# OSAC 2022-S-0040 Standard for Internal Validation of DNA Extraction Methods

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

# Draft OSAC Proposed Standard

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Prepared by
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## Disclaimer:

This OSAC Proposed Standard was written by the Organization of Scientific Area Committees (OSAC) for Forensic Science following a process that includes an open comment period. This Proposed Standard will be submitted to a standards developing organization and is subject to change.

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To be placed on the OSAC Registry, certain types of standards first must be reviewed by a Scientific and Technical Review (STR). The STR process is vital to OSAC's mission of generating and recognizing scientifically sound standards for producing and interpreting forensic science results. The STR shall provide critical and knowledgeable reviews of draft standards or of proposed revisions of standards previously published by standards developing organizations (SDOs) to ensure that the published methods that practitioners employ are scientifically valid, and the resulting claims are trustworthy.

The STR will consist of an independent and diverse panel, including subject matter experts, human factors scientists, quality assurance personnel, and legal experts, which will be tasked with evaluating the proposed standard based on a comprehensive list of science-based criteria.

For more information about this important process, please visit our website at: https://www.nist.gov/topics/organization-scientific-area-committees-forensic-science/scientific-technical-review-panels.

**Keywords:** internal validation, DNA extraction

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## 1. Scope

This document details requirements when performing an internal validation of DNA extraction methods prior to implementation within a forensic DNA laboratory and is intended to be used in conjunction with ASB 038 Standard for Internal Validation of Forensic DNA Analysis.

## 2. Normative References

The following referenced documents are the foundation of these requirements. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document applies.

**ASB 038 Standards for Internal Validation of Forensic DNA Analysis Methods**
**ASB XXX Best Practice Recommendations for Internal Validation of DNA Extraction Methods**

## 3. Terms and Definitions

**3.1**
**Concordance**
Agreement between DNA typing results.

**3.2**
**Degradation**
Fragmentation of DNA by chemical, physical, or biological means.

**3.4**
**DNA extraction**
A technique used to release DNA from cells in a biological sample.

**3.5**
**Inhibition**
Prevention of DNA synthesis during polymerase chain reaction by any substance that either directly interacts with DNA or interferes with the DNA polymerase.

**3.6**
**Internal Validation**
Accumulation 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.

**3.7**
**Sensitivity studies**
Studies performed during validation of DNA or other test methods designed to define the limits of the method.

## 4 Requirements

**4.1** The laboratory shall demonstrate concordance of the new DNA extraction method to previously validated methods or published results.

**4.1.1** DNA typing results obtained from the new DNA extraction chemistry shall be compared to results obtained from a previously validated DNA extraction method or published results.

**4.1.2** Discordant data observed when comparing identical genetic markers using sample(s) from the same individual, and a potential explanation for any discordant results shall be documented in the final validation document.

**4.2** The laboratory shall evaluate the DNA extraction method using known references or casework-like samples and substrates representative of those typically analyzed by the testing laboratory.

**4.2.1** The laboratory shall assess the performance of the DNA extraction method using different substrates, sample types, and sample conditions (e.g. inhibition, degraded samples, etc.)

**4.2.2** The laboratory shall conduct a study utilizing mixed biological samples.

**4.2.3** The laboratory shall compare the results of known and casework-like samples from this method to results from previously validated methods, where applicable.

**4.3** The laboratory shall determine the susceptibility of the DNA extraction method to the introduction of inhibition or degradation.

**4.4** The laboratory shall conduct a sensitivity study to determine the limits of the of the DNA extraction method for obtaining DNA sufficient for analysis.

**4.5** The laboratory shall demonstrate the precision and accuracy of the DNA extraction method.

**4.6** The laboratory shall determine the susceptibility of the DNA extraction method to the introduction of exogenous DNA.

## 5 Conformance

To demonstrate conformance with this standard, the laboratory shall complete and document all applicable validation studies as described above.

## 6 Annex A – Bibliography

1. Butler, John. *Advanced Topics in Forensic DNA Typing: Methodology*. Academic Press, 2012.