Deadline for submission of comments: May 16, 2022
ASB BPR 156, Best Practices for Specimen Collection and Preservation for Forensic Toxicology

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
6	3.6	E	"Suspected poisoning" is not an analysis; it is a condition	Alter definition. Suggest "A case wherein an individual has possibly or probably been exposed to a drug or toxin.	Partial Accept: Please note that comments on a re-circulation are generally accepted only on revised sections of a document. Comments made on text not revised from the previous public comment period are generally not accepted. The term has been updated to "Suspected poisoning toxicology" to better identify the type of testing.
7	3.7	E	Unclear on what or who "safety" pertains to	Suggest adding "…ensure the health and safety of laboratory staff under…"	REJECT: Please note that comments on a re-circulation are generally accepted only on revised sections of a document. Comments made on text not revised from the previous public comment period are generally not accepted. The term is intended to cover everyone who touches the specimen, not just the laboratory staff. In addition, this definition is taken directly out of the approved OSAC Lexicon.
1	4	T	The NOTE in the most recent comment resolution cited "references that have shown that the use of expired tubes had no effect on analytical results when compared to unexpired tubes for blood alcohol." In specific circumstances, there are publications that draw this conclusion, but it is notable that these studies did not address the potential for adverse impact from the presence of microbes. See, for example, the frequently cited Winek (Clinical Chemistry Vol 29, No 11, 1983) "we conclude that alcohol analyses of blood **obtained sterilely** from living humans can be delayed for as long as 14 days without a significant change in alcohol content." (**emphasis added**). As stated in CLSI C60-A (issued as a consensus standard by FDA most recently in 2014) "Nevertheless, the question can still arise as to how the phlebotomist could know with certainty, even if aseptic collection techniques were employed, that no micro-organisms entered the specimen and produced changes in the alcohol concentration." It is also noted that the most recent proposed resolution simply ignores the tube manufacturer's instructions for use and basis for assignment of expiration dates. If this document purports to provide "best practices" it should not prescribe practices that are in direct conflict with manufacturer instructions related to specimen integrity.	If the working group cedes the "best practices" high ground for this document, it should at least explicitly acknowledge that use (including analysis) of a collection vessel beyond the manufacturer's expiration date is not receommended.	PARTIAL ACCEPT: Section 4.1 was updated to "4.1All specimens should be collected and handled using universal precautions. As a general rule, specimens should not be collected in expired tubes. It is recognized, however, that the expiration date may not reflect the suitability of a particular collection tube. Therefore, the laboratory may choose to implement a policy that allows for the collection and testing of specimens using expired tubes."
2	4	T	The most recent comment resolution rejected a comment regarding storage of collection vessels as "outside of the scope of this document" since it begins with collection of a sample. It is an unassailable fact that selection and use of an appropriate collection vessel is an integral and essential part of an acceptable toxicology specimen. The committee states that it is unaware of articles regarding improper storage. Are we really expecting scientists to pursue funding for empirical studies of whether a manufacturer's prescribed storage conditions are unnecessary? Please consider ISO 17025:2017 section 6.6 which requires a lab to put in place procedures to ensure that consumable materials provided to laboratory customers for sampling purposes meet established criteria. The manufacturer has published explicit criteria for storage of its evacutated tubes. Failure to conform to its criteria are analogous to ignoring a manufacturer's prescribed storage conditions for reference materials. You do so at peril for the quality of your analytical work.	If the working group cedes the "best practices" high ground for this document, it should at least explicitly state that collection vessels should be stored in accordance with the manufacturer's instructions.	REJECT: Please note that comments on a re-circulation are generally accepted only on revised sections of a document. Comments made on text not revised from the previous public comment period are generally not accepted. The consensus body continues to believe that this is outside of the scope of this document. There are multiple sections that discuss how specimens should be stored after collection.

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5	4.1	T	The statement on expiry will inevitably cause issues for forensic toxicology laboratories, and is not relevant for us. Tube manufacturers are not assessing expiries for forensic tox aspects. Indeed, the expiry typically reflects the vacuum in the tube and its ability for best practice phlebotomy in obtaining blood/specimens. This is a phlebotomy concern, not a forensic toxicology one. Preservative in its name's sake is designed to withstand time. This could also infer that the expiry date on a tube means we should not/cannot test the sample after that date. An overarching statement like this is problematic and not relevant for us in forensic toxicology.	Remove the recent addition of "Collection vessels with an expiration date should not be used beyond the date provided."	PARTIAL ACCEPT: Section 4.1 was updated to "4.1All specimens should be collected and handled using universal precautions. As a general rule, specimens should not be collected in expired tubes. It is recognized, however, that the expiration date may not reflect the suitability of a particular collection tube. Therefore, the laboratory may choose to implement a policy that allows for the collection and testing of specimens using expired tubes."
9	4.3	T	This seems to suggest that the empty space in a vacutainer tube be filled with sample fluid. This can result in an improper ratio between fluid and additive.	Specify that this does not apply to vacutainer tubes.	REJECT: Please note that comments on a re-circulation are generally accepted only on revised sections of a document. Comments made on text not revised from the previous public comment period are generally not accepted. The consensus body supports that this statement applies to all specimen collection tubes, including vacutainers.
8	4.4	T	Contradictory to 4.7, which advocates collection of specimen in foil	Specify which specimens should be stored in glass or plastic containers.	Partial Accept: Please note that comments on a re-circulation are generally accepted only on revised sections of a document. Comments made on text not revised from the previous public comment period are generally not accepted. The section was updated to "Unless otherwise specified in this document, specimens should be collected and stored in glass or plastic containers. Consult with the laboratory for any potential effects the type of container may have on a specific drug or toxin. If specimens stored in glass are to be frozen, care must be taken to mitigate the potential loss of specimen due to breakage (e.g., plastic sleeve around container)."
3	4.5	E	This section calls for inversions of "capped" tubes. For clarity, this should refer to "filled" tubes.	Replace the term "capped" with "filled"	REJECT: Please note that comments on a re-circulation are generally accepted only on revised sections of a document. Comments made on text not revised from the previous public comment period are generally not accepted. The sentence includes "immediately after collection" which infers that the tube is "filled".
4	4.8	T	As wrtitten, this section is in direct conflict with provisions of the CLSI GP41consensus standard for venipuncture, which requires that each individual blood tube be labeled with: subject's full name and identifying info (usually DOB); date and time of collection; and collector's identification. This section also does not consider the relatively common situation in which multiple specimens are collected from a single individual at different times. If the date and time of collection is on paperwork (but not on the tubes), it markedly increases the very real risk of sample mixups. For toxicology purposes, unambiguous linkage to an individual is not sufficient; collection time matters.	Each individual specimen container shall be labeled with sufficient information to unambiguously identify the person collecting the specimen, the subject, and the date and time of collection. Records that accompany the specimen may include additional relevant information (e.g., post-mortem sample type, type of antiseptic used, expiration date of container).	REJECT: This document is not in conflict with CLSI, additional information may be provided. This document sets a minimum expectation of collection of samples for forensic toxicology which requires only that a sample be unambigously linked to a specific individual. The name of the person (e.g., John Doe) or date of birth may not be known when the samples are collected.
10	4.8	T	Specimen type, and date and time of collection seem like necessary information for the analyst. Also necessary is what test is being requested.	Suggest "specimen type, test requested, and date and time of collection shall also be provided…"	REJECT: The consensus body agrees that only the unambigous linkage of a sample to an individual is required. Additional information may be provided which meets the suggested language provided by the commentor. This is further clarified in the second sentence "The specimen type (e.g., heart blood), date and time of collection, and identity of the collector should also be provided to the laboratory (e.g., on the label, in a requisition form, within chain of custody documentation). "

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11	7	T	Most veterinary species undergoing postmortem exam do not have these volumes of fluid available to sample. Veterinary diagnostic labs generally require 2 mL of whole blood, 6 g of tissue, or 10 mL of urine for tox testing.	Either specify throughout the document that the recommended minimum amounts apply only to humans or add tables with appropriate volumes for veterinary species.	REJECT: Please note that comments on a re-circulation are generally accepted only on revised sections of a document. Comments made on text not revised from the previous public comment period are generally not accepted. This is a best practice document for forensic toxicology laboratories, not veterinary diagnostic labs. There will always be cases in which the minimum volumes may not be able to be collected due to limited specimen volume (e.g., infants, decomposed bodies).
12	10	T	Is this section specific to antemortem suspected poisoning? This is assumed, but not stated. Deceased suspected poisonings would fall under 7.	State specifically that 10 refers to antemortem suspected poisoning.	REJECT: Please note that comments on a re-circulation are generally accepted only on revised sections of a document. Comments made on text not revised from the previous public comment period are generally not accepted. The defined term (see 3.6) specifically states that the individual is living.