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Best Practice Recommendations for the Management and Use of Quality Assurance DNA Elimination Databases in Forensic DNA Analysis

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Best Practice Recommendations for the Management and Use of Quality Assurance DNA Elimination Databases in Forensic DNA Analysis

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Foreword

Monitoring contamination is critical to preserving the integrity of human forensic DNA results. Contamination can occur from individuals such as first responders, medical and laboratory personnel or crime scene technicians transferring DNA to the evidence. An overall quality assurance program includes a comprehensive approach to monitoring for DNA contamination. The primary component of a laboratory's approach to detecting possible contamination is the incorporation of quality control samples such as reagent blanks, extraction controls, and amplification controls. These controls are used to monitor for contamination introduced during the DNA testing process, but do not directly assess the presence of contaminants in individual case samples.

An elimination database is an additional component that can be used to directly evaluate case samples for possible contamination. Elimination databases are important to avoid providing misleading information to investigators, entering errant DNA profiles into CODIS, or, more broadly, to detect contaminants. It can never be known with certainty that a casework or database sample is contamination-free, but detection and tracing efforts are facilitated through the use of elimination databases.

It is essential for each laboratory to develop policies regarding the generation, management, and searching of the elimination database using practices adhering to and in compliance with all applicable laws within their jurisdiction. This document is intended to be used in conjunction with the following documents;

— ANSI/ASB Standard 018, *Standard for Validation of Probabilistic Genotyping Systems*, First Edition, 2020;

— 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;

— ANSI/ASB Standard 040, *Standard for Forensic DNA Interpretation and Comparison Protocols*, First Edition, 2019;

— OSAC 2020-S-0004, *Standard for Interpreting, Comparing and Reporting DNA Test Results Associated with Failed Controls and Contamination Events*, 2021;

— ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories;

— ASB Standard 139, *Reporting DNA Conclusions [not yet published]*

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 (OSAC) for Forensic Science

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Questions, comments, and suggestions for the improvement of this document can be sent to 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: *DNA elimination database, quality assurance, contamination*

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Best Practice Recommendations for the Management and Use of Quality Assurance DNA Elimination Databases in Forensic DNA Analysis

1 Scope

This document provides best practice recommendations for the collection, storing, searching, and retention of DNA elimination samples and/or profiles in a quality assurance database. This document addresses the use of elimination databases as one component of a comprehensive approach to detect and monitor contamination.

2 Normative References

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

3 Terms and Definitions

For purposes of this document, the following definitions apply.

3.1
contamination
Exogenous DNA or other biological material in a DNA sample, PCR reaction, or item of evidence; present before the sample is collected or introduced during collection or testing of the sample

3.2
elimination database
Searchable collection of elimination profiles

3.3
elimination profile
DNA profile from an individual whose access, role, or activities might result in DNA contamination; includes profiles associated with consumables and positive controls; but not case-specific known DNA reference standards or exemplars

3.4
first responders
Any individual responding to a crime scene, including but not limited to: law enforcement, investigative, medical, fire/paramedic, and laboratory personnel

4 Recommendations

4.1 The laboratory should maintain and use an elimination database in accordance with the laws of its jurisdiction.

4.2 The laboratory should have elimination database policies that address the items listed in 4.2 a) through e), in accordance with recommendations 4.3 through 4.10:

a) the purpose of the database;

b) the generation, management, maintenance, and searching of the database;

c) personnel who have access to the database;

d) the evaluation and resolution of candidate matches;

e) the reporting of positive associations.

4.3 An elimination database should be comprised of profiles from the categories in recommendations 4.3.1 through 4.3.3.

4.3.1 Individuals who have direct contact with the evidence, such as:

a) personnel in the forensic biology/DNA unit of the laboratory;

b) first responder personnel who may respond to crime scenes;

c) laboratory personnel who may handle and/or examine evidence prior to the transfer of an item for forensic biology/DNA analysis;

d) investigative or crime scene personnel who collect or handle evidence;

e) medical examiner's/coroner's office personnel, sexual assault nurses, hospital staff and other personnel who may come in direct contact with and handle evidence;

f) laboratory or investigating agency staff who may handle outer evidence packaging;

g) laboratory custodial staff who may enter the forensic biology/DNA laboratory workspace

4.3.2 Individuals with more limited contact with the evidence, such as:

a) laboratory staff regardless of work unit or access level to the forensic biology/DNA laboratory workspace;

b) investigative agency staff and other first responders who may be present at crime scenes;

c) visitors, maintenance staff, and vendor staff who may enter the forensic biology/DNA laboratory workspace.

4.3.3 Additional DNA profiles, such as:

a) profiles attributed to consumable manufacturing staff;

b) unattributed contamination profiles;

c) laboratory positive control profiles.

4.4 All individuals providing samples for the elimination database should sign and receive an information sheet that includes at a minimum, the following:

a) organization managing the elimination database;

b) purpose of the elimination database;

c) the extent to which the samples will be used (e.g., for quality assurance purposes and not for medical research purposes);

d) privacy protections;

e) acknowledgement that associations to their profile will be evaluated and may be reported;

f) the retention, destruction, and expungement policies for the samples, raw data, and the resultant profile.

4.5 Samples collected for inclusion in the elimination database should be typed using the test kit(s) or assay(s) currently in use.

4.5.1 Before a laboratory changes or adds a new DNA typing kit, samples from individuals who come in direct contact with evidence should be retyped with that kit.

4.5.2 Samples from individuals who do not come in direct contact with evidence need not be retyped unless needed to assess potential contamination events.

NOTE A change in typing test kit does not preclude maintaining profiles typed with previous typing test kits.

4.6 All samples tested and profiles entered into the elimination database should be designated with a unique identifier.

4.6.1 Profiles from known individuals should not be labeled with personally identifiable information but should be traceable to the individual from whom the sample originates.

4.6.2 For samples originating from outside of the laboratory, the traceability may be maintained by an external entity such as law enforcement agencies or a product manufacturer.

4.7 The laboratory should have written policies regarding the management of the elimination database that address the recommendations in 4.7.1 through 4.7.4.

4.7.1 Access to the samples and data should be controlled and limited to authorized users to maintain confidentiality and prevent accidental or intentional misuse.

The policy should consider differentiating access levels between those individuals who can view the matches and those individuals who can access the traceability to determine the individual who provided the sample for the database. This may be the same individual or different individuals but should be defined in the policy.

4.7.2 The security of all samples and data in the elimination database should be maintained in a manner that protects against accidental loss, destruction, or manipulation/compromise.

4.7.3 The laboratory should have a mechanism, such as version control, to track when samples are entered/modified/deleted in the elimination database including a review and approval step for all entries, modifications, and deletions made to the database.

4.7.4 The retention time for both samples and data should be defined in the laboratory policy.

Laboratories should retain original samples and/or DNA extracts for the purpose of retesting as new relevant testing methodologies and test kits become available. Laboratories should also retain all profile data. For retention of profiles in the elimination database, consideration should be given to the potential for contamination risk and the expected time period the material handled by individuals will be in the system. It may be reasonable to archive some profiles and make them available for searching only for selected cases (e.g., cold cases, appeals, and post-conviction cases).

4.8 The laboratory should have policies that address the searching parameters and matching criteria for the elimination database.

4.8.1 The policy should describe the categories of profiles (e.g., single source and/or mixture evidentiary profiles, deduced evidentiary profiles, reference profiles) that will be searched against elimination profiles.

It is recommended that all evidentiary profiles deemed interpretable and comparable be searched against the elimination database.

4.8.2 The policy should address the search stringency and match criteria for detecting potential associations, for example, by a minimum statistical threshold, a minimum number of matching loci, or the discrimination power of the profile being searched. The selection of search stringency and match criteria will be guided by the intended goal of the search. Search parameters and the extent of the information contained in the results may vary depending upon the search conducted as well as the number of profiles in the database.

For example, one type of search can be designed with a low association threshold to trigger an investigation. This type of search is effective at detecting true contaminants, even when the level of contamination is very low. Increases in testing sensitivity, however, are paired with decreases in specificity, and the laboratory could expect increased instances of investigating adventitious matches. This would especially be true for complex profiles, very low-level contributors to mixtures, and large elimination databases.

An alternate type of search with a high association threshold would be effective at detecting gross contamination. A laboratory may choose this approach when, for example, the elimination database search is meant to prevent profiles from entering a government database such as CODIS. Benefits of this approach include fewer investigations of adventitious associations, even with larger database sizes. Such an approach should not be used or relied upon to detect lower-level contamination.

4.8.3 The elimination database should be searched prior to a laboratory report being issued, and the search results and parameters used should be documented in the case record.

4.9 The laboratory should have policies (4.9.1 through 4.9.3) addressing the investigation, reporting, and communicating of possible associations to clients and legal parties resulting from an elimination database search.

4.9.1 If contamination is a plausible explanation for the association, this should be documented in the case record and the laboratory should follow its quality system protocols, including root cause analysis.

NOTE If an association is made to non-laboratory personnel, it is incumbent upon the laboratory to report this information to the applicable agency or consumable manufacturer for potential retraining or process improvement.

4.9.2 For associations in which contamination is not a plausible explanation, it may be necessary to disclose the association for possible investigation by law enforcement.

4.9.3 Laboratory policy should specify how to address situations in which an association remains ambiguous and cannot be resolved as either contamination or adventitious.

4.10 The laboratory should have the following policies for reporting elimination database associations that are not resolved by re-testing.

4.10.1 If an elimination database association is made after a report has been issued, the laboratory should communicate the association to the recipients of the original report.

4.10.2 Documentation of elimination database associations should be retained or referenced in the case record and maintained in a centralized log.

Annex A
(informative)

Bibliography

The following bibliography is not intended to be an all-inclusive list, review, or endorsement of literature on this topic. The goal of the bibliography is to provide examples of publications addressed in the standard.

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