PREFACE

The Standards Program Committee (SPC) and the Immunohematology Reference Laboratories Standards Committee (IRL SC) are pleased to present this 14th 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 Subcommittee for the Evaluation of International Variances, and the chairs of the 10 specialty standards committees.

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

Although the *IRL Standards* provides a great amount of technical information concerning immunohematology reference laboratories, other AABB publications provide specific recommendations. When using this edition of the *IRL Standards*, having access to the current edition of the AABB *Technical Manual* and the 14th edition of *Guidance for Standards for Immunohematology Reference Laboratories* (available in the Standards Portal and as a stand-alone published document) could be of service in understanding and implementing these requirements. *Guidance* entries are crafted from member requests for clarification and approved variances.

This 14th edition of *IRL Standards* maintains the AABB's quality system essentials updated in 2023. The quality system essentials were first introduced by AABB in Association Bulletin #97-04 and have served as the framework by which the *IRL Standards* has been presented since 2000 with the 1st edition.

Preface

It has been both an honor and a privilege to serve as chair of the committee responsible for developing the 14th edition of the *IRL Standards*. This edition reflects the dedicated efforts of a broad team of experts, including committee members, liaisons, and representatives from external organizations and regulatory agencies.

Working alongside this team of committed professionals—each sharing a common goal of advancing the quality of care and testing for patients and rare donors—has been truly rewarding. Their insights, constructive debate, and expertise have been invaluable in shaping these standards.

Throughout the revision process, the committee focused on eliminating unnecessary repetition while enhancing clarity where needed. Readers will also notice several refinements intended to harmonize the *IRL Standards* with other AABB *Standards.*

We are especially grateful to Chris Bocquet, AABB Senior Director of Standard Development and Quality Initiatives, and Tracie Nicols, AABB Senior Director of Accreditation Compliance, Accreditation, and Quality. Their deep subject-matter knowledge, thoughtful guidance, and ongoing support were instrumental in achieving the committee's objectives. In particular, we thank them for their efforts in engaging with the Centers for Medicare and Medicaid Services and researching regulatory guidance related to control material requirements for graded or titered test procedures [42 CFR 493.1256(d)(3)(iii)].

Finally, I extend sincere thanks to all individuals who contributed comments and feedback. Your input ensures that these *IRL Standards* are both clear and operationally practical.

We hope this edition, along with its accompanying guidance document, supports your organization in maintaining and enhancing the highest standards of care for the patients and donors you serve.

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