

2008 CATALOG SUPPLEMENT



*Update your library with the latest
global consensus standards,
guidelines, and bench aids—
including all new documents
March 2008–July 2008.*

Advancing Quality in Health Care Testing

Newly Redesigned Specialty Collections

SAVE UP TO 30% off individual document list prices. Buy collections of paper documents available in a three-ring binder or purchase electronic specialty collections at www.clsi.org.

General Microbiology Methodologies (SCM01)

Guidance provided on:

- ✓ Disk and dilution antimicrobial susceptibility testing
- ✓ Quality control of commercially prepared media
- ✓ Fecal ova and parasite detection
- ✓ Protection of laboratory personnel

M02-A9—Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard—Ninth Edition

M02 QG—M02 Quick Guides for Tables 1 and 1A

M07-A7—Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard—Seventh Edition

M07 QG—M07 Quick Guides for Tables 1 and 1A

M22-A3—Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition

M28-A2—Procedures for the Recovery and Identification of Parasites From the Intestinal Tract; Approved Guideline—Second Edition

M29-A3 QG—Personal Protection in the Laboratory Quick Guide

M35-A—Abbreviated Identification of Bacteria and Yeast; Approved Guideline

M47-A—Principles and Procedures for Blood Cultures; Approved Guideline

M47-A QG—Handling, Transport, and Storage of Specimens for Molecular Methods Quick Guide

M100-S18—Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement

Members \$465 Nonmembers \$995
You Save \$185 You Save \$345

Special Microbiology (SCM02)

Standards for susceptibility testing:

- ✓ Anaerobes
- ✓ Fungi
- ✓ Mycobacteria
- ✓ Nocardiae
- ✓ Aerobic Actinomycetes

Guidelines for culture and identification

- ✓ Mycobacteria
- ✓ Virus

M11-A7—Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard—Seventh Edition

M24-A—Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard

M27-A3—Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard—Third Edition

M27-S3—Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Third Informational Supplement

M38-A2—Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi; Approved Standard—Second Edition

M41-A—Viral Culture; Approved Guideline

M48-A—Laboratory Detection and Identification of Mycobacteria; Approved Guideline

Members \$295 Nonmembers \$645
You Save \$125 You Save \$275

General Susceptibility Testing (SCM03)

Guidance for microbiologists performing routine susceptibility testing

- ✓ Disk and dilution testing procedures
- ✓ Interpretive tables for antimicrobial susceptibility tests
- ✓ Safety precautions

M02-A9—Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard—Ninth Edition

M07-A7—Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard—Seventh Edition

M29-A3 QG—Personal Protection in the Laboratory Quick Guide

M39-A2—Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline—Second Edition

M45-A—Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline

M100-S18—Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement

M100 Wallchart, AST QC Quick Guides, M2 and M7 Tables 1 and 1A Quick Guides (AST Bundle)

Members \$450 Nonmembers \$950
You Save \$195 You Save \$360

Anaerobic Antimicrobial and Antifungal Susceptibility Testing (SCM04)

Standards for performing susceptibility testing of:

- ✓ Anaerobic bacteria
- ✓ Yeast
- ✓ Filamentous fungi

M11-A7—Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard—Seventh Edition

M27-A3—Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard—Third Edition

M27-S3—Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Third Informational Supplement

M38-A2—Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi; Approved Standard—Second Edition

M44-A—Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guideline

Members \$220 Nonmembers \$490
You Save \$90 You Save \$210

Mycobacteria—Detection, Identification, and Susceptibility Testing (SCM05)

Guidance for Mycobacteria:

- ✓ Detection
- ✓ Identification
- ✓ Susceptibility Testing

M24-A—Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard

M48-A—Laboratory Detection and Identification of Mycobacteria; Approved Guideline

M48-A QG—Laboratory Detection and Identification of Mycobacteria Quick Guide

Members \$110 Nonmembers \$240
You Save \$45 You Save \$100

Development, Evaluation, and Application of Nucleic Acid-Based Testing for Infectious Diseases (SCM06)

DNA Target Sequencing for classification of:

- ✓ Bacteria
- ✓ Fungi

MM03-A2—Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline—Second Edition

MM09-A—Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline

MM10-A—Genotyping for Infectious Diseases: Identification and Characterization; Approved Guideline

MM18-A—Interpretive Criteria for Identification of Bacteria and Fungi by DNA Target Sequencing; Approved Guideline

M29-A3 QG—Personal Protection in the Laboratory Quick Guide

Members \$175 Nonmembers \$355
You Save \$75 You Save \$145

Veterinary Microbiology—Animals (SCM07)

Guidance for the veterinary professional on:

- ✓ Susceptibility testing
- ✓ Quality control of veterinary antimicrobial agents
- ✓ Parasite detection in feces
- ✓ Personal protection in the laboratory

M29-A3 QG—Personal Protection in the Laboratory Quick Guide

M31-A3—Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals; Approved Standard—Third Edition

M37-A3—Development of *In Vitro* Susceptibility Testing Criteria and Quality Control Parameters for Veterinary Antimicrobial Agents; Approved Guideline—Third Edition

Members \$95 Nonmembers \$185
You Save \$35 You Save \$75

Veterinary Microbiology—Aquatic Animals (SCM08)

Guides the veterinary and aquaculture professionals on:

- ✓ Personal protection in the laboratory
- ✓ Antimicrobial disk susceptibility testing
- ✓ Broth dilution susceptibility testing of bacteria

M29-A3 QG—Personal Protection in the Laboratory Quick Guide

M42-A—Methods for Antimicrobial Disk Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline

M49-A—Methods for Broth Dilution Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline

Members \$95 Nonmembers \$185
You Save \$35 You Save \$75

Laboratory Practices—Accreditation Preparedness (SCQ01)

This companion series to *Essentials for Verifying Test Performance—Accreditation Preparedness (SCQ2)* can be used to prepare for and meet regulatory requirements.

Provides information on:

- ✓ Statistical quality control
- ✓ Continuous quality improvement
- ✓ Proficiency testing to improve laboratory quality
- ✓ Laboratory documentation

GP02-A5—Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition

GP21-A2—Training and Competence Assessment; Approved Guideline—Second Edition

GP22-A2—Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition

GP26-A3—Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition

GP27-A2—Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition

GP29-A—Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline

GP32-A—Management of Nonconforming Laboratory Events; Approved Guideline

HS01-A2—A Quality Management System Model for Health Care; Approved Guideline—Second Edition

ISO 15189—Medical laboratories—Particular requirements for quality and competence

Members \$575 Nonmembers \$1115
You Save \$170 You Save \$380

Essentials for Verifying Test Performance—Accreditation Preparedness (SCQ02)

These documents can assist the clinical laboratory in meeting regulatory requirements.

Verify that test performance complies with laboratory practice requirements:

- ✓ Evaluation of Qualitative Tests
- ✓ Preliminary Evaluation of Quantitative Tests
- ✓ Linearity
- ✓ Interference
- ✓ Precision and Trueness
- ✓ Trueness [bias]
- ✓ Limit of Detection
- ✓ Total Error
- ✓ Quality Control

C24-A3—Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition

EP6-A—Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

EP7-A2—Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition

EP9-A2—Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition

EP10-A3—Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline—Third Edition

EP12-A2—User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition

EP15-A2—User Verification of Performance for Precision and Trueness; Approved Guideline—Second Edition

EP17-A—Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline

EP21-A—Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline

Members \$395 Nonmembers \$870
You Save \$170 You Save \$290

Hemostasis—Collection, Processing, and Analysis (SCH01)

Proper specimen collection, transport, and analysis:

- ✓ Fibrinogen detection
- ✓ PT and PTT testing
- ✓ Von Willebrand and ristocetin cofactor activity

- ✓ INR validation

- ✓ Coagulometer evaluation and validation

H21-A5—Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition

H21-A5 QG—Collection, Handling, Transport, and Storage for Hemostasis Quick Guide

H30-A2—Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline—Second Edition

H47-A2—One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline—Second Edition

H51-A—Assays of von Willebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline

H54-A—Procedures for Validation of INR and Local Calibration of PT/INR Systems; Approved Guideline

H57-A—Protocol for the Evaluation, Validation, and Implementation of Coagulometers; Approved Guideline

M29-A3 QG—Personal Protection in the Laboratory Quick Guide

Serves as a handy resource in the laboratory for all you need to know about hand hygiene and barrier protection.

Members \$270 Nonmembers \$560
You Save \$115 You Save \$240

Phlebotomy Collection (SCH02)

This training tool can be used in continuing education in health care facilities, and as an instructional aid in phlebotomy training programs.

Provides correct methods of obtaining blood specimens:

- ✓ Order of draw
- ✓ Blood culture collection
- ✓ Capillary collection
- ✓ Filter paper collection

H03-A6—Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition

H03-A6 QG—Quality Venipuncture Quick Guide

H04-A5—Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Fifth Edition

H04-A5 QG—Technique for Skin Puncture Quick Guide

LA04-A5—Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fifth Edition

LA04-A5 QG—Set of Two Newborn Screening Quick Guides

M29-A3 QG—Personal Protection in the Laboratory Quick Guide

M47-A—Principles and Procedures for Blood Cultures; Approved Guideline

Members \$235 Nonmembers \$495
You Save \$95 You Save \$195

Two Options for Economical Access to CLSI Documents

- Less than \$15 per document for Members
- Less than \$30 per document for Nonmembers

Electronic Subscription Service

The complete library of CLSI documents at your fingertips.

- Easily view and/or download all approved- and proposed-level standards and guidelines, electronic archived documents, supplements, and reports from the current inventory of available documents.
- Browse this dynamic, online resource that is continuously updated as new documents become available.

New this year:

- Improved search features enable users to search relevant topic areas and key words to easily find relevant documents.

Access to this password-protected site is based on the number of users. The subscription service starts at \$2,750 for a single user, with the additional fee based on the number of users.

Nonmember organizations can now purchase the Electronic Subscription Service starting at \$5,000.



Infobase™ 2008

This user-friendly searchable CD-ROM includes over 180 CLSI standards and guidelines for medical testing best practices.*

Includes Approved- and Proposed-Level Documents With Convenient Search Capabilities

- Includes all approved- AND proposed-level documents published through 31 December 2007;
- Features enhanced search capabilities to quickly and easily search titles, key words, and abstracts or the full document text; and
- Searches for relevant text within multiple documents using sophisticated linking capabilities.

Single-Site Price**

Members \$2,750

(Members who previously purchased the 2007 version of the Infobase \$1,500)

Nonmembers \$4,000

LAN Price***

If you already have the Infobase, you may purchase an LAN license for an additional \$1,000.

Multiple-Site LAN Price

\$1,500 per additional site (CD-ROM included for each site)

Discounts are available for organizations with more than three sites.

Shipping/Handling (flat rates)

Within North America \$10

Outside North America \$35

Publications obtained from this system are copyrighted and protected by United States law and international treaties. To view a complete copyright and licensing agreement for this product, visit www.clsi.org and go to the Shop section.

*Internet access required for search capabilities.

**Single site is for one workstation or stand-alone computer.

***LAN refers to local area network for multiple users at one site.

For more information, call CLSI at +610.688.0100 or e-mail us at customerservice@clsi.org.

New Documents and Products

Proposed standard or guideline = document made available for review and comment in order to achieve consensus so that an approved consensus document can be distributed for use to the health care community.

Approved standard or guideline = document has achieved consensus within the health care community.

ANTIFUNGAL SUSCEPTIBILITY TESTING

Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Guideline—Third Edition (M27-A3) April 2008

This standard addresses the selection and preparation of antifungal agents; implementation and interpretation of test procedures; and quality control requirements for susceptibility testing of yeasts that cause invasive fungal infections.

Members \$60 Nonmembers \$120

Chairholder: John H. Rex, MD, FACP
AstraZeneca

Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Third Informational Supplement (M27-S3) April 2008

This supplemental table provides updated QC ranges and interpretive criteria for broth microdilution testing for CLSI document M27-A3—Reference Methods for Broth Dilution Antifungal Susceptibility Testing of Yeasts. Two charts are laminated for easy posting.

Members \$15 Nonmembers \$35

Chairholder: John H. Rex, MD, FACP
AstraZeneca

Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi; Approved Standard—Second Edition (M38-A2) April 2008

This document addresses the selection of antifungal agents; preparation of antifungal stock solutions and dilutions for testing; implementation and interpretation of test procedures; and quality control requirements for susceptibility testing of filamentous fungi (moulds) that cause invasive fungal infections.

Members \$60 Nonmembers \$120

John H. Rex, MD, FACP
AstraZeneca

CHEMISTRY

Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Proposed Guideline—Third Edition (C28-P3) March 2008

This document provides guidance for determining reference values and reference intervals for quantitative clinical laboratory tests.

Members \$65 Nonmembers \$130

Chairholder: Gary L. Horowitz, MD
Beth Israel Deaconess Medical Center

Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline (C54-A) May 2008

This document provides guidance on how to verify comparability of quantitative laboratory results for individual patients within a health care system.

Members \$60 Nonmembers \$125

Chairholder: Christopher M. Lehman, MD
University of Utah Health Sciences Center

COAGULATION (HEMOSTASIS)

One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline—Second Edition (H47-A2) May 2008

This document provides guidelines for performing the PT and APTT tests in the clinical laboratory, for reporting results, and for identifying sources of error.

Members \$60 Nonmembers \$120

Chairholder: Richard A. Marljar, PhD
Oklahoma City VA Medical Center

IMMUNOLOGY

Clinical Evaluation of Immunoassays; Approved Guideline—Second Edition (I/LA21-A2) June 2008

This document addresses the need for clinical evaluation of new immunoassays and new applications of existing assays, as well as multiple assay formats and their uses. As a guide to designing and executing a clinical evaluation, this document will aid developers of "in-house" assays for institutional use, developers of assays used for monitoring pharmacologic effects of new drugs or biologics, and clinical and regulatory personnel responsible for commercializing products.

Members \$60 Nonmembers \$120

Chairholder: Marilyn M. Lightfoote, MD, PhD
FDA Center for Devices and Radiological Health

LABORATORY INFORMATION SYSTEMS (LIS)

Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition (LIS01-A2) April 2008

This document describes the electronic transmission of digital information between clinical laboratory instruments (those that measure one or more parameters from one or multiple samples) and computer systems (those that are configured to accept instrument results for further processing, storage, reporting, or manipulation).

Members \$65 Nonmembers \$130

Chairholder: David Chou, MD
University of Washington Medical Center

MICROBIOLOGY

Laboratory Detection and Identification of Mycobacteria; Approved Guideline (M48-A) May 2008

This document provides guidance to clinical mycobacteriology laboratories on the most optimum approach for the diagnosis of mycobacterial infections.

Members \$85 Nonmembers \$200

Chairholder: Betty (Betz) A. Forbes, PhD,
D(ABMM)
Medical College of Virginia

Promoting Excellence in Laboratory Performance: CLSI and CAP Provide Tools to Improve Health Care Worldwide

CLSI documents are referenced in the College of American Pathologists (CAP) Laboratory Accreditation Program Inspection Checklists and serve as key resources in establishing laboratory practices that ensure continuous compliance with accreditation requirements.

Stay Compliant.

CAP checklists are updated regularly to include CLSI's standards, guidelines, and other documents as references. Make sure your library is up to date with the latest versions of these documents. Explore, at a glance, the CLSI documents referenced in CAP checklists. Visit www.clsi.org under Resources to view a matrix that crosswalks the CAP checklists with current versions of CLSI documents.

Maximize the quality, efficiency, and effectiveness of your services by utilizing CLSI's expert guidance:

- Build quality
- Improve patient care
- Reduce risk
- Save time
- Cut costs

MOLECULAR METHODS

Verification and Validation of Multiplex Nucleic Acid Assays; Approved Guideline (MM17-A) March 2008

This guideline provides recommendations for analytic verification and validation of multiplex assays, as well as a review of different types of biologic and synthetic reference materials.

Members \$60 Nonmembers \$120

*Co-Chairholders: Jean Amos Wilson, PhD, FACMG Sequenom, Inc.
Michael A. Zoccoli, PhD
Celera*

Interpretive Criteria for Microorganism Identification of Bacteria and Fungi by DNA Target Sequencing; Approved Guideline (MM18-A) April 2008

Sequencing of DNA targets of cultured isolates provides a quantitative metric within which to perceive microbial diversity, and can serve as the basis to identify microorganisms. This document is an effort to catalyze the entry of molecular microbiology into clinical usage by establishing interpretive criteria for microorganism identification.

Members \$60 Nonmembers \$120

*Chairholder: Cathy A. Petti, MD
University of Utah Medical Center*

POINT-OF-CARE TESTING

Implementation Guide of POCT1 for Health Care Providers; Approved Guideline (POCT02-A) May 2008

This document identifies and describes the particular features that a POCT1-compliant device should ideally have. These features are divided into obligatory and desirable categories. Key terms are identified and the most frequent use cases are presented. The guideline thus gives the health care provider or end user a practical basis for establishing a list of features or questions to be addressed by the vendor of a compliant device.

Members \$50 Nonmembers \$100

*Chairholder: Patrick J. St. Louis, PhD, DipCC
Gamma-Dynacare Medical Laboratories*

Performance Metrics for Continuous Interstitial Glucose Monitoring; Proposed Guideline (POCT05-P) March 2008

This document provides consensus guidelines for health care professionals, IVD and medical device manufacturers, and regulatory agencies on how continuous glucose monitor (CGM) data should be: 1) presented; 2) compared between devices; and 3) compared between measurement technologies.

Members \$60 Nonmembers \$120

*Chairholder: David Klonoff, MD, FACP
Mills-Peninsula Health Services*

Guidelines for Comparison of Glucose Methodologies That Use Different Sample Types; Proposed Guideline (POCT06-P) July 2008

This guideline provides information to assist the clinical and point-of-care staff in result comparisons of glucose tests.

Members \$60 Nonmembers \$120

*Chairholder: Mary C. Coyle, MS, MT(ASCP)
Roche Diagnostics Corporation*

QUALITY ASSURANCE (QUALITY CONTROL AND PROFICIENCY TESTING)

Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline—Second Edition (GP29-A2) July 2008

This document offers methods to assess test performance when proficiency testing (PT) is not available; these methods include examples with statistical analyses.

This document is intended for use by laboratory managers and testing personnel in traditional clinical laboratories as well as in point-of-care and bedside testing environments.

Members \$60 Nonmembers \$120

*Chairholder: Stephen J. Sarewitz, MD
Valley Medical Center*

SPECIMEN COLLECTION AND HANDLING

Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Sixth Edition (H04-A6) June 2008

This document provides a technique for the collection of diagnostic capillary blood specimens, including recommendations for collection sites and specimen handling and identification. Specifications for disposable devices used to collect, process, and transfer diagnostic capillary blood specimens are also included.

Members \$60 Nonmembers \$120

*Chairholder: Dennis J. Ernst, MT(ASCP)
Center for Phlebotomy Education*

Technique for Skin Puncture Quick Guide (H04-A6 QG) June 2008

Includes every step in the skin puncture procedure from patient preparation to specimen collection and container labeling. Additional laminated sheets can be purchased separately in sets of 10.

Members \$10 Nonmembers \$20

Platelet Function Testing by Aggregometry; Approved Guideline (H58-A) June 2008

This document provides concrete, standard procedures for using aggregometry to assess platelet function in patient specimens with the intent to achieve greater uniformity of results.

Members \$60 Nonmembers \$120

*Chairholder: Douglas J. Christie, PhD, FAHA
Siemens Medical Solutions Diagnostics*



Stay Compliant
 Numerous CLSI documents are referenced in the College of American Pathologists (CAP) Accreditation Program Inspection Checklist and serve as key resources in satisfying its requirements. Visit www.clsi.org under Resources to view a matrix that crosswalks the CAP checklists with CLSI documents.

Quality Management System



The fundamentals for implementing a quality management system in the clinical laboratory in one easy-to-use resource

A specialty portfolio, with tabs for quick references, showcases the implementation of all 12 Quality System Essentials (QSEs).

It includes:

- **PowerPoint** – Slideshow introduces the CLSI concept of quality management and how *The Key to Quality* can assist in implementing a quality management system.
- **Forms and Templates** – Practical examples and “how to” details, including ready-to-use forms and easy-to-implement templates for each of the 12 QSEs.
- **Cross-References** – A guide to the interrelated elements of the quality management system approaches from CLSI, ISO, CAP, and other organizations.
- **Flowcharts** – Symbols to help you create your own systematic flowcharts and process documents.
- **Checklists** – A compilation of self-assessment checklists to determine the effectiveness of implementation, and to monitor and guide quality improvements.
- **CD-ROM** – Useful presentation for orienting staff to quality systems, as well as representative examples, checklists, and flowcharting tools in an electronic format.

Members \$295 Nonmembers \$495 (K2Q)



Add the new *The Key to Quality* Checklists to your laboratory quality system portfolio.

A series of 12 handy-reference checklists, available in tablet format, which focus on laboratory quality system essentials to ensure you are documenting, implementing, and monitoring best-practice laboratory procedures and performance to facilitate compliance and accreditation.

12 Key to Quality Checklists* (CKQSEALL)

- Documents and Records (CK QSE 1)**
- Organization (CK QSE 2)**
- Personnel (CK QSE 3)**
- Equipment (CK QSE 4)**
- Purchasing and Inventory (CK QSE 5)**
- Process Control (CK QSE 6)**
- Information Management (CK QSE 7)**
- Occurrence Management (CK QSE 8)**
- Assessments—External and Internal (CK QSE 9)**
- Process Improvement (CK QSE 10)**
- Customer Service (CK QSE 11)**
- Facilities and Safety (CK QSE 12)**

The price for each tablet checklist is:

Members \$15 Nonmembers \$30



*not included in *The Key to Quality*.

Bundle *The Key to Quality* binder with two CLSI documents for greater savings. (K2Q PKG)

The Key to Quality + *A Quality Management System Model for Healthcare (HS01-A2)* + *Application of a Quality Management System Model for Laboratory Services (GP26-A3)*

A Quality Management System Model for Healthcare; Approved Guideline—Second Edition (HS01-A2)

Provides a structure for a comprehensive, systematic approach to build quality into a health care service's processes, assess the service's performance, and implement quality improvements.

Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition (GP26-A3)

Describes the clinical laboratory's path of workflow and provides information for laboratory operations that assist the laboratory in improving its processes and meeting regulatory and accreditation requirements.

Package Price:

Members \$395 Nonmembers \$745

Projects in Development

For more information and to participate as a volunteer, visit www.clsi.org.

ANTIMICROBIAL SUSCEPTIBILITY TESTING

Method for Antifungal Disk Diffusion Susceptibility Testing of Filamentous Fungi (M51)

This document will provide guidance on how to perform an agar diffusion disk method for susceptibility testing of filamentous fungi, making this testing more readily available to the clinical laboratory.

Chairholder: Ana EspineIngraff, PhD,
VCU Medical Center

IMMUNOLOGY

Verification of Automated Devices for Immuno-hematologic Testing (I/LA33)

This guideline addresses the verification issues peculiar to automated immuno-hematology devices and present challenges for choosing reference methods and determining the limits of detection during the verification routine.

Chairholder: Katherine Appleton Downes, MD
University Hospital of Cleveland

LABORATORY

Accuracy in Patient Identification (GP33)

This guideline will describe the essential elements of any system, manual or electronic, for patient identification. It addresses criteria for selecting a patient identification system appropriate for a particular health care venue, comprehensive program design and implementation, as well as validation and monitoring of programs to help a provider validate its patient effectiveness.

Chairholder: Sheila M. Woodcock, MBA, FCSMLS(D)
QSE Consulting

Verification of Evacuated Blood Collection Tubes (GP34)

This guideline will provide step-by-step recommendations to conduct this type of device validation, and guidance for evaluating the acceptability/compatibility of the various blood collection devices for clinical performance across all laboratory disciplines.

Chairholder: Nancy Dubrowny, MS, MT(ASCP)SC
BD Preanalytical Systems

METHOD EVALUATION

Presentation of Manufacturer's Risk Mitigation Information for Users of In Vitro Diagnostic Devices (EP22)

This document provides guidance to manufacturers on the establishment and disclosure of information they may choose to share with users regarding the scope and effectiveness of risk mitigation features, and recommended user interventions intended to prevent the production or release of incorrect patient test results.

Chairholder: Greg Cooper, CLS, MHA
Bio-Rad Laboratories, Inc.

Laboratory Quality Control Based on Risk Management (EP23)

This document describes how a user can integrate manufacturer's risk mitigation information with the unique characteristics of their environment to develop effective quality control protocols for *in vitro* diagnostic devices.

Chairholder: James H. Nichols, PhD, DABCC, FACB
Baystate Medical Center

Evaluation of Stability of In Vitro Diagnostic Method Products (EP25)

This guidance document will provide information to manufacturers of IVD methods for the development of shelf life and in-use stability claims.

Chairholder: James F. Pierson-Perry
Siemens Medical Solutions Diagnostics

Evaluating Between Reagent Lot Variation (EP26)

This document will outline a statistically straightforward, quality approach for evaluating quality control patient shifts between reagent lots.

Chairholder: George S. Cembrowski, MD, PhD
University of Alberta Hospital

How to Construct an Error Grid for Diagnostic Assays (EP27)

This document will explain how to construct error grids for any diagnostic assay, with focus on both the region that should include most (95%) of the data—the acceptable result region; and the region(s) that should include (0%) of the data—the erroneous result region.

Chairholder: Jan S. Krouwer, PhD
Krouwer Consulting

MICROBIOLOGY/MOLECULAR METHODS

Screening for Methicillin-Resistant *Staphylococcus aureus*: Principles, Practices, and Potential Problems (X07)

This report will describe the characteristics of methicillin-resistant *Staphylococcus aureus* (MRSA) isolates, methods of detecting MRSA in clinical samples, surveillance cultures, and other potential reservoirs of MRSA; epidemiologic issues surrounding the spread of MRSA isolates in health care and other settings; interventions to halt transmission of MRSA; and public health aspects of MRSA transmission.

Co-Chairholders: Cassandra Salgado, MD, MS
Medical University of South Carolina and
Fred C. Tenover, PhD, ABMM
Centers for Disease Control and Prevention

These projects are in development; they are not available for purchase at this time.

NEWBORN SCREENING

Newborn Screening Guidelines for Premature and/or Sick Newborns (I/LA31)

This guideline will address best practices for Neonatal Intensive Care Unit (NICU) personnel, as well as primary health care providers, and laboratory and follow-up personnel to provide all NICU infants with valid NBS within a reasonable amount of time.

Co-Chairholders: Julie Miller, BS
Nebraska Department of Health & Human Services
Judith Tuerck, RN, MS
Oregon State Public Health Laboratory

Newborn Screening by Tandem Mass Spectrometry (I/LA32)

This guideline is designed to guide and teach newborn screening laboratory personnel in the daily use of tandem mass spectrometry for the detection of metabolic disorders.

Chairholder: Gary L. Hoffman
Wisconsin State Laboratory of Hygiene

POINT-OF-CARE TESTING

Quality Management Procedures: Systematic Approaches to Reducing Errors at the Point of Care (POCT07)

This guideline will provide POCT laboratory sites with a framework of potential sources of error, corresponding performance indicators, and suggested solutions or metrics to address each analytical phase of testing.

Chairholder: Diana DeHoyos, MS, MT(ASCP)
The University of Texas Medical Branch

Quality Practices in Noninstrumented Testing: A Comprehensive Instructional Guideline (POCT08)

This guideline will provide an overview of important considerations when comparing POCT devices and will include a draft checklist of criteria, which users of the document can employ as a starting point for selecting a new device for clinical use.

Chairholder: Diana DeHoyos, MS, MT(ASCP)
The University of Texas Medical Branch

Selection Criteria for POCT Devices (POCT09)

This guideline will provide an overview of important considerations when comparing POCT devices and will include a draft checklist of criteria which users of the document can employ as a starting point for selecting a new device for clinical use.

Chairholder: Marcia L. Zucker, PhD
Response Biomedical Corporation

QUALITY MANAGEMENT SYSTEMS

Development and Use of Quality Indicators for Processing Improvement and Monitoring Laboratory Quality (GP35)

This document will provide guidance on development of quality indicators, and their use in the medical laboratory.

Chairholder: Michael A. Noble, MD, FRCP(C)
University of British Columbia

Become a Member of CLSI

CLSI offers a wide range of membership choices designed to meet every organization's goals, activities, needs, and resources.

Organizations become CLSI members to:

- Receive a member discount for all products—up to a 50% savings off of nonmember prices
- Save money by receiving standards and guidelines as a member benefit
- Participate in the voluntary consensus process and represent your organization's perspectives

Associate Active Membership is open to medical clinics, physician office laboratories, or hospital-affiliated or hospital-based laboratories.

Associate Active Membership Benefits	Level 1	Level 2	Level 3	Level 4
Member discount for all products (up to 50% savings off nonmember price)	✓	✓	✓	✓
Choose 5 documents		✓		
Choose 10 documents			✓	
Receive all proposed and approved documents published in a membership year.				✓
Vote on consensus documents distributed during a membership year.				✓
Option to save \$50 on dues by selecting electronic downloading of documents.		✓	✓	✓
Annual membership dues.	\$350	\$550	\$750	\$1,300

**Does not include ISO documents, reports, electronic products, or other nonconsensus products.*

Active Membership is open to government agencies; manufacturers, independent or commercial laboratories, suppliers, or startup companies; professional, clinical, or trade associations; or consulting firms. Active membership dues vary based on the type of organization with dues starting at \$2,300.

Participation enables you to influence the development of consensus documents by openly presenting your organization's needs and perspectives on issues, and having this input considered deliberately and fairly within the consensus process. Active members receive one or two delegates who administer voting.

Education Membership is for formally organized academic-based or hospital-based education programs concerned with the primary education of professionals involved in medical testing. Education membership dues are \$300 a year and include eight documents a year.

Contact CLSI today to find out what member level is right for your organization, and start saving on standards and guidelines that will help you increase the quality of your health care testing.

Also, Become a Member of US Technical Advisory Group (TAG) to ISO/TC 212

For organizations within the United States, there is the opportunity to participate in the ANSI-Accredited US Technical Advisory Group (TAG) to ISO/TC 212, Clinical laboratory testing and *in vitro* diagnostic test systems, administered by CLSI. A US TAG is the only mechanism through which US organizations and individuals can participate in and influence ISO standards development on a particular topic. Please contact CLSI for more information.

How to Order

NOTE:

MULTIPLE-COPY DISCOUNTS

Discounts for multiple copies of the same title are offered as follows:

# COPIES	PRICE PER COPY
1 - 5	Full price
6 - 10	5% discount
11 - 20	15% discount
21 - 99	25% discount

For even greater discounts on larger quantities, contact:

Customer Service
+610.688.0100
customerservice@clsi.org

If your country is on the World Bank or Global AIDS Program list, or if you are conducting training in these areas, contact customerservice@clsi.org for pricing.

ORDER BY MAIL

Complete the form on page 11 and mail with payment or purchase order to:

Clinical and Laboratory Standards Institute
940 West Valley Road, Suite 1400
Wayne, PA 19087-1898 USA

ORDER BY PHONE: +610.688.0100 OR TOLL-FREE +877.447.1888

Save time by calling us to place your order. Please have your credit card number handy. **We do not accept purchase orders over the phone. Purchase orders must be faxed or mailed.**

ORDER BY FAX: +610.688.0700

When you order by FAX, please do **not** send an additional hard copy by mail. Please include member number to receive member pricing

ORDER VIA OUR WEBSITE: WWW.CLSI.ORG

VISA, MasterCard, American Express, or Discover accepted.

ORDER VIA WIRE TRANSFER:

Commerce Bank, Valley Forge Office
100 East Swedesford Road, Devon, PA 19333 USA
Bank Routing Number (ABA) 031201360
Account number 360967061

SHIPPING/HANDLING

Within North America: add 10% (min. \$7.50). **Outside North America:** International Surface (allow one week for delivery), add 35% (min. \$10); International Express (1-3 day delivery), add 45% (min. \$10). No shipping charge for electronic documents.

FOREIGN CURRENCY

Please contact CLSI for an exchange rate quotation.
All prices are quoted in US currency.

Express Shipping*	2-Day	Standard (overnight)	Priority (early morning)
1-3 documents	\$11	\$16	\$23
4-6 documents	\$14	\$19	\$26
7-10 documents	\$16	\$21	\$28
Specialty Collections	\$15	\$20	\$28
Library	\$40	\$75	\$100

*The express charge is in addition to the regular shipping and handling charges.

Order Form

See order instructions and pricing information on previous page

Bill to: (Please Print)

Name: _____
 Organization: _____
 Address: _____
 City: _____ State/Province: _____
 Zip/Postal Code: _____ Country: _____
 Telephone: _____ FAX: _____
 E-mail: _____

I would not like to receive printed versions of any promotions.

Ship to If different than Bill to (Please Print):

Name: _____
 Organization: _____
 Address: _____
 City: _____ State/Province: _____
 Zip/Postal Code: _____ Country: _____
 Telephone: _____ FAX: _____
 E-mail: _____

Organizational website: _____

Qty.	Order Code	Title	Price		Total
			Member	Nonmbr.	

Prices subject to change.

Membership Status:

- Member Organization
 Nonmember Organization

Account or Member #: _____

Method of payment (Check one):

- Payment enclosed in full.
 VISA MasterCard AMEX Discover

Card Number: _____

Signature: _____

Exp. Date (Mo./Yr.): _____

- Send me an invoice. Purchase order accompanies this order form.
 Full payment is due upon receipt of invoice.

Federal Tax ID #23-7089361

Orders Outside North America

Orders outside North America require a prepayment, a check drawn on a US bank, or credit card.



Subtotal
 Shipping/handling add 10% (min \$7.50)
 Express shipping
 Foreign currency (Amount quoted)
 Sales tax (PA shipments add 6%)
 Total

MAIL TO:

Clinical and Laboratory Standards Institute
 940 West Valley Road, Suite 1400
 Wayne, PA 19087-1898 USA

ORDER BY PHONE: +610.688.0100

ORDER BY FAX: +610.688.0700

WEBSITE: www.clsi.org

E-MAIL: customerservice@cls.org

To place an order using our toll-free order line, dial 877.447.1888. To call toll-free from outside the US and Canada, first dial your country's Direct Access Number, available on the AT&T website at www.att.com.

Thank you for your order!

**Please photocopy this form
 for multiple orders.**

CATSUPP-0508



Nonprofit Org.
U.S. Postage
PAID
Permit No. 50
Downingtown, PA

940 West Valley Road, Suite 1400
Wayne, PA 19087-1898 USA
Phone: +610.688.0100
Fax: +610.688.0700
E-mail: customerservice@clsi.org
Website: www.clsi.org

If you receive a duplicate copy of this catalog, please pass it on to a coworker.

COME VISIT US...



American Society for Microbiology (ASM) 108th General Meeting

1-5 June 2008
Boston, Massachusetts USA
CLSI Booth #447

2008 CLSI and APHL Teleconference Series

Optimize the use of CLSI documents in your laboratory. For more information on available course dates, and to register, visit www.clsi.org.

For more information,
check out our website at
WWW.CLSI.ORG
or contact CLSI
at +610.688.0100 or
toll free at +877.447.1888.

Special Thanks to Sustaining Members

Become a Sustaining Member
Gold: \$10,000 contribution
Silver: \$5,000 contribution

GOLD LEVEL

National Institute of Standards and Technology (NIST)
Ortho-Clinical Diagnostics, Inc.
Siemens Healthcare Diagnostics Inc.

SILVER LEVEL

Abbott
American Association for Clinical Chemistry
AstraZeneca Pharmaceuticals
Bayer Corporation
BD
Beckman Coulter, Inc.
bioMérieux Inc.
College of American Pathologists
GlaxoSmithKline
Pfizer Inc
Roche Diagnostics, Inc.