

Significant Changes and Response to Comments Received to the 8th edition of Standards for Molecular Testing for Red Cell, Platelets, and Neutrophil Antigens

Please note that public comments that were submitted address the proposed 8th edition of Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens (MT Standards), and not the final version. The Molecular Testing Standards Committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 8th edition of MT Standards in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that appear below.

Standard	Significant Change (SC)/Response to Comment (RtC)	Comment	Change made?	Outcome
1.1.1	SC	NA	NA	The committee reorganized standard 1.1.1 to appear as a list, where it previously appeared as a paragraph. The change was made for legibility, however the content nor the intent has not changed.
1.1.1.1 (1.1.1)	SC	NA	NA	Standard 1.1.1.1 is new to the 8th edition, but the content is not. The content previously appeared as a part of standard 1.1.1.
1.1.2.1, #2	SC	NA	NA	The committee removed the clause, “certification as Technologist in Blood Banking (BB) from ASCP”, recognizing that the requirement for the certification of SBB for ASCP contained the certification and was redundant.
1.9 (1.10)	SC	NA	NA	Standard 1.9 previously appeared as standard 1.10 but has been edited to mirror a new standard in every new set of Standards since the release of the 12 th edition of <i>Standards for Cellular Therapy Services</i> . This ensures that there is clear communication between AABB and all accredited laboratories in cases where an event has occurred that has impacted their accreditation status.
1.9.1 (New)	SC	NA	NA	Standard 1.9.1 is new to the 8 th edition and was added to mirror a new standard in every new set of Standards since the release of the 12 th edition of <i>Standards for Cellular Therapy Services</i> . This standard now requires accredited programs contact AABB if they are under investigation by their relevant

				Competent Authority. This ensures AABB accreditation's department is aware of all issues that could potentially impact the program or AABB as an accreditation organization. The standard reads as follows: 1.9.1 If the organization is the subject of regulatory enforcement action by a relevant Competent Authority, the organization shall notify AABB within 7 days in electronic or written format. The committee also added a new definition to the Glossary for "Regulatory Enforcement Action" for clarity which reads as follows: Regulatory Enforcement Action: Measures taken by a Competent Authority that include, but are not limited to, progressive measures (eg, suspension or termination of operations, information notices requiring specific documentation or data, fines incurred) or critical triggers (eg, pattern of recurrent, unresolved issues; deficiencies in risk management systems).
2.2.1	SC	NA	NA	The committee edited standard 2.2.1 for clarity. The committee added the clause, "...under standard operating procedures, with concordant..." The edits ensure that different methodologies in use provide matching results.
Reference Standard 2.2A	SC	NA	NA	The committee elected to edit the column header from "Variant Description" to "Transcript and Genomic Description" for accuracy.
Reference Standard 2.2A, MNS 002	SC	NA	NA	The committee removed the entry, Mt(a+), as it was deemed incorrect and needed to be removed.
Reference Standard 2.2A, MNS 002	RtC	In the table "Reference Standard 2.2A—Minimum DNA Resources – Red Blood Cells" MNS (page 20 of the "Proposed Standards" document) the Mt(a+) antigen is specified as a variant of <i>GYPB</i> .	Yes	The committee reviewed this comment and felt that a change was needed. The committee removed the Mt(a+) as it was deemed inaccurate.

		<table><tr><td>MNS 002</td><td>GYP A NM_002099.5 NC_007470.3 NC_000004.12</td><td>GYP A:c.59C> T GYP A:c.71G> A GYP A:c.72T> G</td><td>GYP A:g.25185C>T GYP A:g.25197G>A GYP A:g.25198T>G</td><td>4:g.144120567G>A 4:g.144120555C>T 4:g.144120554A>C</td><td>n7682260 n7687256 n7658293</td><td>M/N M/N M/N</td></tr><tr><td></td><td>GYP B NM_002100.6 NC_007483.3 NC_000004.12</td><td>GYP B:c.143C> T GYP B:c.230C> T GYP B:c.270>5 g*5</td><td>GYP B:g.27419C>T GYP B:g.29282C>T GYP B:g.29327g*t</td><td>4:g.143999443G>A 4:g.143997580G>A 4:g.143997535c>a</td><td>n7683365 n56172553 n139511876</td><td>S/s M(a+ J U**</td></tr></table> According to the blood group database of the ISBT (https://blooddatabase.isbtweb.org/system/MNS) and “The Blood Group Antigen Facts Book, M.E. Reid, C. Lomas-Francis, M.L. Olsson, Third Edition, 2012, page 89” MNS:14 or Mt(a+) resides on <i>GYP A</i> (<i>GYP A*14</i>):	MNS 002	GYP A NM_002099.5 NC_007470.3 NC_000004.12	GYP A:c.59C> T GYP A:c.71G> A GYP A:c.72T> G	GYP A:g.25185C>T GYP A:g.25197G>A GYP A:g.25198T>G	4:g.144120567G>A 4:g.144120555C>T 4:g.144120554A>C	n7682260 n7687256 n7658293	M/N M/N M/N		GYP B NM_002100.6 NC_007483.3 NC_000004.12	GYP B:c.143C> T GYP B:c.230C> T GYP B:c.270>5 g*5	GYP B:g.27419C>T GYP B:g.29282C>T GYP B:g.29327g*t	4:g.143999443G>A 4:g.143997580G>A 4:g.143997535c>a	n7683365 n56172553 n139511876	S/s M(a+ J U**		
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	GYP B NM_002100.6 NC_007483.3 NC_000004.12	GYP B:c.143C> T GYP B:c.230C> T GYP B:c.270>5 g*5	GYP B:g.27419C>T GYP B:g.29282C>T GYP B:g.29327g*t	4:g.143999443G>A 4:g.143997580G>A 4:g.143997535c>a	n7683365 n56172553 n139511876	S/s M(a+ J U**												
Reference Standard 2.2A, ATP11C 046 (New)	SC	NA	NA	The committee added the new entry as it has now been included and available in the GenBank database.														
Reference Standard 2.2A, MAL 047 (New)	SC	NA	NA	The committee added the new entry as it has now been included and available in the GenBank database.														
Reference Standard 2.2A, PIGZ 048 (New)	SC	NA	NA	The committee added the new entry as it has now been included and available in the GenBank database.														
Reference Standard 2.2B	SC	NA	NA	In conjunction with the edit to reference standard 2.2A, the committee elected to edit the column header from “Variant Description” to “Transcript and Genomic Description” for accuracy.														
Reference Standard 2.2B, HPA-13	SC	NA	NA	In the “Transcript RefSeq Gene Chromosome” Column, the “NC_000022.11” has been removed and replaced with “NC_000005.10” for accuracy.														
Reference Standard 2.2B, HPA-15	SC	NA	NA	In the “Transcript RefSeq Gene Chromosome” Column, the “NC_000017.11” has been removed and replaced with “NC_000006.12” for accuracy.														
Reference Standard 2.2B, HPA-31	SC	NA	NA	In the “Transcript RefSeq Gene Chromosome” Column, the “NC_000017.11” has been removed and replaced with “NC_000003.12” for accuracy.														
Reference Standard 2.2B, HPA-32	SC	NA	NA	In the “Transcript RefSeq Gene Chromosome” Column, the “NC_000003.12” has been removed and replaced with “NC_000017.11” for accuracy.														

Reference Standard 2.2C	SC	NA	NA	In conjunction with the edit to reference standards 2.2A and 2.2B, the committee elected to edit the column header from “Variant Description” to “Transcript and Genomic Description” for accuracy.
Proposed 3.1.1 (deleted)	RtC	We are questioning the value of this new standard and what exactly it will provide labs beyond what is already conducted in IQ/OQ/PQ. Have there been numerous nonconformances related to this topic that a new standard was needed? This standard reads more to what medical device companies need to have in place and not what a testing lab needs.	Yes	When the proposed 8 th edition was released for public comment, the committee included a new standard 3.1.1 focused on “Design Qualification.” Based on this comment and review the committee elected to delete the standard and reconsider for a future edition.
3.6 (deleted)	SC	NA	NA	Based on a review of chapter 3, it was deemed that this standard is redundant to many standards in chapter 3, specifically the 3.5 thread. This standard was also deemed redundant per standard 6.2.2.
3.7 (New)	SC	NA	NA	The committee created new standard 3.7 to ensure that facilities monitor their critical technology infrastructure and that they function as expected. This standard requires that there are defined checks to monitor that technology is working as intended and expected.
3.8.3 (New)	SC	NA	NA	The committee added new standard 3.8.3 to the edition. This addition reflects a gap that previously appeared in the standards. Providing a specific focusing on alarm quality control annually to verify when temperature sensing devices detect an unacceptable temperature. This standard closes this loophole. This standard was initially added to the 14th edition of <i>Standards for Immunohematology Reference Laboratories</i> .
4.2.4	RtC	This change moves from "the lab informing the customer", to "allowing the customer to request information". This opens the door for a wide range of request. We would like the standards guidance to have specific information related to what must be provided along with the allowance to not provide proprietary information.	Yes	When the committee released the proposed 8 th edition for comment standard 4.2.4 had been edited, however based on this comment, the language of standard 4.2.4 was reverted to the language in the 7 th edition.

5.1.1.3 (5.4.2)	SC	NA	NA	Standard 5.1.1.3 previously appeared as standard 5.4.2 but was moved to appear as new standard 5.1.1.3 as a part of the “Change Control” section. The content and the intent of the standard have not changed.
5.3.1, 5.3.1.1, 5.3.1.2 (5.2.3.2, 5.2.3.2.1, 5.2.3.2.2)	SC	NA	NA	The committee moved standards 5.3.1, 5.3.1.1, and 5.3.1.2 from where they previously appeared as standards 5.2.3.2, 5.2.3.2.1, and 5.2.3.2.2 under “Sample Collection”. The committee felt that these standards fit better under the “Test Validation” heading. The content of the standards have not changed.
5.3.3.2, #2 (5.3.2.2, #2)	SC	NA	NA	The committee added additional reference standards in chapter 2 beyond reference standard 2.2A which was previously to only reference standard listed. Without reference standard 2.2B and 2.2C, the standard as written could be interpreted to only focus on red cells, which is not the case.
5.3.3.2, #2 (5.3.2.2, #2)	RtC	By listing Reference Standard 2.2A, this would only make it applicable to Red Blood Cells. We suggest changing the wording to include Reference Standards 2.2B and 2.2C to capture Platelets and Neutrophils.	Yes	The committee reviewed this comment and agreed with its intent. As such, it was decided that the other reference standards were included for completeness.
5.3.4 (New)	SC	NA	NA	The committee created new standard 5.3.4 for completeness. The committee feels that the inclusion of fetal cell-free as a standard was needed as accredited laboratories are using cfDNA. This ensures that there are minimum standards for said users. The committee created a glossary for “Cell-Free DNA” for completeness and to mirror the creation of the standard. The glossary entry reads as follows: Cell-Free DNA (cfDNA): Extracellular fragments of genomic DNA present in the blood stream and in other body fluids.
5.3.5 (5.3.3)	SC	NA	NA	The committee added the clause “...for genomic DNA...” for completeness.

5.4.2, 5.4.2.1 (5.1.11, 5.1.11.1)	SC	NA	NA	Standards 5.4.2 and 5.4.2.1 are new standards, however they previously appeared as standards 5.1.11 and 5.1.11.1. The content of the standard has not changed. The committee felt that this standard did not fit under “General Elements” as previously and better fit under the section “Specific Testing Methods.”
5.6.1, #10 (New)	SC	NA	NA	The committee created new subnumber 10 to mirror the content of subnumber 9 for completeness. Subnumber 9 is focused solely on United States laboratories, lending to the new for a subnumber for facilities outside the United States. Subnumber 10 applies to all laboratories outside of the US, of which there are laboratories accredited by AABB.
5.6.2 (New)	SC	NA	NA	The committee created new standard 5.6.2 to ensure that laboratories participate in the publication of novel alleles with a plan to do so. This is a first step towards a more focused standard requiring this sharing in future editions.
5.6.2 (New)	RtC	Our laboratory does not support the addition of Standard 5.6.2. The identification and external publication of novel alleles is a research activity, not a clinical laboratory function. Accreditation standards are not designed to regulate what laboratories do with incidental scientific observations beyond the clinical result. This standard also lacks the specificity required for meaningful compliance or inspection. There is no defined outcome, timeline, or submission target that an inspector could objectively evaluate. A laboratory's ability to publish or submit externally is governed by institutional research policies, data sharing agreements, and resource constraints, none of which fall within the scope of clinical accreditation. Notably, no equivalent requirement exists in analogous accreditation frameworks. ASHI does not mandate novel allele reporting for clinical HLA laboratories, despite that field's greater rate of novel allele discovery and access to an established curated repository. This absence in a more mature field	No	The committee reviewed this comment and felt that based on its contents that the standard should be updated so as not to impact accredited laboratories negatively, while still allowing for taking a step towards a standard similar to what was proposed.

		reinforces our view that Standard 5.6.2 is premature for clinical accreditation.		
5.6.2 (New)	RtC	The addition of this new standard has its merit but we question how this would be implemented and assessed. Larger labs would potentially have the personnel and time to complete this activity, however, smaller labs may not. This would then become overly burdensome for the labs without a defined benefit.	No	The committee reviewed this comment and felt that based on its contents that the standard should be updated so as not to impact accredited laboratories negatively, while still allowing for taking a step towards a standard similar to what was proposed.
6.2.12.1 (New)	SC	NA	NA	The committee created new standard 6.2.12.1 to supplement standard 6.2.12. This standard ensures that laboratories are destroying their records inline with all applicable regulations, recognizing that these regulations can differ from locality to locality.
7.2.3.1 (New)	SC	NA	NA	The committee created new standard 7.2.3.1.1 to ensure that facilities take steps to determine how a nonconformance occurred if a root cause cannot be determined.
8.3.1	SC	NA	NA	The committee edited the standard 8.3.1 for clarity, replacing the clause “When corrective action is taken...” with “Any corrective action...” The change has not changed the intent of the standard.
Glossary - Accuracy	SC	NA	NA	The committee added this definition to the glossary for completeness. Accuracy: The closeness of agreement between a test result and the reference result.
Glossary - Deoxyribonucleic Acid	SC	NA	NA	The committee added this definition to the glossary for completeness. Deoxyribonucleic Acid (DNA): The molecule that carries genetic information for an organism’s function. DNA consists of two linked strands with backbones of alternating deoxyribose sugar and phosphate groups. Each sugar is attached to one of four bases: adenine (A), cytosine (C), guanine (G), or thymine (T). The order of bases encodes biological information, such as the instructions for making a protein or RNA molecule. Different types of DNA include genomic DNA (gDNA) and cell-free DNA (cfDNA); complementary DNA (cDNA) is

				generated in the laboratory from RNA.
Glossary – Event	SC	NA	NA	The committee added this definition to the glossary for completeness. Event: A generic term used to encompass the terms “incident,” “error,” and “accident.”
Glossary – External Quality Assessment	SC	NA	NA	The committee added this definition to the glossary for completeness. External Quality Assessment (EQA): Interlaboratory comparisons and other performance evaluations that may extend throughout all phases of the testing cycle, including interpretation of results and determination of individual and collective laboratory performance characteristics of examination procedures by means of interlaboratory comparison. EQA involves the structured evaluation of laboratory test results using defined samples from an external proficiency testing program. In contrast, external quality assurance is a broader program, of which EQA is typically a part. See Proficiency Testing.
Glossary – Incident	SC	NA	NA	The committee added this definition to the glossary for completeness. Incident: An unplanned deviation from a facility’s established policy, process, or procedure.
Glossary – Key Quality Indicators	SC	NA	NA	The committee added this definition to the glossary for completeness. Key Quality Indicators (KQIs): Predefined, measurable metrics used to monitor the quality, accuracy, and reliability of laboratory test results, such as red cell genotyping, across the full workflow, including preanalytical, analytical, and postanalytical processes. When KQIs demonstrate that performance is outside of predefined thresholds, corrective actions are triggered.
Glossary – Novel Allele	SC	NA	NA	The committee added this definition to the glossary for completeness. Novel Allele: An allele that has not previously been described and is not found in a publicly available database. These alleles often arise

				from genomic variations, such as single nucleotide variants, and are termed “novel” when they differ from known alleles at a specific genetic locus.
Glossary – Precision	SC	NA	NA	The committee added this definition to the glossary for completeness. Precision: Repeatability of measurements, where results cluster tightly, measuring consistency or reproducibility.
Glossary – Red Cell Genotyping	SC	NA	NA	The committee added this definition to the glossary for completeness. Red Cell Genotyping: A molecular technique used to identify genetic variants responsible for antigens on the surface of red cells, also known as blood group genotyping.
Glossary – Ribonucleic Acid	SC	NA	NA	The committee added this definition to the glossary for completeness. Ribonucleic Acid (RNA): A nucleic acid present in all living cells that has structural similarities to DNA but is typically single-stranded. RNA types include messenger RNA (mRNA), ribosomal RNA (rRNA), and transfer RNA (tRNA).
Glossary - Single Nucleotide Polymorphism	SC	NA	NA	The committee added this definition to the glossary for completeness. Single Nucleotide Polymorphism (SNP): A DNA sequence variant seen in more than 1% of the members of a population. The group of SNPs is a subset of single nucleotide variants.
Glossary - Single Nucleotide Variant	SC	NA	NA	The committee added this definition to the glossary for completeness. Single Nucleotide Variant (SNV): A DNA sequence variant involving a single nucleotide at a specific position in the genome compared with a reference sequence (eg, A>C, A>T, A>G, delA, dupA, insA), without regard to population frequency.