

Deadline of Submission of Comments: 13-May-24

Document Number: ANSI/ASB Std 039

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

Comment #	Text Line # (s)	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		3.5	E	inconsistent definition	make the same	the definition for 3.5 is not the same in 039 and 129	Accept: using the 039 definition in both documents.
2		3.9	technical	infer genotypes and/or calculate...	infer possible genotypes, and resultant statistical support for evidentiary profiles	infer genotypes sounds like one is decided upon. And/or is misleading, as infer possible genotypes is always part of prob gen. LR are not.	Reject: Using previously published definition in Std 018.
3		3.13	E	inconsistent definition	make the same	the definition for 3.13 is not the same in 039 and 129	Accept; using the 129 definition in both documents.
4		3.13	Ballot Comment	Note that the definition for stochastic threshold differs from the definition in BPR 129.			Accept. Additionally we updated the definition to be consistent with SWGDAM documents and OSAC Standard 2021-S-0003. Definition now aligns with 129
5		3.13	technical	above which	where values equal to or above which		Reject with modification: Using previously published definitions from SWGDAM documents and OSAC Standard 2021-S-0003. Definition now aligns with 129
6	first sentence	4.1	T	...and should be supported by relevant developmental validation studies.	...and SHALL be supported by relevant...	It is difficult to envision any scenario where developmental validation studies for amplification kits wouldn't have been conducted and be necessary prior to validation studies being conducted in a lab. Furthermore, developmental validation studies are required in 4.3.1 of the normative reference Standard 038, so "shall" seems required here as well.	Accept
7	last line	4.1	E	shall be described and where needed the data reanalyzed	shall be described and, where needed, the data reanalyzed	comma is grammatically needed	Accept
8		4.1.7 NOTE	E	specificity testing within probabilistic genotyping).	specificity testing within probabilistic genotyping; see ANSI/ASB Standard 018)	additional standard reference is needed in conjunction with 020 and 040 for completeness	Accept with modification; Additional information on mixture studies, the development of interpretation protocols, and probabilistic genotyping systems can be found in ANSI/ASB Standard 020, ANSI/ASB Standard 040, and ANSI/ASB Standard 018.
9		4.1.10.1	technical	These studies shall minimally include processing a set of sample using all DNA extraction and quantitation chemistries utilized by the laboratory to verify compatibility with the new STR test kit.	Remove quantitation requirement	Quantitation is an end process, where products do not go on to CE.	Reject: the product tested using a quantitation method is assessed and the amount of that product that goes on to CE is determined by that quantitation value.
10		4.1.10, 4.1.10.1 & .2	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.
11		5c	E	...and communication to all analysts prior to implementation	...and communication to, with requisite training as needed for, all analysts prior to implementation	It is unlikely that simple communication is adequate for the introduction of a new STR amplification kit. Additional training with appropriate competency testing is very likely needed.	Accepted with modification: c) documented approval of the documents listed in 5(a) and 5(b) by the DNA Technical Leader or other appropriate personnel and communication, with requisite training as needed, to all analysts prior to implementation in the laboratory.

12	last paragraph	5	E	by the DNA mixture test protocols and parameters	by the DNA test protocols and parameters	delete "mixture"; this implies that the studies involving single source samples need not be available. It seems the intent is the entirety of the studies performed, not just mixture studies.	Accept
13		Annex A	Ballot Comment	1) Link for footer "e" does not work (Bibliography #8, page 6).			Accept; Removing link
14		Annex A	Ballot Comment	2) Consider changing the links for Bibliography #10-15 to the SWGDAM general publications webpage https://www.swgdam.org/publications to encompass future/updated SWGDAM documents (pages 6-7).			Accept with modification: Giving a general reference to the SWGDAM website for publications and removing the individual links.