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CONTINUOUSLY REVISED

The Manual of Molecular and Clinical Laboratory Immunology is by its nature a continuously revised work which refines and extends the contributions of previous editions. Since its first edition in 1976, many eminent scientists have contributed to this important reference work. The American Society for Microbiology and its Publications Board gratefully acknowledge the contributions of all of these generous authors over the life of this Manual.
In 1971, I was working at the University of Oxford's Sir William Dunn School of Pathology in the laboratory of James Gowans, the investigator who first definitively showed that the lymphocyte was the source of specific adaptive immunity. I was busily cannulating the thoracic ducts of rats in order to harvest T lymphocytes when I was informed that a transatlantic telephone call was coming in. My first reaction was fear of bad news. Rather, it was a phone call from Earle Spaulding. I knew Earle as the chairman of microbiology at Temple and active in the Eastern Pennsylvania branch of the American Society for Microbiology (ASM). He explained that he was calling as a member of the editorial group of the *Manual of Clinical Microbiology* (MCM), at that time in its first edition. His particular concern was the chapter on immunology, which devoted 100 pages to various serologic tests for infectious organisms with no mention of noninfectious diseases. Earle felt strongly that the field of immunologic diagnosis was growing exponentially and deserved a separate, companion manual. The MCM editorial board agreed, providing I was willing to accept the position of Editor-in-Chief.

I was delighted to receive the invitation. I had recently chaired a “blue ribbon” committee of the American Association of Immunologists (AAI) on the future of clinical immunology. We concluded that there was no space for a new patient-centered clinical specialty, but great need for improved, expanded laboratory support. A comprehensive manual would serve as a great stimulus to the whole field of laboratory-based clinical immunology. I accepted the offer with two qualifications. First, I needed a co-editor, particularly someone well versed at a practical level in immunology related to infectious diseases. Second, I asked that such a manual be cosponsored by the AAI. Both qualifications were agreed to by the ASM Publications Board.

The person I had in mind as co-Editor-in-Chief was Herman Friedman. I knew Herman from contacts arising from our joint interest in allergy research. I knew he understood the practice of laboratory immunology and was one of the few immunologists who actually researched the immunology of infection. Herman readily agreed to partner with me on the *Manual*, and so began a close collaboration that continued for three subsequent editions of the *Manual*, ended only by his untimely death. The AAI also accepted an offer of collaboration and appointed a liaison committee to work with us.

We were off and running, but we had no idea of how to proceed. There had never been a manual describing the entire laboratory practice of immunology. Part of our mission was to include the many applications of immunology devoted to detection and analysis of a wide variety of diseases, not only those induced by microorganisms. Should we approach the subjects disease by disease or method by method? We finally decided to compromise by beginning the book with invited chapters on the common methods used in the immunology laboratory, then continuing with sections covering their application to the main categories of disease. We included a final section on laboratory administration and quality control.

Having developed particular sections, we then sought the most experienced and highly qualified individuals to serve as section editors. Because of the cross-cutting matrix arrangement, there was major concern that some topics would be dealt with twice or even three times. We therefore decided to organize a “stakeholders meeting,” at which all of the section editors met at ASM in Washington, DC, with proposed outlines of their sections. Going through each one systematically, we identified topics where overlap occurred and ensured that everything important was included once, but not more. We also made a fundamental decision that the book would be complete and free-standing. The methods would be described in sufficient detail that the laboratory worker could actually prepare the materials, perform the tests, and interpret the results without consulting other references. It should be understood that, at that time, most laboratory reagents
were prepared within the laboratory and were generally not available as commercial kits. This format required that we keep descriptions terse and the reference lists short.

When the first edition of the *Manual of Clinical Immunology* was published in 1976, we felt it warranted some type of celebration. Herman suggested that we should organize a meeting to mark the birth of the book and to bring together the leaders in clinical laboratory immunology, including our authors and section editors. Eventually, this led to the formation of the Association of Medical Laboratory Immunologists and the American Board of Medical Laboratory Immunology.

The *Manual* continues to be published at regular intervals to the present, as the editorial lineup has evolved. Barbara Detrick and Robert G. Hamilton joined me as Editors for the Sixth Edition, and Dr. Detrick has continued to lead the *Manual* for the Seventh and the present Eighth Edition. I hope the series will go on for many years. Although the *Manual*’s name has changed and the format is altered, the overall aim is still to improve the care of patients with infectious malignant inflammatory and immune-mediated disorders. With the ready availability of validated kits, the job of the clinical laboratory immunologist has shifted toward working with clinical colleagues on the significance and interpretation of laboratory tests.

I’m proud to have been involved in the genesis of this *Manual*. It would not have been possible without the continued support of ASM, the cooperation of AAI, the persistence of succeeding volume and section editors, the contributions of hundreds of practicing clinical laboratory immunologists, and the foresight of a few visionary microbiologists of the 1970 era who realized that immunology had become a discipline and specialty of its own. It never would have happened if Herman Friedman had not joined with me in accepting the challenge. I hope that he will long be remembered for his numerous contributions to immunology.

NOEL R. ROSE, MD, Ph.D.
For over 40 years, the *Manual of Clinical Laboratory Immunology* has been the leading reference source, both in the United States and abroad, to advance the field of laboratory immunology, to foster the best contemporary and most cutting-edge methodologies, and to translate basic immunologic principles into appropriate laboratory tests.

Since the publication of the 7th edition of this *Manual*, remarkable progress has been made in the field of immunology, and these notable advancements have been reflected in the clinical immunology arena as well. The scope of clinical immunology is exceptionally broad and encompasses nearly every medical specialty, including such areas as transplantation, rheumatology, oncology, infectious disease, allergy, hematology, and neurology, to name a few. Because of its strategic position in the hospital setting, it is critical that the clinical immunology laboratory should have a guide to follow with regard to accurate and appropriate laboratory procedures. As the field of clinical immunology continues to expand, we look to the laboratory director as a key person to gather the new basic information and integrate it into useful clinical procedures as well as to serve as a pivotal contact for communication with the various disciplines. In addition to keeping abreast with the most updated testing systems, the goal for this *Manual* is that it must not only serve the needs of today's clinical immunology laboratory but also look to the future, where even more dramatic progress in diagnosis and treatment can be anticipated.

In an effort to capture the new dimensions in this field and to reflect the continuous evolution of clinical immunology, significant changes have been introduced into the 8th edition of the *Manual of Molecular and Clinical Laboratory Immunology*. Several sections of the *Manual* have been notably updated to reflect the latest laboratory approaches in molecular assays as well as the shift to automated testing, kit-based diagnostics, and new technical tools: themes that are carried throughout the book.

New chapters have been introduced to highlight these changes. For example, section D, Flow Cytometry, describes the latest applications of these techniques, such as polychromatic flow cytometry and mass cytometry; section F reviews fresh information on the clinical applications of cytokines and chemokines; the infectious disease sections H, I, and J include the newest strategies used in infectious disease diagnosis and treatment, including the HIV and syphilis algorithms; section K, Immunodeficiency Diseases, presents the recent newborn screening programs for severe combined immune deficiency; and section P, Transplantation Immunology, outlines the usefulness of next-generation sequencing in the human leukocyte antigen (HLA) laboratory.

Once again, this *Manual* is offered not just in print but also electronically as either an EPUB file or a PDF. This special feature will allow a larger audience to review and use the *Manual*.

As we produce the 8th edition of this *Manual*, it is appropriate to celebrate its success. Noel Rose, the *Manual*’s first Editor-in-Chief, has provided a foreword reflecting on how the field has changed over the past 5 decades.

Since the publication of this *Manual* is a joint effort of many dedicated individuals, I wish to acknowledge the outstanding commitment and invaluable support of our volume editors, section editors, and chapter authors, all of whom, as internationally renowned experts in their areas, have contributed their extraordinary experience, energy, and time to the success of this edition. Also, I would like to extend my appreciation to the ASM editorial staff, in particular Ellie Tupper, Senior Production Editor, and Christine Charlip, Director, ASM Press, who have provided their valuable experience and support to complete this edition.

BARBARA DETRICK, Ph.D.
Editor in Chief
Author and Editor
Conflicts of Interest

Cem Akin (coauthor on chapter 85) has consultancy agreements with Novartis and Patara Pharma and receives research funding from Dyax.

Barbara Detrick (Editor in Chief, coauthor on chapter 106) serves as a consultant to Siemens Healthcare Diagnostics, Inc., Abbott Laboratories, and INOVA Diagnostics, Inc.

Deborah Ferriola (coauthor on chapter 113) receives royalties from Omixon. Omixon has licensed the protocol we developed for HLA typing by NGS from the Children’s Hospital of Philadelphia and makes it available as a commercial product named “Holotype HLA.” Omixon is mentioned in this chapter as a company that provides software analysis tools for the genotyping of HLAs using NGS data. It is not mentioned as a company that commercializes HLA typing products/kits, because at the time of writing Omixon had not developed this activity.

Marvin J. Fritzler (coauthor on chapter 88) has been a consultant to or received research gifts in kind from Inova Diagnostics Inc., Euroimmun GmbH, Mikrogen GmbH, Dr. Fsoke Laboratorien GmbH, ImmunoConcepts, GSK Canada, Amgen, Roche, and Pfizer. He is the Director of Mitogen Advanced Diagnostics Laboratory.

Andrea Illingworth (coauthor on chapter 18) has received unrestricted Educational Grant funding and speaker honoraria from Alexion Pharmaceuticals.

Michael Keeney (coauthor on chapters 18 and 19) is a consultant for Beckman Coulter, Canada, and Alexion Pharma, Canada. He has received unrestricted Educational Grant funding and speaker honoraria from Alexion Pharmaceuticals.

Masataka Kuwana (chapter 91) holds a patent on an anti-RNA polymerase III antibody measuring kit.

Curt Lind (coauthor on chapter 113) receives royalties from a licensing agreement between Omixon Biocomputing and the Children’s Hospital of Philadelphia and is an employee of Thermo Fisher Scientific, Transplant Diagnostics.

Robert P. Lisak (coauthor on chapter 99) is on an advisory board for Syntimmune.

Dimitri Monos (coauthor on chapter 113) receives royalties from Omixon. Omixon has licensed the protocol we developed for HLA typing by NGS from the Children’s Hospital of Philadelphia and makes it available as a commercial product named “Holotype HLA.” Omixon is mentioned in this chapter as a company that provides software analysis tools for the genotyping of HLAs using NGS data. It is not mentioned as a company that commercializes HLA typing products/kits, because at the time of writing Omixon had not developed this activity.

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Timothy Niewold (coauthor on chapter 38) has received research grants from Janssen Inc. and EMD Serono Inc.

Maurice R. G. O’Gorman (chapter 20) is a BD Biosciences consultant and contractee.

Paul Sikorski (coauthor on chapter 114) is an employee of One Lambda, Inc., a Thermo Fisher Scientific brand.

Marek Smieja (coauthor on chapter 63) has done small studies with Copan and GenMark.

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Kathleen E. Sullivan (section editor) is a Baxter grant recipient and an Immune Deficiency Foundation consultant.

D. Robert Sutherland (coauthor on chapters 18 and 19) has received speaker fees and consulting fees from Alexion Pharmaceuticals.
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Brent Wood (coauthor on chapter 22) has received research funding and honoraria for Advisory Board participation from Seattle Genetics and Amgen and honoraria from Abbvie for Advisory Board participation.

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