INTRODUCTION

The Standards for Relationship Testing Laboratories (RT Standards) was prepared by the Relationship Testing Standards Program Unit and the Standards Program Committee of the AABB. The goal of the RT Standards is to maintain and enhance the quality and safety of services provided by relationship testing 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 RT Standards:

When does this edition go into effect?
The effective date of this edition is January 1, 2016.

Are the standards requirements or recommendations?
The RT Standards contains requirements to be implemented by AABB-accredited relationship 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 publication relate to other laws and regulations?
The RT 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 relationship 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 RT 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 RT Standards will result in compliance with all applicable laws and requirements. RT 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 RT SPU 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. It should be noted that all records in this 12th edition must be kept for a minimum of 5 years.

**What other tools are available to help me implement the RT 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 *RT Standards*.
- A crosswalk that cross-references the standards in this edition of *RT 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 12th edition. When a public comment is the source of a change, or where the RT SPU did
not make a change suggested by a comment, an explanation is provided.

- Guidance to the 12th edition of RT Standards can be found in the AABB Standards Portal, available online. The portal provides rationales behind significant changes to this edition of RT Standards, and provides recommendations on how to meet the intent of certain standards.

- Contact 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. Request forms for variances can be found at http://www.aabb.org.