Deadline for submission of comments **12/20/2021**

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
2	4	T	Need to ensure the collection vessels, tubes or cups are within their prescribed period of use of "shelf life" and have not expired (or are going to expire prior to analytical testing). The manufacturer Becton Dickinson states the vacutainer tubes used in the collection of blood must not be used past their expiration date.	Create a subsection in #4 that the collection must be in a vessel that is within its prescribed period of use and expired collection vessels are not to be used. The manufacturer records on each collection vessel it's unique date of date of expiration so that this can be checked prior to its employment. The use of expired tubes and collection vessels is not good practice and contravenes the Certificate of Compliance and manufacturer's guidelines for use. The expiration is for the entire collection unit and includes the sterility, tube seal and associated vacuum and any additives. "The shelf life of the evacuated tube is defined by the stability of the addivites as well as vacuum retention." Lack of tube integrity means the sterility is compromised, the ability of the vacuum to draw the required volume as stated in the Certificate of Compliance is affected and the ability of the additives to produce their intended effect after expiration is not guaranteed by the manufacturer. Records from the manufacturer and their product literature codify this need to discard expired collection vessels and reiterates there is no extended time period past the expiration date during which the tubes can be used. Phelbotomy textbooks document "Consumable materials with an expiration date must not be used beyond the date provided."	Partial Accept : Section 4.1 was modified to include "Collection vessels with an expiration date should not be used beyond the date provided." NOTE: The committee does not agree that any usage of expired tubes invalidates analytical results. For example, there are references that have shown that the use of expired tubes had no effect on analytical results when compared to unexpired tubes for blood alcohol.
3	4	T	Storage of collection vessels prior to use- most importantly vacutainer tubes-are affected by environmental conditions. Environmental factors affecting evacuated tubes include temperature, altitude, humidity, light, movement, etc. The manufacturer provides the conditions for storage prior to use to ensure the conditions do not negatively impact the ability of tubes to perform as per their Certificate of Compliance. For example- prolonged storage of blood collection in a police vehicle where they are exposed to temperature fluctuations, gasoline fumes, humidity, light, and jostling are not proper storage conditions and compromise the ability of the tube to perform within specifications. For example- packaging for BD brand evacuated tubes includes a pictograph showing temperature of storage as 4-25 C. Those temperatures may not be realized in the storage of blood collection tubes in a police vehicle.	Create a sub section that clearly defines the proper storage of medical devices used in the collection of biological samples. Lack of proper storage according to the products packaging and Specifications for Use should be reviewed to ensure compliance. Require that biological collection vessels and kits are retrieved from a location adhering to the manufacturers requirements for product storage. Forbid the use of collection units that are undermined as to pre-use storage conditions. This should not be a difficult task as the maunfacturer provides this information with each set of collection vessels.	REJECT: The proposed language is outside of the scope of this document. This document begins with the collection of a sample; not the purchase and storage of collection vessels. Additionally, the committee is unaware of any published articles regarding the improper storage of collection vessels and the effect on analytical results. This document is to delineate special conditions for forensic toxicology.
4	4.3	T	Any specimen container can leak, arguably rubber stoppers may be more prone.	Consider writing "All containers should be checked for a tight seal before transport"	PARTIAL ACCEPT: The sentence was modified to "Containers should be checked for a tight seal before transport. "
5	4.5	E	The last two sentences are confusing when following the first sentence about specifically inversion.	Consider these two sentence to be a new numbered point "Tubes of a similar color may not contain the same additives. Additives should be verified prior to collection."	PARTIAL ACCEPT: The bullet point was clarified to "4.5For collection tubes containing additives (e.g., anticoagulants and/or preservatives), 4.5.1the presence and labeled identity of any additive should be visually confirmed prior to collection, and 4.5.2, ccapped tubes should be inverted a minimum of 8 times immediately after collection. "
6	4.8	T	This may suggest that a specimen container must contain a date and time. If an organization has appropriate measure, this may not be required (i.e., only identifiers are on the specimen container at a minimum).	Consider adding ", on the container or otherwise" to the end of the sentence.	PARTIAL ACCEPT: The bullet point was clarified to "4.8Containers shall be labeled with sufficient information to link the specimen to a specific individual. 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). "
12	4.9	E	Use of the relative term "below". Below is fine in a digital pdf format. Other platforms require side scrolling thus below is no longer relevant. Can also be applied to a hard copy print being on a separate page.	Remove term below and replace with the referenced Tables 1-6.	REJECT: The committee supports the usage of the word "below" as the tables are subsequent to the bulleted point.
7	4.10	T	As there is no definition for 'container', it may insinuate a hard container, when indeed an evidence envelope or plastic sealed bag may also be adequate.	Consider defining 'container' to provide flexibility of different types of packaging. Or, change this sentence to include '...container, package or otherwise,...	REJECT: The committee disagrees that there is an insinuation about the makeup of the secondary container in the sentence.
10	5.3, 5.4	E	The standard should note that reported results should note the fact that a specimen does not meet the recommended criteria and the reason(s) for testing it anyway.	Add "If a specimen that does not meet the recommended criteria is tested, the laboratory shall note this fact and document the reason(s) for testing it anyway."	PARTIAL ACCEPT: The bullet point was updated to "5.3Laboratories may choose to perform testing on specimens that do not meet the recommendations delineated in this document. The laboratory should document the reason(s) for proceeding with testing. "

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final
11	5.5	E	Reporting should be required when there is a significant or substantial chance of an effect. Or, a statement about the inappropropriate containers or conditions should be required in all cases, along with a further statement of how likely it is that this factor affected the results.	Add language: "Reported results shall also document any significant or substantial chance of an effect." Or, add a statement requiring documentation of any inappropropriate containers or conditions followed by a statement of how likely it is that this factor affected the results (this latter suggestion would obviate the need to define 'significant or substantial').	REJECT: Reporting is covered in the published ANSI/ASB 053 document and this document has been updated to include it as a normative reference and the bullet point has been updated to reference the published standard.
8	Table 1 - 6	T	These 'minimum' volumes are very high for current forensic toxicology abilities. This also causes storage space concerns and potentially unnecessary sample collection for individuals. For example, Table 1's 2 x 10 mL of blood for HP casework, or; Table 1's 20 mL of urine, or; Table 2's combined 40 mL of blood are significant quantities. If a laboratory demonstrates performance of comprehensive screening, confirmation and quantitation of their testing scope in under 1 mL of sample which is very feasible, collecting 20-40 times this appears unnecessary. Even considering if defense or reference sample testing is a required.	Consider including language regarding minimum volume saying something to the effect of 'minimum volumes may be decreased if the laboratory demonstrates the ability to perform comprehensive screening, confirmation and quantitation of their testing scope'.	REJECT: The committee supports the recommended minimum collection amounts.
9	Table 1	T	Having the asterisks only for urine seems too specific. All specimens should be checked for leaks and this is mentioned above.	Remove "Check for leaks*"	ACCEPT: Check for leaks was removed thoroughout the document.