

Deadline of Submission of Comments: 13-May-24

Document Number: ANSI/ASB BPR 129

Document Title: Best Practice Recommendations for Internal Validation of Human Short Tandem Repeat Profiling on Capillary Electrophoresis Platforms

Comment #	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				Final Resolution
1	Title	E	Best Practice Recommendations for Internal Validation of Human Short Tandem Repeat Profiling on Capillary Electrophoresis Platforms	Best Practice Recommendations for Internal Validation of Human Short Tandem Repeat Profiling on Capillary Electrophoresis Platforms for Forensic Sciences	ATCC has as currently published standard, ANSI/ATCC ANS-0002-2022 Authentication of Human Cell Lines: Standardization of Short Tandem Repeat (STR) Profiling. The suggestion is to clarify that the use of this standard is in a different capacity to this one. This is simply to provide clarity and prevent confusion for end users. Upon review we have no concerns regarding overlap of the two standards.	Reject: The specificity is covered in the first sentence of the Forward and in the Scope of 039. No need to change the title.
2	general	E	single-source vs. single source		be consistent throughout the document	Accept: Use single-source
3	general	E	casework-like vs. casework like		be consistent throughout the document	Accept: Use casework-like
4	3.5	E	inconsistent definition	make the same	the definition for 3.5 is not the same in 039 and 129	Accept: Using the same definition in both documents
5	3.13	E	inconsistent definition	make the same	the definition for 3.13 is not the same in 039 and 129	Accept: Using the same definition in both documents
6	4.1.9	editorial	current wording	previous wording	verb tense non-agreement in reworded form	Reject: Current wording has been kept based on previous comments.
7	4.1.11	T?	needs to be conducted	Should? Or make a requirement in 039?	is "need" the same as "shall"? If so, this becomes a requirement - which does seem more appropriate than "should". Does this need to be moved into 039?	Accept with modification: Section 4.1.2 from Std 039 has been added to sections 4.1.11 and 4.1.12 for clarification.
8	4.1.14	editorial	procedures used and protocols being developed	procedures and protocols under development	"procedures used" indicates the validation is changing current procedures. "being developed" is an unnecessary past continuous passive voice.	Accept
9	4.2.4.4 a)	T	(i.e., ...)	(e.g.,...)	these seem to be suggestions and not mandatory	Accept
10	4.2.4.5	E	Chromosome	chromosome	capital letter not needed	Accept
11	4.3.3.2	technical	(lower or higher than a single AT)	remove (lower or higher than a single AT)	redundant. By definition, additional values will be lower or higher than one value.	Accept
12	4.7.4.3	editorial	should be evaluated with each sample tested at least in duplicate, with best practice testing in triplicate	should be evaluated in duplicate, at a minimum, or in triplicate, as best practice.	simplified wording	Accept
13	4.11.1	T	assessment	is this word being used in place of "verification" as used in Standard 020? or does it have a different meaning?	It is unclear if "assessment" is different from the required verification step in Standard 020. The word should be changed to "verification" if meant to be the same for consistency across standards, or "assessment" should be defined to provide clarity to the use of the word in this section	Reject: The term assessment was specifically chosen instead of verification in earlier ballots. The dictionary definition is sufficient for this purpose, so no additional definition to be provided.

14	4.11.4	editorial	and different from those previously used for this validation study	and different from those used in other portions of the same validation study	that	Accept with modification: kit and different from those previously used for other portions of this validation study
15	Bibliography	E	dates given for QAS and ISO	suggest removing dates	we generally do not give the specific year of the document so that the current version would be applicable	Reject: We are making a specific reference to these documents and their contents.
16		Ballot Comment		Line 10 needs a closed parenthesis.		Reject: Unable to find. (Error was found in 039 and fixed)
17		Ballot Comment		1) Link for footer "8" does not work (Bibliography #14, page 23).		Accept with modification: Removed the link.
18		Ballot Comment		2) Consider changing the links for Bibliography #10-11 and #14 to the SWGDAM general publications webpage https://www.swgdam.org/-publications to encompass future/updated SWGDAM documents (pages 22-23).		Accept: removed the links and created a new Bibliography item for the SWGDAM Publications webpage
					add normative reference ANSI/ASB Standard 038, Standard for Internal Validation of Forensic DNA Analysis Methods, First Edition, 2020?	Standard 039 references the Normative Document so it's not listed here. Plus Normative References must be followed and this is a Best Practice Document.