PREFACE

The Standards Program Committee (SPC) and the Immunohematology Reference Laboratories Standards Committee (IRL SC) are pleased to present this 12th edition of *Standards for Immunohematology Reference Laboratories (IRL Standards)*.

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 IRL SC developed this 12th edition of *IRL Standards.* The IRL SC used an evidence-based decision making process, when possible, to modify existing requirements or to create new ones.

The process of developing the requirements in *IRL Standards* requires that the final publication reflects 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 their patients. In addition, *IRL 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 IRL SC also consulted the scientific literature on immunohematology laboratory techniques and applications. Accordingly, *IRL Standards* is based on input from a variety of sources, including member and public comments. In an effort to harmonize AABB publications, all standards have incorporated the AABB Quality System Essentials (first identified in Association Bulletin #97-4) as the foundation of the standards.

In addition, the SPC has made a clear distinction between standards and guidance. *IRL Standards* contains requirements that must be implemented by accredited AABB institutions. Requirements are imperative statements, signified by the use of the term "shall." *Guidance for Standards for Immunohematology Reference Laboratories* (available in the Standards Portal and as a published document) could be of service in

understanding and implementing these requirements. *Guidance* entries are crafted from member clarification requests and approved variances.

The IRL SC has published a document providing informal responses to the feedback received during the comment period explaining why the IRL SC adopted a suggestion or did not. This document can be found on the AABB website.

As I begin to close out the remaining assignments as chair of the IRL SC, I reflect on all that has been accomplished over 4 short years. I am extremely proud of the committee and all that we accomplished together. With each new edition, the quality of *Standards* continues to improve, and as a result, our patients continue to receive the highest quality of care from each accredited IRL. This 12th edition is special to me, as I believe it shows the collaborative and creative nature of the committee whose priority was to ensure the standards are supportive and reflective of the services we provide today. We all are aware of the changes occurring in the field of immunohematology, and as a result some of our standards needed to change to remain current. I hope you find the 12th edition to be comprehensive and supportive of the great work you all do every day. I am honored to have been part of this committee, serving as your chair. Thank you to all committee members for your hours of service, collaborative approach, and overall dedication to improving the lives of our patients. I am grateful that you each volunteered your time to work alongside me.

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Chair, Immunohematology Reference
Laboratories Standards Committee

INTRODUCTION

The *Standards for Immunohematology Reference Laboratories* (*IRL Standards*) was prepared by the Immunohematology Reference Laboratories Standards Committee (IRL SC) and the Standards Program Committee of the AABB. The goal of the *IRL Standards* is to maintain and enhance the quality and safety of services provided by immunohematology reference laboratories and to provide a basis for the Accreditation Program of the AABB.

The following frequently asked questions will help users of this publication better understand the 12th edition of *IRL Standards*:

When does this edition go into effect?
The effective date of this edition is April 1, 2022.

Are the standards requirements or recommendations?
The *IRL Standards* contains requirements to be implemented by AABB-accredited reference 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 publication relate to other laws and regulations?
The *IRL Standards* was developed on the basis of good medical practice and, when available, scientific and evidence-based data. The requirements in this publication can be followed by a reference laboratory located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. Accredited facilities must follow the *IRL Standards* as written to ensure continued AABB accreditation in good standing. Although the majority of the standards are intended to be consistent with applicable laws and requirements, no assurances can be given that compliance with *IRL Standards* will result in compliance with all

applicable laws and requirements. *IRL Standards* is not intended as a substitute for legal advice and the content should not be relied upon for legal purposes. Users therefore 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 publication require me to follow my own local laws and regulations?

Yes. In many standards, the IRL SC chose to use the term "specified requirements." This phrase is defined in the glossary to include any applicable requirement under which a 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, 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.

What other tools are available to help me implement the IRL 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 *IRL Standards*.
- A crosswalk that cross-references the standards in this edition of *IRL 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 disposition and resolution of all comments received to this edition. This document is titled, "Response to Public Comments and Significant Changes" to this 12th edition. When a public comment is the source

of a change, or where the IRL SC did not make a change suggested by a comment, an explanation is provided.

- Guidance to the 12th edition of *IRL Standards* can be found in the AABB Standards Portal, available online, or as a printed publication. The guidance provides rationales behind significant changes to this edition of *IRL Standards*, and provides recommendations on how to meet the intent of certain standards.
- Contact the Standards Department for interpretations or to submit a variance request. Variances to standards are effective for the edition of IRL Standards for which they are received. Request forms for variances can be found here and request forms for interpretations can be found here.