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Standard for Interpreting, Comparing and Reporting DNA Test Results Associated with Failed Controls and Contamination Events

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Foreword

Evaluation and reporting of data possibly compromised by failed controls or a contamination event may provide critical and valid information to support the investigation of a criminal case, for example excluding a person of interest. When a control incorporated during forensic DNA testing fails or profile data indicates a handling error or the presence of contaminating DNA, it may be possible to interpret, compare, and report data without any retesting of the sample or DNA extract.

It is intended that this standard be used in conjunction with the laboratory's documented quality assurance program. This would ensure that proper evaluations, root cause analyses, risk assessments, and corrective actions, when necessary, have been performed and appropriately documented for each instance of a failed control or contamination event that occurs in the laboratory. It is also intended that the laboratory performs the requirements in this standard using documented protocols for data interpretation, comparison and reporting with appropriate accompanying validation and protocol verification studies along with adherence to other available standards for forensic DNA testing (e.g., FBI Quality Assurance Standards for DNA Testing Laboratories, ANSI/ASB Standards 018, 020, 040, 136 and 139; see Bibliography) with decision-makers shielded from irrelevant information to avoid bias. This document is not intended to support the reporting of data associated with failed controls and/or contamination events without the associated prerequisite for thorough evaluation of the possible cause, assessment of the scientific integrity of the associated DNA test results and impact of the events on the data obtained.

The American Academy of Forensic Sciences established the Academy Standards Board (ASB) in 2015 with a vision of safeguarding Justice, Integrity and Fairness through Consensus Based American National Standards. To that end, the ASB develops consensus based forensic standards within a framework accredited by the American National Standards Institute (ANSI), and provides training to support those standards. ASB values integrity, scientific rigor, openness, due process, collaboration, excellence, diversity and inclusion. ASB is dedicated to developing and making freely accessible the highest quality documentary forensic science consensus Standards, Guidelines, Best Practices, and Technical Reports in a wide range of forensic science disciplines as a service to forensic practitioners and the legal system.

This document was revised, prepared, and finalized as a standard by the DNA Consensus Body of the AAFS Standards Board. The draft of this standard was developed by the Human Forensic Biology Subcommittee of the Organization of Scientific Area Committees for Forensic Science.

Questions, comments, and suggestions for the improvement of this document can be sent to AAFS-ASB Secretariat, asb@aafs.org or 401 N 21st Street, Colorado Springs, CO 80904.

All hyperlinks and web addresses shown in this document are current as of the publication date of this standard. ASB procedures are publicly available, free of cost, at www.aafs.org/academy-standards-board.

Keywords: *contamination, failed control, reporting DNA results, DNA interpretation, DNA comparison*

Table of Contents *(to be updated prior to publication)*

Standard for Interpreting, Comparing and Reporting DNA Test Results Associated with Failed Controls and Contamination Events

1 Scope

This standard provides requirements for the interpretation, comparison, and reporting of DNA data associated with control failures or contamination where re-testing is not performed. These requirements may be applied to any type of forensic DNA testing technology and methodology used in forensic laboratories.

2 Normative References

There are no normative reference documents, Annex C, Bibliography, contains informative references.

3 Terms and Definitions

For purposes of this document, the following definitions apply.

3.1
comparison
The process of examining two or more DNA data sets to assess the degree of similarity or difference.

3.2
contamination
Exogenous DNA or other biological material in a DNA sample, PCR reaction, or item of evidence, which may be present before the sample is collected or introduced during collection or testing of the sample.

3.3
failed control
A positive control (see 3.7) or negative control (see 3.6) that produces an unexpected result.

3.4
forensic sample
A biological sample originating from and associated with evidence from a crime scene;

NOTE It may include a sample that has been removed from the crime scene.

3.5
interpretation
The process of evaluating DNA data for purposes including, but not limited to, defining assumptions related to mixtures and single source profiles, distinguishing between alleles and artifacts, assessing the possibility of degradation, inhibition, and stochastic effects, and determining whether the data are suitable for comparison.

3.6
negative control
An analytical control that consists of the reagents used in various stages of testing without the introduction of sample; no results are expected from a negative control.

NOTE For DNA testing, negative controls include extraction blanks/reagent blanks and amplification blanks. A negative control in DNA testing is used to detect contamination introduced into the assay during the testing process via reagents, disposables or handling errors (which may impact the results observed from samples tested at the same time).

3.7
positive control
An analytical control sample that is used to determine if a test performed properly; this control consists of the test reagents and a known sample that will provide an expected positive response with the test.

NOTE For DNA testing, positive controls may include extraction positive controls and positive amplification controls.

3.8
reference sample
Biological material obtained from a known individual and collected for the purpose of comparison to evidentiary sample(s).

3.9
suitable for interpretation/comparison
Data deemed appropriate for interpretation/comparison (see 3.1 and 3.5) based on developmental validation studies, the laboratory's internal validation studies, and the laboratory's documented and verified interpretation protocol.

3.10 unsuitable for interpretation/comparison
Data that cannot be used for interpretation/comparison for reasons including, but not limited to, poor or limited data quality, mixture complexity, or a failure to meet quality assurance requirements; this decision is based on developmental validation studies, the laboratory's internal validation studies, and the laboratory's documented and verified interpretation and comparison protocol.

4 Requirements

4.1 The laboratory protocol shall define what constitutes:

a) contamination in a negative control;

b) contamination in a positive control;

c) contamination in forensic or reference sample DNA test results;

d) contamination in reference/database sample DNA test results;

e) a failed positive control;

f) a failed negative control.

4.2 The laboratory shall perform and document the assessment of the integrity of the associated DNA test results to determine the impact of the failed control or contamination.

4.2.1 The assessment shall be based on the laboratory's validation studies and protocols, including but not limited to interpretation and comparison protocol(s) and quality assurance protocols. This assessment shall include a determination of the possible cause and effect of the failed control or contamination, and an assessment of the risks associated with moving forward with data interpretation vs. those associated with re-testing.

4.2.2 If the DNA test results are determined to be suitable for interpretation /comparison within the constraints of the laboratory's internal validation studies and documented interpretation and comparison protocols and the laboratory does not retest, the laboratory shall perform and report the interpretation and comparison(s) with applicable statistical analysis.

4.2.3 If the DNA test results are determined to be compromised to the extent of being unsuitable for interpretation/comparison and retesting is not conducted, the results shall be reported as not suitable for interpretation according to laboratory policy.

NOTE If the DNA test results are determined to be compromised to the extent of being unsuitable for interpretation and retesting is conducted, it may be necessary to report results, interpretations and comparisons from the original test and subsequent test(s).

4.3 When reporting interpretations and comparisons associated with a failed control or contamination event, the report shall identify the associated DNA test results and describe the nature of the event.

NOTE Examples of scenarios where the data are or are not impacted are provided in Annex A.

4.4 The laboratory shall have a written protocol for the release of identifying information for the source of the contamination.

4.5 The case record for each sample associated with a failed control or contamination event must include documentation of the following for the affected sample(s), as applicable:

4.5.1 The forensic sample, reference, or control DNA test result that failed or was contaminated.

4.5.2 The likely or known source of contamination.

NOTE If an individual is determined to be the source, that individual may be identified by name, employment position or other descriptor as permitted by law and agency policies.

4.5.3 The likely or known cause of the failed control or contamination.

4.5.4 The impact of the failed control or contaminant on the integrity of the DNA test results.

4.5.5 The determination of whether an affected DNA test result is suitable, or unsuitable, for interpretation/comparison.

Annex A
(informative)

Supplemental Information – Examples

The following examples describe different scenarios where samples are associated with a failed control or contamination event with some possible outcomes responsive to the requirements of this standard. When reporting interpretations and comparisons associated with a failed control or contamination event, the report identifies the associated DNA test results and describes the nature of the event. Every situation must be evaluated on a case-by-case basis in conjunction with the laboratory's documented interpretation and comparison protocol(s) and quality assurance program, including evaluations, root cause analyses, risk assessments, and applicable corrective actions.

1) No results were obtained for the amplification positive control. The associated forensic samples provided partial or full profiles that corresponded logically to their respective quantitation results and, where predictable, the expected results (e.g., single source DNA profile from a presumed blood stain or sperm fraction; non-sperm/epithelial fraction results consistent with complainant; duplicate amplifications of a DNA extract). Amplification results consistent with expectations confirm the PCR amplification was successful and that the allele calling by the software was appropriate. Based on the laboratory's root cause investigation, it was determined that the analyst most likely did not add the known DNA to the amplification positive control sample, and the associated profiles were interpreted and used for comparison purposes. The issue and resolution were documented in the case record and the results were reported per the laboratory protocol since the results were not directly impacted by the failed control.

2) The DNA profile from the forensic sample associated with a failed positive control demonstrated the presence of a mixture of at least six individuals. The assessment of the impact of the failed positive control determined that the interpretation of the forensic sample profile was not affected since the laboratory's protocol does not permit the interpretation of mixtures of greater than four individuals. No retesting was performed; the forensic sample profile was reported as not suitable for comparison purposes due to the high number of contributors.

3) The DNA profile of a member of the laboratory was detected as a minor component of a two-person mixture profile detected from a forensic sample. The laboratory staff member was the individual who performed the latent print examination on the sample prior to the DNA testing. The DNA profile was interpreted and used for comparison under the assumption that the laboratory staff member was one of the contributors to the mixture.

4) A low-level DNA profile was detected in the extraction reagent blank that was consistent with the low-level DNA profile detected from the forensic sample. The forensic sample and DNA extract were consumed during testing. Investigation could not determine the cause of the contamination event (e.g., whether cross contamination occurred or whether the reagents themselves were contaminated). The results for the forensic sample were reported as not suitable for comparison purposes.

5) The DNA profile of the analyst was detected in the epithelial cell fraction of a sexual assault kit sample and there was no indication of contamination of the sperm fraction profile. Because the remaining contributor profile in the epithelial cell fraction was consistent with the complainant,

retesting was not performed. Results from both the epithelial cell fraction and sperm cell fraction were interpreted, used for comparison and reported.

6) The DNA profile of the analyst who performed an amplification set up was detected in the negative amplification control. A review of the associated sample profiles showed that the profiles were not impacted by the contamination and no retesting was performed. The issue and resolution were documented in the case record and the results were reported per the laboratory protocol.

7) The DNA profiles from an amplification plate showed a low-level contaminant throughout, indicating that there may have been contamination of the amplification master mix. Because of the way the contaminant presents, the associated forensic sample profiles were determined to be unsuitable for comparison. The DNA amplified included the consumed extract of a single swab (also consumed) from the neckline of a shirt. The neckline of the shirt was resampled by taking and consuming a second swab, and an interpretable and comparable profile was obtained. The laboratory report addressed both the first and second sampling of the neckline of the shirt.

Annex B
(informative)

Bibliography

1] ANSI/ASB Standard 018, *Validation Standards for Probabilistic Genotyping Systems,* First Edition, 2020.[a]

2] ANSI/ASB Standard 020, *Standard for Validation Studies of DNA Mixtures, and Development and Verification of a Laboratory's Mixture Interpretation Protocol*, First Edition, 2018.[b]

3] ANSI/ASB Standard 040, *Standard for Forensic DNA Interpretation and Comparison Protocols*, First Edition, 2019.[c]

4] ANSI/ASB Standard 136, *Forensic Laboratory Standards for Prevention, Monitoring, and Mitigation of DNA Contamination*, (currently in review at ASB; also out for public comments)

5] ANSI/ASB Standard 139, Reporting DNA Conclusions (currently in review at ASB; also out for public comments)

6] Forensic Science Regulator. *Forensic Science Providers: Codes of Practice and Conduct*. 2014.[d]

7] Federal Bureau of Investigation. *Quality Assurance Standards for Forensic DNA Testing Laboratories*.[e]

8] ISO/IEC 17025 *Testing and Calibration Laboratories*.[f]

9] SWGDAM. Contamination Prevention and Detection Guidelines for Forensic DNA Laboratories.[g]

[a] Available from: https://www.aafs.org/asb-standard/standard-validation-probabilistic-genotyping-systems
[b] Available from: https://www.aafs.org/asb-standard/standard-validation-studies-dna-mixtures-and-development-and-verification-laboratorys
[c] Available from: https://www.aafs.org/asb-standard/standard-forensic-dna-interpretation-and-comparison-protocols
[d] Available from: https://www.gov.uk/government/collections/forensic-science-providers-codes-of-practice-and-conduct
[e] Available from: https://www.fbi.gov/file-repository/quality-assurance-standards-for-forensic-dna-testing-laboratories.pdf/view
[f] Available from: https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html
[g] Available from: https://www.swgdam.org/_files/ugd/4344b0_c4d4dbba84f1400a98eaa2e48f2bf291.pdf

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