Deadline of Submission of Comments: 27-Mar-23
Document Number: ANSI/ASB BPR 129
Document Title: Best Practice Recommendations for Internal Validation of Human Short Tandem Repeat Profiling on Capillary Electrophoresis Platforms

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
5	overall	T	These procedures would seem to be critical. Is there a reason this is a best practice recommendation and not a standard? The concern is that if it stays a 'best practice recommendation,' legal stakeholders will assume that none of this is critical. If the reasoning for the best practices approach is that there are occasional exceptional circumstances that would justify not following them, then the standard could be written to permit an FSSP to opt out under specified circumstances, provided the FSSP produces a written explanation that is readily available to the public.	Change to a standard or offer reason that the procedures are not required.	Reject: There is a Standard Document and this is a BPR in support of Standard 039, they will be out for all public comments together.
26	General	E	"Samples Used for Experimental Method" each have "NOTE See 4.2.4" with no other sentence. Should "NOTE" be deleted since there is no phrase for the Note to be modifying?	delete the word "NOTE" unless this is the correct format	Reject. Added additional information to make it clear.
12	Foreword - added sentence	T	This document seems to include the amplification step as well as data analysis for STR kits but that is not included in this sentence; only mentions validation of the CE	Clarify what steps of the DNA testing process this document is intended to cover and modify the sentence as needed	Accept: The validation of STR profiling kits is one part of the process of generating a DNA result. There are steps prior to and after this amplification step and their impact on the STR profiling kit validation studies should be considered.
13	Foreword - added sentence	E	suggest breaking sentence up and adding more contextual information	The validation of CE is one part of the process…a DNA result. There are additional steps in the DNA testing process prior to and after the use of a capillary electrophoresis platform that should be considered and included as necessary in the internal validation study	Accept: The validation of STR profiling kits is one part of the process of generating a DNA result. There are steps prior to and after this amplification step and their impact on the STR profiling kit validation studies should be considered.
1	3	E	If 039 and 129 are connected, only 039 has interpretation defined	Add in definition from 129 into 039: interpretation The process of evaluating DNA data for purposes including, but not limited to, defining assumptions related to mixtures and single source profiles, distinguishing between alleles and artifacts, assessing the possibility of degradation, inhibition, and stochastic effects, and determining whether the data are suitable for comparison.	Accept
2	3.8	E	If 039 and 129 are connected, only 129 has precision study(s) vs 039 just listed as precision	Either stick with only precision or modify to precision study(s) to be consistent	Accept
3	3.14	E	If 039 and 129 are connected, only 129 has precision study(s) vs 039 just listed as precision	Select one or the other for both documents: The process of performing and evaluating a set of experiments that establish/establishes the efficacy, reliability, and limitations of a method, procedure or modification thereof; establishing recorded documentation that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes. May include developmental and/or internal validation.	Accept: Used establishes in the definition for "validation" not "precision study"
14	4.1.6	E	change "in" to "of"	concentration OF each extract	Accept
15	4.1.9	E	add "and" between calibrations and maintenance and remove comma	…calibrations AND maintence, and should meet the…	Accept with modification: Instrumentation should meet the laboratory's criteria for use in casework including being current on calibrations and maintenance..
16	4.1.11, 4.1.12	E	comma needed after "implementation"	purification), prior to implementation, additional validation… (or move "prior to implementation" to the end of the sentence)	Accept
17	4.1.14	T	in the addition - delete "being" and add statement at the end for better clarity	"modifications to the procedures used and protocols developed" (or change to "procedures to be used")	Accept with modification: These results may dictate the need for additional testing and/or modifications to the procedures used and protocols being developed.

6	4.2.3	T	Performing replicates of the samples selected with an emphasis on testing DNA is useful for collecting and examining STR data where allele dropout is expected: This is informative for establishing and verifying a stochastic threshold and for the use of probabilistic genotyping software. Not clear why a lab would try to establish a stochastic threshold without doing this first.	Make this a requirement, or somehow make clearer that it should be done, rather than just being "useful."	Accept with modification: This is a BPR and only a "considerations" section, so a requirement here is not appropriate, used "recommended". Additionally, more information on this topic is addressed later in the document. NOTE that this is a companion document to ASB Standard 039, this document contains best practice recommendations to implement the requirements in Std 039
7	4.2.4.3(b)	T	Again, testing "lower concentrations where allelic dropout is observed" as well as more robust samples in establishing thresholds seems critical. Why is this merely a suggestion? (same with part (a) - it says a "minimum" of 5 - why wouldn't this be a standard?	Change to a standard or offer reason that the procedures are not required.	Reject: BPR so should is appropriate here. NOTE that this is a companion document to ASB Standard 039, this document contains best practice recommendations to implement the requirements in Std 039
18	4.2.4.4 a)	E	should the comma between DNA and multiple be a semi-colon? The sentence doesn't read smoothly as written.	improve readability of the sentence	Accepted: added the word "and"
19	4.3.3.2	T	not sure what "an overall AT" is, and not in the definitions.	Maybe simply remove the parenthetical phrase and change "different AT values" to "multiple" or "several" AT values	Accept with modification: both instances of "overall AT" have been revised to "single AT" for clarification.
8	4.4.3.2	T	Again, this seems like a standard - why would it be OK for a lab to use peak area when the software isn't suitable for that purpose?	Change to a standard or offer reason that the procedures are not required.	Reject with modification: Section revised to read: "Measurements of peak area may be substituted for peak height, and if selected, peak area should be used for all studies." NOTE that this is a companion document to ASB Standard 039, this document contains best practice recommendations to implement the requirements in Std 039
20	4.5.5.8	E	the last added phrase is redundant	delete the last phrase; could add "several" or "multiple" in front of "single-source" on the first line	Reject: need "single-source" to describe casework-like samples
9	4.7.1-4.7.2	T	If these are requirements, not clear why this is only a best practice guide	Change to a standard or offer reason that the procedures are not required.	Reject: The text referers to the standard being described
21	4.7.2	E	Add Standard 040 since it is specifically covers the protocol requirements for these topics	Add ANSI/ASB Standard 040 along with 020.	Accept
22	4.7.4.3	T	add the word "minimum" back in	Samples should be tested at a minimum in triplicate.	Reject: Returned to original Ballot 01 language with a minimum of duplicate and receommended best practice of triplicate.
10	4.7.4.3	T	Originally seemed like a requirement for testing in duplicate; now seems like a best practice for testing in triplicate. But now there's nothing requiring duplicate anymore.	Note that duplicate is minimum requirement and triplicate is best practice?	Accept
11	4.7.6.1	T	Seems like a critical requirement (using different samples for verification than for initial validation). Why not a standard?	Change to a standard or offer reason that the procedures are not required.	Accept: This is a BPR document and not a Standards Document. This section references Std 020 in this section. NOTE that this is a companion document to ASB Standard 039, this document contains best practice recommendations to implement the requirements in Std 039
4	4.11.1	E	If 039 and 129 are connected, minor change to capilalization in 129 for known and casework	The laboratory shall conduct studies utilizing known and casework-like samples with a range of sample types representative of those regularly analyzedexpected to be encountered by the testing laboratory."	Accept with modification: Changed text but removed capitalization.
23	4.11.1	E	Capital letters not needed for Known and Casework - not proper names/nouns (also not used with capital letters in the section below)	change to lower case letters	Accept with modification: Changed text but removed capitalization.
24	4.11.1	T	The original intent of the requirement that this flows from seems to have been completed removed. It seems verification was the critical assessment for the original requirement. The modifications made alters the entire intent of the requirement. Unclear why this got changed.	Return to the original concept of verification covered by the original requirement.	Reject: Use of the term Verification was purposefully removed from the Std and BPR
25	4.11.4 b) 4)	T	DNA samples used should be reflective of what is expected from casework - not based on prior studies; using similar samples to those used in the validation studies defeats the purpose of the verification step	change to: similar levels of complexity to the samples expected to be encountered in casework and different from those used in the validation study.	Accept with modification: Changed 4.11.4 to "The testing laboratory should analyze known references and casework-like samples representative of those expected to be encountered by the laboratory for casework using the new STR test kit *and different from those previously used for this validation study.*