Deadline for submission **5/31/2021**

ASB BPR 156, Guidelines for Specimen Collection and Preservation for Forensic Toxicology.

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final
1	Foreword	E	The phrase, " . . . may be a consideration in instances of . . ." is rather awkward.	Change it to " . . . could be considered in instances of . . ."	ACCEPT WITH MODIFICATION: The sentence was changed to: "Alternative specimen collection could be considered in instances of degradation or limited specimen availability
20	Scope	E	non-regulated occupational testing is listed in 3.4 which makes you wonder about regulated occupational testing. Should regulated occupational testing be excluded from the scope	It is not intended for the area of breath alcohol toxicology or regulated occupational testing mandated under federal statutes.	REJECT: The consensus body did not feel it was necessary to specifically call out regulated testing. The document clearly defines later that this applies only to non-regulated testing.
2	4.1	E	Shouldn't all labs practice universal precautions when handling evidence? It can be a requirement rather than a recommendation.	Change "should" to "shall"	REJECT: This document is intended as a guideline for the customers collecting specimens as opposed to the laboratory.
21	4.2	E	Add sentence about use of alcohol based antiseptic preparation	If an isopropanol based antiseptic is used for alcohol analysis, the analysis shall differentiate between ethanol and isopropanol.	REJECT: This document is intended as a guideline for the customers collecting specimens as opposed to the laboratory.
9	4.2	T	Specification of the type of antiseptic used for cleansing a venipuncture site, while necessary, is wholly insufficient to ensure that the integrity of the specimen is protected. Under consensus venipuncture standards (CLSI GP41), the collection must be performed using aseptic techniques to prevent the introduction of microbial contaminants to the specimen. Aseptic techniques include use of sterile equipment (e.g., needles and evacuated tubes) and quality control practices to prevent contamination of the sample by viable microorganisms (e.g., letting the antiseptic dry prior to insertion of the needle; starting the cleaning process over if anything touches the injection site after application of the antiseptic).	"Blood specimens should be collected from injection sites that have been cleansed using aseptic techniques and a suitable non-alcohol based antiseptic (e.g., povidone-iodine, hydrogen peroxide, aqueous chlorhexidine)."	ACCEPT WITH MODIFICATION: The sentence was updated to "Except in postmortem cases, blood specimens should be collected using aseptic techniques and a suitable non-alcohol based antiseptic (e.g., povidone-iodine, hydrogen peroxide, aqueous chlorhexidine). "
16	4.2	T	The representativeness of a blood specimen can be affected by medical treatment and conditions.The data user should be made aware of potentially interfering conditions.	"If a forensic specimen is collected after medical treatment, or from an intravenous port, the specific conditions should be documented in the forensic collection records."	REJECT: The proposed concept is information that may be important for interpretation, but is outside the scope of this document on specimen collection.
3	4.5	T	This recommendation (a minimum of 8 time) should be supported by a reference.	Add a citation in Bibilography	REJECT: This document is intended as a guideline for the customers collecting specimens as opposed to the laboratory. Inversion of a tube 8 times is a generally accepted practice.
10	4.5	T	Instructions from manufacturers of evacuated tubes prescribe immediate inversions of evacuated tubes containing additives - including, but not limited to anti-coagulants.	"For evacuated blood tubes containing additives, filled tubes should be inverted a minimum of 8 times immediately after collection."	ACCEPT WITH MODIFICATION: The sentence was updated to "For collection tubes containing additives (e.g., anticoagulants and/or preservatives), capped tubes should be inverted a minimum of 8 times immediately after collection."
11	4.6	T	The color of an evacuated blood tube stopper is a convenient means of quickly assessing the type of tube, but the color is not reliably correlated with the actual type or amount of additives. This document makes repeated references to gray top tubes. If the reference to stopper colors is deemed to be convenient enough to merit its use, the document needs to explicitly state that only a single configuration of gray stoppered tube has the types and quantities of additives required for a forensic blood specimen (there are many gray stoppered tubes that don't).	IF it is decided to stick with the stopper color convention: "Tubes containing a gel separator (orange, red/gray, or gold stoppers for serum; green/gray or light green stoppers for plasma) should not be used for the collection of serum or plasma.	ACCEPT WITH MODIFICATION: The sentence was updated to "Tubes containing a gel separator (e.g., orange, red/gray, gold, light green, green/gray) should not be used."
12	4.6	T	If the purpose of this section is to prevent the collection of serum or plasma samples, this needs to be explicitly stated. If a toxicology result will be compared to a legal threshold concentration in whole blood, then testing should be performed on a whole blood specimen.		REJECT: No proposed resolution. The sentence was updated to clarify that these types of samples should not be collected for any reason "Tubes containing a gel separator (e.g., orange, red/gray, gold, light green, green/gray) should not be used." The collection of serum or plasma samples may still be useful in some types of toxicological testing.

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13	4.8	T	Individual toxicology specimens should be unambiguously labeled with information to identify the specimen donor AND the date and time of collection. Venipuncture standards (CLSI GP41) require that identifying information be entered to each individual tube before the phlebotomist leaves the subject's side (including: full name of subject; identifying infomration of subject (usually birthdate); date and time of collection; and initials of phlebotomist. it is simply not sufficient to include essential identifying information on paperwork that accompanies a sample - it is simply too easy for paperwork to get mixed up.	"Each specimen container shall be labeled with sufficient information to unambiguously identify the subject (full name and date of birth or medical record number) and the specific collection (date and time of collection; iidentity of the collector)."	REJECT: The consensus body believes the sentence as written already requires sufficient information to link a specimen to a specific person. How the customer provides that information is their decision. Additionally, medical record numbers do not exist for all types of samples collected for forensic toxicology.
14	5.1	T	Agencies that store toxicology specimens need to be informed of their responsibilities to provide proper storage conditions for biological specimens (e.g., refrigeration; freezing; protection from light).	"This may include storage conditions and timelines that could minimize degradation."	ACCEPT: The sentence was updated to the recommended change.
4	5.3 (now 5.5)	T	It is not clear how a lab can meet this recommendation. If, for instance, blood was collected in a green top tube and there is no stability study on effects of drugs found in a particular case in green top tubes, we need to disclose this? This may be too burdensome.	Clarify how a lab can meet this recommendation	ACCEPT: The sentence was updated to "Reports should include a disclaimer when results are known to be affected by inappropriate use of specimen containers or storage conditions (e.g., vitreous chemistry profile requested on a specimen collected in a gray top container)." This clarifies that the lab must use a disclaimer only with known limitations.
27	5.4 (now 5.6)	E	This document refers to specimens throughout, but sample is used in 5.4	Change to: Laboratories should inform customers under what circumstances a specimen may be consumed during testing.	ACCEPT: The word was modified to "specimen".
22	Table 1	E	Minimum amount in the column title infers that if you have less than this amount that you cannot do analyses.	Change "Minimum Amount" to "Desired Amount" or "Suggested Amount"	ACCEPT WITH MODIFICATION: The word was changed to "recommended minimum amount"
23	Table 1	E	Analyses can be performed on serum/plasma, but it may not be the prefered specimen. Serum/plasma may still be a common specimen in human performance toxicology like the title of the table infers. Serum/plasma is preferred over urine in most cases.	Add line for serum/plasma specimens	REJECT: The recommended specimen for human performance is whole blood. Serum/plasma may still be analyzed for these types of cases, but if the customer is using this guide to determine what sample should be collected, they should state "whole blood" rather than blood, serum, or plasma.
6	Table 1 Column 4	E	Units associated with temperature ranges are not consistently displayed. Some units have a space between the value and unit and some do not.	Add a space between value and unit where missing.	ACCEPT WITH MODIFICATION: The space between value and unit was removed for all instances
15	6	T	Table 1 presents requirements for the quantities of additives in an inconsistent manner: % and mg/ml. Evacuated tubes that are sterile inside are essential. Also, consider removing the reference to "gray top" as if that provided clear definition of specifications (it doesn't; see comments under item 4.6).	"Sterile 10 ml evacuated tube containing (nominally) 100 mg sodium fluoride and 20 mg potassium oxalate"	ACCEPT WITH MODIFICATION: Units were all changed to %; gray top tubes were provided as an example as they typically have sodium fluoride and potassium oxalate as their additives.
24	Table 2	E	The storage for whole blood, urine, and oral fluid are not consistent with other tables.	Change "Refrigerate (2 °C to 8°C)" to "≤ 8°C"	ACCEPT: document was changed to : (2 °C to 8°C)" to "≤ 8°C"
7	Table 2 through Table 6 Column 4	E	Units associated with temperature ranges may not be displayed consistently with similar values in Table 1.	Add a space between value and unit where missing, or otherwise edit to ensure consistency within and between tables.	ACCEPT WITH MODIFICATION: The space between value and unit was removed for all instances
25	Table 3	E	Oral fluid and hair are becoming more common specimens used in court ordered testing in department of child services cases and OVWI probation compliance testing	Add these specimens	ACCEPT: These specimens were added into the table.
5	Table 6	E	There should be a space between "100" and "mg"; "3" and "g"	Change "100mg" and "3g" to "100 mg" and "3 g", respectively	ACCEPT: The spaces were added.
26	Table 6	T	The font for "Table 6" in the sentence prior to the table looks to be the wrong font	update font for "Table 6"	ACCEPT: The font was changed to the correct one.
8	Table 6 Bottom Row Column 2	E	Units associated with mass ranges are not consistently displayed. Some units have a space between the value and unit and some do not.	Add a space between value and unit where missing.	ACCEPT: The spaces were added.
17	Annex A Bibliography	T	The complete lack of references regarding blood specimens is conspicuous, particularly given the frequency and importance of blood DUI testing	GP41, Clinical and Laboratory Standards Institute, *Collection of Diagnostic Venous Blood Specimens, 7th Edition,* April 2017	ACCEPT: Reference was added

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18	Ditto	T	Ditto	GP39-A6, Clinical and Laboratory Standards Institute, *Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard - Sixth Edition,* December 2010	ACCEPT: Reference was added.
19	Ditto	T	Ditto	C60-A, Clinical and Laboratory Standards Insitute, *Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline,* September 1997	ACCEPT: Reference was added