Significant Changes to the 5th edition of Standards for Molecular Testing for Red Cell, Platelet and Neutrophil Antigens

Standard	Change
1.0	The committee elected to edit standard 1.0 for clarity. The committee replaced the clause "molecular testing" in the first sentence with "laboratory performing molecular testing" and replaced "molecular testing reports" with "reports containing molecular test results." The changes did not alter the intent of the standard, they merely ensure that the standard is clear.
1.1	The committee added the term "team" to the stem of the standard for completeness. The stem of the standard now reads, "The laboratory shall have a defined executive management **team**." This change better reflects what exists in current leadership structures in a molecular testing laboratory.
1.1, #5 (1.8 – deleted)	Subnumber 5 is not new to the 5th edition, but previously appeared as standard 1.8. The committee elected to move the requirement to appear as subnumber 5 to match the way the standard appears in the Standards for Immunohematology Reference Laboratories. The committee felt that moving this requirement to appear directly under executive management would ensure that senior leadership was fully aware of the requirement.
1.1.1	The committee added the term "relevant" into the standard to ensure that laboratory directors are qualified and trained to cover the actual activities covered in this set of *MT Standards*. The wording now appears as such, "The laboratory shall have a director who has a doctoral degree in medical, biological, clinical laboratory sciences, or genetics and has at least 2 years of relevant training…"
1.1.2	The committee elected to remove the term "and" from standard 1.1.2 to mimic the language in standard 1.1.1. The standard now reads as such, "The laboratory shall have a supervisor who is qualified by training ~~and/~~or experience."
1.1.2.1	The committee edited the stem of standard 1.1.2.1 to include the requirement that the laboratory supervisor have "relevant" experience in molecular testing to match the language added to standard 1.1.1. The standard now reads as such, "The supervisor shall have at least 2 years of relevant experience…"
1.1.2.1, #2	The committee added the clause "…from the American Society for Clinical Pathology (ASCP) to subnumber 2 to ensure that users did not interpret the standard as requiring that individuals had to have all the certifications listed in subnumber 2. The committee also added, "or" prior to the final requirement in the standard to reinforce that not all certifications are required. The standard now reads as such: 2) Certification as a Specialist in Blood Banking (SBB) from the American Society for Clinical Pathology (ASCP), or Certified Histocompatibility Specialist (CHS) from the American Board of Histocompatibility and Immunogenetics (ABHI), or Certified in Molecular Biology by ASCP, or certification from an agency issuing an equivalent credential.

1.1.2.1.1 (New)	The committee created new standard 1.1.2.1.1 to ensure that individuals were aware that there are instances where the Molecular Testing Accreditation Committee can consider an individual's qualifications on a case by case basis. This standard is similar to a standard that appears in the 11th edition of *Standards for Immunohematology Reference Laboratories*.
1.4 (New)	The committee created new standard 1.4 to ensure that facilities have plans in place to ensure operational continuity in the event that operational status is at risk as a result of events that would not be characterized as "disasters."
2.1.2	The committee edits standard 2.1.2 by replace the clause "activities affecting quality" with "critical tasks." This change provides greater specificity than the wording that previously appeared and aligns these Standards with the 11th edition of *Standards for Immunohematology Reference Laboratories*. The standard now reads as such, "The laboratory shall have a process for identifying training needs and shall provide for the training of all personnel performing ~~activities affecting quality~~ **critical tasks**.
2.1.5	The committee edited the content of standard 2.1.5 to mimic the lifecycle of the Molecular Testing Standards moving from an annual completion of 12 continuing education hours to 24 hours every two years. The intent of the standard has not changed.
2.2	The committee elected to remove the clause "appropriate reference" from the standard as it was deemed difficult to assess. The committee also replaced the clause, "target polymorphisms" with "variants" for accuracy.
2.2.1	The committee replaced the term "Reference" with "Previously characterized" for accuracy. The term "reference" in relation to samples is no longer accurate.
2.2.1.1 (deleted)	The committee deleted former standard 2.2.1.1 as it was no longer deemed relevant.
Reference Standard 2.2A	The committee edited reference standard 2.2A for accuracy and completeness. The committee added a column for containing HGVS Allele nomenclature as well as removing the "Comments" column. The expansion of the table runs in concert with currently available products. HGVS-nomenclature is used to report and exchange information regarding variants found in DNA, RNA and protein sequences and serves as an international standard.
Reference Standard 2.2B	The committee edited reference standard 2.2B in conjunction with the edits made in reference standard 2.2A. HGVS nomenclature was added to the reference standard and removed the column concerning "Comments." The changes will allow for the reference standard to be streamlined in its content.
Reference Standard 2.2C (Reference Standard 2.2C, and 2.2D)	The committee elected to incorporate the contents from reference standard 2.2D into reference standard 2.2C for completeness. The committee also included a column for HGVS alleles as they had in reference standards 2.2A and 2.2B.

3.3	The committee elected to replace the title of standard 3.3, "Critical Equipment" with "Unique Identification of Equipment." The committee felt that this was more accurate and it also ensures that the standard remains in concert with other AABB Standards.
3.4.2	The committee added a reference to 21 CFR 803.30, which covers medical device reporting, for completeness.
3.5 (New), 3.5.1 (New), 3.5.2 (New)	The committee added standards 3.5 – 3.5.2 concerning the need for alarm systems, when they are set to activate and what to do in the case where an alarm is activated. These standards appear in all other sets of AABB Standards that have products that are stored. The standards read as such: **3.5 Alarm Systems** **Storage devices for specimens, and/or reagents shall have alarms and shall conform to the following standards (Standard 5.1.4 applies):** **3.5.1 The alarm shall be set to activate under conditions that will allow enough time for proper action to be taken before specimens and/or reagents reach unacceptable conditions.** **3.5.2 Activation of an alarm shall initiate a process for immediate action, investigation and appropriate corrective action.**
3.6.2 (3.5.2), 3.6.3 (3.5.3), 3.6.4 (3.5.4), Glossary Equipment	The committee elected to replace the term "computer systems" with "information systems" throughout this edition for accuracy. The term "computer system" is outdated and no longer relevant.
5.1.2	The committee elected to remove the clause "through an external exchange" from the standard recognizing that not all countries where molecular testing laboratories operate have an external proficiency testing program.
5.1.2.1 (New)	In conjunction with the change to standard 5.1.2 the committee created new standard 5.1.2.1 to allow facilities in countries where external proficiency testing programs are not available to determine accuracy and reliability of test results with their own or existing systems. The standard reads as follows: **5.1.2.1** When an external proficiency testing program is not available, there shall be a system for determining the accuracy and reliability of test results.

5.1.3.1	The committee elected to replace the term "regular" with "defined" as it relates to determining the effectiveness of operational control measures. Defined time periods are easier to assess than the more nebulous requirement of "regular."
5.1.4.3 (New)	The committee created new standard 5.1.4.3 for completeness. The standard has basis on a similar standard in the 11th edition of Standards for Immunohematology Reference Laboratories. This standard ensures that test result compatibility is uniform from one laboratory to the next based on the equipment or method used. The standard reads as follows: **5.1.4.3** Laboratories that use different methods, instruments, or testing sites shall have a process that evaluates the comparability of test results obtained. This shall be performed twice annually.
5.1.5	The committee added a reference to 21 CFR 606.65(e) which requires that supplies and reagents are used in a manner consistent with manufacturer's instructions.
5.1.5.2	The committee removed the term "written" from standard 5.1.5.2 for consistency and also added the clause, "unlicensed tests" for clarity. The standard reads as such: **5.1.5.2** Appropriate controls shall be used to ensure reliability of the test results when deviating from manufacturer's ~~written~~ instructions **or unlicensed tests**.
5.1.6.1	The committee added the clause "critical equipment" to standard to pair with "critical materials" as it relates to traceability of samples. The addition was made for completeness. **5.1.6.1** The laboratory shall ensure the identification and traceability of samples, critical materials, **and critical equipment**.
5.1.6.3	The committee edited this standard to ensure that it was clear that only laboratories that do label products are required to have a procedure in the case where a modification needs to take place. The committee also added the CFR and FDA Guidance references for completeness.
5.1.7.1	The committee added a cross-reference to standard 5.5 to the standard for completeness. Standard 5.5 requires that accredited laboratories review all results from laboratory testing.
5.2.1	The committee edited this standard to ensure that testing performed on donor units were done so in a manner consistent with the consent given by the donor and the procedure articulated. The standard was also re-titled to "Donor Consent" removing the element of patient consent.
5.2.2 (New)	With the edit of standard 5.2.1 to focus solely on donor consent, the committee created new standard 5.2.2 which is focused on "Patient Orders." The committee created this standard to focus on the patient side for completeness, noting that patient consent is not obtained in a molecular testing laboratory. The standard reads as such: **5.2.2 Patient Orders** A health-care provider order for testing shall be obtained in accordance with applicable law.

5.3.1	The committee edited standard 5.3.1 for clarity. With the existence of the novel test system described in standard 5.3.2 the committee did not feel that this standard as originally written was necessary. The committee removed the clause "at a minimum" as Standards are already minimum requirements that can be exceeded in practice and as such redundant.
5.3.2	The committee added a record retention requirement to standard 5.3.2. All validation records of novel test methods must be retained for 10 years.
5.6.1, #1	The committee edited subnumber 1, adding the clause "and/or" in place of just "and." There are circumstances where a laboratory may not have both the patient name and a unique identifier.
5.6.1, #3 (New)	In an effort to remain parallel to the requirements in the cited federal regulations "42 CFR 493.1291(c)", the committee added new subnumber 3 which requires that the name of the referring laboratory or health-care provider be maintained. This also ensures that these Standards remain parallel with the 11th edition of Standards for Immunohematology Reference Laboratories.
5.6.1, #8 (New)	In an effort to remain parallel to the requirements in the cited federal regulations "42 CFR 493.1291(c)", the committee added new subnumber 8 which requires that a disclaimer for when testing samples have been rejected for laboratory defined requirements. This also ensures that these Standards remain parallel with the 11th edition of Standards for Immunohematology Reference Laboratories.
6.1.7	The committee elected to edit standard 6.1.7 to be written in a manner to read more broadly than previously. The committee added the clause "…and transmission" and replaced the term "legibility" with "data integrity." The replacement of legibility for data integrity ensures that the standard is in line with current practice. The standard now reads as such: **6.1.7** Storage **and transmission** in a manner that preserves **data integrity** ~~legibility~~, and protects from accidental or unauthorized access, destruction, or modification.
6.2.5 (New)	The committee added new standard 6.2.5 in order to remain parallel with other sets of AABB Standards. This standard ensures that records are created at the same time as the activity is performed. The standard reads as follows: **6.2.5** Records shall be created concurrently with performance of each critical activity.
7.1.1, #1	The committee edited subnumber 1 by adding the clause, "and notification for…" for completeness. The standard now reads as such: **7.1.1** The laboratory shall have a process for: 1) The identification **and notification for** quarantine, retrieval, and recall of units with nonconforming test results.
7.2	The committee edited standard 7.2 to better represent the content of this edition of standards. The committee replaced the term "product" with "test results and reports" throughout the standard itself. The standard now reads as such: **7.2 Released Nonconforming Test Results and Reports ~~Products~~** **Test results or reports** ~~Products~~ that are determined after release not to conform to specified requirements shall be evaluated to determine the effect of the nonconformance on the quality of the **test result** ~~product~~. In cases where quality may have been affected, the nonconformance shall be reported to the customer. Records of the nature of nonconformances and subsequent actions taken,

	including acceptance for use, shall be maintained in conformance with Chapter 6, Documents and Records.
7.3.2	The committee elected to delete the second sentence that previously appeared in standard 7.3.2 as it was deemed redundant to the cross reference to standard 9.1 that already exists in the standard and details the actions that previously appeared in the sentence.
7.4	The committee added a cross reference to standard 2.1.3.1 in the standard which requires that action be taken when competence has not been demonstrated.
10.1.1 (New), 10.1.1.1 (New), 10.1.1.1.1 (New)	Standards 10.1.1 – 10.1.1.1.1 are new to this edition and have been added to all other sets of AABB Standards that have a liquid nitrogen storage device component. The standards read as follows: **10.1.1 Where liquid nitrogen is stored, specific hazards shall be addressed.** **10.1.1.1 Facilities with liquid nitrogen tanks shall have a system in place to monitor oxygen levels and an alarm system set to activate under conditions that will allow action to be taken.** **10.1.1.1.1 Oxygen alarm activation shall require personnel to investigate and document the condition activating the alarm and to take immediate corrective action as necessary.**
Blood Groups - Glossary	The committee edited the definition for the term "Blood Groups" for clarity. The entry now reads as follows: Blood Groups: Antigenic determinants present on **red** blood cells. **For the purposes of these *MT Standards*, blood groups** include platelet and neutrophil antigens ~~for the purposes of these MT Standards~~.
Molecular Testing - Glossary	The committee edited the definition for the term "Molecular Testing" for clarity. The entry now reads as follows: For the purpose of these MT Standards, molecular testing is defined as the analysis of nucleic acid to determine blood group alleles **and** ~~predict the~~ **phenotypes**.
Phenotype - Glossary	The committee edited the definition for the term "Phenotype" for clarity. The entry now reads as follows: The expression **or absence of blood group antigens determined by molecular and/or serologic methods** ~~on a cell membrane detected by an antibody. The observed biochemical, physiological, and/or morphological characteristics of an individual, as determined by the interaction of the genotype and the environment in which it is expressed.~~
Glossary - Polymorphism	The committee elected to delete this term from the glossary as it no longer appears in the Standards.
Glossary – Predicted Phenotype	The committee elected to delete this term from the glossary as it no longer appears in the Standards.
Glossary – Sample (noun)	The committee edited the definition for the term "Sample" for clarity. The entry now reads as follows: The biological substance from which DNA **or RNA** can be extracted.

Glossary – Single Nucleotide Variant (SNV)	The committee edited the definition for the term "Single Nucleotide Variant" for clarity. The entry now reads as follows: A sequence **variation of** ~~variant involving a change in~~ a single nucleotide ~~found in a population~~.