CATALOG 1 • 2006

CLINICAL AND LABORATORY STANDARDS INSTITUTE™

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Advancing Quality in Healthcare Testing

CLINICAL AND LABORATORY STANDARDS INSTITUTE ™

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PLUS NEW DOCUMENTS

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PLUS

Specialty Collections

Purchase documents in a convenient, bound collection.

CLSI Specialty Collections provide related standards and guidelines in key subject areas. The purchase price reflects a significant savings over the combined list price of the individual documents for both member and nonmember organizations.

Please refer to the collections below for a listing of the individual document titles, individual purchase prices, and the locations in the catalog for descriptions. CLSI Specialty Collections are also available for purchase electronically at www.clsi.org.

Evaluation Protocols (SC1-L)

This volume provides help in choosing the right instruments and analytical methods for desired procedures, which is critical to the efficient operation of clinical laboratories. Included are procedures for evaluating precision, linearity, stated performance characteristics, and guidelines on clinical sensitivity and specificity.

EP5-A2 – Precision (page 9)
Members $85 Nonmembers $200
EP6-A – Linearity (page 9)
Members $60 Nonmembers $120
EP7-A2 – Interference (page 9)
Members $85 Nonmembers $200
EP9-A2 – Comparison of Methods (page 9)
Members $60 Nonmembers $120
EP10-A2 – Preliminary Evaluation (page 9)
Members $60 Nonmembers $120
EP12-A – Qualitative Test Performance (page 9)
Members $60 Nonmembers $120
EP14-A2 – Evaluation of Matrix Effects (page 9)
Members $60 Nonmembers $120
EP15-A2 – Verification of Performance (page 9)
Members $60 Nonmembers $120
EP17-A – Limits of Detection and Quantitation (page 9)
Members $60 Nonmembers $120
GP10-A – Assessment of Tests (page 10)
Members $50 Nonmembers $100

Members $340 Nonmembers $645

Specimen Collection (SC2-L)

SC2-L can be used to establish collection criteria for laboratory procedure manuals, patient care units, and phlebotomy team training manuals. This convenient reference includes standards with procedures for collection of venous, arterial, and capillary blood specimens, as well as single and timed urine specimens.

GP16-A2 – Routine Urinalysis (page 10)
Members $60 Nonmembers $120
H3-A5 – Venipuncture (page 11)
Members $85 Nonmembers $200
H4-A5 – Capillary (page 11)
Members $60 Nonmembers $120
H11-A4 – Arterial Collection (page 9)
Members $60 Nonmembers $120
H21-A4 – Coagulation Specimens (page 11)
Members $85 Nonmembers $200
M15-A – Parasitic Diseases (page 14)
Members $60 Nonmembers $120
M28-A2 – Fecal Parasitology (page 14)
Members $60 Nonmembers $120
M29-A3 – Protection of Laboratory Workers (page 14)
Members $100 Nonmembers $200

Members $280 Nonmembers $570

General Hematology (SC7-L)

Guidance for the laboratorian performing routine hematology procedures. Manual methodologies for determining the erythrocyte sedimentation rate and packed cell volume are included. The collection also provides recommendations for specimen processing; immunophenotyping lymphocytes and counting reticulocytes by flow cytometry; and a reference method for automated differential counting.

H2-A4 – Erythrocyte Sedimentation Rate (ESR) (page 11)
Members $50 Nonmembers $100
H7-A3 – Microhematocrit (page 11)
Members $60 Nonmembers $120
H18-A3 – Handling and Processing (page 11)
Members $60 Nonmembers $120
H20-A – Differential Count (page 11)
Members $50 Nonmembers $100
H42-A – Flow Cytometry (page 12)
Members $50 Nonmembers $100
H44-A2 – Reticulocyte Counting (page 12)
Members $50 Nonmembers $100
H45-A2 – Bleeding Time Test (page 12)
Members $50 Nonmembers $100

Members $190 Nonmembers $400

Laboratory Safety (SC10-L)

The universally applicable staple of any clinical laboratory. The protocols to ensure a safe environment for employees. Because of its wide application, we recommend that this specialty collection be purchased as a complement to any or all of the other collections.

GP5-A2 – Laboratory Waste (page 10)
Members $60 Nonmembers $120
GP17-A2 – Laboratory Safety (page 10)
Members $60 Nonmembers $120
M29-A3 – Protection of Laboratory Workers (page 14)
Members $100 Nonmembers $200
X3-R – Needlestick (page 26)
Members $65 Nonmembers $150
ISO 15190 – Medical laboratories – Requirements for safety (page 18)
Members $150 Nonmembers $200

Members $175 Nonmembers $400

CLIA Collection (SC11-L)

The documents in this collection include a group of four standards and guidelines selected because of their value in helping laboratorians adapt the CLIA '88 requirements to their settings. These documents include principles and definitions of internal quality control; preliminary evaluation of test methods; preparation of technical procedure manuals; and quality assurance procedures for culture media.

C24-A2 – Quality Control (page 8)
Members $60 Nonmembers $120
EP10-A2 – Preliminary Evaluation (page 9)
Members $60 Nonmembers $120
GP2-A4 – Procedure Manuals* (page 10)
Members $85 Nonmembers $200
M22-A3 – Media QC (page 14)
Members $60 Nonmembers $150

Members $150 Nonmembers $300

Coagulation (SC12-L)

Procedures for collecting, transporting, and storing blood samples for coagulation testing, and reporting of test results and precautions. This collection contains general guidelines for performing the one-stage PT, APTT, and fibrinogen assay in the clinical laboratory.

H21-A4 – Coagulation Specimens (page 11)
Members $85 Nonmembers $200
H30-A2 – Fibrinogen (page 11)
Members $60 Nonmembers $120
H47-A – One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test (page 12)
Members $50 Nonmembers $100

Members $85 Nonmembers $185

Laboratory Information Systems (SC14-L)

This collection of former ASTM standards provides diverse information relating to clinical laboratory computer systems. Includes documents of general interest as reference sources, as well as others of primary importance to instrument manufacturers.

LIS1-A – Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems (page 7)
Members $65 Nonmembers $120
LIS2-A2 – Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems (page 7)
Members $65 Nonmembers $120
LIS3-A – Standard Guide for Selection of a Clinical Laboratory Information Management System (page 7)
Members $60 Nonmembers $120

LIS4-A – Standard Guide for Documentation of Clinical Laboratory Computer Systems (page 7)
Members $60 Nonmembers $120
LIS5-A – Standard Specification for Transferring Clinical Observations Between Independent Computer Systems (page 7)
Members $60 Nonmembers $120
LIS6-A – Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems (page 7)
Members $60 Nonmembers $120
LIS7-A – Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory (page 7)
Members $60 Nonmembers $120
LIS8-A – Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems (page 7)
Members $60 Nonmembers $120
LIS9-A – Standard Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures (page 7)
Members $60 Nonmembers $120

Members $250 Nonmembers $500

Technical Laboratory Management (SC15-L)

A series of documents specifically designed to assist in technical laboratory management. These standards and guidelines include requirements for reagent grade water and methods to monitor water quality; principles and definitions of internal quality control; protocol for determining reference intervals; recommendations on writing procedure manuals; procedure for the handling and transport of specimens; and guidelines for handling and processing specimens.
C3-P4 – Reagent Water (page 8)
Members $60 Nonmembers $120
C24-A2 – Quality Control (page 8)
Members $60 Nonmembers $120
C28-A2 – Reference Intervals (page 8)
Members $60 Nonmembers $120
EP10-A2 – Preliminary Evaluation (page 9)
Members $60 Nonmembers $120
GP2-A4 – Procedure Manuals* (page 10)
Members $85 Nonmembers $200
H18-A3 – Handling and Processing (page 11)
Members $60 Nonmembers $120

Members $185 Nonmembers $410

Administrative Laboratory Management (SC16-L)

This collection is designed to assist laboratory managers in effective laboratory operations and training. These standards and guidelines include recommendations for inventory control systems; choosing a referral laboratory; establishing a workable cost accounting system; designing a laboratory; developing new data management systems; developing a training verification program; and implementing a quality system model.
GP9-A – Referral Laboratory (page 10)
Members $50 Nonmembers $100
GP11-A – Cost Accounting (page 10)
Members $60 Nonmembers $120
GP18-A – Laboratory Design (page 10)
Members $50 Nonmembers $100
GP19-A2 – Laboratory Instruments and Data Management Systems (page 7)
Members $60 Nonmembers $120
GP21-A2 – Training and Competence Assessment (page 10)
Members $50 Nonmembers $100
GP26-A3 – Laboratory Services (page 10)
Members $85 Nonmembers $200

Members $200 Nonmembers $460

Point-of-Care Testing (SC17-L)

The guidelines in this collection provide recommendations used in establishing a point-of-care testing (POCT) program, as well as POCT procedures including quality control and calibration; skin puncture; ancillary glucose testing; and the design, preparation, and maintenance of technical procedure manuals.
AST2-A – *In Vitro* Diagnostic (page 16)
Members $60 Nonmembers $150
AST3-A – Wellness Testing (page 16)
Members $50 Nonmembers $100
C30-A2 – Blood Glucose Testing (page 8)
Members $60 Nonmembers $120
GP2-A4 – Procedure Manuals* (page 10)
Members $85 Nonmembers $200
GP16-A2 – Routine Urinalysis (page 10)
Members $60 Nonmembers $120
H4-A5 – Capillary (page 11)
Members $60 Nonmembers $120
POCT1-A – Connectivity (page 16)
Members $100 Nonmembers $150

Members $265 Nonmembers $545

Body Fluid and Tissue Specimen Collection (SC18-L)

Guidelines for the collection of specimens for sweat testing, Papanicolaou smears, routine urinalysis, and fine needle aspiration biopsy (FNAB). Specimen transport requirements, container specifications, and safety are also included.
GP15-A2 – Papanicolaou Technique (page 10)
Members $60 Nonmembers $120
GP20-A2 – Fine Needle Techniques (page 10)
Members $50 Nonmembers $100
GP23-A – Nongynecologic Specimens (page 10)
Members $60 Nonmembers $120
M29-A3 – Protection of Laboratory Workers (page 14)
Members $100 Nonmembers $200

Members $150 Nonmembers $280

Blood Collection Centers (SC20-L)

This specialty collection brings together documents that deal with the collection, processing, and handling of blood specimens for laboratory testing, and is useful for establishing a blood collection and processing training manual. Includes guidance on specimen collection by venipuncture and skin puncture, along with safety guidelines and needlestick and sharps prevention.
H3-A5 – Venipuncture (page 11)
Members $85 Nonmembers $200
H4-A5 – Capillary (page 11)
Members $60 Nonmembers $120
H18-A3 – Handling and Processing (page 11)
Members $60 Nonmembers $120
H21-A4 – Coagulation Specimens (page 11)
Members $85 Nonmembers $200
LA4-A4 – Newborn Screening (page 13)
Members $60 Nonmembers $120
M29-A3 – Protection of Laboratory Workers (page 14)
Members $100 Nonmembers $200
X3-R – Needlestick (page 26)
Members $65 Nonmembers $150

Members $240 Nonmembers $480

Susceptibility Testing (SC21-L)

All susceptibility testing consensus documents in a single volume for the microbiology laboratory. The collection addresses disk, dilution, and bactericidal testing procedures, including interpretive tables for antimicrobial, antifungal, and veterinary susceptibility tests.
M2-A9 – Disk Susceptibility Tests (page 13)
Members $150 Nonmembers $275
M7-A7 – Aerobic Susceptibility Testing (page 13)
Members $150 Nonmembers $275
M11-A6 – Anaerobic Susceptibility Testing (page 13)
Members $85 Nonmembers $200
M21-A – Serum Bactericidal Test (page 14)
Members $60 Nonmembers $120
M23-A2 – Test Development (page 14)
Members $150 Nonmembers $250
M26-A – Bactericidal Activity (page 14)
Members $60 Nonmembers $120
M27-A2 – Antifungal Reference Method (page 14)
Members $60 Nonmembers $120
M31-A2 – Veterinary Antimicrobial (page 14)
Members $60 Nonmembers $120
M38-A – Filamentous Fungi (page 15)
Members $60 Nonmembers $120
M39-A2 – Analysis and Presentation (page 15)
Members $60 Nonmembers $120
M100-S16 – Susceptibility Testing Supplement (page 13)

Members $465 Nonmembers $880

General Microbiology (SC22-L)

A new collection providing guidance for the microbiologist performing aerobic or anaerobic antimicrobial susceptibility testing and routine quality assurance of commercially prepared culture media. Guidance is included for protection from infectious diseases transmitted by blood, body fluids, and tissue and instrument biohazards.
M2-A9 – Disk Susceptibility Tests (page 13)
Members $150 Nonmembers $275
M7-A7 – Aerobic Susceptibility Testing (page 13)
Members $150 Nonmembers $275
M11-A6 – Anaerobic Susceptibility Testing (page 13)
Members $85 Nonmembers $200
M15-A – Parasitic Diseases (page 14)
Members $60 Nonmembers $120
M22-A3 – Media QC (page 14)
Members $60 Nonmembers $150
M29-A3 – Protection of Laboratory Workers (page 14)
Members $100 Nonmembers $200
M35-A – Rapid Identification (page 14)
Members $60 Nonmembers $120
M100-S16 – Susceptibility Testing Supplement (page 13)

Members $375 Nonmembers $725

Flow Cytometry (SC23-L)

A series of documents specifically designed to guide laboratorians in flow cytometric analyses. Includes recommendations for the performance of immunophenotyping leukemias and lymphomas, and performance of reticulocyte counting by flow cytometry, as well as guidelines for establishing quality assurance procedures for immunophenotyping lymphocytes.

H42-A – Flow Cytometry (page 12)
Members $50 Nonmembers $100
H43-A – Leukemia Immunophenotyping (page 12)
Members $50 Nonmembers $100
H44-A2 – Reticulocyte Counting (page 12)
Members $50 Nonmembers $100
H52-A – Fetal Red Cell Detection (page 12)
Members $60 Nonmembers $120
M29-A3 – Protection of Laboratory Workers (page 14)
Members $100 Nonmembers $200

Members $160 Nonmembers $330

Quality Series (SC24-L)

This collection contains a series of documents intended for healthcare managers who wish to improve their programs through quality management activities. Guidelines are for statistical quality control, training verification, continuous quality improvement, a quality system model, and using proficiency testing.

ISO 15189 – Medical laboratories – Particular requirements for quality and competence (page 18)
Members $150 Nonmembers $200
GP2-A4 – Procedure Manuals* (page 10)
Members $85 Nonmembers $200
GP21-A2 – Training and Competence Assessment (page 10)
Members $50 Nonmembers $100
GP22-A2 – Continuous Quality Improvement (page 10)
Members $85 Nonmembers $200
GP26-A3 – Laboratory Services (page 10)
Members $85 Nonmembers $200
HS1-A2 – A Quality Management System Model for Health Care (page 6)
Members $85 Nonmembers $200
HS4-A – Respiratory Services (page 6)
Members $50 Nonmembers $100
HS5-A – Medical Imaging Services (page 6)
Members $50 Nonmembers $100
HS10-A – Inpatient Medication Use (page 6)
Members $50 Nonmembers $100

Members $370 Nonmembers $730

Molecular Methods (SC25-L)

The documents in this collection provide guidance on the performance, quality assurance, and application of various molecular methods and formats used for detection of genetic diseases/ disorders; gene rearrangements and translocations; and infectious diseases.

MM1-A – Molecular Genetics (page 15)
Members $60 Nonmembers $120
MM2-A2 – Molecular Hematology (page 15)
Members $60 Nonmembers $120
MM3-A2 – Molecular Microbiology (page 15)
Members $60 Nonmembers $120
MM4-A – Immunocytochemistry (page 15)
Members $60 Nonmembers $120
MM5-A – PCR-Based Assays (page 15)
Members $60 Nonmembers $120
MM6-A – Infectious Diseases (page 16)
Members $60 Nonmembers $120
MM7-A – FISH Methods for Medical Genetics (page 16)
Members $60 Nonmembers $120
MM9-A – Nucleic Acid Sequencing (page 16)
Members $60 Nonmembers $120
MM14-A – Proficiency Testing (page 16)
Members $60 Nonmembers $120

Members $270 Nonmembers $570

Veterinary Microbiology (SC26-L)

This collection provides guidance for the veterinary professional on quality assurance procedures for culture media; protection from infectious diseases transmitted by blood, body fluids, and tissue; veterinary susceptibility tests; and detection of antibodies that cause Lyme disease.

M22-A3 – Media QC (page 14)
Members $60 Nonmembers $150
M29-A3 – Protection of Laboratory Workers (page 14)
Members $100 Nonmembers $200
M31-A2 – Veterinary Antimicrobial Susceptibility Tests (page 14)
Members $60 Nonmembers $120
M34-A – Lyme Disease (page 14)
Members $60 Nonmembers $120
M37-A2 – Veterinary Test Development (page 15)
Members $60 Nonmembers $120
M42-P – Disk AST Aquatic Animals (page 15)
Members $60 Nonmembers $120
M49-P – Dilution AST Aquatic Animals (page 15)
Members $60 Nonmembers $120

Members $230 Nonmembers $450

Includes CD-ROM

Laboratory Automation (SC27-L)

This collection of interrelated automation standards was developed to allow customers (laboratories) and vendors to enjoy products that function together (with Plug-N-Play capabilities), and buyers and suppliers to agree on a format for laboratory automation systems.

AUTO1-A – Specimen Container/Specimen Carrier (page 6)
Members $50 Nonmembers $100
AUTO2-A2 – Specimen Identification (page 6)
Members $50 Nonmembers $100
AUTO3-A – Systems Communications (page 6)
Members $50 Nonmembers $100
AUTO4-A – Systems Status (page 6)
Members $50 Nonmembers $100
AUTO5-A – Electromechanical Interfaces (page 7)
Members $50 Nonmembers $100
GP18-A – Laboratory Design (page 10)
Members $50 Nonmembers $100
GP19-A2 – Laboratory Instruments and Data Management Systems (page 7)
Members $60 Nonmembers $120
POCT1-A – Connectivity (page 16)
Members $100 Nonmembers $150

Members $350 Nonmembers $650

Patient Assessment and Requisition (SC28-L)

This specialty collection is designed to provide information for respiratory service professionals and other healthcare practitioners responsible for the collection of samples for arterial blood gas and pH determination and related measurements. The documents in this collection focus on preanalyzed variables related to these measurements.

C31-A2 – Ionized Calcium (page 8)
Members $60 Nonmembers $120
C46-A – Blood Gas and pH Analysis (page 8)
Members $60 Nonmembers $120
GP15-A2 – Papanicolaou Technique (page 10)
Members $60 Nonmembers $120
H11-A4 – Arterial Collection (page 9)
Members $60 Nonmembers $120
LA4-A4 – Newborn Screening (page 13)
Members $60 Nonmembers $120

Member $150 Nonmember $320

Quality Basics (SC30-L)

This collection provides medical laboratories with specific tactics for implementing quality guidelines.

ISO 15189 – Medical laboratories – Particular requirements for quality and competence (page 18)
Members $150 Nonmembers $200
GP26-A3 – Laboratory Services (page 10)
Members $85 Nonmembers $200
HS1-A2 – A Quality Management System Model for Health Care (page 6)
Members $85 Nonmembers $200
GP22-A2 – Continuous Quality Improvement (page 10)
Members $85 Nonmembers $200

Members $190 Nonmembers $350

Regulatory Compliance (SC31-L)

This collection contains a series of documents that will help laboratories comply with regulatory requirements.

C24-A2 – Quality Control (page 8)
Members $60 Nonmembers $120
C28-A2 – Reference Intervals (page 8)
Members $60 Nonmembers $120
GP2-A4 – Procedure Manuals* (page 10)
Members $85 Nonmembers $200
GP22-A2 – Continuous Quality Improvement (page 10)
Members $85 Nonmembers $200
GP26-A3 – Laboratory Services (page 10)
Members $85 Nonmembers $200
GP27-A – Proficiency Testing (page 11)
Members $50 Nonmembers $100
H3-A5 – Venipuncture (page 11)
Members $85 Nonmembers $200
H21-A4 – Specimen Coagulation (page 11)
Members $85 Nonmembers $200
H47-A – One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test (page 12)
Members $50 Nonmembers $100
M22-A3 – Media QC (page 14)
Members $60 Nonmembers $150
M29-A3 – Protection of Laboratory Workers (page 14)
Members $100 Nonmembers $200

Members $375 Nonmembers $850

*For Specialty Collections SC11-L, SC15-L, SC24-L, and SC31-L, the revised edition, GP2-A5, *Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition*, will be sent for orders received after 1 March 2006.

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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.

Report = document that has not been subjected to consensus review and is released by the Board of Directors.

Reaffirmation = two-thirds majority approval of the full membership (abstentions excluded) of the area committee(s) decides that neither comments received nor any other reasons support any changes in the document.

FDA = The U.S. Food and Drug Administration (FDA) has evaluated and recognized these approved-level consensus standards for use in satisfying a regulatory requirement.

 = a document for national application.

** 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.*

HEALTHCARE SERVICES

A Quality Management System Model for Health Care; Approved Guideline – Second Edition (HS1-A2) *2004*

This document provides a model for healthcare services that will assist with implementation and maintenance of effective quality management systems. (See related publications HS4-A, HS5-A, HS10-A, and GP26-A2.)

Members $85 Nonmembers $200

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

Provider-Performed Microscopy Testing; Approved Guideline (HS2-A) *2003*

This guideline provides recommendations for provider-performed microscopy (PPM) procedures in settings outside the traditional clinical laboratory, such as physicians' offices, outpatient clinics, public health clinics, health maintenance organizations, and medical training programs. These consensus recommendations focus on producing accurate diagnostic information from microscopy procedures as an adjunct to clinical laboratory testing.

Members $50 Nonmembers $100

Chairholder: Mina L. Harkins, MT(ASCP)
Quest Diagnostics, Inc.

Pulse Oximetry; Approved Guideline (HS3-A) *2005*

Pulse oximetry is a widely used device for the clinical assessment of arterial oxygenation and pulse rate. The clinical applications, quality assessment, and limitations are discussed in this guideline.

Members $50 Nonmembers $100

Chairholder: Judy Dye, MA
University of Arizona Medical Center

Application of a Quality System Model for Respiratory Services; Approved Guideline (HS4-A) *2002*

This document provides a model for providers of respiratory services that will assist with implementation and maintenance of an effective quality system.

Members $50 Nonmembers $100

Chairholder: Susan Blonshine, RRT, RPFT, FAARC Tech Ed
This document is intended for use with HS1 when developing a quality system for the clinical laboratory.

Application of a Quality System Model for Medical Imaging Services; Approved Guideline (HS5-A) *2002*

This guideline provides the necessary background information and infrastructure to develop a quality system that defines a structure for a comprehensive, systematic approach to build quality into the imaging services processes, assess its performance, and implement quality improvements. Individual service areas, such as diagnostic radiology, CT, ultrasound, interventional radiology, magnetic resonance imaging (MRI), mammography, and nuclear medicine, will benefit from applying this model to their respective operations. To provide a practical example of how a quality system is developed and implemented, suggestions for diagnostic radiology are included.

Members $50 Nonmembers $100

Chairholder: Judy Dye, MA
University of Arizona Medical Center
This document is intended for use with HS1 when developing a quality system for the clinical laboratory.

Studies to Evaluate Patient Outcomes; Approved Guideline (HS6-A) *2004*

This guideline describes the essential issues in planning outcomes research including resources needed, formulating a research question, validity and sources of error, feasibility, and ethical issues; addresses the design and implementation of a patient outcomes research plan including study design, study subjects, measurements, interventions, and analysis; summarizes recommendations for reporting patient outcomes research; and includes definitions, references, and resources for those interested in planning, conducting, and using patient outcomes research.

Members $50 Nonmembers $100

Chairholder: D. Joe Boone, PhD
Centers for Disease Control and Prevention

Application of a Quality System Model for Inpatient Medication Use; Approved Guideline (HS10-A) *2004*

This document describes the path of workflow for inpatient medication use, which is defined as the sequential processes in preservice, service, and postservice activities that transform a physician's medication order into an administered medication. Pharmacy-specific information and examples for the path of workflow and quality system essentials are provided.

Members $50 Nonmembers $100

Chairholder: Steven P. Gray, MS, DAHCE, FAAHC
Superior Consultant Company

A Model for Managing Medical Device Alerts (Hazards and Recalls) for Healthcare Organizations; Approved Guideline (HS11-A) *2005*

NEW

This document provides a framework for healthcare delivery organizations to respond to externally generated notifications of medical device hazards and recalls while focusing on the quality constructs of process control, occurrence management, and process improvement.

Members $50 Nonmembers $100

Chairholder: Peggy Prinz Luebbert, MS, MT(ASCP), CHSP, CIC
Alegent Health

AUTOMATION AND INFORMATICS

Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard (AUTO1-A) *2000*

This document provides standards for the design and manufacture of specimen containers and carriers used for collecting and processing liquid samples, such as blood and urine, for clinical testing in laboratory automation systems.

Members $50 Nonmembers $100

FDA

Chairholder: Paul J. Orsulak, PhD
VA North Texas Health Care System

Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard – Second Edition (AUTO2-A2) *2005*

NEW

This standard defines the way bar-coded sample identification labels are applied to clinical specimen containers, documenting the form, placement, and content of bar-code labels on specimen container tubes used on clinical laboratory analyzers. AUTO2-A2 enables the production of reliable bar-coded symbols that are readable by any complying clinical laboratory analyzer and automation system.

Members $50 Nonmembers $100

Chairholder: Paul J. Mountain, MSc, MT(ASCP)

Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard (AUTO3-A) *2000*

This document provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements. ***AUTO3 has adapted and incorporated HL7 triggers, messages, and segments, with permission from Health Level Seven (HL7).***

Members $50 Nonmembers $100

FDA

Chairholder: Charles D. Hawker, PhD
ARUP Laboratories

Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard (AUTO4-A) *2001*

This document describes operational requirements, characteristics, and required information elements of clinical laboratory automation systems. This information is used to determine the status of a clinical specimen within the clinical laboratory automation system, as well as the status of the actual components of the clinical laboratory automation system.

Members $50 Nonmembers $100

FDA

Chairholder: Russell H. Tomar, MD
Cook County Hospital

Laboratory Automation: Electromechanical Interfaces; Approved Standard (AUTO5-A) *2001*

This document provides standards for the development of an electromechanical interface between instruments and specimen processing and handling devices used in automated laboratory testing procedures.

Members $50 **Nonmembers $100** FDA

Chairholder: Richard A. McPherson, MD
Medical College of Virginia Hospitals

Laboratory Automation: Data Content for Specimen Identification; Approved Standard (AUTO7-A) *2004*

This document provides specifications for the content of linear bar codes on specimen container tubes in the clinical laboratory and for use on laboratory automation systems.

Members $150 **Nonmembers $250** FDA

Chairholder: Randy R. Davis
Dade Behring Inc.

Protocols to Validate Laboratory Information Systems; Proposed Guideline (AUTO8-P) *2005*

This document provides guidance for developing a protocol for validation of the Laboratory Information System (LIS) as well as protocols for assessing the dependability of the LIS when storing, retrieving, and transmitting data.

Members $50 **Nonmembers $100**

Chairholder: Sandy Pearson, MT(ASCP)
Center for Medicare & Medicaid Services

Remote Access to Clinical Laboratory Diagnostic Devices via the Internet; Approved Standard (AUTO9-A) *2006*

AVAILABLE FEB. 2006

This document provides a standard communication protocol that will allow remote connections to laboratory devices, which can be used to monitor the instrument's subsystems to determine proper operation; collect diagnostic data for remote system troubleshooting; and collect data that would allow for electronic inventory management.

Members $50 **Nonmembers $100**

Chairholder: Randy R. Davis
Dade Behring Inc.

Autoverification of Clinical Laboratory Test Results; Proposed Guideline (AUTO10-P) *2006*

NEW

This document provides a new set of guidelines to take laboratorians beyond traditional autoverification to the next generation, allowing the use of more sophisticated algorithms to meet laboratory needs, as well as accurately reflecting the medical philosophy of the laboratory. AUTO10-P provides a framework for each laboratory to easily design, implement, validate, and customize rules based on the needs of its own patient population.

Members $50 **Nonmembers $100**

Chairholder: William Neeley, MD, FACP, DABCC
Detroit Medical Center University Laboratories

IT Security of *In Vitro* Diagnostic Instruments and Software Systems; Proposed Standard (AUTO11-P) *2006*

AVAILABLE FEB. 2006

This document provides technical and operational requirements as well as technical implementation guidelines related to security of IVD systems (devices, analytical instruments, data management systems, etc.) installed at a healthcare organization.

Members $50 **Nonmembers $100**

Chairholder: Andrzej J. Knafel, PhD
Roche Instrument Center AG

Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline – Second Edition (GP19-A2) *2003*

This document identifies important factors that designers and laboratory managers should consider when developing new software-driven systems and selecting software user interfaces. Also included are simple rules to help prepare validation protocols for assessing the functionality and dependability of software.

Members: $60 **Nonmembers: $120** FDA

Chairholder: Andrzej J. Knafel, PhD
Roche Instrument Center AG

Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems (LIS1-A) *2003*

This specification 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: $120** FDA

Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard – Second Edition (LIS2-A2) *2004*

This document covers the two-way digital transmission of remote requests and results between clinical laboratory instruments and information systems. It enables any two such systems to establish a logical link for communicating text to send result, request, or demographic information in a standardized and interpretable form.

Members $65 **Nonmembers $120** FDA

Chairholders: Rodney S. Markin, MD, PhD
University of Nebraska Medical Center, and
Andrzej J. Knafel, PhD
Roche Instrument Center AG

Standard Guide for Selection of a Clinical Laboratory Information Management System (LIS3-A) *2003*

This guide covers the selection, purchase, use, enhancement, and updating of computer technology supplied by a vendor as a complete system in the clinical laboratory. The purpose of the guide is to assist hospitals, clinics, and independent laboratories through the entire automation project in order to minimize the risks and maximize the benefits. It also includes checklists of items and design aids to be considered at each stage of planning to assist in carrying out the project.

Members: $60 **Nonmembers: $120** FDA

Standard Guide for Documentation of Clinical Laboratory Computer Systems (LIS4-A) *2003*

This guide covers documentation (defined as the information needed to install, use, maintain, or modify the system) for a computer system operating in a clinical laboratory.

Members: $60 **Nonmembers: $120** FDA

Standard Specification for Transferring Clinical Observations Between Independent Computer Systems (LIS5-A) *2003*

This specification details how clinical observations can be transferred between independent computer systems.

Members: $60 **Nonmembers: $120** FDA

Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems (LIS6-A) *2003*

This practice describes a system for collecting data, maintaining records, and reporting on the reliability of operating clinical laboratory computer systems. The reliability measure will be achieved by documenting the number, severity, cause, impact, and duration of the failures that a system experiences. This practice can be implemented with paper forms or computer records.

Members: $60 **Nonmembers: $120** FDA

Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory (LIS7-A) *2003*

This specification identifies the way bar-coded sample identification labels are applied to clinical specimen containers. It documents the form, placement, and content of bar-code labels on specimen tubes that are used on clinical laboratory analyzers. It enables Laboratory Information System vendors to produce reliable bar-coded symbols that are readable by any complying clinical laboratory analyzer vendor.

Members: $60 **Nonmembers: $120** FDA

Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems (LIS8-A) *2003*

This guide covers the capabilities needed for a logical structure of a Clinical Laboratory Information Management System (CLIMS). It was written so that both vendors/developers of CLIMS and laboratory managers would have a common understanding of the requirements and logical structure of a laboratory data system. This guide will also provide more uniformity in the way that requirements are expressed from one laboratory to another.

Members: $60 **Nonmembers: $120** FDA

Standard Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures (LIS9-A) *2003*

This guide covers the process of defining and documenting the capabilities, sources, and pathways of data exchange within a given network architecture of a Health Information Network (HIN) serving a set of constituents.

Members: $60 **Nonmembers: $120** FDA

Currently, the newly adopted LIS documents are not part of the member benefits package. As documents are revised through our consensus process, they will be distributed to members according to membership category.

CLINICAL CHEMISTRY AND TOXICOLOGY

Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline – Second Edition (AST4-A2) *2005*

This document contains guidelines for performance of point-of-care (POC) glucose monitoring systems that stress quality control, training, and administrative responsibility.

Members: $60 Nonmembers: $120

Chairholder: Louis J. Dunka, Jr., PhD, FACB
LifeScan, Inc.

Preparation and Testing of Reagent Water in the Clinical Laboratory; Proposed Guideline – Fourth Edition (C3-P4) *2005*

This document provides guidelines on water purified for clinical laboratory use; methods for monitoring water quality and testing for specific contaminants; and water system design considerations.

Members: $60 Nonmembers: $120

Chairholder: W. Gregory Miller, PhD
Virginia Commonwealth University

Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline – Second Edition (C24-A2) *1999*

This guideline provides definitions of analytical intervals; plans for quality control procedures; and guidance for quality control applications.

Members: $60 Nonmembers: $120 FDA

Chairholder: James O. Westgard, PhD
University of Wisconsin

How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline – Second Edition (C28-A2) *2000*

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

Members: $60 Nonmembers: $120 FDA

Chairholder: Basil T. Doumas, PhD
Medical College of Wisconsin

Standardization of Sodium and Potassium Ion-Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard – Second Edition (C29-A2) *2000*

REAFFIRMED JUNE 2003

This standard contains recommendations for the expression of results of ion-selective electrode measurement of sodium and potassium ion activities in undiluted serum, plasma, or whole blood in clinical practice.

Members: $60 Nonmembers: $120 FDA

Chairholder: Paul D'Orazio, PhD
Instrumentation Laboratory

Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Second Edition (C30-A2) *2002*

This document provides guidance for performing point-of-care blood glucose tests, with an emphasis on quality control, training, and administrative responsibility.

Members: $60 Nonmembers: $120

Chairholder: David B. Sacks, MD
Brigham and Women's Hospital and Harvard Medical School

Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling; Approved Guideline – Second Edition (C31-A2) *2001*

This document addresses preanalytical considerations – such as patient condition, specimen choice, collection, and handling – that can influence accuracy and clinical utility of ionized calcium measurements.

Members: $60 Nonmembers: $120 FDA

Chairholder: Paul D'Orazio, PhD
Instrumentation Laboratory

Sweat Testing: Sample Collection and Quantitative Analysis; Approved Guideline – Second Edition (C34-A2) *2000*

REAFFIRMED SEPT. 2005

This guideline describes sweat stimulation, collection, and the quantitative analysis of sweat chloride and sodium with an emphasis on avoiding evaporation and contamination. Quality control issues and possible sources of error associated with sweat testing are discussed.

Members: $60 Nonmembers: $120 FDA

Chairholder: Vicky A. LeGrys, DrA, MT(ASCP)
University of North Carolina School of Medicine

Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline (C37-A) *1999*

This guideline details procedures for the manufacture and evaluation of human serum pools for cholesterol measurement.

Members: $60 Nonmembers: $120 FDA

Chairholder: Gary L. Myers, PhD
Centers for Disease Control and Prevention

Control of Preanalytical Variation in Trace Element Determinations; Approved Guideline (C38-A) *1997*

This document contains guidelines for patient preparation, specimen collection, transport, and processing for the measurement of trace elements in a variety of biological matrices.

Members: $60 Nonmembers: $120

Chairholder: Gillian Lockitch, MD, FRCPC
British Columbia's Children's Hospital

A Designated Comparison Method for the Measurement of Ionized Calcium in Serum; Approved Standard (C39-A) *2000*

This document describes a designated comparison method to standardize the ionized calcium measurements made by ion-selective electrode (ISE) potentiometry. This system can be used to assign ionized calcium concentrations to a commercially available, serum-based material to improve the traceability and transferability of results for ionized calcium measurements in the clinical laboratory.

Members: $60 Nonmembers: $120 FDA

Co-Chairholders: Paul D'Orazio, PhD, Instrumentation Laboratory, and Gary A. Graham, PhD, DABCC, Ortho-Clinical Diagnostics

Analytical Procedures for the Determination of Lead in Blood and Urine; Approved Guideline (C40-A) *2001*

This document offers guidance for the measurement of lead in blood and urine, including specimen collection, measurement by GFAAS and ASV, quality assurance, and quality control.

Members: $60 Nonmembers: $120

Chairholder: Patrick J. Parsons, PhD, CChem, FRSC
New York State Department of Health

Erythrocyte Protoporphyrin Testing; Approved Guideline (C42-A) *1996*

REAFFIRMED SEPT. 2001

This document contains recommended guidelines for the measurement, reporting, and interpretation of erythrocyte protoporphyrin using hematofluorometric and extraction measurement methods.

Members $50 Nonmembers $100 FDA

Chairholder: Noel V. Stanton, MS
Wisconsin State Laboratory of Hygiene

Gas Chromatography/Mass Spectrometry (GC/MS) Confirmation of Drugs; Approved Guideline (C43-A) *2002*

This document provides guidance for establishing uniform practices necessary for producing quality data for quantitation and identification of a drug or drug metabolite using the GC/MS method; specific quality assurance criteria for maintaining and documenting optimal instrument performance are also presented.

Members: $60 Nonmembers: $120

Chairholder: Larry D. Bowers, PhD, DABCC
U.S. Anti-Doping Agency

Harmonization of Glycohemoglobin Measurements; Approved Guideline (C44-A) *2002*

This document describes an established program to harmonize glycohemoglobin (GHB) testing results among laboratories to a common, outcomes-based reference system and includes recommendations for the clinical application of harmonized GHB testing results.

Members: $60 Nonmembers: $120

Chairholder: David E. Goldstein, MD
University of Missouri School of Medicine

Measurement of Free Thyroid Hormones; Approved Guideline (C45-A) *2004*

This document addresses analytical and clinical validation of free (nonprotein-bound) thyroid hormone (FTH) measurement procedures. An NCCLS-IFCC joint project.

Members $60 Nonmembers $120

Chairholder: Linda Thienpont, PhD
University of Ghent

Blood Gas and pH Analysis and Related Measurements; Approved Guideline (C46-A) *2001*

*American National Standard.** This document provides clear definitions of the several quantities in current use, and provides a single source of information on appropriate specimen collection, preanalytical variables, calibration, and quality control for blood pH and gas analysis and related measurements.

Members: $60 Nonmembers: $120 FDA

Chairholder: W. Gregory Miller, PhD
Virginia Commonwealth University

Application of Biochemical Markers of Bone Turnover in the Assessment and Monitoring of Bone Diseases; Approved Guideline (C48-A) *2004*

Biochemical markers of bone turnover are increasingly used in clinical chemistry. This guideline provides information on how bone markers can be applied to facilitate and harmonize data interpretation and to help answer clinical questions in the area of bone diseases. An NCCLS-IFCC joint project.

Members $60 Nonmembers $120

Chairholder: Hubert Vesper, PhD
Centers for Disease Control and Prevention

Procedures for the Collection of Arterial Blood Specimens; Approved Standard – Fourth Edition (H11-A4) *2004*

*American National Standard.** This standard describes principles for collecting, handling, and transporting arterial blood specimens. The document is aimed at reducing collection hazards and ensuring integrity of the arterial specimen.

Members $60 Nonmembers $120

Chairholder: Susan Blonshine, BS, RRT, RPFT
Tech Ed/AARC

Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation; Approved Standard (H17-A) *1998*

This document provides methods for determining serum iron and total iron-binding capacity; and describes the measurement of serum iron concentration as well as the determination of the percent saturation of transferrin with iron.

Members: $60 Nonmembers: $120

Chairholder: Onno W. van Assendelft, MD, PhD
Centers for Disease Control and Prevention

Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline (T/DM6-A) *1997*

REAFFIRMED SEPT. 2002

This document provides technical and administrative guidance on laboratory procedures related to blood alcohol testing, including specimen collection, methods of analysis, quality assurance, and reporting of results.

Members $50 Nonmembers $100 FDA

Chairholder: Kurt M. Dubowski, PhD
University of Oklahoma

Urine Drug Testing in the Clinical Laboratory; Approved Guideline (T/DM8-A) *1999*

This guideline addresses the development of procedures for urine analysis to determine the presence of certain controlled substances. Specimen collection and processing, methods of analysis, quality assurance, and reporting of results are also described.

Members $50 Nonmembers $100

Chairholder: M. Jeffery Shoemaker, PhD
Pennsylvania Department of Health

EVALUATION PROTOCOLS

Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition (EP5-A2) *2004*

This document provides guidance for designing an experiment to evaluate the precision performance of quantitative measurement methods; recommendations on comparing the resulting precision estimates with manufacturer's precision performance claims and determining when such comparisons are valid; as well as manufacturer's guidelines for establishing claims.

Members $85 Nonmembers $200 FDA

Chairholder: Daniel W. Tholen, MS
Dan Tholen Statistical Services

Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (EP6-A) *2003*

This document provides guidance for characterizing the linearity of a method during a method evaluation; for checking linearity as part of routine quality assurance; and for determining and stating a manufacturer's claim for linear range.

Members: $60 Nonmembers: $120

Chairholder: Daniel W. Tholen, MS
Dan Tholen Statistical Services

Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition (EP7-A2) *2005*

NEW

This guideline outlines procedures for manufacturers to screen potentially interfering substances, quantify interference effects, and confirm interference in patient samples. Also describes procedures for clinical laboratories to verify interference claims, and to investigate discrepant results caused by unsuspected interfering substances. Includes background information on interference testing concepts, tables of recommended test concentrations for analytes and potential interference, and data collection and analysis worksheets.

Members $85 Nonmembers $200

Chairholder: Robert J. McEnroe, PhD
Roche Diagnostics Operations, Inc.

Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition (EP9-A2) *2002*

This document addresses procedures for determining the bias between two clinical methods, and the design of a method comparison experiment using split patient samples and data analysis.

Members: $60 Nonmembers: $120 FDA

Chairholder: Jan S. Krouwer, PhD
Krouwer Consulting

Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline – Second Edition (EP10-A2) *2002*

This guideline addresses experimental design and data analysis for preliminary evaluation of the performance of a measurement procedure or device. (See related publication GP10-A in General Laboratory Practices section.)

Members: $60 Nonmembers: $120 FDA

Chairholder: Jan S. Krouwer, PhD
Krouwer Consulting

User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline (EP12-A) *2002*

This document contains a protocol that optimizes the experimental design for the evaluation of qualitative tests, to better measure performance and provide a structured data analysis.

Members: $60 Nonmembers: $120 FDA

Chairholder: Larry W. Clark, MS
Bayer Corporation

Laboratory Statistics – Standard Deviation; A Report (EP13-R) *1995*

This report provides correct methods for calculating standard deviation and the means to test related software.

Members $60 Nonmembers $120

Chairholder: Allan Louderback, PhD
Clinical Chemistry Consultants

Evaluation of Matrix Effects; Approved Guideline – Second Edition (EP14-A2) *2005*

This document provides guidance for evaluating the bias in analyte measurements that is due to the sample matrix (physiological or artificial) when two measurement procedures are compared.

Members: $60 Nonmembers: $120

Chairholder: Fred D. Lasky, PhD
Genzyme Diagnostics

User Verification of Performance for Precision and Trueness; Approved Guideline – Second Edition (EP15-A2) *2006*

NEW

This protocol for demonstrating method precision and trueness for quantitative methods performed within the laboratory is designed to be completed within five working days. Included are guidelines for the duration, procedures, materials, data summaries, and interpretation techniques that are adaptable for the widest possible range of analytes and device complexity.

Members $60 Nonmembers $120

Chairholder: R. Neill Carey, PhD, FACB
Peninsula Regional Medical Center

Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline (EP17-A) *2004*

This document provides guidance for determining the lower limit of detection of clinical laboratory methods, for verifying claimed limits, and for the proper use and interpretation of these limits. An NCCLS-IFCC joint project.

Members $60 Nonmembers $120

Chairholder: Daniel W. Tholen, MS
Dan Tholen Statistical Consulting

Quality Management for Unit-Use Testing; Approved Guideline (EP18-A) *2002*

This guideline recommends a quality management system for unit-use devices that will aid in the identification, understanding, and management of sources of error and help to ensure correct results. It is targeted for those involved in the supervision of laboratory-testing quality management, and it addresses issues related to specimen collection through reporting of test results.

Members: $60 Nonmembers: $120 FDA

Chairholder: David L. Phillips
LifeScan

A Framework for NCCLS Evaluation Protocols; A Report (EP19-R) *2002*

This document describes the different types of performance studies that are conducted to evaluate clinical assays.

Members: $60 Nonmembers: $120

Chairholder: Jan S. Krouwer, PhD
Krouwer Consulting

Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline (EP21-A) *2003*

This document provides manufacturers and end users with a means to estimate total analytical error for an assay. A data collection protocol and an analysis method which can be used to judge the clinical acceptability of new methods using patient specimens are included. These tools can also monitor an assay's total analytical error by using quality control samples.

Members: $60 Nonmembers: $120

Chairholder: Jan S. Krouwer, PhD
Krouwer Consulting

GENERAL LABORATORY PRACTICES

Laboratory Documents: Development and Control; Approved Guideline – Fifth Edition (GP2-A5) *2006*

AVAILABLE MARCH 2006

This guideline presents the important components of writing and managing documents for the clinical laboratory. This guideline describes common and specific sections for inclusion in laboratory documents. Several examples of process and procedure documents for preexamination, examination, and postexamination laboratory activities are provided in the form of appendixes; such appendixes are simply illustrative, and not prescriptive.

Members $95 Nonmembers $225

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

Clinical Laboratory Waste Management; Approved Guideline – Second Edition (GP5-A2) *2002*

Based on U.S. regulations, this document provides guidance on safe handling and disposal of chemical, infectious, radioactive, and multihazardous wastes generated in the clinical laboratory.

Members $60 Nonmembers $120

Chairholder: Peter A. Reinhardt, MA
University of North Carolina

Selecting and Evaluating a Referral Laboratory; Approved Guideline (GP9-A) *1998*

This guideline provides an outline of reasons and criteria for choosing a referral laboratory. A checklist for evaluating potential referral laboratories is included to assist in the decision process.

Members $50 Nonmembers $100

Chairholder: Robert R. Rickert, MD
St. Barnabas Medical Center

Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline (GP10-A) *1995*

REAFFIRMED MAY 2001

This document provides a protocol for evaluating the accuracy of a test to discriminate between two subclasses of subjects where there is some clinically relevant reason to separate them. In addition to the use of ROC plots, the importance of defining the question, selecting the sample group, and determining the "true" clinical state are emphasized. (See related publication EP10-A2 in the Evaluation Protocols section.)

Members $50 Nonmembers $100

FDA

Chairholder: Mark H. Zweig, MD
National Institutes of Health

Basic Cost Accounting for Clinical Services; Approved Guideline (GP11-A) *1998*

This document provides principles and techniques to help laboratory managers establish a workable cost-accounting system.

Members $60 Nonmembers $120

Chairholder: Eleanor M. Travers, MD, MHA
Department of Veterans Affairs, Office of Patient Care Services

Papanicolaou Technique; Approved Guideline – Second Edition (GP15-A2) *2001*

This guideline addresses procedures for cervicovaginal specimen collection, as well as the preparation, fixation, staining, and storage of Papanicolaou slides. (See related publications GP20-A2 and GP23-A.)

Members: $60 Nonmembers: $120

Chairholder: Nina Dhurandhar, MD
Tulane University Medical Center

Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline – Second Edition (GP16-A2) *2001*

This guideline describes routine urinalysis test procedures that address materials and equipment, macroscopic examinations, clinical analyses, and microscopic evaluations.

Members: $60 Nonmembers: $120

FDA

Chairholder: Stephen J. Sarewitz, MD
Valley Medical Center

Clinical Laboratory Safety; Approved Guideline – Second Edition (GP17-A2) *2004*

*American National Standard.** This document contains general guidelines for implementing a high-quality laboratory safety program. The framework is adaptable to any laboratory. An NCCLS-CAP joint project.

Members $60 Nonmembers $120

Chairholder: Sheila M. Woodcock, ART, MBA
QSE Consulting

Laboratory Design; Approved Guideline (GP18-A) *1998*

This guideline provides a foundation of information about laboratory design elements that can be used to help define the issues being considered when designing a laboratory.

Members $50 Nonmembers $100

Chairholder: Pennell C. Painter, PhD, FACB
University of Tennessee Medical Center

Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline – Second Edition (GP20-A2) *2003*

This document contains recommended procedures for performing fine needle aspiration biopsies of superficial (palpable) and deep-seated (nonpalpable) lesions, from patient preparation through staining the smear. (See related publications GP15-A2 and GP23-A.)

Members $50 Nonmembers $100

Chairholder: Nina Dhurandhar, MD
Tulane University Medical Center

Training and Competence Assessment; Approved Guideline – Second Edition (GP21-A2) *2004*

This document provides background and recommended processes for the development of training and competence assessment programs that meet quality/regulatory objectives.

Members $50 Nonmembers $100

Chairholder: Sheila M. Woodcock, ART, MBA
QSE Consulting

Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline – Second Edition (GP22-A2) *2004*

This guideline considers continuous quality improvement (CQI) as five integrated quality system components, which include Quality Planning, Quality Teamwork, Quality Monitoring, Quality Improvement, and Quality Review.

Members $85 Nonmembers $200

Chairholder: Gary B. Clark, MD, MPA
Wellness for Life

Nongynecologic Cytologic Specimens: Collection and Cytopreparatory Techniques; Approved Guideline (GP23-A) *1999*

This document provides recommended procedures for the collection, handling, transport, and processing of cytologic specimens from nongynecologic sources. (See related publications GP15-A2 and GP20-A2.)

Members: $60 Nonmembers: $120

Chairholder: Kenneth D. McClatchey, MD, DDS
Loyola University Medical Center

Application of a Quality Management System Model for Laboratory Services; Approved Guideline – Third Edition (GP26-A3) *2004*

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.

Members $85 Nonmembers $200

Chairholder: Lucia M. Berte, MA, MT(ASCP), SBB, DLM; CQA(ASQ)CQMgr
Quality System Consultant

This document is intended for use with HS1 when developing a quality system for the clinical laboratory.

Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline (GP27-A) *1999*

REAFFIRMED MARCH 2002

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

Members $50 **Nonmembers $100** FDA

Co-chairholders: Gary B. Clark, MD, MPA, Quality Laboratory Management Associates, and Stephen J. Sarewitz, MD, Valley Medical Center

Microwave Device Use in the Histology Laboratory; Approved Guideline (GP28-A) *2005*

This document provides recommendations for reproducing the performance of microwave-accelerated procedures to prepare biological specimens in the histology laboratory.

Members $60 **Nonmembers $120**

Chairholder: Gary R. Login, DMD, DMSc Harvard School of Dental Medicine

Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline (GP29-A) *2002*

This document offers methods to asess 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

HEMATOLOGY

Tubes and Additives for Venous Blood Specimen Collection; Approved Standard – Fifth Edition (H1-A5) *2003*

*American National Standard.** This standard contains requirements for blood collection tubes and additives including heparin, EDTA, and sodium citrate.

Members $50 **Nonmembers $100** FDA

Chairholder: Charles F. Arkin, MD Lahey Clinic

Reference and Selected Procedure for the Erythrocyte Sedimentation Rate (ESR) Test; Approved Standard – Fourth Edition (H2-A4) *2000*

*American National Standard.** This document provides a description of the principle, materials, and procedure for reference and standardized ESR methods, as well as a procedure to evaluate routine methods, and an outline of quality control programs for the ESR test.

Members $50 **Nonmembers $100**

Co-chairholders: John A. Koepke, MD, Duke University Medical Center, and Onno W. van Assendelft, MD, PhD, Centers for Disease Control and Prevention

Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard – Fifth Edition (H3-A5) *2003*

This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children. It also includes recommendations on order of draw.

Members $85 **Nonmembers $200** FDA

Chairholder: Charles F. Arkin, MD Lahey Clinic

See related publication X3-R on page 26.

Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard – Fifth Edition (H4-A5) *2004*

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

See videotape section for H4-A3-V information.
See related publication X3-R on page 26.

Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard – Third Edition (H7-A3) *2000*

*American National Standard.** This standard describes the standard microhematocrit method for determining packed-cell volume. It also addresses recommended materials and potential sources of error.

Members $60 **Nonmembers $120** FDA

Chairholder: Onno W. van Assendelft, MD, PhD Centers for Disease Control and Prevention

Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard – Third Edition (H15-A3) *2000*

*American National Standard.** This document describes the principle, materials, and procedure for reference and standardized hemoglobin determinations. It includes specifications for secondary hemiglobincyanide (HiCN) standards.

Members $50 **Nonmembers $100** FDA

Chairholder: Onno W. van Assendelft, MD, PhD Centers for Disease Control and Prevention

Procedures for the Handling and Processing of Blood Specimens; Approved Guideline – Third Edition (H18-A3) *2004*

This document includes criteria for preparing an optimal serum or plasma sample and for the devices used to process blood specimens.

Members $60 **Nonmembers $120** FDA

Chairholder: Roger R. Calam, PhD St. John Hospital

Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard (H20-A) *1992*

This standard describes automated differential counters and establishes a reference method based on the visual (or manual) differential count for leukocyte differential counting, to which an automated or manual test method can be compared.

Members $50 **Nonmembers $100** FDA

Chairholder: John A. Koepke, MD Duke University Medical Center

Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline – Fourth Edition (H21-A4) *2003*

This guideline contains procedures for collecting, transporting, and storing blood; processing blood specimens; storing plasma for coagulation testing; and provides general recommendations for performing the tests.

Members $85 **Nonmembers $200** FDA

Chairholder: Charles F. Arkin, MD Lahey Clinic

Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard (H26-A) *1996*

This document addresses performance goals for analytical accuracy and precision for multichannel hematology analyzers; the relationship of these goals to quality control systems and medical decisions; and recommendations for minimum calibrator performance and the detection of measurement errors. (See related publications H7-A3, H15-A3, and H20-A in this section.)

Members $50 **Nonmembers $100** FDA

Chairholder: A. Richardson Jones, MD Coulter Corporation

Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline – Second Edition (H30-A2) *2001*

This document provides general guidelines for performing the fibrinogen assay in the clinical laboratory. It also includes reporting of results and *in vivo* and *in vitro* conditions that may alter results. (See related publication H21-A4 in this section.)

Members: $60 **Nonmembers: $120** FDA

Chairholder: Richard Marlar, PhD Denver VA Medical Center

Calibration and Quality Control of Automated Hematology Analyzers; Proposed Standard (H38-P) *1999*

This document addresses calibration and quality control strategies for multichannel hematology analyzers; assignment of values to calibrator materials; calibration using stabilized blood controls; internal quality control; pair difference analysis; and use of the weighted moving average ($\bar{x}_B$) method. An NCCLS-ICSH joint project.

Members $50 **Nonmembers $100**

Co-Chairholders: John A. Koepke, MD, Durham, North Carolina, and Onno W. van Assendelft, MD, PhD, Centers for Disease Control and Prevention

Clinical Applications of Flow Cytometry: Quality Assurance and Immunophenotyping of Lymphocytes; Approved Guideline (H42-A) *1998*

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

Members $50 Nonmembers $100 FDA

Chairholder: Michael Borowitz, MD, PhD
The Johns Hopkins University

Clinical Applications of Flow Cytometry: Immunophenotyping of Leukemic Cells; Approved Guideline (H43-A) *1998*

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

Members $50 Nonmembers $100 FDA

Chairholder: Michael Borowitz, MD, PhD
The Johns Hopkins University

Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes); Approved Guideline – Second Edition (H44-A2) *2004*

This document provides guidance for the performance of reticulocyte counting by flow cytometry. It includes methods for determining the trueness and precision of the reticulocyte flow cytometry instrument and a recommended reference procedure. An NCCLS-ICSH joint project.

Members $50 Nonmembers $100

Chairholder: Bruce H. Davis, MD
Maine Medical Center Research Institute

Performance of the Bleeding Time Test; Approved Guideline—Second Edition (H45-A2) *2005*

This document contains guidelines for performing the template bleeding time test. A descriptive list of variables that can affect the results of the test is also included.

Members $50 Nonmembers $100

Chairholder: Bruce H. Davis, MD
Maine Medical Center Research Institute

One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline (H47-A) *1996*

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 $50 Nonmembers $100 FDA

Chairholder: Charles F. Arkin, MD
Boston University Medical Center

Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline (H49-A) *2004*

This guideline provides guidance to users and manufacturers of point-of-care coagulation devices for monitoring of heparin and warfarin anticoagulant therapy and to ensure reliable results comparable to those obtained by routine clinical laboratory testing.

Members $50 Nonmembers $100 FDA

Chairholder: Jack E. Ansell, MD
Boston University Medical Center

Assays of von Willebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline (H51-A) *2002*

This guideline describes appropriate test specimens, reagents and materials, methods of platelet agglutination and ELISA, preparation of reference curves, determination of reference intervals, quality control procedures, result interpretation, and sources of error for assays of von Willebrand factor antigen and ristocetin cofactor activity. A brief description of von Willebrand disease and its various subtypes is included, as well as a list of references to more comprehensive reviews of this commonly inherited and rarely acquired bleeding disorder.

Members $60 Nonmembers $120 FDA

Chairholder: Richard Marlar, PhD
Denver VA Medical Center

Fetal Red Cell Detection; Approved Guideline (H52-A) *2001*

This document provides guidance for the quantitation of fetal red blood cells in blood and other biologic fluids. The performance characteristics of various flow cytometric and microscopic assays are reviewed, recommendations are made for control usage, and principles for distinction of F cells and fetal red cells are discussed.

Members $60 Nonmembers $120

Chairholder: Bruce H. Davis, MD
Maine Medical Center

Procedures for Validation of INR and Local Calibration of PT/INR Systems; Approved Guideline (H54-A) *2005*

This document, published as two stand-alone guidelines, describes the use of certified plasmas to enhance performance of the prothrombin time (PT)/International Normalized Ratio (INR) system test; reviews limitations of the INR system that may occur when a manufacturer-determined ISI is used without local verification or calibration; and provides a rationale for performing local ISI verification with recommendations as to when PT calibration may be indicated. Part I is a detailed, expanded account for manufacturers and Part II is an abbreviated version useful for the clinical laboratory.

Members $50 Nonmembers $100

Chairholder: Dorothy M. Adcock, MD
Esoterix Coagulation

Body Fluid Analysis for Cellular Composition; Proposed Guideline (H56-P) *2005*

This guideline provides users with recommendations for collection and transport of body fluids, numeration and identification of cellular components, and guidance for qualitative and quantitative assessment of body fluid. A CLSI-IFCC joint project.

Members $50 Nonmembers $100

Chairholder: Diane I. Szamosi, MA, MT(ASCP)SH
Greiner Bio-One North America, Preanalytics

IMMUNOLOGY AND LIGAND ASSAY

Quality Assurance for the Indirect Immunofluorescence Test for Autoantibodies to Nuclear Antigen (IF-ANA); Approved Guideline (I/LA2-A) *1996*

This document addresses the criteria for immunofluorescence ANA testing, including test components, quantification of results, and classification criteria.

Members $50 Nonmembers $100 FDA

Chairholder: Robert M. Nakamura, MD
Scripps Clinic and Research Foundation

Apolipoprotein Immunoassays: Development and Recommended Performance Characteristics; Approved Guideline (I/LA15-A) *1997*

REAFFIRMED SEPT. 2001

This guideline describes the characterization and preparation of immunogens, antibodies, samples, and methods, and provides guidance for immunochemical testing of apolipoproteins.

Members $50 Nonmembers $100

Chairholder: Robert F. Ritchie, MD
Foundation for Blood Research

Evaluation Methods and Analytical Performance Characteristics of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies of Defined Allergen Specificities; Approved Guideline (I/LA20-A) *1997*

REAFFIRMED SEPT. 2001

This document provides guidance for the design, analytical performance, standardization, and quality assurance of laboratory assays used in the measurement of total serum IgE and IgE antibodies of defined allergen specificity.

Members $50 Nonmembers $100 FDA

Chairholder: Per N.J. Matsson, PhD
Pharmacia & Upjohn

Clinical Evaluation of Immunoassays; Approved Guideline (I/LA21-A) *2002*

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

Members $50 Nonmembers $100 FDA

Chairholder: Linda Ivor
Gen-Probe Incorporated

Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guideline (I/LA23-A) *2004*

This guideline addresses components for harmonizing and assessing the quality of immunoassay systems for several commonly used dose-response indicator categories, e.g., radioisotopes, enzymes, fluorescence, luminescence, reagents, and experimental components criteria essential to characterizing an immunoassay.

Members $50 Nonmembers $100 FDA

Chairholder: W. Harry Hannon, PhD
Centers for Disease Control and Prevention

Fluorescence Calibration and Quantitative Measurement of Fluorescence Intensity; Approved Guideline (I/LA24-A) *2004*

This guideline describes the basic principles, reference materials, and laboratory procedures upon which quantitative fluorescence calibration is based.

Members $50 Nonmembers $100

Co-Chairholders: Gerald E. Marti, MD, PhD, FDA Ctr for Biologics Evaluation/Research, and Robert F. Vogt, Jr., PhD, Centers for Disease Control and Prevention

Maternal Serum Screening; Approved Standard (I/LA25-A) *2004*

This document addresses the steps required to provide reliable screening and reporting using examples of serum markers currently in common use (AFP, hCG, uE3, DIA). Outcome evaluation, information management, and calculation of risk are also emphasized in this standard.

Members $50 Nonmembers $100

Chairholder: Sanda Clejan, PhD
Tulane University School of Medicine

Performance of Single Cell Immune Response Assays; Approved Guideline (I/LA26-A) *2004*

This document contains methods of intracellular cytokine evaluation, major histo-compatibility complex (MHC) tetramer quantitation, and enzyme-linked immunospot (ELISPOT) technology. This document provides basic aspects of specimen collection, transport, and preparation, in addition to quality assurance and test validation approaches. A NCCLS-IFCC joint project.

Members $50 Nonmembers $100

Chairholder: Alan L. Landay, PhD
Rush Presbyterian-St. Luke's Medical Center

Newborn Screening Follow-up; Proposed Guideline (I/LA27-P) *2005*

NEW

This document describes the basic principles, scope, and range of follow-up activities within the newborn screening system, a process by which infants are screened for congenital diseases, which must be detected early for the prevention of morbidity and mortality. Intended for maternity and newborn healthcare providers, the medical home provider, the confirmatory services, and subspecialty medical consultants, as well as the family.

Members $60 Nonmembers $120

Chairholder: Judith Tuerck, RN, MS
Oregon Health & Science University

Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard – Fourth Edition (LA4-A4) *2003*

This document addresses the issues associated with specimen collection, the filter paper collection device, and the transfer of blood onto filter paper, and provides uniform techniques for collecting the best possible specimen for use in newborn screening programs.

Members $60 Nonmembers $120

Chairholder: W. Harry Hannon, PhD
Centers for Disease Control and Prevention

See videotape section for LA4-A3-V information.

Quality Assurance for Immunocytochemistry; Approved Guideline (MM4-A) *1999*

This document provides recommendations for the performance of immunocytochemical assays on cytologic and surgical pathology specimens. It is intended to promote a better understanding of the requirements, capabilities, and limitations of these diagnostic methods; to improve their intra- and inter-laboratory reproducibility; and to improve their positive and negative predictive values in the diagnosis of disease.

Members $60 Nonmembers $120

Chairholder: Timothy J. O'Leary, MD, PhD
Armed Forces Institute of Pathology

MICROBIOLOGY

MICROBIOLOGY: Susceptibility Testing

Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard – Ninth Edition (M2-A9) *2006*

NEW

The latest methods for disk susceptibility testing, with updated tables for interpretive zone diameters. Updates include information for new antimicrobial agents; expanded information on inoculum preparation; added and changed QC ranges; and new guidelines for testing fastidious and problem organisms. Includes M100-S16.

Members $150 Nonmembers $275

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*

NEW

Standard broth dilution (macrodilution and microdilution) and agar dilution techniques for measuring the *in vitro* susceptibility of bacteria to antimicrobial agents. Updates include information for new antimicrobial agents; expanded recommendations for inoculum preparation; added and changed QC ranges; and new guidelines for testing fastidious and problem organisms. Includes M100-S16.

Members $150 Nonmembers $275

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

Performance Standards for Antimicrobial Susceptibility Testing; Sixteenth Informational Supplement (M100-S16) *2006*

NEW

Only available with purchase of M2, M7, or both documents. The latest recommendations for detecting emerging resistance. Updates include: information for new antimicrobial agents; added and changed QC ranges; and clarification of incubation temperature.

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

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

M2-A9 + M7-A7 + M100-S16 tables
Members **$250** Nonmembers **$375**

Buy M2 and M7 and Save $100

AST QC Quick Guides

NEW

The ultimate "cheat sheet" to quality control (QC) for AST. Easy-to-use flowcharts 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.

Members $70 Nonmembers $120

Wallchart — Glossary of Antimicrobial Terms and Abbreviations Wallchart: Sixteenth Informational Supplement (based on M100-S16)

NEW

This wallchart 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.

Members $35 Nonmembers $60

Protocols for Evaluating Dehydrated Mueller-Hinton Agar; Approved Standard – Second Edition (M6-A2) *2005*

NEW

This standard describes three protocols for the evaluation of dehydrated Mueller-Hinton agar in the disk diffusion procedure for antimicrobial susceptibility testing—the first for use by manufacturers to evaluate production lots of Mueller-Hinton agar; and the second and third for selection and stability testing of primary and secondary reference lots of Mueller-Hinton agar.

Members $50 Nonmembers $100

Chairholder: Robert P. Rennie, PhD
Provincial Laboratory for Public Health

Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard – Sixth Edition (M11-A6) *2004*

*American National Standard.** This standard 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 2004.**

Members $85 Nonmembers $200

FDA

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

For multiple copies of the same document we offer substantial savings—see page 36.

AST Searchable CD-ROM

NEW

See page 26.

Laboratory Diagnosis of Blood-borne Parasitic Diseases; Approved Guideline (M15-A) *2000*

This document contains guidelines for specimen collection, blood film preparation, and staining procedures. Recommendations for optimum timing of specimen collection to assist laboratories in detecting, identifying, and reporting certain parasites are also included.

Members $60 **Nonmembers $120**

FDA

Chairholder: Lynne S. Garcia, MS, F(AAM)
Diagnostic Medical Parasitology

Methodology for the Serum Bactericidal Test; Approved Guideline (M21-A) *1999*

This guideline describes a direct method of antimicrobial susceptibility testing using a patient's serum to measure the activity of serum against bacterial pathogen isolated from the patient. (See related publication M26-A in this section.)

Members $60 **Nonmembers $120**

Chairholder: James H. Jorgensen, PhD
University of Texas Health Science Branch

Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard – Third Edition (M22-A3) *2004*

This standard contains quality assurance procedures for manufacturers and users of prepared, ready-to-use microbiological culture media.

Members $60 **Nonmembers $150**

Chairholder: Karen Krisher, PhD, D(ABMM)
Oregon Public Health

Development of *In Vitro* Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline – Second Edition (M23-A2) *2001*

This document addresses the required and recommended data needed for the selection of appropriate interpretive standards and quality control guidelines for antimicrobial agents.

Members $150 **Nonmembers $250**

FDA

Chairholder: Mary Jane Ferraro, PhD, MPH
Massachusetts General Hospital

Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard (M24-A) *2003*

This standard provides protocols and related quality control parameters and interpretive criteria for the susceptibility testing of mycobacteria, *Nocardia spp.*, and other aerobic actinomycetes.

Members $60 **Nonmembers $120**

Chairholder: Gail L. Woods, MD
Merck & Company, Inc.

Quality Control MIC Limits for *Mycobacterium peregrinum* and *Staphylococcus aureus* (When Testing Rapidly Growing Mycobacteria); Informational Supplement (M24-S1) *2005*

NEW

This supplemental table provides new QC ranges for susceptibility testing for CLSI/NCCLS document M24-A – *Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard*. It is available as a laminated chart for easy posting.

Members $15 **Nonmembers $35**

Chairholder: Gail L. Woods, MD
ARUP Research Institute

Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline (M26-A) *1999*

This guideline contains procedures for determining the lethal activity of antimicrobial agents. (See related publication M21-A in this section.)

Members $60 **Nonmembers $120**

Chairholder: James H. Jorgensen, PhD
University of Texas Health Science Branch

Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard – Second Edition (M27-A2) *2002*

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: Michael A. Pfaller, MD
University of Iowa College of Medicine

Quality Control Minimal Inhibitory Concentration (MIC) Limits for Broth Microdilution and MIC Interpretive Breakpoints (M27-S2) *2005*

NEW

This supplemental table provides updated QC ranges and interpretive criteria for broth microdilution testing for CLSI/NCCLS document M27-A2—*Reference Methods for Broth Dilution Antifungal Susceptibility Testing of Yeasts*. Two charts are laminated for easy posting.

Members $15 **Nonmembers $35**

Procedures for the Recovery and Identification of Parasites From the Intestinal Tract; Approved Guideline – Second Edition (M28-A2) *2005*

This guideline addresses the collection, processing, and examination of intestinal tract specimens for the identification of parasites.

Members $60 **Nonmembers $120**

Chairholder: Lynne S. Garcia, MS
LSG & Associates

Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline – Third Edition (M29-A3) *2005*

Based on U.S. regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

Members $100 **Nonmembers $200**

Chairholder: David L. Sewell, PhD
Veterans Affairs Medical Center
See videotape section for M29-A2 information.
See related publication X3-R on page 26.

Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Approved Standard – Second Edition (M31-A2) *2002*

This document provides the currently recommended techniques for antimicrobial agent disk and dilution susceptibility testing, criteria for quality control testing, and interpretive criteria for veterinary use.

Members $60 **Nonmembers $120**

Chairholder: Thomas R. Shryock, PhD
Elanco Animal Health

Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Informational Supplement (M31-S1) *2004*

This document provides updated tables for the antimicrobial susceptibility testing standard M31-A2.

Members $35 **Nonmembers $60**

Chairholder: Thomas R. Shryock, PhD
Elanco Animal Health

Evaluation of Lots of Dehydrated Mueller-Hinton Broth for Antimicrobial Susceptibility Testing; Proposed Guideline (M32-P) *2001*

This document describes methods for evaluation of production lots of Mueller-Hinton broth by manufacturers of the dehydrated product. Performance of production lots is determined by testing defined organism/antimicrobial combinations. The results of testing must conform to defined quality control limit ranges for each combination of antimicrobial and ATCC quality control strain. Guidelines are provided for ranges of specific ion contents (cations and anions) that will provide results within the defined quality control limit ranges.

Members $60 **Nonmembers $120**

Chairholder: Robert P. Rennie, PhD
University of Alberta Hospital

Antiviral Susceptibility Testing: Herpes Simplex Virus by Plaque Reduction Assay; Approved Standard (M33-A) *2004*

This document provides a protocol for the performance of the plaque reduction assay for phenotypic antiviral susceptibility testing of herpes simplex virus.

Members $60 **Nonmembers $120**

Co-Chairholders: Richard L. Hodinka, PhD, Children's Hospital of Philadelphia, and Ella M. Swierkosz, PhD, St. Louis University

Western Blot Assay for Antibodies to *Borrelia burgdorferi*; Approved Guideline (M34-A) *2000*

This document addresses technical and interpretive considerations for use of Western blot assays that detect antibodies to *Borrelia burgdorferi* and other Borrelia species that cause Lyme Disease.

Members $60 **Nonmembers $120**

Chairholder: Alan G. Barbour, MD
University of California Irvine College of Medicine

Abbreviated Identification of Bacteria and Yeast; Approved Guideline (M35-A) *2002*

This document provides a series of microbial identification protocols that are designed to minimize the use of expensive, time-consuming laboratory tests, allowing timely reporting of accurate organism identification.

Members $60 **Nonmembers $120**

Chairholder: Ellen Jo Baron, PhD
Stanford University Medical School

Clinical Use and Interpretation of Serologic Tests for *Toxoplasma gondii*; Approved Guideline (M36-A) *2004*

This guideline provides the user with information about the biology of *Toxoplasma gondii*, the methods available for use in the laboratory diagnosis of human toxoplasmosis, techniques that should be performed for specific clinical situations, and how to interpret laboratory results.

Members $60 **Nonmembers $120**

Chairholder: Lynne S. Garcia, MS, F(AAM)
LSG and Associates

Development of *In Vitro* Susceptibility Testing Criteria and Quality Control Parameters for Veterinary Antimicrobial Agents; Approved Guideline – Second Edition (M37-A2) *2002*

This document addresses the required and recommended data needed for selection of appropriate interpretative standards and quality-control guidance for veterinary antimicrobial agents.

Members $60 Nonmembers $120

Chairholder: Thomas R. Shryock, PhD
Elanco Animal Health

Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi; Approved Standard (M38-A) *2002*

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

Chairholder: Michael A. Pfaller, MD
University of Iowa College of Medicine

Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline – Second Edition (M39-A2) *2005*

NEW

Guidelines for clinical laboratories and their data analysis software providers on the routine generation and storage of susceptibility data, and the compilation of susceptibility statistics. Provides recommendations for consistent and effective use of cumulative susceptibility statistics, to enable clinicians to select the most appropriate agents for empiric antimicrobial therapy.

Members $60 Nonmembers $120

Chairholder: Janet F. Hindler, MCLS, MT(ASCP)
UCLA Medical Center

Quality Control of Microbiological Transport Systems; Approved Standard (M40-A) *2003*

This standard provides criteria to manufacturers and end-users of transport devices to assist with provision of dependable products for the transport of microbiological clinical specimens. Quality control considerations are presented, as well as techniques, control organisms, and acceptability criteria. This document provides a consistent protocol for initial testing or microbiological transport devices by manufacturers and a method by which laboratories can validate manufacturer claims and compare devices. An NCCLS-DIN pilot project.

Members $60 Nonmembers $120

Co-Chairholders: Judy C. Arbique, ART(CSMLS) CLS(NCA), Arbique-Rendell Onsite Training and Consulting, and Barbara Ann Body, PhD, D(ABMM), LabCorp

Viral Culture; Proposed Guideline (M41-P) *2006*

NEW

Guidance for viral culture and identification procedures typically performed in the clinical virology laboratory setting using commercially available cell cultures and reagents. Identifies critical elements that must be addressed in devising a viral culture procedure, including the selection, assessment and maintenance, and verification and quality control of cell cultures; culture medium preparation and quality control; specimen collection and preparation; isolate identification; and result reporting and interpretation.

Members $50 Nonmembers $100

Chairholder: Lorraine M. Clarke, PhD
New York State Dept. of Health

Methods for Antimicrobial Disk Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Proposed Guideline (M42-P) *2005*

This document provides the most up-to-date techniques for disk diffusion susceptibility testing of aquatic species isolates and criteria for quality control testing.

Members $60 Nonmembers $120

Co-Chairholders: John P. Hawke, PhD, Louisiana State University, and Renate Reimschuessel, PhD, VMD, Center for Veterinary Medicine, FDA

Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guideline (M44-A) *2004*

This guideline provides newly established methodology for disk diffusion testing of *Candida* spp., zone interpretive criteria, and recommended quality control ranges.

Members $85 Nonmembers $200

Chairholder: Daniel J. Sheehan, PhD
Pfizer Inc

Zone Diameter Interpretive Standards and Corresponding Minimal Inhibitory Concentration (MIC) Interpretive Breakpoints (M44-S1) *2005*

NEW

This supplemental table provides new zone diameter interpretive standards and corresponding minimal inhibitory concentrations (MIC) breakpoints for CLSI/NCCLS document M44-A—*Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guideline.* It is available as a laminated chart for easy posting.

Members $15 Nonmember $35

Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Proposed Guideline (M45-P) *2005*

NEW

This document provides guidance to clinical microbiology laboratories for standardized susceptibility testing of infrequently isolated or fastidious bacteria that are not presently included in CLSI documents M2, M7, or M11. The tabular information in this document presents the most current information for drug selection, interpretation, and quality control for the infrequently isolated or fastidious bacterial pathogens included in this guideline.

Members $60 Nonmembers $120

Chairholder: James H. Jorgensen, PhD, University of Texas Health Science Center

Methods for Broth Dilution Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Proposed Guideline (M49-P) *2005*

This document provides the most up-to-date techniques for the determination of minimal inhibitory concentrations (MICs) of aquatic bacteria by broth micro- and macrodilution, and criteria for quality control testing.

Members $60 Nonmembers $120

Co-Chairholders: John P. Hawke, PhD, Louisiana State University, and Renate Reimschuessel, PhD, VMD, FDA Center for Veterinary Medicine

MOLECULAR METHODS

Molecular Diagnostic Methods for Genetic Diseases; Approved Guideline (MM1-A) *2000*

This document provides guidance for the use of molecular biologic techniques for clinical detection of heritable mutations associated with genetic disease.

Members $60 Nonmembers $120

FDA

Chairholder: Dale H. Altmiller, PhD
University of Oklahoma Health Sciences Center

Immunoglobulin and T-Cell Receptor Gene Rearrangement Assays; Approved Guideline – Second Edition (MM2-A2) *2002*

This document provides guidance on the performance of gene rearrangement assays, including indication; specimen collection, transport, and processing; assessment of specimen adequacy; and quality control.

Members $60 Nonmembers $120

Chairholder: Russel K. Enns, PhD
Vysis, Inc.

Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline – Second Edition (MM3-A2) *2006*

NEW

This guideline addresses topics relating to clinical applications, amplified and nonamplified nucleic acid methods, selection and qualification of nucleic acid sequences, establishment and evaluation of test performance characteristics, inhibitors, and interfering substances, controlling false-positive reactions, reporting and interpretation of results, quality assurance, regulatory issues, and recommendations for manufacturers and clinical laboratories.

Members $60 Nonmembers $120

Chairholder: Frederick S. Nolte, PhD
Emory University Hospital

Quality Assurance for Immunocytochemistry; Approved Guideline (MM4-A) *1999*

This document provides recommendations for the performance of immunocytochemical assays on cytologic and surgical pathology specimens. It is intended to promote a better understanding of the requirements, capabilities, and limitations of these diagnostic methods; to improve their intra- and inter-laboratory reproducibility; and to improve their positive and negative predictive values in the diagnosis of disease.

Members $60 Nonmembers $120

FDA

Chairholder: Timothy J. O'Leary, MD, PhD
Armed Forces Institute of Pathology

Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline (MM5-A) *2003*

This guideline addresses the performance and application of assays for gene rearrangement and translocations by both polymerase chain reaction (PCR) and reverse transcriptase polymerase chain reaction (RT-PCR) techniques and includes information on specimen collection, sample preparation, test reporting, test validation, and quality assurance.

Members $60 Nonmembers $120

FDA

Chairholder: Timothy J. O'Leary, MD, PhD
Armed Forces Institute of Pathology

Quantitative Molecular Methods for Infectious Diseases; Approved Guideline (MM6-A) *2003*

This document provides guidance for the development and use of quantitative molecular methods, such as nucleic acid probes and nucleic acid amplification techniques of the target sequences specific to particular microorganisms. It also presents recommendations for quality assurance, proficiency testing, and interpretation of results.

Members $60 **Nonmembers $120**

Chairholder: Roberta M. Madej, MS, MT
Roche Molecular Systems, Inc.

Fluorescence *In Situ* Hybridization (FISH) Methods for Medical Genetics; Approved Guideline (MM7-A) *2004*

This document addresses FISH methods for medical genetic determinations, identification of chromosomal abnormalities, and gene amplification. Topics addressed include probe and assay development, qualification, and validation; instrument requirements; quality assurance; and recommendations for evaluation of results.

Members $60 **Nonmembers $120**

Chairholder: Russel K. Enns, PhD
Cepheid

Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline (MM9-A) *2004*

This document addresses automated, PCR-based, dideoxyterminator and primer extension sequencing done on gel- or capillary-based sequencers. Topics covered include: specimen collection and handling; isolation of nucleic acid; amplification and sequencing of nucleic acids; interpretation and reporting results; and quality control/assessment considerations as appropriate.

Members $60 **Nonmembers $120** FDA

Chairholder: Michael A. Zoccoli, PhD
Celera Diagnostics

Genotyping for Infectious Diseases: Identification and Characterization; Proposed Guideline (MM10-P) *2005*

This guideline describes currently used analytical approaches and methodologies applied to identify the clinically important genetic characteristics responsible for disease manifestation, outcome, and response to therapy in the infectious disease setting. It also provides guidance on the criteria to be considered for design, validation, and determination of clinical utility of such testing.

Members $60 **Nonmembers $120**

Chairholder: Stephen P. Day, PhD
Third Wave Technologies, Inc.

Diagnostic Nucleic Acid Microarrays; Proposed Guideline (MM12-P) *2005*

This guideline provides recommendations for many aspects of the array process including: a method overview; nucleic acid extraction; the preparation, handling, and assessment of genetic material; quality control; analytic validation; and interpretation and reporting of results. A CLSI–IFCC joint project.

Members $60 **Nonmembers $120**

Chairholder: Joseph L. Hackett, PhD
FDA Center for Devices and Radiological Health

Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline (MM13-A) *2006*

NEW

This document addresses topics that relate to proper and safe biological specimen collection for molecular methods, as well as nucleic acid isolation and purification. Included are methods of collection, recommended storage and transport conditions, and available nucleic acid purification technologies for each specimen/nucleic acid type. A CLSI-IFCC joint project.

Members $60 **Nonmembers $120**

Chairholder: Lynne Rainen, PhD
BD Diagnostics, Preanalytical Systems

Proficiency Testing (External Quality Assessment) for Molecular Methods; Approved Guideline (MM14-A) *2005*

This document provides guidelines for a quality proficiency testing program including reliable databases; design control in the choice of materials and analytes; good manufacturing processes; documentation procedures; complaint handling; corrective and preventive action plans; and responsive timing of reports. A CLSI-IFCC joint project.

Members $60 **Nonmembers $120**

Chairholder: Roberta M. Madej, MS, MT
Roche Molecular Systems, Inc.

Use of External RNA Controls in Gene Expression Assays; Proposed Guideline (MM16-P) *2005*

This document provides protocols supporting the use of external RNA controls in microarray and QRT-PCR based gene expression experiments, including preparation of control transcripts, design of primers and amplicons, quality control, use in final experimental or clinical test application, and analysis and interpretation of data obtained.
A CLSI–IFCC joint project.

Members $60 **Nonmembers $120**

Chairholder: Janet A. Warrington, PhD
Affymetrix

POINT-OF-CARE TESTING

Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline (AST2-A) *1999*

This document contains guidelines for users of *in vitro* diagnostic (IVD) devices outside the clinical laboratory to produce reliable results comparable to those obtained in the clinical laboratory.

Members $60 **Nonmembers $150**

Chairholder: Barbara M. Goldsmith, PhD
St. Christopher's Hospital for Children

Wellness Testing Using IVD Devices; Approved Guideline (AST3-A) *1999*

This document provides procedures and recommendations for implementing a quality wellness-testing program.

Members $50 **Nonmembers $100**

Chairholder: Nina Peled, PhD
Cygnus, Inc.

Point-of-Care Connectivity; Approved Standard (POCT1-A) *2001*

This document provides the framework for engineers to design devices, work stations, and interfaces that allow multiple types and brands of point-of-care devices to communicate bidirectionally with access points, data managers, and laboratory information systems from a variety of vendors. An NCCLS, IFCC, CIC joint publication.

Members: $100 **Nonmembers: $150**

Chairholder: Jeffrey A. DuBois, PhD
Nova Biomedical Corporation FDA
Note: Distributed on CD-ROM

Electronic Archived Documents

These documents are no longer being reviewed as part of our consensus process. However, because of their usefulness to a limited segment of the healthcare community, we are continuing to make the documents available for their informational content. These are available in electronic format only.

Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials—Second Edition; Approved Guideline **(DI2-A2)** *1993*
Members: $25 Nonmembers: $75

Agglutination Analyses: Antibody Characteristics, Methodology, Limitations, and Clinical Validation; Approved Guideline **(DI3-A)** *1993*
Members: $25 Nonmembers: $75

Labeling of Laboratory Prepared Materials **(GP4-P)** *1984*
Members: $15 Nonmembers: $25

Inventory Control Systems for Laboratory Supplies; Approved Guideline **(GP6-A)** *1994*
Members: $50 Nonmembers: $100

Labeling for Home-Use *In Vitro* Testing Products; Approved Guideline **(GP14-A)** *1996*
Members: $35 Nonmembers: $85

Histochemical Method for Leukocyte Alkaline Phosphatase; Proposed Standard **(H22-P)** *1984*
Members: $25 Nonmembers: $75

Determination of Factor Coagulation Activities **(H48-A)** *1997*
Members: $25 Nonmembers: $75

Temperature Calibration of Water Baths, Instruments, and Temperature Sensors—Second Edition; Approved Standard **(I2-A2)** *1990*
Members: $25 Nonmembers: $75

Standard for Relating Spectrophotometer Performance Characteristics to Analytical Goals **(I3-A)** *1980*
Members: $15 Nonmembers: $25

Service of Clinical Laboratory Instruments **(I6-A)** *1984*
Members: $15 Nonmember: $25

Determining Performance of Volumetric Equipment **(I8-P)** *1984*
Members: $15 Nonmembers: $25

Temperature Monitoring and Recording in Blood Banks **(I16-T)** *1986*
Members: $15 Nonmembers: $25

Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of Test Products in the Clinical Laboratory; Approved Guideline **(I/LA6-A)** *1997*
Members: $25 Nonmembers: $75

Specifications for Immunological Testing for Infectious Diseases; Approved Guideline-Second Edition **(I/LA18-A2)** *2001*
Members $50 Nonmembers $100

Primary Reference Preparations Used to Standardize Calibration of Immunochemical Assays for Serum Prostate Specific Antigen (PSA); Approved Guideline **(I/LA19-A)** *1997*
Members: $25 Nonmembers: $75

Assessing the Quality of Radioimmunoassay Systems; Approved Guideline - Second Edition **(LA1-A2)** *1994*
Members $25 Nonmembers $75

Sourcebook of Reference Methods, Materials, and Related Information for the Clinical Laboratory; Proposed Guideline **(NRSCL12-P)** *1994*
Members: $50 Nonmembers: $100

The Reference System for the Clinical Laboratory: Criteria for Development and Credentialing of Methods and Materials for Harmonization of Results; Approved Guideline **(NRSCL13-A)** *2000*
Members: $50 Nonmembers: $100

International Organization for Standardization (ISO) Documents

The International Organization for Standardization Technical Committee (ISO/TC) 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*, was formed in 1995 based on a proposal by Clinical and Laboratory Standards Institute (CLSI). ISO granted the Secretariat to the American National Standards Institute (ANSI), who in turn delegated the Secretariat responsibility to us. As manager of ISO's standards-development process in this field, our role is a global one carried out on behalf of the patient-testing community throughout the world. ISO/TC 212 is not a CLSI-sponsored activity and officially, ANSI, as the U.S. member of ISO, is listed as the Secretariat of ISO/TC 212.

As a separate, distinct national responsibility, CLSI also manages the U.S. TAG for ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*, and the U.S. TAG for ISO/TC 76, *Transfusion, infusion, and injection equipment for medical and pharmaceutical use*, on behalf of ANSI.

Through an agreement with ANSI, we are able to offer ISO/TC 212 and ISO/TC 76 approved and draft standards. To purchase ISO/TC 76 approved and draft standards, visit Shop at www.clsi.org.

Customers from outside the United States may order these ISO standards from their national standards bodies.

LEGEND

TR	Technical report
DTR	Draft technical report
CD	Committee draft
DIS	Draft international standard

ISO/TC 212 STANDARDS

Medical laboratories – Particular requirements for quality and competence (ISO 15189) *2003 (formerly Quality management in the medical laboratory)*

This International Standard specifies requirements for quality management of a medical laboratory.

Members $150 Nonmembers $200

Medical laboratories – Requirements for safety (ISO 15190) *2003 (formerly Safety management for medical laboratories)*

This International Standard specifies requirements for quality management of a medical laboratory.

Members $150 Nonmembers $200

In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Presentation of reference measurement procedures (ISO 15193) *2002*

This International Standard specifies requirements for the drafting of a reference measurement procedure.

Members $100 Nonmembers $135

In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Description of reference materials (ISO 15194) *2002*

This International Standard specifies requirements and formats for the description of reference materials.

Members $95 Nonmembers $125

Laboratory medicine – Requirements for reference measurement laboratories (ISO 15195) *2003 (formerly Requirements for laboratories performing reference procedures)*

This International Standard describes the specific requirements for reference measurement laboratories in laboratory medicine.

Members $90 Nonmembers $120

In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197) *2003*

This International Standard specifies procedures for the determination of performance criteria for quantitative *in vitro* blood glucose monitoring systems for management of diabetes mellitus.

Members $150 Nonmembers $200

Clinical laboratory medicine – *In vitro* diagnostic medical devices – Validation of user quality control procedures by the manufacturer (ISO 15198) *2004*

This International Standard specifies procedures for manufacturers of *in vitro* diagnostic devices for validating the recommendations provided in the device labeling for user quality control which assures adequate performance.

Members $80 Nonmembers $110

In vitro diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials (ISO 17511) *2003*

This International Standard specifies how to assure the metrological traceability of values assigned to calibrators and control materials intended to establish or verify trueness of measurement.

Members $125 Nonmembers $165

Clinical laboratory testing and *in vitro* diagnostic test systems – *In vitro* monitoring systems for anticoagulant therapy self-testing (ISO/DIS 17593)

This draft International Standard specifies requirements for *in vitro* monitoring systems for vitamin-K antagonist therapy, including performance, quality assurance and user training, and procedures for the verification and the validation of performance by the intended users under actual and simulated conditions of use.

Members $50 Nonmembers $100

Clinical laboratory testing and *in vitro* diagnostic test systems – *In vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling) (ISO/CD 18113)

Part 1: General requirements

This International Standard will specify general requirements for information supplied by the manufacturer of *in vitro* diagnostic test systems.

Members $50 Nonmembers $100

Part 2: *In vitro* diagnostic reagents for professional use

This International Standard will specify requirements for information supplied by the manufacturer of *in vitro* diagnostic reagents, for professional use. This Standard will also apply to information supplied by the manufacturer with calibrators, control materials and accessories intended for use with *in vitro* diagnostic reagents for professional use.

Members $50 Nonmembers $100

Part 3: *In vitro* diagnostic instruments for professional use

This International Standard will specify the requirements for the contents of instructions for use for *in vitro* diagnostic instruments including apparatus, equipment, calibrators and control materials for professional use.

Members $50 Nonmembers $100

In vitro diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials (ISO 18153) *2003*

This International Standard specifies how to assure the traceability of assigned values to calibrators and control materials intended to establish or verify trueness of measurement of the catalytic concentration of enzymes. The calibrators and control materials are those provided by the manufacturers as part of, or to be used together with, *in vitro* diagnostic medical devices.

Members $80 Nonmembers $110

In vitro diagnostic medical devices – Information supplied by the manufacturer with *in vitro* diagnostic reagents for staining in biology (ISO 19001) *2002*

This International Standard specifies requirements for information supplied with reagents used in staining in biology.

Members $100 Nonmembers $135

Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility devices – Part 1: Reference methods for testing the *in vitro* activity of antimicrobial agents against bacteria involved in infectious diseases (ISO/DIS 20776-1) *2005*

This document, jointly developed with CEN/TC 140, describes the reference method for *in vitro* antimicrobial susceptibility testing of rapidly growing aerobic bacteria with importance in human infections.

Members $50 Nonmembers $100

Medical laboratories – Reduction of error through risk management and continual improvement (ISO/TS 22367)

This technical specification characterizes the application of ISO 15189:2003 as a system to reduce laboratory error and improve patient safety.

Members $50 Nonmembers $100

Medical laboratories – Guidance on laboratory implementation of ISO 15189 (ISO/TR 22869)

This Technical Report provides guidance to laboratories on how to meet the requirements contained in ISO 15189: 2003 for competence and quality that are particular to medical laboratories.

Members $50 Nonmembers $100

Point-of-care testing (POCT) – Requirements for quality and competence (ISO/DIS 22870)

This draft annex for ISO 15189 specifies quality management for point-of-care testing.

Members $50 Nonmembers $100

Projects in Development

NOTE:

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

Clinical Chemistry and Toxicology

Analysis of Body Fluids in Clinical Chemistry (C49)

This proposed project will lead to the development of guidelines for the application of widely available analytic methods for testing body fluids and for reporting and interpreting those results. Emphasis will be placed on defining the common clinical situations for this use; acceptable practice for measuring analytes without extended method validation for abnormal body fluids; influence of biologic and analytic variation on interpretation of results; and variability in comparing results between different instrument manufacturers.
A CLSI-IFCC joint project

Chairholder: Richard A. McPherson, MD
Virginia Commonwealth University

Mass Spectrometry in the Clinical Laboratory (C50)

This guideline will provide a series of guideposts, references, standards, and quality assurance markers to ensure ease of implementation and correct operation of an NMS system for the many applications in the clinical laboratory. This document will also include information regarding optimization of the analysis including maintaining optimum performance, approaches to ensuring accurate and precise mass measurement, quality control of assays and troubleshooting instrument problems versus sample preparation problems, limitations of the technology, interpretation of results, the use of relative concentrations ratios of compounds, and qualitative diagnostic profiling including protein profiling versus quantitative analysis for therapeutic monitoring.

Chairholder: Donald H. Chace, PhD
Pediatrix Screening

Expression of Uncertainty of Measurement in Clinical Laboratory Medicine (C51)

This guideline is intended for diagnostic test manufacturers, clinical laboratories, and regulatory agencies. It will describe, in clear terms understood by these three groups, the principles required for estimating measurement uncertainty as stated in the GUM. It also will discuss the limitations of the concepts of uncertainty. This document will also provide advice on how to estimate measurement uncertainty in the healthcare field in an objective, economic manner and present techniques for validating uncertainty estimates gained from simulations by experimental investigations.

Chairholder: Richard R. Miller, Jr.
Dade Behring Inc.

Validate and Implement Secondary Reference Materials (C53)

This guideline will provide recommendations on tests or procedures that should be performed to characterize secondary reference materials in a patient sample matrix.

Chairholder: Hubert Vesper, PhD
Centers for Disease Control and Prevention

Verification of Comparability of Patient Results Within One Healthcare System (C54)

This guideline will provide statistical protocols at stated power to verify the agreement between patients' results when measured on two or more instruments or methods for the same analyte.

Chairholder: Chris Lehman, MD
University of Utah

Evaluation Protocols

Principles of Manufacturer's Validation of Risk Mitigation Using Quality Controls (EP22)

This document will describe the principles, and give procedural examples, for validation of the capability of the quality controls to mitigate the identified risks.

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

General Laboratory Practices

Human Tissue Procurement (GP30)

The scope of this guideline will cover all healthcare institutions or clinics that may collect human tissue for research purposes, by providing recommendations for the collection in accordance with the practice of ethical, legislative, and legal concerns. It will also help to ensure that human tissue procurement and use for medical research can be differentiated from that involving cloning, stem cell, and organ development/replacement research. The separation is important to prevent broad actions brought against all "genetic research" involving humans from disabling diagnostic and pharmaceutical research involving human tissue and molecular genetics.

Co-Chairholders: Sofia Gitis,
Zoion, and Kathleen M. Smith, PhD
DNAX Research Inc.

Laboratory Instrument Evaluation, Verification, and Maintenance (GP31)

Designed to provide useful information in a systematic, easy-to-use format, this document provides recommendations for achieving accurate, precise, and high-quality data for patient care at a reasonable cost. Includes recommended instrument performance criteria that should be considered, and discussion of proper functioning of instrumentation based on theory or experience, when necessary; and references for further information.

Chairholder: William J. Castellani, MD
Truman Medical Center

Microbiology

Methods for Antimicrobial Susceptibility Testing of Human Mycoplasmas (M43)

This project will lead to a consensus guideline for methods and interpretation of *in vitro* antimicrobial susceptibilities for mycoplasmas of human origin. The protocols will be limited to methodology and interpretive criteria for *Mycoplasma pneumoniae*, *Mycoplasma hominis*, and *Ureaplasma urealyticum/parvum*. (Although other mycoplasmas may occur in human infections, disease associations and cultivation conditions are not so well established and, therefore, these organisms are not practical to study in a project of this nature.)
A CLSI-IFCC joint project.

Chairholder: Ken B. Waites, MD
University of Alabama at Birmingham

Diagnostic Microbiology for Limited Resources Laboratories (M46)

This document describes the performance of these tasks within the realm of the limited resources laboratory (i.e., those that have minimal means with which to perform microbiological analyses). Addressed in this document are the environment in which such diagnostic methods can be employed, minimal materials necessary for diagnostic microbiology, the education and training of personnel performing this testing, and the procedures for the production of clinically relevant patient test results within these constraints. To assist the limited resources laboratory, this document will include minimal standards of adherence necessary for good microbiology laboratory practices.

Chairholder: Susan Sharp, PhD
Kaiser Permanente – NW

Principles and Procedures for Blood Cultures (M47)

This guideline is intended to provide guidance to clinical microbiologists for the recovery of pathogens from blood specimens taken from patients who are suspected of having bacteremia or fungemia. Specific recommendations will be offered for the collection, transport, and processing of blood cultures.

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

Laboratory Diagnosis of Mycobacterial Infections (M48)

This guideline is intended to provide guidance to laboratories on the total testing process for patients with suspected mycobacterial infections. Recommendations will be offered for the collection, preservation, and transport of clinical specimens. Procedures for the direct detection of mycobacteria by microscopy and amplification techniques, the optimal recovery of mycobacteria from clinical specimens, and the identification of mycobacterial species by traditional (phenotypic) and alternative (phenotypic and genotypic) laboratory methods will be addressed.

Chairholder: Betty A. Forbes, PhD
Medical College of Virginia

Molecular Methods

Molecular Methods for Bacterial Strain Typing (MM11)

This guideline will examine the biology behind molecular strain typing and the process of characterizing and validating typing systems. The guideline will describe the prevalent methods with particular attention to Pulse Field Gel Electrophoresis (PFGE) and multilocus sequence typing (MLST).

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

Determining Clinical Utility of Genetic Tests (MM15)

Several government advisory committees have recently advocated that genetic testing not be performed unless "clinical utility" has been clearly demonstrated. However, this concept does not yet have a defined form in law, regulation, or guideline. The proposed project will focus on the benefits and challenges of genetic knowledge and genetic testing. The consensus guideline will provide means by which users (i.e., regulatory agencies, laboratorians, clinicians) can evaluate potential clinical utility in all phases of genetic testing. A CLSI-IFCC joint project.

Chairholder: Timothy J. O'Leary, MD, PhD
Armed Forces Institute of Pathology

Point-of-Care Testing

Implementation Guide of POCT1 for Healthcare Providers (POCT2)

This guideline will provide the healthcare provider or end user with clear and concise information on what features to expect in a connectivity-compliant device. Also includes practical advice on how to apply these features to their daily operation/practice.

Co-Chairholders: Patrick St. Louis, PhD
Sainte-Justine Hospital, and
Louis J. Dunka, Jr., PhD
LifeScan, Inc.

Implementation Guide of POCT1 for Manufacturers (POCT3)

This guideline will provide a framework for IVD manufacturers to implement POCT1 into their device software.

Chairholder: Andy Quintenz
Biosite Inc.

ISO/TC 212

ISO 18113

Clinical laboratory testing and *in vitro* diagnostic test systems – *In vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling)

Part 4: *In vitro* diagnostic reagents for self-testing

This International Standard will specify requirements for information supplied by the manufacturer of *in vitro* diagnostic reagents, for self-testing. This Standard will also apply to information supplied by the manufacturer with calibrators, control materials and accessories intended for use with *in vitro* diagnostic reagents for self-testing.

Part 5: *In vitro* diagnostic instruments for self-testing

This International Standard specifies the requirements for the contents of instructions for use for *in vitro* diagnostic instruments including apparatus, equipment, calibrators and control materials for self-testing.

ISO/AWI 20776

Susceptibility Testing

This project will focus on standardization in the field of bacteriology relating to the performance of antimicrobial susceptibility devices which are used for testing the susceptibility of bacteria to antibiotics in most medical laboratories. This standard will be developed as a joint activity of ISO/TC 212 and CEN/TC 140.

Videotapes

Quality Microcollection (H4-A3-V)

Details are given on the importance of blood collection and handling using the skin puncture method. The video also illustrates how to obtain the highest quality skin puncture specimen for laboratory testing. It is divided into six sections: safety, advantages, supplies, skin puncture procedure, handling and labeling, and a review of the skin puncture procedure. Based on the H4-A3 standard, the video package includes the video, a copy of the H4-A5 standard, and three laminated summary sheets. For more information on this document, see the entry in the Hematology section. (18 min.)

Members $95 Nonmembers $175

Making a Difference Through Newborn Screening: Blood Collection on Filter Paper (LA4-A3-V)

This video provides a visualization of each step in the blood specimen collection process and depicts the standard of practice, as defined by our consensus process, for collecting such specimens on filter paper. It explains how to select and prepare the safest puncture site; choose the appropriate equipment; puncture the skin and apply blood to filter paper; care for the puncture site; identify and verify a valid specimen; and handle and mail the specimen to the laboratory. LA4-A4 accompanies the videotape, along with laminated summary sheets. For more information on this document, see the entry in the Immunology and Ligand Assay section. (25 min.)

Members $95 Nonmembers $175

Additional laminated sheets can be purchased separately in sets of 10.
Members $25 Nonmembers $50

Disk Susceptibility Testing: Step By Step (M2-A5-V)

Includes M2-A9 and the M100 tables!

This video illustrates preparation and standardization of a test inoculum; inoculation of plates; and reading of zone sizes. It also explains in detail the use of tables when interpreting results and outlines the criteria for quality control testing. A special troubleshooting section is included, depicting the possible results when an inoculum is incorrectly made, when the plates are streaked improperly, or when the disks are applied inappropriately. The M2-A9 standard accompanies the videotape, along with laminated summary sheets. For more information on this document, see the entry in the Microbiology section. (23 min.)

Members $95 Nonmembers $175

Preventing Blood-borne Pathogen Infection: Improved Practice Means Protection (M29-A2-V)

Designed to reduce the risk of acquiring an infectious disease, this educational videotape provides authoritative and practical safety recommendations. This videotape explains standard and contact precautions that should be practiced to protect the laboratorian, and provides a visualization of proper techniques to implement these precautions. Along with the M29-A3 guideline, this educational video will be useful in forming the foundation for your OSHA-required yearly blood-borne pathogen safety training. Laminated summary sheets are also included in the videotape package. For more information on this document, see the entry in the Microbiology section. (21 min.)

Members $115 Nonmembers $200

Also available in DVD. Please indicate M29-A2-DVD on order form.

VIDEO DISCOUNTS

Discounts for multiple copies of the same title are offered. See page 36.
Visit the online store at: www.clsi.org

Infobase 2006

This user-friendly, searchable* CD-ROM includes all 180+ CLSI/NCCLS standards and guidelines. Quickly and easily access all clinical laboratory and medical-testing best practices by locating single words or phrases used in the text.

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Shipping and Handling outside North America	$25.00

TOOLKITS

The CLSI Procedure Manual Toolkit (GP2-A5-C)

Improving procedure writing in the clinical laboratory

AVAILABLE MARCH 2006

The major concepts of document development and control are presented in a user-friendly format that is easy to read and implement, thanks to this toolkit. The *Toolkit* includes the following nine templates with illustrative examples that provide the framework for developing procedures and communicating and organizing information:

- Analytical quantitative procedures;
- Analytical qualitative procedures (e.g., dipstick, slide, immunohematology tests);
- Pre- and post-nonanalytical procedures;
- Analyzer procedures;
- Laboratory information system procedures;
- Master document index (an Excel template is also included to facilitate sorting of data);
- Document change request form for approving new documents or changing previously approved documents;
- Comparison of analytic-specific attributes by analyzer type; and
- Analytic attributes for analyzers.

These templates enable one to establish a starting point for creating one's own laboratory-specific procedure manual. The templates allow the user to enter information into a "boiler plate" file where the parameters are preformatted – headers and footers are set. The user can simply open the template and fill in the blanks.

The *Toolkit* includes a copy of the revised, approved-level document GP2-A5—*Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition.*

This essential *Toolkit* is applicable to any size laboratory, and will be a valuable resource for creating quality procedures.

Members: $150 **Nonmembers: $250**

System Requirements

- Microsoft Windows 98/NT/2000/XP
- Microsoft Word for Windows 2000/2002/2003

Training and Competence Assessment Toolkit

(GP21-A2-C) NEW

The *GP21 Training and Competence Assessment Toolkit* is based on CLSI/NCCLS document GP21-A2—*Training and Competence Assessment; Approved Guideline—Second Edition*, which provides useful information for the development of training and competence assessment programs to verify that staff demonstrate the knowledge and skills necessary for their assigned work processes and procedures.

This toolkit is a powerful device for implementing GP21-A2. It lays the foundation for:

- ensuring that training has taken place and is documented, and
- assessing the competence of personnel in their assigned job tasks, initially and periodically thereafter.

The templates contained herein can be applied when training new employees, introducing new processes or methods, assessing initial competence, and performing periodic reassessments of competence.

The *GP21 Training and Competence Assessment Toolkit* includes a copy of the document GP21-A2—*Training and Competence Assessment; Approved Guideline—Second Edition* and the following Microsoft Word templates:

For training:

- Training Guide Form
- Trainer Responsibilities Form
- Learner Responsibilities Form
- Evaluation of Training Experience Form
- Training Checklist Form

For competence assessment:

- Written Assessment Form
- Direct Observation Checklist Form
- Competence Assessment Form—Quantitative Parallel Testing
- Competence Assessment Form—Qualitative Parallel Testing
- Follow-up of Competence or Learning Assessment Requiring Remediation Form

System Requirements

- Microsoft Windows 98/NT/2000/XP
- Microsoft Word for Windows 97/2000/2002
- Adobe Acrobat Reader 4 or above is required for viewing the User Manual and the GP21-A2 document. The newest version is available from http://www.adobe.com. Adobe Acrobat Reader 6.0 is located in the *GP21 Training and Competence Assessment Toolkit* program directory (usually c:\program files\gp21).

User Requirements

- Basic understanding of Windows user interface and file system
- Basic to intermediate understanding of Microsoft Word

Members $120 **Nonmembers $235**

The CLSI Quality System Toolkit (HS1-A2-C)

The **Toolkit** is based on Clinical and Laboratory Standards Institute document HS1-A2—*A Quality Management System Model for Health Care; Approved Guideline—Second Edition*, which provides useful information for designing, implementing, and maintaining an effective quality management system. An electronic copy of the guideline is also provided in the **Toolkit**.

The **Toolkit** is a powerful device for implementing HS1-A2. It lays the foundation for:
- developing quality policies based on Quality System Essentials;
- outlining quality processes;
- controlling documents; and
- reporting and tracking occurrences.

The templates can be applied when training new employees, introducing new processes or methods, assessing initial competence, and performing periodic reassessments of competence.

In addition to the document, the **Toolkit** includes templates for developing documentation that supports your quality management system in a consistent format. The **Toolkit** includes the following templates in Microsoft Word unless otherwise indicated:

For table of contents creation:
- Quality Manual Table of Contents

For policy or process creation:
- Quality Policy Template
- Quality Process Template
- Flowchart Template

For document management:
- Master Document Index
- Master Document Index in Microsoft Excel
- Document Change Request Form

For occurrence management:
- Occurrence Report Form Template
- Occurrence Tracking Form Template
- Occurrence Tracking Form Template in Microsoft Excel

System Requirements
- Microsoft Windows 98/NT/2000/XP
- Microsoft Word for Windows 2000/2002/2003
- Microsoft Excel (for two templates that are duplicated in Word)

Please note that you need Adobe Acrobat Reader in order to view or print the documents on this CD.

Members: $120 **Nonmembers: $235**

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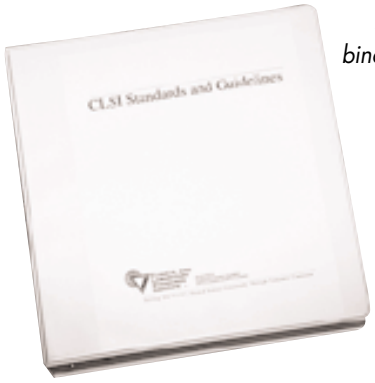
Nonmembers $20
plus shipping and handling as follows:
North America – $7.50
Outside North America – $10.00



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CLSI Publications

Our publications focus on medical-testing procedures, bench and reference methods, quality control, and scientific evaluation protocols. They provide reliable and realistic working standards and guidelines that healthcare professionals can use in daily activities and in solving practical problems.

Consensus is achieved through broad input from the medical-testing community. We encourage thorough review of all standards and guidelines, particularly at the proposed level.

Proposed: A proposed standard or guideline undergoes the first stage of review within the consensus process. It should receive wide and thorough review, including an overall review of its scope and approach, and a line-by-line review of technical and editorial content. This review is intended to ensure the utility and readability of approved standards and guidelines, reflecting a broad consensus.

Approved: An approved standard or guideline should be reviewed to assess utility of the final document and attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional standards.

The **Electronic Subscription Service** *is available to member organizations! Organizations that subscribe to the service can view and/or download an unlimited number of standards and guidelines. Access to this password-protected site is based on the number of users. The subscription service starts at $2750 for a single user, with the additional fee based on the number of users.*

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Antimicrobial Susceptibility Testing Searchable CD-ROM*

NEW

This CD-ROM includes all the M100-S16 tables for the Disk Diffusion (M2) and Aerobic Dilution (M7) susceptibility testing documents. The newly published corresponding methodology documents, M2-A9 and M7-A7, are also included on the CD-ROM.

Members $250 **Nonmembers $375**

*Internet access required for search capabilities.

Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory; A Report (X3-R)

This report presents a stepwise approach for implementing safer medical devices that reduce or eliminate sharps injuries to laboratory personnel. In an expanded checklist format, X3-R outlines a process that goes beyond general recommendations, and specifically addresses the needs of professionals performing specimen collection and clinical laboratory procedures. It outlines the important steps laboratory professionals must take to:

- identify devices that have the potential for causing injury;
- select safer medical devices for evaluation;
- evaluate selected devices;
- adopt the new devices for routine use; and
- implement a continuous quality improvement process.

Members: $65 **Nonmembers $150**

The "Needlestick Report" is an essential reference source for implementing requirements of the *Revised OSHA Bloodborne Pathogen Standard*, as well as analyzing and improving practices, with the goal of providing a safer work environment.

Working Group on Needlestick Prevention

Geraldine L. Barnes, MT(ASCP), MS, Clinical and Laboratory Standards Institute
M. Clare Edelmayer, MT(ASCP), RN, MS, Doylestown Hospital
Beverly Kovanda, PhD, Columbus State Community College
Donna M. Meyer, PhD, CHRISTUS Health
David Sewell, PhD, Veterans Affairs Medical Center

Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report (X4-R)

This document provides guidance on steps to be taken by the clinical laboratory to be prepared in the event of an emergency. X4-R is written for use by laboratory managers, directors, and supervisors, and is intended to provide a checklist of considerations to be used to assess preparedness and begin planning for continuance and redirection of clinical laboratory services during emergency situations.

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Working Group on Emergency Response

J. Rex Astles, PhD, FACB, Centers for Disease Control and Prevention
Thomas L. Hearn, PhD, Centers for Disease Control and Prevention
Lawrence B. Kaplan, PhD, FACB, Bellevue Hospital Center
Anthony R. Sambol, MA, SM(NRM), SV(ASCP), CBSP, Nebraska Health and Human Services System
Thomas L. Williams, MD, FACB, FASCP, FCAP, Methodist Hospital

Proceedings From the *QC for the Future* Workshop; A Report (X6-R)

CLSI, in conjunction with its organizing partners, convened the *QC for the Future* workshop in Baltimore, MD, on 18 March 2005. The purpose of this workshop was to provide attendees with the opportunity to learn about current and new technologies for quality control, to discuss potential approaches for future quality control, and to develop new ideas for implementing quality control for the future. CLSI and the workshop co-sponsors anticipate that these proceedings will serve as a focal point for continued discussion and informed action on this important topic.

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- ☐ $2,100 (Gross sales to $500,000)
- ☐ $3,700 (To $2 million)
- ☐ $5,100 (To $5 million)
- ☐ $7,000 (To $10 million)
- ☐ $8,800 (To $25 million)
- ☐ $10,700 (To $50 million)
- ☐ $12,600 (To $100 million)
- ☐ $14,400 (To $250 million)
- ☐ $16,600 (To $500 million)
- ☐ $18,700 (To $750 million)
- ☐ $20,300 (To $1 billion)
- ☐ $23,000 (Over $1 billion)

Start-up Company dues are $1,070 per year.

☐ **Trade Assn.** ☐ **Gov't. Agency** ☐ **Prof. Society**
Selected Interest dues $1,400 per year.
Broad Interest dues are $3,500 per year.

☐ **Consulting Firm**
Annual dues are $750 for firms with 1-2 employees and $1,100 for firms with more than 3 employees.

ASSOCIATE ACTIVE MEMBERS

☐ **Healthcare Delivery Systems**

_____ Comprehensive $1,800 $ _____

_____ Basic Service Site(s)*@$275 each $ _____
($50 discount does not apply)

☐ **Comprehensive** $1,500**
☐ **Core** $1,100

***In order to be eligible for Healthcare Delivery Systems membership, contact names and addresses for each site MUST be included.*

***Includes the Infobase on CD-ROM; contact CLSI for LAN prices*

CORRESPONDING MEMBERS

☐ **Comprehensive** $1,300**
☐ **Customized** $600***
☐ **Core** $900
☐ **Basic** $300
($50 discount does not apply)

***Includes the Infobase on CD-ROM; contact CLSI for LAN prices*
****Coupons do not apply for ISO documents*

EDUCATION MEMBERS

☐ Formalized Education Program $300

TOTAL MEMBERSHIP FEE

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TOTAL ENCLOSED* **$** _____

***Subtract $50 discount from your membership fee if you choose to receive membership documents in electronic format only. Benefits apply to documents published during your membership year.**

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Annual HIMSS Conference and Exhibition

12-16 February 2006
San Diego, California, USA
CLSI Booth #7328

CLMA ThinkLab '06

18-21 March 2006
Charlotte, North Carolina, USA

Critical Components for Assuring Quality in Laboratory Testing

From writing and managing a technical procedure manual, to proficiency testing for quality improvement, CLSI Executive Vice President, Glen Fine, MS, MBA will moderate this CLMA Educational Track session covering the essentials in developing and implementing a quality management system that will benefit healthcare organizations and improve patient safety. This practical, results-oriented session will be led by experts including internationally renowned quality consultant Lucia Berte, Roche Molecular Systems' Roberta Madej, and Dade Behring's Richard Miller, and will conclude with a Q&A session.

Saturday, 18 March 2006
1:00 p.m. - 5:30 p.m. (4.5 credit hours)

2006 Clinical and Laboratory Standards Institute Leadership Conference

26-28 April 2006
Sheraton Premiere at Tysons Corner
Vienna, Virginia, USA

Risk Management Tools for Improved Patient Safety Workshop

This follow-up to 2005's landmark *QC for the Future* workshop will focus specifically upon defining current problems in risk management, reviewing solutions, and describing a systematic risk management approach, providing attendees with concrete tools with which to return to their workplaces for practical application. The program will feature practical training sessions, with available topics including process mapping, FME(C)A, fault tree analysis, and HACCP.

Register online at www.clsi.org or contact us at +610.688.0100.

For more information, check out our website www.clsi.org or contact CLSI at +610.688.0100

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