PREFACE

The Standards Program Committee (SPC) and the Molecular Testing Standards Committee (MT SC) are pleased to present this 8th edition of *Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens (MT Standards),* 20 years after inception of these standards. During the latest editions, the MT SC steadily expanded the international representation on the roster. An effort was made to render the *MT Standards* more appealing as a reliable resource for any laboratory worldwide, even for those that are not accredited by AABB at this time.

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 8th 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 the MT SC focused 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 committee members updated all previously covered information, adding three new blood group systems since the last edition, now detailing 48 blood group systems and two regulatory genes, and providing the complete listing of the 35 recognized platelet genes and five neutrophil genes.

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 recog-

nized experts in the field and the best interest of donors and patients. 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.

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).

This 8th edition of *MT Standards* maintains the AABB's quality system essentials (QSEs) updated in 2023. The QSEs, first introduced by AABB in Association Bulletin #97-04, have served as the framework by which the *MT Standards* has been presented since its first edition.

Laboratories will encounter novel gene variants (alleles) with some regularity during their routine clinical services. The documentation of such alleles in the public domain would be contributing to the development of the field and be eventually instrumental to enhancing patient care and patient safety. Although the MT SC members agreed on these concepts, standard setting is mostly limited to maintaining the established processes and quality within the field rather than expanding the field. Still, in the 8th edition, the MT SC addressed possible processes for how to proceed with novel alleles when they inevitably are encountered. The finding of a novel allele must be made transparent in the laboratory's reporting, which became a new standard. And the wider documentation of novel alleles is encouraged, while not made mandatory, with ample discussion and guidelines, which are worth the read, in the guidance document for the *MT Standards*. The perception and acceptance of these processes by users of these *MT Standards* will help determine how these processes will be expanded and implemented further in future editions.

MT Standards contains requirements that must be implemented by AABB-accredited institutions. Requirements are statements, signified

by use of the term "shall." The 8th edition of *Guidance for Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens* could be of assistance in understanding and implementing these requirements, but it is only the standards upon which a facility will be assessed. 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.

Among the 17 members of the MT SC, four reside outside the Americas, covering Europe and Asia, including one consultant specifically for international affairs. The two junior members of the past committee were promoted to full members, and two new junior members joined the current team. Liaisons were delegated from three other Standards committees: Molecular Testing Accreditation Committee (MT AC), Relationship Testing Standards Committee (RT SC), and Immunohematology Reference Laboratories Standards Committee (IRL SC). Representatives were sent from two other organizations: American Red Cross/American Rare Donor Program (ARC/ARDP) and American Society for Histocompatibility and Immunogenetics (ASHI). I am honored to have contributed to MT SC for four editions beginning in 2019 and as chair since 2023. And it was my pleasure working with several teams of dedicated committee members on major overhauls and expansions, which culminated in the current *MT Standards*' 8th edition, to be effective January 1, 2027.

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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 8th edition of *MT Standards*.

When does this edition go into effect?

The effective date of this edition is January 1, 2027.

Are the standards in this document requirements or recommendations?

The *MT Standards* contains requirements to be 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 follow the *MT Standards* as written to ensure continued AABB accredita-

tion in good standing. Although the majority of the standards here are intended to be consistent with applicable laws and requirements, no assurance 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, instruction for the intended use of a device, or a requirement from 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 record retention tables at the end of each chapter, and the complete 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 this 8th edition.
- Follow guidance for the 8th edition of *MT Standards*, which can be 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 on the AABB website (https://www.aabb.org/standards-accreditation/standards/about-aabb-standards/requesting-a-variance). Renewals of previously granted variance requests must be submitted prior to the effective date.