

## PREFACE

**T**he Standards Program Committee (SPC), along with the Molecular Testing Standards Committee (MT SC), are pleased to present this 4th edition of *Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens*.

The SPC is the umbrella committee whose primary role is to oversee the creation, development, and revision of all 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 Interpretation Committee, as well as the chairs of the seven specialty program units.

The MT SC consists of a chairperson and members from the molecular testing field (including medical technologists, laboratory directors, medical and laboratory professionals, and quality experts); liaisons from other AABB task forces, including an associated accreditation unit, committees, and work groups; representatives from other organizations; and an ethicist. The MT SC meets in person during the two-year revision cycle and has frequent conference calls to discuss requests for variances from each edition of *MT Standards* and requests for standards interpretations.

The overarching principle of this document is to guide the field of molecular blood group testing by providing standards based on the available scientific information while focusing on advocacy and optimal care for both our recipients and donors. The *MT Standards* are intended to be simple, clear, and practical. The use of these *MT Standards* should aid materially in developing and maintaining policies, processes, and procedures that will provide safe and effective transfusion and transplantation, as well as a safe work environment for blood bank and transfusion service personnel.

These *MT Standards* represent the minimum requirements under which a laboratory specializing in molecular testing should operate. The MT laboratory director, who should have expertise in this area, may wish to have more stringent requirements. In contrast to the *IRL*

*Standards*, the requirement for DNA resources is not mandatory for all items but rather only those for which the laboratory performs molecular testing. Because of additional ethical concerns as well as local and state laws regarding consent for DNA testing, the MT lab is urged to obtain legal counsel in regard to testing.

In addition, the SPC has made a clear distinction between standards and guidance. *MT Standards* contains requirements that must be implemented by accredited AABB institutions. Requirements are imperative statements, signified by the use of the term, “shall.” All guidance to *MT Standards* is located in the version of the 4th edition that exists in the AABB Standards Portal. Guidance is provided to clarify the difference between requirements and recommendations. The intent of guidance is to provide rationales for standards or examples of how standards might be implemented. Along with this guidance, the MT SC has provided rationales for any significant changes to this 4th edition of *MT Standards*, which also exists in the Standards Portal. The Standards Portal can be accessed on the AABB website at the following address: <http://standards.aabb.org>

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 at the following address: <http://www.aabb.org/sa/standards/Pages/library.aspx>

On a personal note, it has been a great pleasure for me to have worked with true genotyping experts over the past several editions of *MT Standards*, and I am grateful for their time and commitment to producing these high-quality standards. We hope this reference document will be useful to our colleagues in molecular testing laboratories.

Mark H. Yazer, MD  
Chair, Molecular Testing Standards Committee

## INTRODUCTION

**T**he *Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens (MT Standards)* was prepared by the Molecular Testing Standards Committee 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 4th edition of *MT Standards*:

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

The effective date of this edition is October 1, 2018.

### **Are the MT Standards 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* were 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 your federal, state, and/or local laws and regulations. Accredited facilities must follow 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 these applicable laws and requirements, no assurances can be given that compliance with *MT Standards* will result in compliance with all applicable laws and requirements. These *MT Standards* are not intended as a substitute for legal advice and the content should not be relied upon for legal purposes. You, therefore, must make your 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 Standards Committee (SC) chose to use the term “specified requirements.” This phrase is defined in the glossary to include any applicable requirement under which your service 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, you 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 also want to:

- Visit [www.aabb.org](http://www.aabb.org) for a document that details the disposition and resolution of all comments received to this edition. This document is entitled, “Response to Public Comments” to this 4th edition. When a public comment is the source of a change, or where the MT SC did not make a change suggested by a comment, an explanation is provided.
- Guidance to the 4th edition of *MT Standards* can be found in the AABB Standards Portal, available online. The portal provides rationales behind significant changes to this edition of *MT Standards*, and provides recommendations on how to meet the intent of certain standards.
- Contact [standards@aabb.org](mailto:standards@aabb.org) for interpretations or to submit a variance request. Variances to standards are effective for the edition of *Standards* for which they are received. Requests for variance can be made online at the following address: <http://www.aabb.org/sa/standards/Pages/Requesting-a-Variance.aspx>.