
PREFACE

The Standards Program Committee (SPC) along with the Relationship Testing Standards Committee (RT SC) are pleased to present this 16th edition of *Standards for Relationship Testing Laboratories (RT 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 Subcommittee for the Evaluation of International Variances, and the chairs of the nine specialty standards committees.

The RT SC consists of a chair, members providing full representation of the relationship testing field (including medical technologists, laboratory directors, medical and laboratory professionals, and quality experts), liaisons from other AABB committees, representatives from other organizations, and an ethicist. The RT SC meets during the 2-year revision cycle and has frequent conference calls to discuss requests for variances from each edition of *RT Standards* and requests for standards interpretations.

The guiding principle of this document is to be consistent with available scientific information while focusing on patient advocacy and optimal care for clients. The requirements are intended to be simple, clear, and practical. The use of these *RT Standards* should aid materially in developing and maintaining policies, processes, and procedures that will contribute to acceptable results as well as a safe work environment for laboratory personnel.

While the *RT Standards* provides a great amount of technical information concerning the relationship testing community, other AABB publications provide specific recommendations. When using this edition of the *RT Standards*, having access to the current edition of the AABB *Technical Manual* and the 16th edition of *Guidance for Standards for Relationship Testing Laboratories* (available in the Standards Portal and as a stand-alone published document) could be of service in understanding and

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

The 16th edition of the *RT Standards* will have a visibly new appearance with the incorporation of AABB's updated Quality System Essentials. The formatting of the chapters has been standardized for these *RT Standards* and across all the AABB published *Standards*. The new format provides ease of review, highlights key points, and more closely reflects the quality practices of the field.

Another key change in the 16th edition is the expansion of the standards to address not only fragment analysis for parentage and relationship testing, but to capture testing that is performed by single nucleotide polymorphism (SNP) analysis. This change was incorporated to ensure that the state of the industry currently in practice has guidance for performing non-traditional testing, in particular testing for the purposes of genetic genealogy. This edition of the standards has been developed to ensure that accredited genealogy testing is performed following adherence to quality practices.

Additional changes in this 16th edition further clarified the experience necessary for a technical leader (TL) working as a laboratory director. This change was first incorporated in the 14th edition; this standard clarifies the appropriate experience of the TL when it is obtained in a non-AABB-accredited laboratory.

Finally, a clarification was made for interpretation of likelihood ratios for nonparentage two-party family studies. The standards for interpretation of these tests were incorporated in the 13th edition; these standards clarify the wording of these interpretations but do not change the intent of the original standards.

As the COVID pandemic continued to disrupt laboratories and lives during the production of the 16th edition of the *RT Standards*, these standards could not have been completed without the dedication of the AABB staff and the hard work of the RT Standards Committee. The efforts and dedication of these talented individuals is greatly appreciated.

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Chair, Relationship Testing Standards Committee

INTRODUCTION

The *Standards for Relationship Testing Laboratories (RT Standards)* was prepared by the Relationship Testing Standards Committee 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 16th edition of *RT Standards*:

When does this edition go into effect?

The effective date of this edition is January 1, 2024.

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 sub-

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stitute 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 Relationship Testing Standards Committee 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 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. It should be noted that all records in this 16th 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 for a document that details the disposition and resolution of all comments received to this edition, as well as significant changes. This document is titled “Significant Changes and Response to Comments” to this 16th edition. When a public com-

ment is the source of a change, or where the Relationship Testing Standards Committee did not make a change suggested by a comment, an explanation is provided.

- Guidance for the 16th edition of *RT Standards* can be found in the AABB Standards Portal, available online and as a printed stand-alone copy of the published Guidance. The Guidance 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 www.aabb.org.