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**Advancing Quality in Healthcare Testing**

# New Quality Management System



*The Key to Quality* is universal and can be applied to any operation, from simple to complex, and regardless of where you reside on the quality spectrum.

- Streamline laboratory processes
- Enhance employee potential
- Meet accreditation requirements
- Reduce risk of medical errors
- Improve patient care

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



With the increased emphasis on education and communication in the regulatory and accreditation process, laboratories must boost their efforts to meet requirements and provide the highest level of quality patient care. Now, CLSI has taken its premier quality systems protocols, as well as elements of ISO 15189, to create an easy-to-use product for laboratory professionals: *The Key to Quality*. It's a specialty portfolio, with tabs for quick references, that showcases the implementation of all 12 Quality System Essentials (QSEs).

## **The Key to Quality (K2Q) includes:**

- **Essentials** – PowerPoint introduction to the CLSI concept of quality management and how *The Key to Quality* can assist in implementing a quality management system.
- **Examples** – Practical samples 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.
- **Evaluations** – A compilation of self-assessment checklists to determine the effectiveness of implementation, and to monitor and guide quality improvements.
- **CD-ROM** – A slide-show presentation useful for orienting staff to quality systems, as well as representative examples, checklists, and flowcharting tools in an electronic format.

**Members \$295 Nonmembers \$495**

## **Bundle Documents for Greater Savings (K2Q Plus)**

*The Key to Quality + A Quality Management System Model for Health Care (HS1-A2) + Application of a Quality Management System Model for Laboratory Services (GP26-A3)*

### **A Quality Management System Model for Health Care; Approved Guideline—Second Edition (HS1-A2)**

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

The document includes 12 “quality system essentials” or “QSEs,” which provide information on the processes and procedures needed to meet customer, regulatory, and accreditation requirements, and to provide for the highest level of patient safety.

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

This guideline describes the clinical laboratory's path of workflow and provides information for laboratory operations that will assist the laboratory in improving its processes and meeting government and accreditation requirements.

#### **Package Price:**

**Members \$395 Nonmembers \$745**

# Infobase™ 2007

This user-friendly searchable\* CD-ROM includes 173 CLSI standards and guidelines for medical testing best practices.

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- Includes all approved- AND proposed-level documents published through 31 December 2006;
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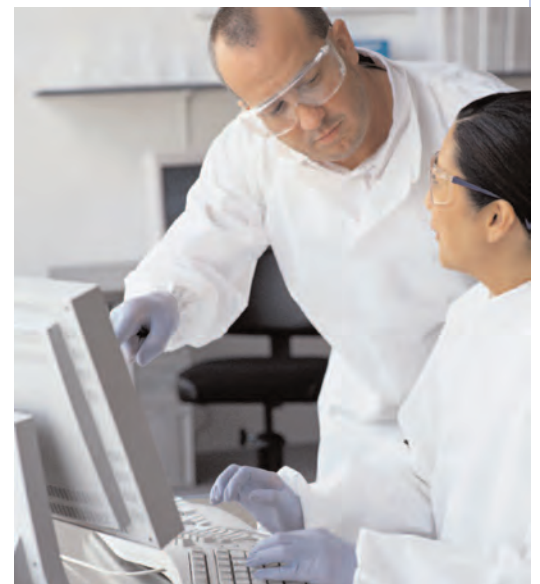
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# Standards and Guidelines

**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 healthcare community.

**Approved standard or guideline** = document has achieved consensus within the healthcare community.

\*American National Standards have been approved by the American National Standards Institute (ANSI). Clinical and Laboratory Standards Institute submits selected standards as candidate American National Standards when such status will enhance their national or international usefulness.

## CLINICAL CHEMISTRY AND TOXICOLOGY

### Analysis of Body Fluids in Clinical Chemistry; Approved Guideline (C49-A) April 2007

This document provides guidance for the application of widely available measurement procedures for testing body fluids and for reporting and interpreting those results. It emphasizes defining the common clinical situations for this use; acceptable practice for measuring analytes without extended method verification for abnormal body fluid; influence of biologic and analytic variation on interpretation of results; and variability in comparing results between different instrument manufacturers. This document does not consider serum, plasma, whole blood, or fluids for which assays typically have performance claims in the measurement procedure documentation.

**Members \$65 Nonmembers \$125**

Chairholder: Richard A. McPherson, MD  
Virginia Commonwealth University

### Mass Spectrometry in the Clinical Laboratory: General Principles and Guidelines; Proposed Guideline (C50-P) February 2007

This guideline provides a general understanding of mass spectrometry and the principles that dictate its application in the clinical laboratory. It includes guidance, references, and quality assurance markers that will assist with the implementation and correct operation of a mass spectrometry (MS) system for its many applications. Information on maintaining optimum performance, approaches to ensuring accurate and precise mass measurement, verification of methods, quality control of assays within and between instruments, instrument troubleshooting, sample preparation, interpretation of results, and limitations of the technology are included.

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Chairholder: Donald H. Chace, PhD  
Pediatrix Screening Inc.

### Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline—Second Edition (C52-A2) May 2007

This guideline addresses drug testing in the clinical laboratory, both for clinical and forensic purposes, and pertains to both drugs of abuse and other drugs normally encountered and analyzed by hospital laboratories. The guideline discusses the preanalytical, analytical, and postanalytical considerations for specimen collection, methods of analysis, quality assurance, and the reporting and interpretation of results.

**Members \$60 Nonmembers \$120**

Chairholder: David A. Armbruster, PhD,  
DABCC, FACB  
Abbott Laboratories

## GENERAL LABORATORY PRACTICES

### Laboratory Design; Approved Guideline—Second Edition (GP18-A2) February 2007

This document provides a foundation of information about laboratory design elements and guidance to help define the issues to be considered when designing a clinical laboratory.

**Members \$50 Nonmembers \$100**

Chairholder: Karen K. Mortland, AIA, MT(ASCP)  
Mortland Planning & Design, Inc.

### Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition (GP27-A2) February 2007

This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool.

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Chairholder: Daniel W. Tholen, MS  
American Association for Laboratory Accreditation

### Laboratory Instrument Implementation, Verification, and Maintenance; Proposed Guideline (GP31-P) April 2007

This guideline provides information about assessing instrument performance and function from the time of instrument purchase to the routine performance of clinical testing. A CLSI-CAP joint project.

**Members \$95 Nonmembers \$150**

Chairholder: William J. Castellani, MD  
Penn State Hershey Medical Center

### Management of Nonconforming Laboratory Events; Proposed Guideline (GP32-P) April 2007

This guideline provides an outline and the content for developing a program to manage a healthcare service's nonconforming events that is based on the principles of quality management and patient safety.

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Chairholder: Lucia M. Berte, MA, MT(ASCP),  
SBB, DLM:CGA(ASQ)CQMgr  
Quality Systems Consultant

## IMMUNOLOGY AND LIGAND ASSAY

### Immunoassay Interference by Endogenous Antibodies; Proposed Guideline (I/LA30-P) March 2007

The guideline discusses the nature and causes of interfering antibodies as well as their effects on immunoassays and mechanisms by which interference occurs. Methods to identify and characterize the interferences will be addressed along with assessment of methods used to eliminate interference.

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Chairholder: Joan H. Howanitz, MD  
SUNY Brooklyn

## HEMATOLOGY

### Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition (H20-A2) January 2007

This document is a reference method for the evaluation of automated differential counters, based on the visual differential count.

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Chairholder: John A. Koepke, MD  
Durham, NC

### Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline—Second Edition (H42-A2) April 2007

This document provides guidance for the immunophenotypic analysis of non-neoplastic lymphocytes by immunofluorescence-based flow cytometry; sample and instrument quality control; and precautions for acquisition of data from lymphocytes.

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Chairholder: Jan W. Gratama, MD, PhD  
Erasmus University Medical Center-Daniel  
Den Hoed

### Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline—Second Edition (H43-A2) April 2007

This document provides performance guidelines for the immunophenotypic analysis of neoplastic hematolymphoid cells using immunofluorescence-based flow cytometry; for sample and instrument quality control; and precautions for acquisition of data from neoplastic hematolymphoid cells.

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Chairholder: Maryalice Stetler-Stevenson, MD, PhD  
National Institutes of Health

## MICROBIOLOGY

## Antimicrobial Susceptibility Testing Updates

**Performance Standards for Antimicrobial Susceptibility Testing; Seventeenth Informational Supplement (M100-S17) January 2007**

The latest recommendations for detecting emerging resistance. Includes updated tables from CLSI's newest disk (M2-A9) susceptibility and MIC (M7-A7) testing standards.

**Updates:**

- new disk diffusion and MIC interpretive criteria for colistin and polymyxin B;
- new antimicrobial agents and QC ranges;
- preparation of stock solutions for antimicrobial agents provided with activity expressed as units;
- added information on the development of resistance and testing of repeat isolates;
- modified recommendations for testing and reporting of designated clusters of agents with similar interpretive results and clinical efficacy;
- recommendations for reporting critical results; and
- suggestions for verification and confirmation of susceptibility testing results for *Neisseria meningitidis*.

**New feature:** Three pages of adhesive index tabs, which can be inserted for quick access to each table in the document.

**Members \$90 Nonmembers \$225**

Chairholder: Matthew A. Wikler, MD, MBA, FIDSA  
Mpx Pharmaceuticals, Inc.

**Buy M2 and M7  
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**Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard—Ninth Edition (M2-A9) 2006**

The latest methods for disk susceptibility testing, with updated tables for interpretive zone diameters. Includes M100-S17.

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Chairholder: Matthew A. Wikler, MD, MBA, FIDSA  
Peninsula Pharmaceuticals, Inc.

**Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard—Seventh Edition (M7-A7) 2006**

Standard broth dilution (macrodilution and microdilution) and agar dilution techniques for measuring the *in vitro* susceptibility of bacteria to antimicrobial agents. Includes M100-S17.

**Members \$150 Nonmembers \$275**

Chairholder: Matthew A. Wikler, MD, MBA, FIDSA  
Peninsula Pharmaceuticals, Inc.

**Antimicrobial Susceptibility Testing Searchable CD-ROM\* January 2007**

Includes all of the M100-S17 tables for the Disk Diffusion (M2) and Aerobic Dilution (M7) susceptibility testing documents. The corresponding methodology documents, M2-A9 and M7-A7, are also included on the CD-ROM so you can easily link from document to document. For those with Internet access, search capabilities give this convenient CD added flexibility.

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\*Internet access required for search capabilities.

**AST QC Quick Guides (AST-QC Quick) January 2007**

The ultimate "cheat sheet" to quality control (QC) for AST. Easy-to-use flow-charts guide you through daily QC testing for both disk diffusion and aerobic dilution. Once required daily QC has been documented, users can convert to weekly QC with a flip of a page. Also included are guides to QC testing frequency and troubleshooting. 8 1/2 x 11 laminated sheets on convenient detachable ring. Based on current editions of M2, M7, and M100.

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**M2 Tables 1 and 1A Quick Guides (M02 Quick Guides) January 2007**

The M2 Tables 1 and 1A quick guides provide suggested groupings of antimicrobial agents that should be considered for routine testing and reporting by clinical laboratories. These guides serve as a useful reference for laboratories seeking to meet requirements for proficiency testing and accreditation. Laminated and detachable for convenient, shared use in the laboratory. Based on current editions of M2 and M100.

**Members \$45 Nonmembers \$120**

**M7 Tables 1 and 1A Quick Guides (M07 Quick Guides) January 2007**

The M7 Tables 1 and 1A quick guides provide suggested groupings of antimicrobial agents that should be considered for routine testing and reporting by clinical laboratories. These guides serve as a useful reference for laboratories seeking to meet requirements for proficiency testing and accreditation. Laminated and detachable for convenient, shared use in the laboratory. Based on current editions of M7 and M100.

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**Wallchart—Glossary of Antimicrobial Terms and Abbreviations Wallchart: Seventeenth Informational Supplement (M100-S17 Wall) January 2007**

This wallchart (based on M100-S17) features important terminology (drug classes, subclasses, and dosage forms) for all antimicrobial agents featured in M100. This format serves as a handy reference for laboratorians in "speaking the language" when transmitting important clinical susceptibility information to the clinician. The chart also features a comprehensive listing of abbreviations used around the world to identify antimicrobials in *in vitro* diagnostic products, such as automated susceptibility test systems and antimicrobial agent disks.

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M2 and M7 Tables 1 and 1A Quick Guides  
(M02/M07 Quick Guides)

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

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

January 2007

American National Standard.\* This document provides reference methods for the determination of minimal inhibitory concentrations (MICs) of anaerobic bacteria by agar dilution and broth microdilution. THIS DOCUMENT IS COMPLETE WITH TABLES FOR AST OF ANAEROBIC BACTERIA UPDATED FOR 2007.

### Updates:

- new QC and interpretive criteria for Moxifloxacin;
- new QC strain *Clostridium difficile* with QC ranges for various antimicrobials agents;
- alternative methods for generating an anaerobic environment provided; and
- new antimicrobial agents and QC ranges to test for and report.

**Members \$90 Nonmembers \$225**

Chairholder: David W. Hecht, MD  
Loyola University Medical Center

## Principles and Procedures for Blood Cultures; Approved Guideline (M47-A) June 2007

This document provides recommendations for the collection, transport, and processing of blood cultures as well as guidance for the recovery of pathogens from blood specimens taken from patients who are suspected of having bacteremia or fungemia.

**Members \$60 Nonmembers \$120**

Chairholder: Michael L. Wilson, MD  
Denver Health Medical Center

## Laboratory Detection and Identification of Mycobacteria; Proposed Guideline (M48-P) February 2007

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



## MOLECULAR METHODS

### Molecular Methods for Bacterial Strain Typing; Approved Guideline (MM11-A) April 2007

This guideline examines the biology behind molecular strain typing and the process of characterizing and validating typing systems. The prevalent methods are described with particular attention to pulsed-field gel electrophoresis (PFGE) and multilocus sequence typing (MLST).

**Members \$65 Nonmembers \$150**

Chairholder: Robert D. Arbeit, MD  
Paratek Pharmaceuticals, Inc.

## POINT-OF-CARE TESTING

### Implementation Guide of POCT1 for Healthcare Providers; Proposed Guideline (POCT2-P) March 2007

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 healthcare 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

## 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 satisfying regulatory requirements.

### Stay Compliant.

CAP checklists are updated regularly to include CLSI's standards, guidelines, and other documents as references, but may not reflect the most current versions. 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](http://www.clsi.org) 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



The fundamentals for implementing all 12 Quality System Essentials (QSEs) for the clinical laboratory in one easy-to-use resource. (K2Q)

For more details, see page 2 or visit [www.clsi.org](http://www.clsi.org).



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## Projects in Development

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### Clinical Chemistry and Toxicology

#### Protocol for Establishment of Sample Stability in Clinical Chemistry and Toxicology (C55)

This document will provide recommendations on procedures that should be performed to characterize analyte stability in a serum matrix. Recommendations for this guideline will be limited to serum samples only, but will also highlight the difficulties and concerns for using other matrices, such as urine (precipitation) and plasma (anticoagulants and incomplete removal of fibrinogen), if extending stability studies to these matrices.

The document will also include guidelines for establishing sample stability testing designs, and it will also attempt to describe procedures that may not be published elsewhere.

Chairholder: Pennell C. Painter, PhD  
Dynacare Tennessee Laboratory

**NOTE:**

This is a project in development; it is not available for purchase at this time.



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**Membership in CLSI is the most effective way to participate in the voluntary consensus process. We offer a wide range of membership choices designed to meet every organization's goals, activities, needs and resources. You can self-select the level you want based on your requirements and budget. We also give you the option to switch levels as your needs change when you renew your annual membership. Listed below are the membership categories.**

**Active Members** include professional, clinical, and trade associations; government agencies; medical testing consultants; start-ups; and large and small companies in the medical testing and *in vitro* diagnostic products fields. These organizations participate through representation on committees and voting on technical and administrative issues in the development and evaluation of standards and guidelines. There are two membership options for government, trade associations, and professional societies. Broad interest members are organizations that have interests related to a significant number of CLSI standards projects and/or whose mission is focused on patient testing. Selected interest organizations do not meet the criteria outlined above.

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**Education Members** are formally organized education programs concerned with the primary education of professionals involved with medical testing. The membership provides an important communication network allowing educators to seek solutions to educational issues from other professionals in the field.

All membership levels provide your organization with standards, guidelines, and related products at a very reasonable cost. CLSI standards and guidelines can:

- be incorporated in procedure and training manuals;
- help you prepare for inspection;
- increase the effectiveness of your quality control procedures;
- reduce risk of medical errors; and
- improve patient health care.

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### 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 or electronically. 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.

### ORDER VIA OUR WEBSITE: WWW.CLSI.ORG

Use this site for ordering standards, guidelines, videotapes, and applications with VISA, MasterCard, American Express, or Discover.

### 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).

### FOREIGN CURRENCY

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

Express Shipping*	2-Day	Standard	Priority
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

Membership Identification #: \_\_\_\_\_

## 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 MUST be faxed or mailed.

Full payment is due upon receipt of invoice.

Federal Tax ID #23-7089361

## Orders Outside North America

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

Shipping/handling (See previous page)

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**

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**WEBSITE: [www.clsi.org](http://www.clsi.org)**

**E-MAIL: [customerservice@clsi.org](mailto:customerservice@clsi.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](http://www.att.com).

*Thank you for your order!*

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

**CATSUPP-0507**



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22–24 May 2007  
Toronto, Ontario, Canada  
**CLSI Booth #102**

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15–19 July 2007  
San Diego, California USA

### **47th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC™)**

17–19 September 2007  
Chicago, Illinois USA  
**CLSI Booth #453**

For more information,  
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