# PREFACE

The Standards Program Committee (SPC) and the Molecular Testing Standards Committee (MT SC) are pleased to present this 7th edition of *Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens (MT Standards).*

The SPC is the umbrella committee whose primary role is to oversee the creation, development, and revision of all Association for the Advancement of Blood & Biotherapies (AABB) standards to ensure harmonization and consistency in AABB's standard-setting activities. The SPC consists of a committee chair, the chair of the Standards Subcommittee for the Evaluation of International Variances, and the chairs of the 10 standards committees.

The MT SC developed this 7th edition of *MT Standards* using an evidence-based decision-making process, when possible, to modify existing requirements or to create new ones. Besides setting standards for molecular testing, the MT SC intended to build a resource for practitioners and researchers in the field. While focusing on the United States, the needs of international audiences were also addressed. With the aim to bridge these diverse approaches, several committee members were recruited with the international perspective in mind. The *MT Standards* content remained in essence unchanged as the field progressed but has undergone substantial transformation in the 2 years since the 6th edition. The committee members aimed to expand all previously covered information, adding blood group systems that were left out in previous editions, now detailing all 45 blood group systems and two regulatory genes, and also providing a complete listing for the recognized platelet and neutrophil antigens.

The process of developing the requirements in *MT Standards* requires that the final publication reflect the concerns and priorities of several different aspects of the discipline, including the input of recognized experts in the field and the best interests of donors and patients. The MT SC has published a document providing informal responses to the comments received during the comment period, explaining why

the MT SC adopted a suggestion or did not. This document can be found on the AABB website (https://www.aabb.org/standards-accreditation/standards/about-aabb-standards/standards-library).

In addition, the *MT Standards* was developed in the context of the global drive for quality in health care and internationally recognized principles of quality management. To this end, the MT SC members consulted the scientific literature on current molecular testing techniques and applications. Accordingly, the *MT Standards* is based on input from a variety of sources, including MT SC members and public comments. A facility will be assessed only on activities it performs.

*MT Standards* contains requirements that must be implemented by accredited AABB institutions. Requirements are statements, signified by use of the term "shall." *Guidance for Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens*, 7th edition, could be of assistance in understanding and implementing these requirements, but a facility will be assessed only upon the standards. Guidance for specific standards that appear in this edition of the *MT Standards* will be published in the Standards Portal and in printed form. Guidance entries are crafted from MT SC member input, approved variances, and public clarification requests.

In an effort to harmonize AABB publications, all standards have incorporated the AABB's recently updated quality system essentials as the foundation of the standards. This 7th edition of *MT Standards* implements AABB's updated quality system essentials, first introduced by AABB in Association Bulletin #97-04 and serving as the framework through which the *MT Standards* have been presented since 2008 with its 1st edition. The quality requirements in the *MT Standards* (and all sets of AABB *Standards*) have been updated on an as-needed basis, with changes occurring incrementally but not in a universally applicable fashion.

The current updated version of the quality system essentials has been standardized in terms of language and style, and will be incorporated in all sets of AABB *Standards* beginning with the 16th edition of *Standards for Relationship Testing Laboratories*, which was effective January 1, 2024. The updated quality system essentials include the following updates:

- All standards are written in the active voice.
- Once a requirement has been stated, it is not repeated.
- Each chapter begins with a description of what the standards therein cover.
- Each chapter contains a list of key terms that relate to the content of the chapter, with their definitions.
- Each chapter contains a list of examples of objective evidence that an assessor could look for during an on-site assessment; however, this list is not comprehensive, nor will it be assessed against by an assessor. It is merely for guidance purposes only.
- Each chapter now concludes with the record retention table for that chapter. Note that a comprehensive record retention table still exists at the end of Chapter 6.

The AABB did a marvelous job in creating this standard language for quality assurance, which the MT SC introduced throughout all chapters. Those paragraphs will now reflect common topics across the various AABB *Standards*; much of the information specific to the *MT Standards* became slimmer and more concise, hopefully making a more accessible and easier read. Because of these efforts, the length of the *MT Standards* may still have doubled when going from the 6th to the 7th edition. However, once familiar with the new, more standardized structure of this and all other editions of AABB *Standards*, relevant information will in fact be quicker to locate. The MT SC concurred with AABB staff that these updates across the current and all AABB *Standards* will provide a reset and upgrade to the previous version of the quality system essentials and will allow these *MT Standards* to take the next step in quality.

Among the 16 members of the MT SC, three reside outside the Americas, including one consultant specifically for international affairs. The two junior members of the previous committee were promoted to full members, and two new junior members joined the dedicated team. Liaisons were delegated from three other Standards Committees: the Molecular Testing Accreditation Committee (MT AC), Relationship Testing Standards Committee (RT SC), and Immunohematology Reference Laboratories Standards Committee (IRL SC). Representatives were sent from other organizations, the American Red Cross/American Rare

Donor Program (ARC/ARDP) and the American Society of Histocompatibility and Immunogenetics (ASHI). It was my pleasure working with the committee members on this major formal overhaul and expansion in technical detail of the *MT Standards'* 7th edition.

Willy Albert Flegel, MD
Chair, Molecular Testing Standards Committee

# INTRODUCTION

The *Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens (MT Standards)* was prepared by the Molecular Testing Standards Committee (MT SC) and the Standards Program Committee of the AABB. The goal of the *MT Standards* is to provide requirements for facilities using molecular methods to predict blood group antigens on red cells, platelets, and neutrophils, as well as quality system requirements, operational standards, and a detailed list of inventory resources necessary for the identification of targeted nucleotides that encode these antigens.

The following frequently asked questions will help users of this book better understand this 7th edition of *MT Standards*:

**When does this edition go into effect?**

The effective date of this edition is January 1, 2025.

**Are the standards in this document requirements or recommendations?**

The *MT Standards* contains requirements implemented by AABB-accredited molecular testing laboratories. A requirement contains the word "shall," which indicates that the statement is mandatory. Failure to meet the requirement would constitute a nonconformance under the AABB Accreditation Program. There are rare instances in which a standard uses the term "may." A statement that uses "may" is not a requirement.

**How does this book relate to other laws and regulations?**

The *MT Standards* was developed on the basis of good medical practice and, when available, scientific and evidence-based data. The requirements in this book can be followed by a molecular testing laboratory located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. Accredited facilities must fol-

low the *MT Standards* as written to ensure continued AABB accreditation in good standing. Although the majority of the standards here are intended to be consistent with applicable laws and requirements, no assurances can be given that compliance with *MT Standards* will result in compliance with all applicable laws and requirements. The *MT Standards* is not intended as a substitute for legal advice, and the content should not be relied upon for legal purposes. Therefore, readers must make their own determinations as to how best to ensure compliance with all applicable laws and requirements, including consulting legal counsel familiar with these issues.

### Does this book require me to follow my own local laws and regulations?

Yes. In many standards, the MT SC chose to use the term "specified requirements." This phrase is defined in the glossary to include any applicable requirement under which the facility might operate. These could include, but are not limited to, a federal regulation, a customer agreement, a practice standard, the instructions for the intended use of a device, or a requirement of an accrediting organization.

### What does the pen symbol (✎) mean?

When the pen symbol precedes a standard, users have to maintain a record of that activity in order to meet the standard. Readers should refer to the reference standard at the end of Chapter 6 to determine what that record must contain, as well as the required record retention time.

### What other tools are available to help me implement the MT Standards?

There are several other resources to assist users. This publication also includes:

- A glossary, which reflects the usage of specific words or phrases in the context of these *MT Standards*.
- A crosswalk that cross-references the standards in this edition of *MT Standards* with those in the previous edition.

In addition, users of this edition may want to:

- Visit the AABB website for a document that details the significant changes to this edition. This document is titled "Significant Changes and Response to Comments" to the 7th edition.
- Follow guidance for the 7th edition of *MT Standards*, found in the AABB Standards Portal online or in the printed publication. The guidance provides rationales behind significant changes to this edition of *MT Standards* and provides recommendations on how to meet the intent of certain standards.
- Contact the Standards Department (standards@aabb.org) to ask for interpretations or to submit a variance request. Variances to standards are effective for the edition of *MT Standards* for which they are received. Request forms for variances can be found in the Standards section of the AABB website. Renewals of previously granted variance requests must be submitted before the effective date.