Significant Changes and Response to Comments Received to the 6th edition of Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens

Please note that public comments that were submitted address the proposed 6th edition of Molecular Testing Standards, and not the final version. The changes are best understood when the proposed Standards are compared to the final published version. The committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 6th edition of Molecular Testing Standards in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that what appears below.

Standard	SC/RC	Comment	Change Made?	Outcome
1.1.2.1, #2	SC	NA	NA	The committee replaced the term "Board" with "College" for accuracy as it relates to the American College of Histocompatibility.
1.1.2.1, #3	SC	NA	NA	The committee replaced the term "related" with "relevant" as it strengthened the intent of the standard, allowing the entry to read as follows, "Advanced science degree in a relevant field."
1.9 (New)	SC	NA	NA	The committee created new standard 1.9 "Assessment of Risk" for completeness. This standard has been included in other sets of Standards (specifically, the CT Standards, Perioperative Standards and RT Standards.) This standard now reads as follows, "The laboratory shall have a process in place to perform risk assessments for critical activities at defined intervals."
2.1.3	SC	NA	NA	The committee updated the language in standard 2.1.3 to mirror the language that exists in all other sets of Standards for which AABB provides accreditation. The standard now reads as follows, "Evaluation of competence shall be performed before independent performance of assigned activities and at specified intervals."
Reference Standard 2.2A	SC	NA	NA	The committee added a third column to the reference standard focused on "Chromosome Position" which relates to chromosome position from the current human reference genome assembly. This provides completeness for the reference standard.
Reference Standard 2.2B	SC	NA	NA	The committee added a third column to the reference standard focused on "Chromosome Position" which relates to chromosome position from the current human reference genome assembly. This provides completeness for the reference standard.
Reference Standard 2.2C	SC	NA	NA	The committee added a third column to the reference standard focused on "Chromosome Position" which relates to chromosome position from the current human reference genome assembly. This provides completeness for the reference standard.
3.6.6 (New)	SC	NA	NA	The committee added new standard 3.6.6 for completeness. This standard has been incorporated into all sets of AABB Standards to date. The new standard reads as follows, "The laboratory shall have a process in place to minimize the risk and impact of an internal and external data breach."
Chapter 4, 4.0	SC	NA	NA	The committee has replaced the title of chapter 4 and standard 4.0 from "Supplier and Customer Issues" to "Suppliers and

				Customers" to reflect similar changes made in every other set of Standards.
5.0	SC	NA	NA	The committee replaced the term "products" with "reports." In a molecular testing laboratory the product put forth is a final report. This change has been made throughout the edition.
5.1.1	SC	NA	NA	The committee added a crossreference to standard 2.1.2 for completeness. Standard 2.1.2 is focused on training and the training needs of all personnel performing critical tasks.
5.1.2	SC	NA	NA	The committee added the term "regulations" to the standard for completeness. The requirement now reads as follows, "The laboratory shall participate in a proficiency testing program, or verify the accuracy and reliability of test results twice annually or as required by applicable federal, state, and local laws and regulations."
5.1.2.1 (New)	SC	NA	NA	The committee included new standard 5.1.2.1 to include laboratories that operate outside the United States to allow for compliance with the Standards without having to request a variance. This language exists in all other sets of AABB Standards that require proficiency testing. The standard reads as follows, "Laboratories not subject to US regulation shall participate in an external proficiency testing or external quality assessment program, if available, for each analyte."
5.1.3.1	RtC	"Defined intervals" may lead to confusion and variability amongst different institutions. According to who, what document, or what guidance, defines these intervals? If these refer to manufacturer-defined intervals, it should be explicitly stated so. If the manufacturer doesn't define them, and no regulations state so, then the medical director may be responsible for making a "reasonable" judgement.	YES	When the committee submitted the standards for public comment, the committee had replaced the clause "defined basis" with "defined intervals" however based on this comment the committee retained the clause "defined basis."

5.1.4.1.1 (New)	SC	NA	NA	Standard 5.1.4.1.1 is new to this edition, and was built off of the second sentence that previously appeared in standard 5.1.5.2.1. The committee felt that this concept better fit under the quality control heading. The standard reads as follows, “The laboratory shall have policies for repeating any testing runs that have failed.
5.1.4.2	SC	NA	NA	The committee edited standard 5.1.4.2 to replace the term “investigated” with “completed” understanding that while quality control failures do need to be investigated, it is a requirement, the committee notes that the investigation needs to be completed before it can be shared.
5.1.4.3	SC	NA	NA	The committee elected to replace the term “instruments” with “critical equipment” for clarity. Critical equipment involves more than just instruments, while including instruments as well as other equipment critical to the work of a molecular testing laboratory. The standard now reads, “Laboratories that use different methods, critical equipment, or testing sites shall have a process that evaluates the comparability of test results obtained. This evaluation shall be performed twice annually.
5.1.5.2 (5.1.5.2.1)	SC	NA	NA	The committee elected to delete standard 5.1.5.2.1 and created new standard 5.1.5.2 which contains the same content as the first sentence of the former standard 5.1.5.2.1.
5.1.5.3 (5.1.5.2)	SC	NA	NA	The committee elected to delete standard 5.1.5.2.1 and created new standard 5.1.5.3 from the basis of the second sentence of said standard. Standard 5.1.5.3 now reads as follows, “When deviating from the manufacturer’s written instructions or using unlicensed tests, materials shall be qualified for use and shall meet specified requirements and appropriate controls shall be used to ensure reliability of the test results when deviating from manufacturers’ instructions of FDA licensed tests."
5.1.6.1	SC	NA	NA	The committee added the term “specimens” from standard 5.1.6.1 for clarity.
5.1.6.2	SC	NA	NA	The committee added a new sentence to standard 5.1.6.2 ensuring that patient orders were complete and to provide needed information to the laboratory. The standard now reads as such, “Patient orders shall include the health-care provider’s identifying information.
5.1.6.3 (5.1.6.2)	SC	NA	NA	The committee created new standard 5.1.6.3. This standard previously appeared as the second sentence in standard 5.1.6.2. Note that the content of the standard has not changed, but the committee felt that the content should appear as a standalone standard.
5.1.9	SC	NA	NA	The committee added the term “regulations” to the standard for completeness. The requirement now reads as follows, “The laboratory shall have a policy to ensure that the molecular testing results are private and confidential as required by applicable federal, state, and local laws and regulations.”
5.2.3	SC	NA	NA	The committee edited the content of standard 5.2.3 for legibility and clarity, however the intent of the standard has not changed. The standard now reads as such, “The laboratory shall define collection methods that maintain the integrity of the sample and minimize the potential for contamination.”

5.2.3	RtC	*We do not support the addition of Standard 4.2 Agreements to this standard. Contractual agreements between the healthcare provider and the laboratory do not provide this level of detail. The application of Standard 4.2 can limit other methods such as an order request which can define expectations for sample collection.*	YES	When the proposed edition was submitted for comment, the committee had added a crossreference to standard 4.2 as a part of this standard that focused on agreements. However, based on this comment, the committee elected to remove the crossreference to standard 4.2 and expanded in guidance to detail what is usually contained in a shared document.
5.2.3.1	SC	NA	NA	The committee removed the term “sufficient” as it was not deemed valuable. Laboratories labeling products have differing content based on whether the product comes from a donor (which typically has space for more content) or a patient (which typically has less space.) The edit does not change the intent of the standard. The committee intends to strengthen the guidance around this standard.
5.2.3.1	RtC	"Sufficient" is better defined as: "at least two unique identifiers". Similar to a T&S specimen.	NO	The committee noted this comment but did not feel that this change was appropriate at this time. The committee notes that many laboratories labeling products have differing content based on whether the product comes from a donor or a patient.
5.3.1	SC	NA	NA	The committee edited standard 5.3.1 for clarity by removing the clause, "an allele or” from the standard for clarity. Alleles would be incorporated into variants which is already included in the standard.
5.4.1, #1	SC	NA	NA	The committee elected to edit subnumber 1 of standard 5.4.1, replace the clause “DNA control” with “a size standard.” The replacement allows the standard to be more encompassing.
5.4.1, #3	SC	NA	NA	The committee elected to edit subnumber 3 for clarity. The committee removed the clause “…and preferential amplification…”as it was deemed redundant.
6.2.1.2	SC	NA	NA	The committee edited the format of this standard for legibility. The committee has moved the content from the second sentence to a list for clarity. Also, subnumber 3 has been expanded to read as “identified as a copy.”
6.2.3	SC	NA	NA	The committee edited the standard replacing the term “product” with “report” as the report is the product that these MT

				Standards are focused on. This change has been made in other standards throughout the document.
6.2.7.1.1	RtC	The word "off-site location" may be simply stated as "designated location". This may be on-site at the same location but a different room, or using a PHI-encrypted storage cloud system.	NO	The committee reviewed this comment, but did not feel that a change was needed at this time. The committee notes that in the case of the standard, the term “off-site” is meant to be located elsewhere from the facility, not in the same space, such as a different room on the same campus.
6.2.8	SC	NA	NA	The committee restructured the format of standard 6.2.8 to place elements in subnumer 2 in a formatted list for clarity. This restructuring has not changed the content of the standard or its intent.
6.2.9	SC	NA	NA	The committee edited this standard to mirror other changes being put forth in other sets of AABB Standards. The intent of the standard has not changed. The standard now reads as follows, “Confidential content shall be protected during the destruction of records.”
7.1.1	SC	NA	NA	The committee edited the opening sentence of standard 7.1.1 by including a new opening to the standard to read as, “For nonconforming test results…” The intent of the standard has not changed.
7.1.1, #1	SC	NA	NA	The committee elected to remove the term “nonconforming” from subnumber 1 as it was deemed redundant with the change to the opening sentence.
7.1.1, #2	SC	NA	NA	The committee edited subnunmber 2 for clarity, replaced "with nonconforming tests results” with “of associated products, if applicable.” This ensures that any associated product associated with a nonconforming test result is considered as a part of corrective action.
8.0	SC	NA	NA	The committee elected to edit standard 8.0 for clarity. The committee added terms “policies” and “and procedures” to mirror the way other standards are presented. The committee also added the clause “and external” in terms of assessments for completeness. Finally, the committee removed the clause, “and that external assessments (inspections, surveys) are obtained at appropriately defined intervals.” as it was deemed redundant. The standard now reads as such, “The laboratory shall have policies, processes, and procedures to ensure that internal and external assessments of operations and the quality system are scheduled and conducted.”
8.0	RtC	We do not support the laboratory having policies and procedures	NO	The committee noted this comment but did not feel that a change was needed at this time. In this case, outside agencies that require external assessments would not require an assessment be performed if it was impossible due to a number of potential reasons, such as pandemic, disaster, staffing etc.

		to ensure external assessments of operations and the quality system are scheduled and conducted. As demonstrated during the pandemic, the laboratory has no control when external agencies delay.		
9.1, #3	SC	NA	NA	The committee edited subnumber 3 for clarity, noting that corrective action might not be necessary in all occasions. The clause "evaluation of the need for" replaced "determination of the."
9.1, #4	SC	NA	NA	The committee added the clause "as necessary" to subnumber 4 in conjunction with the edit made to subnumber 3 recognizing corrective action is not always needed. The change was made for parallel construction.
10.1	SC	NA	NA	The committee added the term "patients" for clarity, understanding there are cases where the patient can be in the laboratory. The "as applicable" is included in instances where not all laboratories would have all of the listed individuals in their laboratory.
10.1.1, #1 (New)	SC	NA	NA	The committee added new subnumber 1 to standard 10.1.1 for completeness. The new requirement reads as follows, "Visible signage posted both inside and outside the storage space." This terminology is based off of language in AABB's CT and IRL Standards.
10.1.1, #1 (New)	RtC	"Visible signage" should be defined to include a MSDS label.	NO	The committee noted this comment but did not think that a definition in the glossary would be needed at this time. The committee will update the guidance and recommends that individuals refer to OSHA.
10.1.1, #2 (New)	SC	NA	NA	The committee added new subnumber 2 to standard 10.1.1 for completeness. The new requirement reads as follows, "Ventilation and airflow adequate to the space where the liquid nitrogen is stored." This terminology is based off of language in AABB's CT and IRL Standards.
10.2.1	SC	NA	NA	The committee added the term "measures" following "biochemical" for completeness. Along with physical barriers, this ensures that all means of separation are included.
10.2.1	RtC	We suggest that the standard state "The laboratory shall	YES	In the proposed edition the committee had removed the term "barrier" but it was noted that physical measures was not accurate to the reality of what laboratories actually

		perform preamplification (upstream) and post amplification (downstream) procedures in areas separated by physical barriers and/or biochemical measures to prevent nucleic acid contamination". The word "barrier" appears to have been inadvertently removed. This addition would provide clarity to this standard.		have in place. As such, the term "barrier" was reintroduced to the 6th edition.