if requirements are already incorporated within other laboratory documents. This standard does not address analytical procedures and report writing of forensic DNA analysis procedures.

2. Normative References

The document contains no normative references.

3. Terms and Definitions

3.1. 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.

3.2. 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.

3.3. Serology
In general, 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.

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

3.5. Work product
The material that is generated as a function of analysis, which may include extracts and amplified product as defined by the laboratory.

4. Requirements of the Standards

4.1. Safety

a) The laboratory shall have a documented environmental health and safety program. This program shall include documented training in blood borne pathogen and chemical hygiene plans and shall be reviewed annually.

b) A laboratory shall have a safety policy that includes proper use and disposal of personal protective equipment.

4.2. Contamination Prevention

a) The laboratory shall have methods (e.g. controls) in place to monitor for contamination.

b) The laboratory shall have cleaning and sample handling procedures to prevent the potential indirect transfer of cellular material onto items of evidence.

c) Disposable gloves shall be used at all times when handling evidence. When wearing gloves, contact with person or personal items should be avoided to prevent the possibility of secondary transfer.

d) Gloves shall be replaced or decontaminated if they become visibly or potentially soiled or are defective.

e) Gloves shall be replaced or decontaminated when moving between items of evidence, dissimilar areas of collection or testing, and/or distinct areas of a crime scene/evidence.

f) Tools and work surfaces shall be decontaminated in an effort to remove possible adventitious sources of biological material. For example, using bleach or other commercial products demonstrated to be capable of eliminating biological contamination, with subsequent steps (e.g., water rinses) to ensure residual bleach or cleanser does not remain on the tools and work surfaces.

g) Tools shall be decontaminated before use, between items or areas of examination, as they become visibly or potentially soiled, and after their final use on a given workday.

h) Work surfaces shall be decontaminated before use, as they become visibly or potentially soiled, and after their final use on a given workday. Disposable paper and tools may be used and shall be changed between items or areas of examination or when visibly or potentially soiled.

i) Examinations shall be conducted on one item or set of similar items (e.g. a set of vaginal swabs from the same individual) at a time to prevent potential indirect transfer between items.

j) Materials for use in forensic biology (sterile or contamination free) shall be used for analysis and testing procedures when the sample has the potential to move to the DNA process.

4.3. Equipment Calibration and Maintenance

a) The laboratory shall have a documented program for conducting performance checks.

b) The laboratory shall have a documented program to ensure that instruments and equipment are properly maintained. The laboratory shall retain documentation of scheduled maintenance, service, or calibration.

c) Instruments and equipment that would affect the outcome of a test (e.g. automated sperm search) that have undergone repair, service or calibration, shall be performance checked before use in casework.

4.4. Analytical Procedures

a) The laboratory shall have a technical leader that oversees the forensic serology program.

b) The laboratory shall have validated and documented analytical procedures for each testing method used.

c) The laboratory's standard operating procedures shall be reviewed annually and the review shall be documented.

d) Procedures shall specify reagents, chemicals, equipment, controls, sample preservation and processing used in the testing and its interpretation.

e) Reagents and equipment used shall be appropriate to the testing being performed.

f) The laboratory shall have documented procedures specifying acceptable commercial reagents and for the formulation of in-house reagents, as appropriate.

g) At a minimum, reagents shall be labeled with the identity of the reagent and the expiration date as provided by the manufacturer or as determined by the laboratory.

h) The laboratory shall define and document quality assurance procedures for the evaluation of reagents (e.g., sensitivity or specificity requirements).

i) The laboratory shall have documented procedures for monitoring the performance of its reagents and/or analytical procedures using appropriate controls.

j) The laboratory shall define the frequency in which controls are performed (e.g., concurrently, daily, before use, etc.).

k) Controls shall yield acceptable results prior to conducting any analytical procedures. The results of the controls shall be documented.

l) The laboratory shall have documented procedures designed to minimize loss, contamination, total consumption, and/or deleterious change of evidence and work product.

m) The laboratory shall have a policy for the preservation of biological material for DNA testing. (If a limited amount of biological material is present, serological testing may not be appropriate.)

n) The laboratory shall have a policy that addresses best practices for presumptive and confirmatory testing and potential future DNA testing aimed at maximizing sample preservation.

o) The laboratory shall classify their testing methods as presumptive or confirmatory and define potential interferences.

p) The laboratory shall have documented procedures for conveying the serological results and location of any potential biological material identified.

q) The laboratory shall document all the serological tests performed and the results.

r) The laboratory shall have documented procedures for the interpretation of test results. The procedures shall include the acceptance criteria for all controls, the conclusions that can be drawn based on the results of a test or combination of tests, and the limitations of the testing procedures.

s) The laboratory shall have requirements for deviating from documented procedures.

4.5. Reporting and Reviews

a) The laboratory shall have documented procedures for:

i. Recording and maintaining case notes and analytical documentation related to the testing.

ii. Retaining, in hard copy or electronic format, sufficient data or description of results for each technical analysis to support the reported conclusions such that another qualified individual could evaluate and interpret the test results.

iii. Addressing the release of reports and supporting documentation.

iv. Conducting technical and administrative reviews.

b) Casework reports shall include the following elements:

i. Case identifier

ii. Description of evidence examined

iii. Results and/or conclusions of each item tested

iv. Date issued

v. Disposition of evidence

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

vii. The limitations of the tests used to generate the reported conclusions shall be clearly conveyed.

c) The laboratory shall conduct and document technical and administrative reviews of all case files and reports to ensure conclusions and supporting test results are reasonable and within the constraints of scientific knowledge.

d) An individual conducting technical reviews shall be or have been qualified in the methodology being reviewed to ensure there is an appropriate and sufficient basis for the scientific conclusions.

e) A technical review shall include and document:

i. A review of all case notes, worksheets, and photographs supporting the conclusions.

ii. A review of all required controls to verify that the expected results were obtained.

iii. A review of the contents of the report to verify that the results and conclusions are supported by the data.

iv. A review of chain of custody and disposition of evidence.

f) An administrative review shall include a review of the case file and final report for consistency with laboratory policies and editorial correctness.

g) The laboratory shall document the completion of the technical and administrative review.

h) The laboratory shall have a documented procedure to address unresolved discrepant conclusions between reporting personnel and reviewers.

i) The laboratory shall have a documented procedure to monitor each individual's court testimony.

ANNEX A

(informative)

Bibliography

1) Scientific Working Group on the DNA Analysis Methods, (SWGDAM): *Guidelines for the Collection and Serological Examination of Biological Evidence*, issue date 01/15/2015: https://docs.wixstatic.com/ugd/4344b0_b3deba7a272b4b268d7f522840607410.pdf