Scientific & Technical Review Panel Final Report for 2021-S-0028 Standard for Use of Serological Testing Methods Associated with Forensic Investigations

Organization of Scientific Area Committees (OSAC) for Forensic Science

STRP Final Report
2021-S-0028
Standard for Use of Serological Testing Methods Associated with Forensic Investigations

Organization of Scientific Area Committees (OSAC) for Forensic Science
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Scientific & Technical Review Panel Members

- Dawn Boswell , University of North Texas Health Science Center (UNTHSC) - Center for Human Identification
- Rolando Carol, Auburn University at Montgomery
- Mark Lancaster, Battelle
- Melissa LaVigne, Tampa Bay Regional Operations Center
- Jennifer Mihalovich, Oakland Police Department Criminalistics Division (Retired) • Shawn O'Toole, Denver Police Department
- Mark Stolorow, National Institute of Standards and Technology (NIST) • Jessica Trout, Baltimore County Police Department

Report Summary:

The Scientific and Technical Review Panel (STRP) for "Standard for Use of Serological Testing Methods Associated with Forensic Investigations" is an independent panel appointed by the National Institute of Standards and Technology (NIST). A STRP is established with a range of experts to consider how well a standard meets the needs of the forensic science, law enforcement, and legal communities, and to recommend improvements to the standards under review. The STRP appreciates the efforts of Christie Smith, Human Forensic Biology Subcommittee member, while serving as the subcommittee liaison to this STRP during the review process.

The STRP began its review process with a kickoff meeting on August 26, 2021 and concluded with this STRP final report. The panel reviewed the draft standard and prepared comments for the Human Forensic Biology Subcommittee.

Report Components:

The STRP reviewed this draft standard against OSAC's *STRP Instructions for Review* which include the following content areas: scientific and technical merit, human factors, quality assurance, scope and purpose, terminology, method description and reporting results. The details below contain a brief description of each reviewed content area and the STRP's assessment of how that content was addressed in the Draft OSAC Proposed Standard.

1. **Scientific and Technical Merit:** OSAC-approved standards must have strong scientific foundations so that the methods practitioners employ are scientifically valid, and the resulting claims are trustworthy. In addition, standards for methods or interpretation of results must include the expression and communication of the uncertainties in measurements or other results.

    1.1 Consensus View – The STRP believes the proposed standard adequately addresses the scientific and technical merit of serological testing methods associated with forensic investigations. The standard recognizes the importance of

using validation studies and scientific literature when developing and performing serological analytical procedures. The use of controls, contamination prevention, and the limitations of testing procedures are all recognized. While the standard gives guidance on minimal requirements for documentation and interpretation of serological testing, it still leaves discretion for laboratories to develop internal policies for case-specific issues such as presumptive testing and sampling of items. One issue the subcommittee may want to consider addressing is the utility of semi-quantitative opinions when describing color-changing serological tests, such as “weak” or “strong” positives. These are subjective terms and may lead to downstream inferences in the DNA analysis.

1.2 Minority View – None

2. **Human Factors:** All forensic science methods rely on human performance in acquiring, examining, reporting, and testifying to the results. In the examination phase, some standards rely heavily on human judgment, whereas others rely more on properly maintained and calibrated instruments and statistical analysis of data.

2.1. Consensus View – Generally, the draft adequately addresses most issues related to human factors and performance. Specifically, this draft acknowledges the importance of education, experience, training, competency testing, and technical and administrative review required for serological testing. Further, the draft recognizes the potential influence of subjectivity and bias during documentation and interpretation and encourages mitigating actions such as requiring report evaluation by a second qualified analyst who is not the report author. Additionally, this draft standard acknowledges the imperfect nature of human memory and automaticity and suggests that all written analytical procedures be readily available to those in the lab.

Documenting serological testing in a reproducible way for later review presents unique challenges. While defining needed specificity relating to documentation can be problematic given varied laboratory practices, the STRP recommends including some additional guidance about documenting examinations to strengthen these areas of the standard. For example, additional guidance suggesting more detailed and specific documentation in relation to location selection and the orientation of selected samples position in the overall item being sampled would be useful. This information provides assurance that sufficient records will exist so another qualified individual can evaluate what was tested and interpret the test results, and it also enables future stakeholders to make decisions about additional testing requests. While the standard already incorporates some details of potential considerations for sufficient and detailed documentation including “written notes, photography, drawing, photocopying or scanning”, providing additional considerations about methods and specificity of documentation (especially location) might be helpful.

Other potential impacts of bias, specifically on report interpretation and evaluation, could be reduced further but would likely require unrealistic and/or impractical modifications.

2.2. Minority View – None

3. **Quality Assurance:** Quality assurance covers a broad range of topics. For example, a method must include quality assurance procedures to ensure that sufficiently similar results will be obtained when the methodology is properly followed by different users in different facilities.

3.1. Consensus View – The STRP believes that the appropriate quality assurance topics are covered in this draft standard. The standard requires the important

aspects of quality assurance including, but not limited to: using approved validated methods and proper controls; monitoring of analytical procedures, including annual review and approval of documents; monitoring of personnel, including proficiency testing and competency testing; and monitoring of records of testing, including technical and administrative reviews and discrepant conclusions during review. The standard also addresses requirements for laboratory facilities, equipment, including maintenance and calibration, reagents and chemicals, including handling, use and storage.

3.2. Minority View – None

4. **Scope and Purpose:** Standards should have a short statement of their scope and purpose. They should list the topics that they address and the related topics that they do not address. Requirements, recommendations, or statements of what is permitted or prohibited do not belong in this section.

4.1. Consensus View – The STRP believes the proposed standard adequately defines the scope and purpose of the standard. The scope is broad and defines minimum requirements allowing a wide range of laboratories to successfully meet the standards. The STRP agrees that while the use of conventional serological testing has declined as the sensitivity of DNA analysis methods has increased, there is still a need for quality assurance requirements when performing and documenting forensic serological methods to evaluate body fluids.

4.2. Minority View – None

5. **Terminology:** Standards should define terms that have specialized meanings. Only rarely should they give a highly restricted or specialized meaning to a term in common use among the general public.

5.1. Consensus View – The draft appropriately defines terms with specialized

meaning as they relate to serological testing. The standard accounts for and incorporates terminology in the approved OSAC Lexicon. It also attempts to promote consistency by considering the terminology used in guidance provided by other relevant organizations. The STRP recommends using OSAC preferred terms when available. The STRP also recognizes that there is some inconsistency in terms and concerns about their use that exist and should be resolved. In particular, the Human Factors group expressed meritorious concern about the use of "conclusions" that warrant resolution by the OSAC generally. The OSAC should work to resolve that Human Factors groups' concern while recognizing the laboratory's need to continue to use certain terminology in some instances. It should also explore other areas of needed resolutions to promote clarification and standardization.

Recognizing that the adoption of the instant recommendation may result in inconsistencies in terminology, the STRP still recommends removing the word

"unintentional" in the definition of contamination. The subcommittee's initial exclusion of that word is more appropriate.

5.2. Minority View – None

6. **Method Description:** There is no rule as to the necessary level of detail in the description of the method. Some parts of the method may be performed in alternative ways without affecting the quality and consistency of the results. Standards should focus on standardizing steps that must be performed consistently across organizations to ensure equivalent results. Alternatively, standards can define specific performance criteria that are required to be demonstrated and met rather than specifying the exact way a task must be done. For example, it may be enough to specify the lower limit for detecting a substance without specifying the equipment or method for achieving this limit of detection.

6.1. Consensus View – The standard does not address exact methods employed in serology testing but rather provides guidance as to how analytical procedures are developed and implemented. The STRP considers that the proposed standard meets the Method Description requirement. This opinion is based on the fact that the standard provides terms and definitions (section 3) encompassing processes used in methods (i.e. confirmatory tests, controls, material modification, performance checks, and presumptive tests). The standard provides data on Analytical Procedures (Section 4.3) including that they are based on validation studies and scientific literature and gives guidance information needed in the procedure (i.e. 4.3.2 a – presumptive or confirmatory test, 4.3.2 d – equipment, reagents and chemicals, 4.3.2 h – deviations from procedures, 4.3.2 j – interpretations, 4.3.2 k – limitations, and 4.3.2 m – reporting). Additionally, the standard addresses the monitoring of the analytical procedure (Section 4.3.3), the approval of analytical procedures (Section 4.3.4) and the material modification of analytical procedures (Section 4.3.6).

The STRP does recommend drafting additional standards to further guide the development and implementation of specific serological testing procedures.

6.2. Minority View – None

7. **Reporting Results:** Methods must not only be well described, scientifically sound, and comprehensive but also lead to reported results that are within the scope of the standard, appropriately caveated, and not overreaching.

7.1. Consensus View – The methods "must … lead to reported results that are within the scope of the standard…" However, the scope of this standard specifically states "This document **does not address** details of validation, training, evidence handling, sample collection and preservation, **reporting of analyses**, testimony, and safety." Therefore, evaluating Reporting Results is beyond the scope of this standard. However, the STRP strongly recommends the OSAC Human Forensic

Biology Subcommittee draft best-practice documents for specific forensic serological methods and reporting and testimony.

7.2. Minority View – None