

Deadline of Submission of Comments: 13-Oct-25

Document Number: ASB Std 136

Document Title: Forensic Laboratory Standard for Prevention, Monitoring, and Mitigation of Human DNA Contamination

Comment #	Text Line # (s)	Document Section	Updated Document Section	Type of Comment	Current Document Wording	Proposed Revision	Revision Justification	For Working Group and Consensus Body use only, not to be completed by commenter.	
				E-Editorial T-Technical				Working Group Resolution	Final Resolution
1	4	Forward		E	This document discusses the standards required for a laboratory conducting PCR-polymerase chain reaction (PCR)-based analysis to limit, detect, assess the source of, and mitigate contamination events as they pertain to human forensic DNA analysis	This document discusses the standards required for a laboratory conducting PCR-polymerase chain reaction (PCR)-based analysis to limit, detect, assess the source of, and mitigate contamination events as they pertain to human forensic DNA analysis.	period after analysis was missing	Accept	
2		Forward		E	It can never be known with certainty that a casework or database sample is contamination-free, but detection and tracing efforts facilitated through the use of appropriate controls and quality assurance measures, including the use of elimination databases which contain the DNA profiles of laboratory personnel, first responders, law enforcement, and medical personnel can assist in the identification of contamination.	It can never be known with certainty that a casework or database sample is contamination-free, but detection and tracing efforts facilitated through the use of appropriate controls and quality assurance measures, including the use of elimination databases which may contain the DNA profiles of laboratory personnel, first responders, law enforcement, and medical personnel can assist in the identification of contamination.	the insertion of the word, "may" is necessary since, as written, it implies that first responders, law enforcement, and medical personnel will be part of the elimination database, and those profiles are not always feasible or legal for labs to obtain.	Accept	
3		Foreword, 4th paragraph; 4th line		E	This affects the interpretation of the sample, including comparisons to known individuals.	This affects the interpretation of DNA profile data and its comparison to DNA profiles from known individuals.	Correct the meaning - samples can't be interpreted and can't be compared to individuals	Accept	
4				Ballot Comment	minor comment #1: add the period after the first sentence of the foreword.			Accept	
5		1 Scope		grammatical	This standard provides requirements for limiting, detecting, assessing the source of, and mitigating the effect of DNA contamination as applied to polymerase chain reaction (PCR)-based human DNA analysis conducted within a forensic laboratory (i.e., casework including Rapid DNA and DNA analysis conducted within a forensic laboratory (i.e., casework, Rapid DNA, and DNA database).	This standard provides requirements for limiting, detecting, assessing the source of, and mitigating the effect of DNA contamination as applied to polymerase chain reaction (PCR)-based human DNA analysis conducted within a forensic laboratory (i.e., casework including Rapid DNA and DNA analysis conducted within a forensic laboratory (i.e., casework, Rapid DNA, and DNA database).	The change simplifies and clarifies the list in parentheses.	Reject- The suggested change is too wordy and complicated.	
6		4.2.4		E	( )	remove the extra set of ( )	typo	Accept	
7		4.2.4		E	4.2.4 Evidence and evidence derivative /work product shall be packaged and handled in a manner to minimize the transfer of biological material().	4.2.4 Evidence and evidence derivative/work product shall be packaged and handled in a manner to minimize the transfer of biological material().	removal of empty parentheses	Accept	
8		4.3.3 Note (both places)		T	NOTE: It is up to the laboratory to define the definition of "time" or "space" based upon validation	Note: It is incumbent upon the laboratory to define "time" and "space" based upon validation data.	Define the definition is redundant. Validation data is clearer than simply validation.	Accept with modification- The notes were made into separate requirements (4.3.4 and 4.3.5) and rewritten to:  "4.3.4 For non-databasing laboratories, the separation by time or space used for requirements 4.3.3 e) and f) shall be defined in the laboratory protocol.  4.3.5 The choice of time or space shall be supported by validation data."	
9	128, 132	4.3.3 e&f Notes		T	NOTE It is up to the laboratory to define the definition of "time" or "space" based upon validation.	NOTE It is up to the laboratory to define the the scope of "time" and "space" based upon validation, when applicable (e.g., appropriate space between samples if concurrently run on a robotic system). OR NOTE The laboratory can define the scope of "time" and "space" when validation has demonstrated the risk of contamination is negligible.	"Define the definition" is redundant. Not sure if 'scope' is the ideal word but I hope the intent isn't a measurement (e.g., 5 ft of space or 30 minutes of time). Also, it feels like these notes need a little more context. Is it expected that a lab validate the obvious? (e.g., completing a task then cleaning a bench before doing the task on the next item or doing the tasks in separate rooms/stations) I think the intent of the note is to define time and space when it can be a gray area or when there is a risk of contamination occurring during a process. If a lab never processes Evidence and Ref samples (or high and low samples) together, then there is not really anything to define. (This is a tough one)	Accept with modification- The notes were made into separate requirements (4.3.4 and 4.3.5) and rewritten to:  "4.3.4 For non-databasing laboratories, the separation by time or space used for requirements 4.3.3 e) and f) shall be defined in the laboratory protocol.  4.3.5 The choice of time or space shall be supported by validation data."	

10		4.3.6 Note	4.3.8	T	NOTE: 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). The use of negative controls helps assess the overall robustness of the testing process but cannot be used to determine whether a particular sample is free from contamination.	Note: the use of negative controls assists in assessing wide-spread contamination events, but may not always detect isolated contamination events.	Simplifies and clarifies the meaning; a negative control may not always detect isolated contamination events. It is unclear what robustness means in this context. Where the contaminate may originate from is already discussed elsewhere in the document.	Reject- The note provides additional information to help the laboratory.	
11		4.3.8	4.3.10	T	Exceptions can be made if a profile is associated with a known reference sample in the case (e.g., a DNA profile from a vaginal swab...)	delete	It's unclear what this statement has to do with elimination databases. Or maybe it goes under 4.3.9 (but doesn't seem necessary there either)?	Reject with modification- Sentence revised to "Exceptions can be made and shall be documented"	
12	165-166	4.3.8.1	4.3.10.1	E	...vendors, and employees involved in any criminal proceedings who may have handled evidence in post-conviction cases).	...vendors) and employees involved in any criminal proceedings who may have handled evidence prior to additional DNA testing (e.g., in post-conviction cases).	I'd remove employees involved in criminal proceedings from the list of examples of "DNA laboratory visitors and individuals involved in ..." but keep it as an additional thought in the sentence.	Reject- The list is an e.g. Employees in the laboratory may not be DNA laboratory personnel.	
13		4.3.11 e)	4.3.13 e)	T	4.3.11 If the laboratory uses probabilistic genotyping software, or other software, the laboratory shall use such software within its validated capabilities to detect contamination in casework and database samples to include: e) determining a likelihood ratio threshold value (or defined threshold value for laboratories using non-probabilistic genotyping software) to report for comparisons to an elimination database.	e) determining a likelihood ratio threshold value (or defined threshold value for laboratories using non-probabilistic genotyping software) for further investigation (of suspect contamination).	Simplifies defined purpose	Reject- The comment is unclear. This section refers to an elimination database and not an investigation.	
14		4.3.12	4.3.14	T	The threshold value should be documented in the case record and in the report.	This should be removed	1. It is not standard practice for laboratories to report this for lab reports. 2. Reports are used to convey the results of any serological testing, the DNA profiling and statistical comparisons to references of interest. 3. The findings of such comparisons, if performed, would be available if the entire casefile is reviewed.	Accept with modification- "and report" was deleted.	
15	192	4.3.12	4.3.14	T	e) determining a likelihood ratio threshold value (or defined threshold value for laboratories using non-probabilistic genotyping software) to report for comparisons to an elimination database. 4.3.12 The threshold value should be documented in the case record and in the report.	4.3.12 Comparisons to an elimination database sample that surpass the threshold value should be documented in the case record and in the report.	I foresee a threshold value being documented in a procedure. I think the intent of the previously used "this" was that comparisons to an elimination database sample that surpass the threshold should be reported?	Accept with modification- "and report" was deleted.	
16		4.3.12	4.3.14	E	the entire recommendation	make as a note perhaps?	This statement is a subset of 4.3.11 e) and not a stand alone recommendation.	Accept with modification- "and report" was deleted. It cannot be a subset of the list, as the list are all requirements, and this statement is a recommendation.	
17	226	4.6.2		T	4.6.2 Rapid DNA instrumentation shall be maintained in rooms outside of evidence storage areas, evidence examination areas, and those containing amplified DNA.	Except as provided in Standard 4.6.2.1, Rapid DNA instrumentation shall be maintained in areas outside of rooms containing amplified DNA. 4.6.2.1 If maintained inside a room containing amplified DNA, the sample cartridge/chip shall be loaded in an area that does not contain amplified DNA.	The standard this statement was based on was revised in QAS2025: [STANDARD 18.4 Except as provided in Standard 18.4.1, a Rapid DNA instrument/System used for processing casework reference samples and/or forensic samples shall be maintained in areas outside of rooms containing amplified DNA. 18.4.1 If maintained inside a room containing amplified DNA, the sample cartridge/chip shall be loaded in an area that does not contain amplified DNA.] Additional info from Guidance Doc: The amplified DNA generated by the Rapid DNA instrument/System is fully encapsulated in the Rapid DNA cartridge/chip and therefore does not contribute to a room being identified as containing amplified DNA.	Accept with modification. 4.6.2 revised to read: 4.6.2 Except as provided in 4.6.3, Rapid DNA instrumentation and cartridges/chips shall be maintained in dedicated spaces away from other laboratory areas used for evidence and DNA extract storage, examination, and testing, including rooms containing amplified DNA.	
18	248-249	Annex A		E	5] FBI, Quality Assurance Standards for Forensic DNA Testing Laboratories g 248 . 2020. 6] FBI, Quality Assurance Standards for DNA Databasing Laboratories g 249 . 2020.	5] FBI, Quality Assurance Standards for Forensic DNA Testing Laboratories g 248 . 2025. 6] FBI, Quality Assurance Standards for DNA Databasing Laboratories g 249 . 2025.	New version of QAS issued 7/1/25	Accept with modification- Year was removed so the reference is always to the current version.	