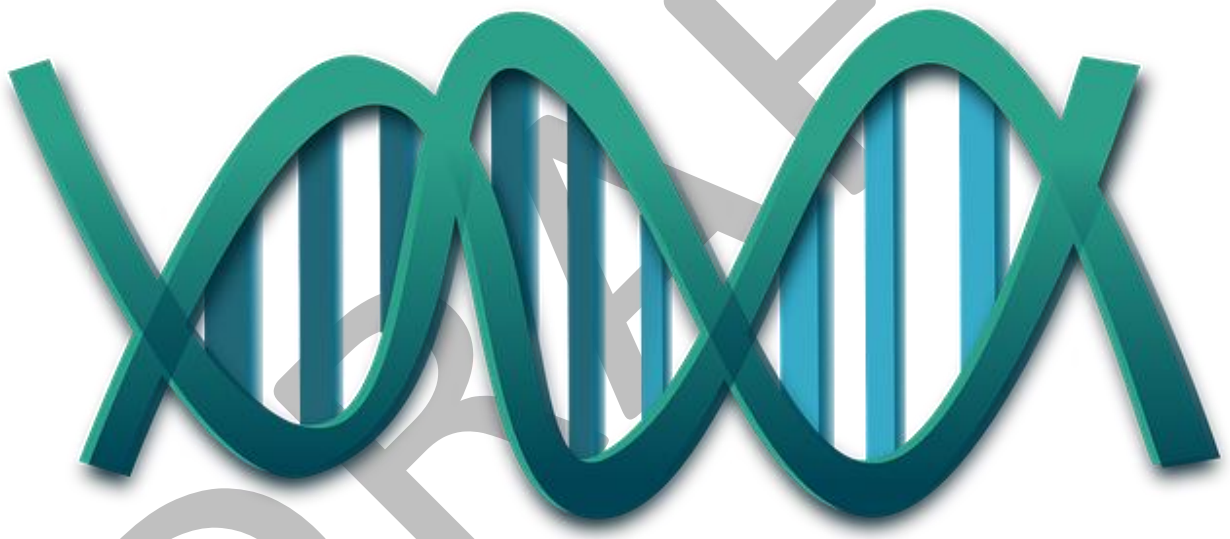
This document has been accepted by the Academy Standards Board (ASB) for development as an American National Standard (ANS). For information about ASB and their process please refer to asb.aafs.org. This document is being made available at this stage of the process so that the forensic science community 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 VALIDATION STUDIES OF DNA MIXTURES AND DEVELOPMENT AND VERIFICATION OF A LABORATORY'S MIXTURE INTERPRETATION PROTOCOL
DRAFT

DRAFT DOCUMENT

ASB Standard 00XX
2016

Standards for Validation Studies of DNA Mixtures and Development and Verification of a Laboratory's Mixture Interpretation Protocol



ASB Standard 00XX
2016

Standards for Validation Studies of DNA Mixtures and Development and Verification of a Laboratory's Mixture Interpretation Protocol

Keywords: DNA mixture *validation, mixture interpretation guidelines and protocols, verification of mixture interpretation protocols*

Abstract
These standards were designed to provide direction and guidance to laboratories for the development of DNA mixture interpretation protocols that consistently produce reliable and reproducible interpretations and conclusions, which are supported by internal validation data.

Foreword

It is imperative that laboratories only interpret mixed DNA data for which there are supporting internal validation studies and data, and relevant and appropriate interpretation protocols in the laboratory. Internal validation allows for the determination of the capabilities and limitations of a system and provides the rationale for the interpretation of data developed within the system.

DNA samples containing mixtures often include a range of DNA input, from low template (i.e., where stochastic effects occur) to high template, and a range of contributor numbers and ratios. Validation studies performed using known samples created under specified conditions enable the laboratory to assess observed versus expected data (e.g., for STR testing, genotypes detected, peak heights with associated ratios of input DNA and allele sharing, and estimated number of contributors) and determine the accuracy and limitations of the testing. These data will allow the development of interpretation parameters that are supported by the data. Following development, it is critical for a laboratory to verify that the interpretation protocols work as designed.

These standards were originally developed by the Mixture Interpretation Verification Task Group of the Biology DNA Interpretation and Reporting Subcommittee. The Biology DNA Interpretation and Reporting Subcommittee is under the Biology Scientific Area Committee (SAC) and is involved in developing and vetting standards and guidelines related to forensic DNA interpretation.

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Table of Contents

1. Scope	5
2. Normative References	6
3. Terms and Definitions	7
4. Requirements	8
5. Conformance	10
Annex A Bibliography	11

Standards for Validation Studies of DNA Mixtures and Development and Verification of a Laboratory's Mixture Interpretation Protocol – 2016 Edition

1. Scope

1.1. These standards are for the design and evaluation of internal validation studies for mixed DNA samples and the development of appropriate interpretation protocols for mixtures based on the validation studies performed. These standards include a requirement that the laboratory verify and document that the mixture interpretation protocols developed from the completed validation studies generate reliable and consistent interpretations and conclusions for the types of mixed DNA samples typically encountered by the laboratory.

1.2. These standards apply to any type of DNA testing technology and methodology used, including but not limited to, STR testing, DNA sequencing, SNP testing, haplotype testing, traditional and rapid protocols, etc., where mixtures of DNA may be encountered, analyzed and interpreted.

1.3. Laboratories are advised to review their previous validation for compliance with these standards, supplement validation where necessary, and modify existing protocols accordingly.

2. Normative References

The following referenced documents are indispensable for the application of this document.

Federal Bureau of Investigation, (2011) *Quality Assurance Standards for Forensic DNA Testing Laboratories*, available at http://www.fbi.gov/about-us/lab/codis/qas-standards-for-forensic-dna-testing-laboratories-effective-9-1-2011

3. Terms and Definitions

For purposes of this document, the following definitions apply. For additional definitions of terms, please refer to the OSAC Biology/DNA Glossary.

3.1

Case-type samples

Samples from known individuals with known testing results prepared within the laboratory to simulate a range of samples typically encountered by the testing laboratory in casework. The use of a range of test samples in validation studies the development of protocols for casework.

3.2

Consistent/consistency

Obtaining a similar output, within an acceptable limited range of variation (as defined by the laboratory), when using the same methods and procedures over time.

3.3

Internal validation

The accumulation and evaluation of test data within the laboratory for developing the laboratory standard operating procedures and demonstrating that the established protocols for the technical steps of the test and for data interpretation perform as expected in the laboratory. The parameters included in the test protocol used by the laboratory should have validation studies conducted with samples of known origin similar to the types of samples routinely accepted and tested by the laboratory supporting the application and procedures used.

3.4

Mixed DNA sample

Any biological sample containing DNA from more than one individual.

3.5

Validation

The process of performing a set of experiments that establish the efficacy, reliability, and limitations of a method, procedure or modification thereof; establishing recorded documentation that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.

4. **Requirements**

4.1 The laboratory shall perform DNA mixture studies as part of the internal validation to support interpretation protocols prior to their use for casework samples in the laboratory. The mixture studies shall include, at a minimum, mixed DNA samples that:

4.1.1. Are representative of those typically encountered and interpreted by the testing laboratory;

4.1.2. Span the dynamic range of the detection platform;

NOTE The samples used for mixture validation should include a range of DNA input, from low template to high template.

4.1.3. Include each number of contributors to be interpreted by the laboratory;

4.1.4. Are constructed from extracted DNA samples of known origin (having known genotypes or sequences, etc.) and combined in varied input ratios that are based on the estimated DNA template amounts of the individual contributors;

NOTE The use of known samples allows for the assessment of observed versus expected data.

4.2. The data from the validation studies performed by the laboratory shall be the basis for the interpretation parameters and protocols developed by the laboratory and shall provide guidance for the types of mixed DNA profiles that will be interpreted by the laboratory. The studies shall:

4.2.1. Support all of the interpretation methods and protocols used for DNA mixture analysis;

4.2.1.1. The validation summary shall describe how the validation studies performed led to the parameters described in the interpretation protocol.

4.2.2. Aid in assessing and defining the limitations of the methodologies used for the range of samples to be tested and the interpretation of the data generated;

NOTE Limitations may result from a number of factors including sample degradation and inhibition, the number of contributors that may be interpreted, and potential stochastic effects.

4.2.3. Establish testing and interpretation parameters for samples containing mixtures of DNA, including:

4.2.3.1. Criteria for establishing the minimum and assumed number of contributors to a DNA mixture.

4.3. The laboratory shall verify and document that the mixture interpretation protocols developed from the validation studies generate reliable and consistent interpretations and conclusions for the types of mixed DNA samples typically encountered by the laboratory.

4.3.1. Verification of the mixture protocols shall be performed on mixed DNA samples of known origin that are different from those in the initial validation studies used to establish the protocol.

4.3.1.1. Verification of the mixture interpretation protocols shall include evaluating the ability of the protocol to correctly include true contributors and exclude non-contributors, as well as the parameters considered in the interpretation protocols.

NOTE Parameters may include, but are not limited to, assessment of the number of contributors, evaluation of contributor ratios, etc.

4.3.2. Verification shall include a determination of consistency in the analysis and interpretation of mixed DNA data between analysts in the laboratory or laboratory system.

4.3.3. Verification shall be performed on new, existing, and modified mixture interpretation protocols.

5. Conformance

Documentation demonstrating conformance with the standards described here will be approved by the laboratory's DNA technical leader and will be made readily available in hard copy and/or electronic format for review.

Annex A
(informative)

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Scientific Working Group on DNA Analysis and Methods, (2012) *Validation Guidelines for DNA Analysis Methods,* available at www.swgdam.org

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