PREFACE

The Standards Program Committee (SPC) along with the Molecular Testing Standards Committee (MT SC) are pleased to present this 5th 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 eight 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 committees and work groups including an associated accreditation committee, representatives from other organizations, and an ethicist. The MT SC meets during the 2-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 recipients and donors. The *MT Standards* is intended to be simple, clear, and practical. The use of the *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.

The *MT Standards* represents 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. The requirement for

DNA resources is not mandatory for all items but rather only those for which the laboratory performs molecular tests. Because of the potential ethical concerns as well as local and state laws that may regard red cell, platelet, and neutrophil testing as genetic testing, the MT laboratory is urged to obtain legal counsel in regards 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 5th edition that exists in the AABB Standards Portal and in the printed publication *Guidance for Standards for Molectural Testing for Red Cell, Platelet, and Neutrophil Antigens*. 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 5th 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

I speak for my committee members when I state that we are pleased to have been members of a dedicated team who compiled this 5th edition of *Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens.* We forged new ground by harmonizing the *MT Standards* nomenclature with Human Genome Variation Society terminology and nucleotide designations. Molecular testing results are no longer regarded as "predicted phenotypes"; rather, such testing designates red cell, platelet, and neutrophil antigens. Finally, the good news for laboratories considering accreditation is that world-wide DNA repositories are making it easier to obtain the reference material needed to meet the *MT Standards*. These resources include the Food

and Drug Administration repository with information freely available from J Mol Diagn 2019;21:525-37. It is hoped that the *MT Standards* will serve as a guide to elevate the both the breadth and quality of testing in transfusion medicine.

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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 5th edition of *MT Standards*:

When does this edition go into effect?

The effective date of this edition is October 1, 2020.

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

The *MT Standards* contains requirements implemented by AABB-accredited molecular resting 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 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 also want to:

- Visit the AABB website for a document that details the significant changes to this edition. This document is titled, "Significant Changes to the 5th edition."
- Follow guidance to the 5th 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 on the AABB website at http://www.aabb.org/sa/standards/Pages/Requesting-a-Variance.aspx. Renewals of previously granted variance requests must be submitted prior to the effective date.