

The American Society for Microbiology (ASM) Practice Guidelines: Development and Publication

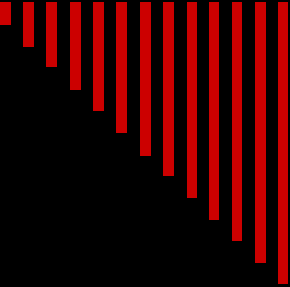
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Microbiology Specialists Incorporated

Houston, Texas

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Cumitech = Cumulative Techniques and Procedures in Clinical Microbiology



Single booklets: \$19.95

3 or more booklets: \$15.00 each

On-line subscription: \$249.95 + \$99.95 per year renewal



Cumitech Editorial Board

- Alice Weissfeld, *Chair*
 - Maria Appleman
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 - Linda Cook
 - Lynne Garcia
 - Mark LaRocco
 - Susan Mottice
 - Mike Saubolle
 - David Sewell
 - Dan Shapiro
 - Susan Sharp
 - Jim Snyder
 - Allan Truant
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How are Areas Identified for Development?

- Editorial board member suggestions
 - Core tests (urine cultures, lower respiratory tract cultures)
 - Identified gaps (cystic fibrosis)
 - New technologies (*Chlamydia trachomatis* and *Neisseria gonorrhoeae* molecular tests)
 - New procedures (platelet contamination)
 - Management (validation and verification, competency testing)
 - Member suggestions (CMV)
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Collaborative Approach

- Update of Quality Control and Quality Assurance Cumitech
 - Coordinating editor: Dave L. Sewell
 - Stakeholders: ASM, CDC, ISO, NCCLS
 - Authors: Dave L. Sewell
Alice S. Weissfeld
Ron Zabransky – NCCLS
Mike Noble – ISO
Nancy Anderson – CDC
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Process of Developing a Cumitech

- Topic identified
 - Coordinating editor assigned
 - Authors identified from potential stakeholders
 - First draft manuscript written
 - Review by coordinating editor
 - Submission to entire editorial board for peer review
 - Discussion of points raised by coordinating editor and authors
 - Revision of manuscript, if necessary
 - Final review by Chair of the editorial board
 - Publication by ASM Press
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Cumitechs in Progress

- Upper Respiratory Tract Infections
 - ABCs of Reimbursement and Coding
 - Infections Following Transplant: Solid Organ
 - Infections Following Transplant: Bone Marrow
 - *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Molecular Tests
 - Blood Cultures
 - Cystic Fibrosis
 - Sentinel Laboratory Procedures (12)
 - Quality Systems in the Clinical Microbiology Laboratory
 - Benchmarking Productivity
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Key Differences from Clinical Guidelines

- Does not focus on clinical presentations
 - Focuses on preanalytical variables as well as appropriate test selection
 - Describes analytical approaches including performance and clinical utility
 - Identifies key postanalytical issues including report configuration and quality assurance
 - Does not focus on patient management issues other than those affecting test selection
 - Evaluates both laboratory and diagnostic performance characteristics as required by CLIA in each methods-based publication
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Cumitech Mission Statement

Effective as of January 2000, the purpose of the Cumitech series is to provide consensus recommendations regarding the judicious use of clinical microbiology and immunology laboratories and their role in patient care. Each Cumitech is written by a team of clinicians, laboratorians, and other interested stakeholders to provide a broad overview of various aspects of infectious disease testing. These aspects include a discussion of relevant clinical considerations; collection, transport, processing, and interpretive guidelines; the clinical utility of culture-based and non-culture-based methods and emerging technologies; and issues surrounding coding, medical necessity, frequency limits, and reimbursement. The recommendations of Cumitechs do not represent the official views or policies of any third-party payer.



National Recognition for Cumitech Series

- National Coverage Decision (urine cultures)
 - During Negotiated Rulemaking (1997), the Infectious Disease Subcommittee co-chaired by Dr. Vickie Baselski used the pre-publication Cumitech, Laboratory Diagnosis of Urinary Tract Infections, as a reference for clinical indications
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Current Cumitechs

- 1B: Blood Cultures III
 - 2B: Laboratory Diagnosis of Urinary Tract Infections
 - 3A: Quality Control and Quality Assurance Practices in Clinical Microbiology
 - 5A: Practical Anaerobic Bacteriology
 - 6A: New Developments in Antimicrobial Agent Susceptibility Testing: a Practical Guide
 - 7B: Lower Respiratory Tract Infections
 - 12A: Laboratory Diagnosis of Bacterial Diarrhea
 - 13A: Laboratory Diagnosis of Ocular Infections
 - 16A: Laboratory Diagnosis of the Mycobacterioses
 - 18A: Laboratory Diagnosis of Hepatitis Viruses
 - 19A: Laboratory Diagnosis of *Chlamydia trachomatis* Infections
 - 21: Laboratory Diagnosis of Viral Respiratory Disease
 - 23: Infections of the Skin and Subcutaneous Tissues
 - 24: Rapid Detection of Viruses by Immunofluorescence
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Current Cumitechs (continued)

- 25: Current Concepts and Approaches to Antimicrobial Agent Susceptibility Testing
 - 26: Laboratory Diagnosis of Viral Infections Producing Enteritis
 - 27: Laboratory Diagnosis of Zoonotic Infections: Bacterial Infections Obtained from Companion and Laboratory Animals
 - 28: Laboratory Diagnosis of Zoonotic Infections: Chlamydial, Fungal, Viral, and Parasitic Infections Obtained from Food Animals and Wildlife
 - 29: Laboratory Safety in Clinical Microbiology
 - 30A: Selection and Use of Laboratory Procedures for Diagnosis of Parasitic Infections of the Gastrointestinal Tract
 - 31: Verification and Validation of Procedures in the Clinical Microbiology Laboratory
 - 32: Laboratory Diagnosis of Zoonotic Infections: Viral, Rickettsial, and Parasitic Infections Obtained from Food Animals and Wildlife
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Current Cumitechs (continued)

- 33: Laboratory Safety, Management, and Diagnosis of Biological Agents Associated with Bioterrorism
 - 34: Laboratory Diagnosis of Mycoplasmal Infections
 - 35: Postmortem Microbiology
 - 36: Biosafety Considerations for Large-Scale Production of Microorganisms
 - 37: Laboratory Diagnosis of Bacterial and Fungal Infections Common to Humans, Livestock, and Wildlife
 - 38: Human Cytomegalovirus
 - 39: Competency Assessment in the Clinical Microbiology Laboratory
 - 40: Packing and Shipping of Diagnostic Specimens and Infectious Substances
 - 41: Detection and Prevention of Clinical Microbiology Laboratory-Associated Errors
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Fast-Track Approach

- Sentinel (Level A) Lab Protocols for response to a bioterrorism event
 - ASM brought together subject matter experts and wrote 11 guidelines that are posted on the ASM web-site
 - Clinical Laboratory Bioterrorism Readiness Plan Template
 - Introduction to Level A Laboratory Protocols
 - Anthrax Guideline
 - Brucella Guideline
 - Botulism Toxin Guideline
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Fast-Track Approach (continued)

- Packaging and Shipping Guideline
 - Unknown Viruses Guideline
 - Staphylococcal Enterotoxin B Guideline
 - *Burkholderia mallei* and *B. pseudomallei* Guideline
 - *Coxiella burnetii* Guideline
 - Tularemia Guideline
 - Ricin Guideline (in progress)
 - Vickie Baselski used these guidelines to prepare a training program which was subsequently adopted by National Laboratory Training Network
 - Jim Snyder is coordinating turning these guidelines into Cumitechs
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