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

Biological Data Interpretation & Reporting Subcommittee
Biology/DNA Scientific Area Committee
Organization of Scientific Area Committees (OSAC) for Forensic Science

OSAC Proposed Standard

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

Prepared by
Biological Data Interpretation & Reporting Subcommittee
Version: 1.0
December 2019

Disclaimer:

This document has been developed by the Biological Data Interpretation & Reporting Subcommittee of the Organization of Scientific Area Committees (OSAC) for Forensic Science through a consensus process and is *proposed* for further development through a Standard Developing Organization (SDO). This document is being made available so that the forensic science community and interested parties can consider the recommendations of the OSAC pertaining to applicable forensic science practices. The document was developed with input from experts in a broad array of forensic science disciplines as well as scientific research, measurement science, statistics, law, and policy.

This document has not been published by an SDO. Its contents are subject to change during the standards development process. All interested groups or individuals are strongly encouraged to submit comments on this proposed document during the open comment period administered by the AAFS Standards Board (ASB) https://www.asbstandardsboard.org/.

Foreword

Monitoring contamination is critical to preserving the integrity of forensic DNA results generated for criminal cases. As part of an overall quality assurance program, forensic DNA laboratories have 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 extensively, to detect contaminants. It is essential for each laboratory to determine the purpose of its elimination database as this decision may affect the laboratory's policies regarding the generation, management, and searching of the elimination database.

The draft of this standard was developed by the Biological Data Interpretation and Reporting Subcommittee of the Organization of Scientific Area Committees. All hyperlinks and web addresses shown in this document are current as of the publication date of this standard.

Keywords: DNA Elimination Database, Quality Assurance, Contamination

Table of Contents

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 references for these best practice recommendations. Annex B Bibliography, contains informative references.

3 Terms and Definitions

Contamination Exogenous DNA or other biological material in a DNA sample, PCR reaction, or item of evidence; the exogenous DNA or biological material could be present before the sample is collected, or introduced during collection or testing of the sample.

Elimination Profile: A DNA profile from an individual whose access, role, and/or activities are deemed a potential DNA contamination risk. Also included are profiles that may be the source of laboratory contamination (e.g., profiles associated with consumables and positive controls).

Elimination Database: A searchable collection of elimination profiles.

4 Best Practice Recommendations

Refer to Annex A, Recommendations-Supporting Information, for additional information on the following recommendations.

4.1 The laboratory should have and use an elimination database.

4.2 The laboratory should have elimination database policies that address the following:

a) the purpose of the database;
b) the generation, management, and searching of the database;
c) personnel who have access to the database;
d) the evaluation and resolution of candidate matches; and
e) the reporting of positive associations.

4.3 An elimination database should be comprised of profiles from the following categories.

4.3.1 Individuals who have direct contact with the evidence. These individuals are considered high priority for elimination database entry and include:

a) Personnel in the forensic biology/DNA unit of the laboratory
b) Laboratory personnel who may handle and/or examine evidence prior to the transfer of an item to the forensic biology/DNA unit
c) Investigative or crime scene personnel who collect or handle evidence
d) Medical examiner's office personnel, sexual assault nurses, and other hospital staff who may come in direct contact with and handle evidence
e) Laboratory or investigating agency staff who may handle outer evidence packaging
f) Laboratory custodial staff who may enter the forensic biology/DNA unit

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 unit
b) Investigative agency staff who may be present at the crime scene
c) Visitors, maintenance staff, or vendor staff who may enter the forensic biology/DNA unit

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 have a signed consent form, regardless of whether the sample is voluntarily submitted or required, that includes at a minimum:

a) Organization managing the elimination database
b) Purpose of the elimination database
c) The extent to which the samples will be used
d) Applicable privacy protections
e) Acknowledgement that associations to their profile will be evaluated and may be reported, as necessary
f) The retention policy for the samples, raw data, and the resultant profile
g) A signature of the individual providing the sample acknowledging their consent

4.5 Samples typed by the laboratory should utilize the typing test kit(s) currently in use.

4.5.1 Profiles from individuals that come in direct contact with evidence should be retyped in a timely manner if the laboratory changes or adds a new typing test kit. It is recommended that this be done before the new kit is put into use.

4.5.2 Other profiles in the elimination database should be evaluated and retyped if 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.

4.7 The laboratory should have policies that address the management of the elimination database.

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.

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 in place to ensure version control of the elimination database.

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

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

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. This policy will be guided by the intended purpose of the database (see Annex A).

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

4.9 The laboratory should have policies addressing the investigation of possible associations resulting from an elimination database search.

4.9.1 If contamination is a plausible explanation for the association, the laboratory should follow its quality system protocols.

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 can not be resolved as either contamination or adventitious.

4.10 The laboratory should have a policy 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 is issued, the laboratory should have a mechanism in place to report the association.

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)
Recommendations - Supporting Information

4.7.1 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 donated the sample. This may be the same individual or different individuals but should be defined in the policy.

4.7.4 It is recommended to retain original samples for the purpose of retesting as new relevant testing methodologies become available. 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).

4.8.1 When feasible, it is recommended that all evidentiary profiles deemed interpretable but not associated to a reference profile should be searched against the elimination database.

4.8.2 The purpose of the elimination database should be determined prior to establishing the search parameters. Search parameters and the extent of the information contained in the results will both vary depending upon the intended purpose in combination with the number of profiles in the database.

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. The benefit is that this approach could be relied upon as a primary means of detecting contamination. 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 could not be used or relied upon to detect lower level contamination.

4.9.1 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.

Annex B
(informative)
Bibliography

1. SWGDAM Interpretation Guidelines for Autosomal STR Typing by Forensic DNA Testing Laboratories. Available at www.swgdam.org.
2. SWGDAM Contamination Prevention and Detection Guidelines for Forensic DNA Laboratories. Available at www.swgdam.org
3. FSR-P-302 Protocol: DNA contamination detection-The management and use of staff elimination DNA databases.
4. ISO/IEC 27001:2013 Information technology—Security Techniques—Information security management systems--Requirements
5. Reporting DNA results and conclusions for DNA profiles associated with contamination or failed controls. ASB Standard #
6. Forensic Laboratory Standards for Prevention, Monitoring, and Mitigation of DNA Contamination ASB Standard #
7. Manufacturer contamination of disposable plastic-ware and other reagents-An agreed position statement by ENFSI, SWGDAM, and BSAG. FSI:Genetics. July 2010, Vol. 4, issue 4. Pg 269-270