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CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE®

(Formerly NCCLS)



Advancing Quality in Healthcare Testing

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New Quality Management System

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

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

The Key to Quality (K2Q) portfolio includes:

- **Essentials** – PowerPoint introduction to the CLSI concept of quality management and how *The Key to Quality* can assist in implementing a quality management system.
- **Examples** – Practical samples and "how to" details, including ready-to-use forms and easy-to-implement templates for each of the 12 QSEs.
- **Flowcharts** – Symbols to help you create your own systematic flowcharts and process documents.
- **Cross-References** – A guide to the interrelated elements of the quality management system approaches from CLSI, ISO, CAP, and other organizations.

Members \$295 Nonmembers \$495

- **Evaluations** – A compilation of self-assessment checklists to determine the effectiveness of implementation, and to monitor and guide quality improvements.
- **CD-ROM** – A slide-show presentation useful for orienting staff to quality systems, as well as representative examples, checklists, and flowcharting tools in an electronic format.

Bundle Documents for Greater Savings (K2Q Plus)

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

Members \$395 Nonmembers \$745



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

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

Introducing Infobase™ 2007

This user-friendly searchable CD-ROM includes 165 CLSI standards and guidelines for medical testing best practices.*

- Includes all approved- AND proposed-level documents published through 31 December 2006;
- Features enhanced search capabilities to quickly and easily search titles, key words, and abstracts or the full document text; and
- Searches for relevant text within multiple documents using sophisticated linking capabilities.

Single-Site Price**

If you previously received Infobase as a benefit of your CLSI membership, you may now purchase it at the reduced cost of just \$1,000.

Members \$1,500

LAN Price***

Members \$3,750
Nonmembers \$5,000

Multiple-Site LAN Price -

\$1,500 per additional site
Discounts are available for organizations with more than three sites.

Shipping/Handling (flat rates)

Within North America \$7.50
Outside North America \$25.00

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

* Internet access required for search capabilities.

** Single site is for one workstation or standalone computer.

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

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-A3 – Preliminary Evaluation (page 9)

Members \$60 Nonmembers \$120

EP12-A – Qualitative Test Performance (page 10)

Members \$60 Nonmembers \$120

EP14-A2 – Evaluation of Matrix Effects (page 10)

Members \$60 Nonmembers \$120

EP15-A2 – Verification of Performance (page 10)

Members \$60 Nonmembers \$120

EP17-A – Limits of Detection and Quantitation (page 10)

Members \$60 Nonmembers \$120

GP10-A – Assessment of Tests (page 10)

Members \$50 Nonmembers \$100

Members \$340 Nonmembers \$900

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 12)

Members \$85 Nonmembers \$200

H4-A5 – Capillary (page 12)

Members \$60 Nonmembers \$120

H11-A4 – Arterial Collection (page 9)

Members \$60 Nonmembers \$120

H21-A4 – Coagulation Specimens (page 12)

Members \$85 Nonmembers \$200

M28-A2 – Fecal Parasitology (page 16)

Members \$60 Nonmembers \$120

M29-A3 – Protection of Laboratory Workers

(page 16)

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 12)

Members \$50 Nonmembers \$100

H18-A3 – Handling and Processing (page 12)

Members \$60 Nonmembers \$120

H20-A2 – Differential Count (page 12)

Members \$50 Nonmembers \$100

H42-A2 – Flow Cytometry (page 12)

Members \$50 Nonmembers \$100

H44-A2 – Reticulocyte Counting (page 12)

Members \$50 Nonmembers \$100

Members \$100 Nonmembers \$300

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 16)

Members \$100 Nonmembers \$200

X3-R – Needlestick (page 30)

Members \$65 Nonmembers \$150

ISO 15190 – Medical laboratories – Requirements for safety (page 21)

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-A3 – Quality Control (page 8)

Members \$60 Nonmembers \$120

EP10-A3 – Preliminary Evaluation (page 9)

Members \$60 Nonmembers \$120

GP2-A5 – Laboratory Documents (page 10)

Members \$95 Nonmembers \$225

M22-A3 – Media QC (page 16)

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 12)

Members \$85 Nonmembers \$200

H30-A2 – Fibrinogen (page 12)

Members \$60 Nonmembers \$120

H47-A – One-Stage Prothrombin Time (PT)

Test and Activated Partial Thromboplastin Time (APTT)

Test (page 13)

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.

L151-A – Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems (page 7)

Members \$65 Nonmembers \$120

L152-A2 – Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems (page 7)

Members \$65 Nonmembers \$120

L153-A – Standard Guide for Selection of a Clinical Laboratory Information Management System (page 8)

Members \$60 Nonmembers \$120

LIS4-A – Standard Guide for Documentation of Clinical Laboratory Computer Systems (page 8)
Members \$60 Nonmembers \$120

LIS5-A – Standard Specification for Transferring Clinical Observations Between Independent Computer Systems (page 8)

Members \$60 Nonmembers \$120

LIS6-A – Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems (page 8)

Members \$60 Nonmembers \$120

LIS7-A – Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory (page 8)

Members \$60 Nonmembers \$120

LIS8-A – Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems (page 8)

Members \$60 Nonmembers \$120

LIS9-A – Standard Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures (page 8)

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-A4 – Reagent Water (page 8)

Members \$60 Nonmembers \$120

C24-A3 – Quality Control (page 8)

Members \$60 Nonmembers \$120

C28-A2 – Reference Intervals (page 8)

Members \$60 Nonmembers \$120

EP10-A3 – Preliminary Evaluation (page 9)

Members \$60 Nonmembers \$120

GP2-A5 – Laboratory Documents (page 10)

Members \$95 Nonmembers \$225

H18-A3 – Handling and Processing (page 12)

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

GP18-A2 – 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 11)

Members \$50 Nonmembers \$100

GP26-A3 – Laboratory Services (page 11)

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.

C30-A2 – Blood Glucose Testing (page 8)

Members \$60 Nonmembers \$120

GP2-A5 – Laboratory Documents (page 10)

Members \$95 Nonmembers \$225

GP16-A2 – Routine Urinalysis (page 10)

Members \$60 Nonmembers \$120

H4-A5 – Capillary (page 12)

Members \$60 Nonmembers \$120

POCT1-A2 – Connectivity (page 18)

Members \$100 Nonmembers \$150

POCT2-P – Implementation Guide of POCT1 (page 18)

Members \$50 Nonmembers \$100

POCT4-A2 – *In Vitro* Diagnostic (page 18)

Members \$65 Nonmembers \$150

Members \$300 Nonmembers \$600

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 11)

Members \$50 Nonmembers \$100

GP23-A – Nongynecologic Specimens (page 11)

Members \$60 Nonmembers \$120

M29-A3 – Protection of Laboratory Workers

(page 16)

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 12)

Members \$85 Nonmembers \$200

H4-A5 – Capillary (page 12)

Members \$60 Nonmembers \$120

H18-A3 – Handling and Processing (page 12)

Members \$60 Nonmembers \$120

H21-A4 – Coagulation Specimens (page 12)

Members \$85 Nonmembers \$200

LA4-A4 – Newborn Screening (page 14)

Members \$60 Nonmembers \$120

M29-A3 – Protection of Laboratory Workers

(page 16)

Members \$100 Nonmembers \$200

X3-R – Needlestick (page 30)

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 15)

Members \$150 Nonmembers \$275

M7-A7 – Aerobic Susceptibility Testing (page 15)

Members \$150 Nonmembers \$275

M11-A7 – Anaerobic Susceptibility Testing (page 15)

Members \$85 Nonmembers \$200

M21-A – Serum Bactericidal Test (page 16)

Members \$60 Nonmembers \$120

M23-A2 – Test Development (page 16)

Members \$150 Nonmembers \$250

M26-A – Bactericidal Activity (page 16)

Members \$60 Nonmembers \$120

M27-A2 – Antifungal Reference Method (page 16)

Members \$60 Nonmembers \$120

M31-A2 – Veterinary Antimicrobial (page 16)

Members \$60 Nonmembers \$120

M38-A – Filamentous Fungi (page 17)

Members \$60 Nonmembers \$120

M39-A2 – Analysis and Presentation (page 17)

Members \$60 Nonmembers \$120

M45-A – Fastidious Bacteria (page 17)

Members \$60 Nonmembers \$120

M100-S17 – Susceptibility Testing Supplement (page 14)

Members \$90 Nonmembers \$225

Members \$500 Nonmembers \$960

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 15)

Members \$150 Nonmembers \$275

M7-A7 – Aerobic Susceptibility Testing (page 15)

Members \$150 Nonmembers \$275

M11-A7 – Anaerobic Susceptibility Testing (page 15)

Members \$85 Nonmembers \$200

M22-A3 – Media QC (page 16)

Members \$60 Nonmembers \$150

M28-A2 – Recovery and Identification of Parasites (page 16)

Members \$60 Nonmembers \$120

M29-A3 – Protection of Laboratory Workers (page 16)

Members \$100 Nonmembers \$200

M35-A – Rapid Identification (page 16)

Members \$60 Nonmembers \$120

M45-A – Fastidious Bacteria (page 17)

Members \$60 Nonmembers \$120

M100-S17 – Susceptibility Testing Supplement (page 14)

Members \$90 Nonmembers \$225

Members \$425 Nonmembers \$820

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and SAVE UP TO 50% off
individual document
list prices.**

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place orders at www.clsi.org**

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-A2 – Flow Cytometry (page 12)

Members \$50 Nonmembers \$100

H43-A2 – Neoplastic Hematolymphoid Cells (page 12)

Members \$50 Nonmembers \$100

H44-A2 – Reticulocyte Counting (page 12)

Members \$50 Nonmembers \$100

H52-A – Fetal Red Cell Detection (page 13)

Members \$60 Nonmembers \$120

M29-A3 – Protection of Laboratory Workers (page 16)

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 21)

Members \$150 Nonmembers \$200

GP2-A5 – Laboratory Documents (page 10)

Members \$95 Nonmembers \$225

GP21-A2 – Training and Competence Assessment (page 11)

Members \$50 Nonmembers \$100

GP22-A2 – Continuous Quality Improvement (page 11)

Members \$85 Nonmembers \$200

GP26-A3 – Laboratory Services (page 11)

Members \$85 Nonmembers \$200

HS1-A2 – A Quality Management System Model for Health Care (page 11)

Members \$85 Nonmembers \$200

HS4-A2 – Respiratory Services (page 11)

Members \$50 Nonmembers \$100

HS5-A2 – Medical Imaging Services (page 11)

Members \$50 Nonmembers \$100

HS10-A2 – Inpatient Medication Use (page 11)

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-A2 – Molecular Genetics (page 17)

Members \$60 Nonmembers \$120

MM2-A2 – Molecular Hematology (page 17)

Members \$60 Nonmembers \$120

MM3-A2 – Molecular Microbiology (page 17)

Members \$60 Nonmembers \$120

MM4-A – Immunocytochemistry (page 18)

Members \$60 Nonmembers \$120

MM5-A – PCR-Based Assays (page 18)

Members \$60 Nonmembers \$120

MM6-A – Infectious Diseases (page 18)

Members \$60 Nonmembers \$120

MM7-A – FISH Methods for Medical Genetics (page 18)

Members \$60 Nonmembers \$120

MM9-A – Nucleic Acid Sequencing (page 18)

Members \$60 Nonmembers \$120

MM13-A – Collection and Handling of Specimens for Molecular Methods (page 18)

Members \$60 Nonmembers \$120

MM14-A – Proficiency Testing (page 18)

Members \$60 Nonmembers \$120

Members \$300 Nonmembers \$650

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 16)

Members \$60 Nonmembers \$150

M29-A3 – Protection of Laboratory Workers (page 16)

Members \$100 Nonmembers \$200

M31-A2 – Veterinary Antimicrobial Susceptibility Tests (page 16)

Members \$60 Nonmembers \$120

M34-A – Lyme Disease (page 16)

Members \$60 Nonmembers \$120

M37-A2 – Veterinary Test Development (page 17)

Members \$60 Nonmembers \$120

M42-A – Disk AST Aquatic Animals (page 17)

Members \$60 Nonmembers \$120

M49-A – Dilution AST Aquatic Animals (page 17)

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 7)

Members \$50 Nonmembers \$100

AUTO2-A2 – Specimen Identification (page 7)

Members \$50 Nonmembers \$100

AUTO3-A – Systems Communications (page 7)

Members \$50 Nonmembers \$100

AUTO4-A – Systems Status (page 7)

Members \$50 Nonmembers \$100

AUTO5-A – Electromechanical Interfaces (page 7)

Members \$50 Nonmembers \$100

GP18-A2 – Laboratory Design (page 10)

Members \$50 Nonmembers \$100

GP19-A2 – Laboratory Instruments and Data Management Systems (page 7)

Members \$60 Nonmembers \$120

POCT1-A2 – Connectivity (page 18)

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.

C46-A – Blood Gas and pH Analysis (page 9)

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 14)

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 21)

Members \$150 Nonmembers \$200

GP26-A3 – Laboratory Services (page 11)

Members \$85 Nonmembers \$200

HS1-A2 – A Quality Management System Model for Health Care (page 11)

Members \$85 Nonmembers \$200

GP22-A2 – Continuous Quality Improvement (page 11)

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-A3 – Quality Control (page 8)

Members \$60 Nonmembers \$120

C28-A2 – Reference Intervals (page 8)

Members \$60 Nonmembers \$120

GP2-A5 – Laboratory Documents (page 10)

Members \$95 Nonmembers \$225

GP22-A2 – Continuous Quality Improvement (page 11)

Members \$85 Nonmembers \$200

GP26-A3 – Laboratory Services (page 11)

Members \$85 Nonmembers \$200

GP27-A2 – Proficiency Testing (page 11)

Members \$50 Nonmembers \$100

H3-A5 – Venipuncture (page 12)

Members \$85 Nonmembers \$200

H21-A4 – Specimen Coagulation (page 12)

Members \$85 Nonmembers \$200

H47-A – One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test (page 13)

Members \$50 Nonmembers \$100

M22-A3 – Media QC (page 16)

Members \$60 Nonmembers \$150

M29-A3 – Protection of Laboratory Workers (page 16)

Members \$100 Nonmembers \$200

Members \$375 Nonmembers \$850

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

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 primarily for US 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.*

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

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

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

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

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

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

Chairholder: Randy R. Davis
Dade Behring Inc.

Managing and Validating Laboratory Information Systems; Approved Guideline (AUTO8-A) 2006

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

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; Approved Guideline (AUTO10-A) 2006



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. It provides a framework that will allow each laboratory to easily design, implement, validate, and customize rules for autoverification 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; Approved Standard (AUTO11-A) 2006



This document provides technical and operational requirements as well as technical implementation procedures 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

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) 2002

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

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

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

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

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

Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems (LIS6-A) 2002

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

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

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

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

* 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 them available for informational content.

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; Approved Guideline – Fourth Edition (C3-A4) 2006

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 Measurement Procedures: Principles and Definitions; Approved Guideline – Third Edition (C24-A3) 2006

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

Members \$60 Nonmembers \$120

*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

*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

*Chairholder: Paul D'Orazio, PhD
Instrumentation Laboratory*

FDA

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*

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

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

FDA

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

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

FDA

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, FRCP
British Columbia's Children's Hospital*

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*

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 NCCLSI/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

Chairholder: W. Gregory Miller, PhD
Virginia Commonwealth University

FDA

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 NCCLSI/IFCC joint project.

Members \$60 Nonmembers \$120

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

Analysis of Body Fluids in Clinical Chemistry; Proposed Guideline (C49-P) 2006

This document provides guidance for the application of widely available analytic methods for testing body fluids and reporting and interpreting those results. It emphasizes defining the common clinical situations for this use; acceptable practice for measuring analytes without extended method verification for abnormal body fluid; influence of biologic and analytic variation on interpretation of results; and variability in comparing results between different instrument manufacturers. This document does not consider serum, plasma, whole blood, or fluids for which assays are typically FDA cleared. A CLSI/IFCC joint project.

Members \$65 Nonmembers \$125

Chairholder: Richard A. McPherson, MD
Virginia Commonwealth University

General Principles and Guidelines on the Use of Mass Spectrometry in the Clinical Laboratory; Proposed Guideline (C50-P) 2007

NEW

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

Members \$65 Nonmembers \$175

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

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

Chairholder: Kurt M. Dubowski, PhD
University of Oklahoma

FDA

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

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

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

Chairholder: Jan S. Krouwer, PhD
Krouwer Consulting

FDA

Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline – Third Edition (EP10-A3) 2006

NEW

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

Members \$60 Nonmembers \$120

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



Chairholder: Larry W. Clark, MS
Bayer Corporation

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

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



Chairholder: David L. Phillips
LifeScan

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

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

See page 25 for The CLSI Procedure Manual Toolkit (GP2-A5-C).

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



Based on US 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



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-A3 in the Evaluation Protocols section.)

Members \$50 Nonmembers \$100



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

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



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
GSE Consulting

Laboratory Design; Approved Guideline – Second Edition (GP18-A2) 2007



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

Members \$50 Nonmembers \$100

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

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

See page 26 for Training and Competence Assessment Toolkit (GP21-A2-C).

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 to Improve the Clinical Laboratory; Approved Guideline – Second Edition (GP27-A2) 2007



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

Members \$50 Nonmembers \$100

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

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 assess test performance when proficiency testing (PT) is not available; these methods include examples with statistical analyses. This document is intended for use by laboratory managers and testing personnel in traditional clinical laboratories as well as in point-of-care and bedside testing environments.

Members \$60 Nonmembers \$120

Chairholder: Stephen J. Sarewitz, MD
Valley Medical Center

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



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

Members \$95 Nonmembers \$150

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

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

See page 27 for The CLSI Quality System Toolkit (HS1-A2-C).

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 Management System Model for Respiratory Services; Approved Guideline – Second Edition (HS4-A2) 2006

This guideline describes the respiratory services path of workflow and provides information for respiratory services operations that will assist the services in improving their processes and meeting government and accreditation requirements.

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.

Application of a Quality Management System Model for Medical Imaging Services; Approved Guideline – Second Edition (HS5-A2) 2006

This guideline describes the medical imaging services path of workflow and provides information for imaging services operations that will assist the services in improving their processes and meeting government and accreditation requirements.

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 Management System Model for Inpatient Medication Use; Approved Guideline – Second Edition (HS10-A2) 2006

This guideline describes the hospital inpatient medication system path of workflow, and provides information for medication system operations that will assist the hospital pharmacy in improving its medication-related processes and meeting government and accreditation requirements.

Members \$50 Nonmembers \$100

Chairholder: Judy Dye, MA
University of Arizona Medical Center

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

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

Management of Nonconforming Events; Proposed Guideline (HS12-P) 2007



The purpose of programs to manage nonconforming events is to identify and characterize problem-prone processes in health care so that improvement projects can be prioritized, designed, and implemented. A nonconforming event management program should identify systematic problems and gain management's commitment to removing the causes. This guideline offers a suggested outline and contents for a nonconforming event management program and is based on principles of quality management and patient safety.

Members \$60 Nonmembers \$120

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

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



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



Chairholder: Charles F. Arkin, MD
Lahey Clinic

See related publication X3-R on page 30.

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 30.

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

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

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



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

Members \$50 Nonmembers \$100

Chairholder: John A. Koepke, MD
Durham, NC

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

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-A2 in this section.)

Members \$50 Nonmembers \$100



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



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

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



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

Members \$50 Nonmembers \$100

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

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



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

Members \$50 Nonmembers \$100

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

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

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

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

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

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; Approved Guideline (H56-A) 2006

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 CLSHFCC 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 of Laboratory Tests for Autoantibodies to Nuclear Antigens: (1) Indirect Fluorescence Assay for Microscopy and (2) Microtiter Enzyme Immunoassay Methods; Approved Guideline - Second Edition (I/LA2-A2) 2006

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

Members \$50 Nonmembers \$100

Chairholder: Marilyn M. Lightfoote, MD, PhD
FDA Ctr. for Devices/Rad. Health

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

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

REAFFIRMED
SEPT. 2001

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

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

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

REAFFIRMED
SEPT. 2001

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

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

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 histocompatibility 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 NCCLSHFCC joint project.

Members \$50 Nonmembers \$100

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

Newborn Screening Follow-up; Approved Guideline (I/LA27-A) 2006

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 \$50 Nonmembers \$100

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

* This document is no longer being reviewed as part of our consensus process. However, because of its usefulness to a limited segment of the healthcare community, we are continuing to make it available for informational content.

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

Antimicrobial Testing

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



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

Updates:

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

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

Members \$90 Nonmembers \$225

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

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

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*Internet access required for search capabilities.

AST QC Quick Guides (AST-QC Quick)

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**

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

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

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

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

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

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
University of Alberta Hospital

Vice-Chairholder: Donald R. Callihan, PhD
BD Diagnostic Systems



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

NEW

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

Members **\$35** Nonmembers **\$60**

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

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

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

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

Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard – Seventh Edition (M11-A7) 2007

NEW

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

Updates:

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

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

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

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

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

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

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

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

Chairholder: John H. Rex, MD, FACP
AstraZeneca

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 30.

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

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. Arbiq, ART(CSMLS) CLS(NCA),
Arbiq-Rendell Onsite Training and Consulting,
and Barbara Ann Body, PhD, D(ABMM), LabCorp

Viral Culture; Approved Guideline (M41-A) 2006

This document provides guidance for viral culture and identification procedures typically performed in the clinical virology laboratory setting using commercially available cell cultures and reagents. It 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; Approved Guideline (M42-A) 2006

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,
FDA Center for Veterinary Medicine

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

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; Approved Guideline (M45-A) 2006

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

Principles and Procedures for Blood Cultures; Proposed Guideline (M47-P) 2006

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

Members \$60 Nonmembers \$120

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

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

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

Members \$85 Nonmembers \$200

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

Methods for Broth Dilution Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline (M49-A) 2006

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 – Second Edition (MM1-A2) 2006

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

Co-Chairholders: Wayne W. Grody, MD, PhD
UCLA School of Medicine, and
Carolyn Sue Richards, PhD, FACMG
Oregon Health Sciences University

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

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

* This document is no longer being reviewed as part of our consensus process. However, because of its usefulness to a limited segment of the healthcare community, we are continuing to make it available for informational content.

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

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

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, dideoxylterminator 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

Chairholder: Michael A. Zoccoli, PhD
Celera Diagnostics

Genotyping for Infectious Diseases: Identification and Characterization; Approved Guideline (MM10-A) 2006

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.

Vice-Chairholder: Max Q. Arens, PhD
Washington University School of Medicine

Molecular Methods for Bacterial Strain Typing; Proposed Guideline (MM11-P) 2006

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

Members \$65 Nonmembers \$150

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

Diagnostic Nucleic Acid Microarrays; Approved Guideline (MM12-A) 2006

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 CLSHFCC 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) 2005

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 CLSHFCC 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 CLSHFCC 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; Approved Guideline (MM16-A) 2006



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 CLSHFCC joint project.

Members \$60 Nonmembers \$120

Chairholder: Janet A. Warrington, PhD
Affymetrix

POINT-OF-CARE TESTING

Point-of-Care Connectivity; Approved Standard - Second Edition (POCT1-A2) 2006



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. A CLSI, IFCC, CIC joint publication.

Members \$100 Nonmembers \$150

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

Note: Distributed on CD-ROM

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



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

Members \$50 Nonmembers \$100

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

Point-of-Care In Vitro Diagnostic (IVD) Testing; Approved Guideline - Second Edition (POCT4-A2) 2006



This document provides guidance to users of *in vitro* diagnostic (IVD) devices outside the clinical laboratory, to ensure reliable results comparable to those obtained within the clinical laboratory. Replaces AST2-A and AST3-A.

Members \$65 Nonmembers \$150

Chairholder: Ellis Jacobs, PhD, DABCC, FACB
New York State Dept. of Health

Facilitate licensure, satisfy accreditation requirements, build credibility, reduce operating costs, and achieve success

The implementation of a strong quality management system provides a platform for continuous improvement in service delivery: enhancing customer service, meeting regulatory and accreditation assessments, and creating a culture of total service excellence.

CLSI can help...

CLSI provides essential resources that organizations need to improve the quality of patient testing and healthcare services and to meet regulatory and accreditation requirements.

A Quality Management System Model for Health Care (HS1-A2) provides a structure for a comprehensive, systematic approach to build quality into a healthcare service's processes, assess the service's performance, and implement quality improvements.

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

Members \$85

Nonmembers \$200

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

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

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

PLUS

The CLSI Quality System Toolkit (HS1-A2-C) January 2006

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. A pdf of the guideline is also provided in the **Toolkit**.

Members \$120

Nonmembers \$235

Introducing: The Key to Quality

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

For more details see page 3 or visit www.clsi.org

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.

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

Members \$60 Nonmembers \$120

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

Members \$60 Nonmembers \$120

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

Members \$50 Nonmembers \$100

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

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

Members \$60 Nonmembers \$120

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

Members \$60 Nonmembers \$120

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

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

Members \$60 Nonmembers \$120

Labeling for Home-Use *In Vitro* Testing Products; Approved Guideline **(GP14-A)** 1996

Members \$35 Nonmembers \$85

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

Members \$60 Nonmembers \$120

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

Members \$50 Nonmembers \$100

Histochemical Method for Leukocyte Alkaline Phosphatase; Proposed Standard **(H22-P)** 1984

Members \$25 Nonmembers \$75

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

Members \$50 Nonmembers \$100

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. 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.

Through an agreement with ANSI, we are able to offer ISO/TC 212 approved and draft standards.

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 \$170 Nonmembers \$225

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

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

Members \$170 Nonmembers \$225

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 \$105 Nonmembers \$145

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 \$100 Nonmembers \$135

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 \$160 Nonmembers \$215

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 \$130 Nonmembers \$175

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 \$200 Nonmembers \$265

In vitro diagnostic medical devices for professional use – Summary of regulatory requirements for information supplied by the manufacturer (ISO/TR 18112) 2006

This Technical Report summarizes regulatory requirements and associated guidance for information supplied by the manufacturer with IVD medical devices intended for professional use.

Members \$255 Nonmembers \$340

Clinical laboratory testing and in vitro diagnostic test systems – In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) (ISO/DIS 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 \$140 Nonmembers \$185

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 \$85 Nonmembers \$110

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 \$75 Nonmembers \$100

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.

Members \$140 Nonmembers \$185

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.

Members \$140 Nonmembers \$185

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 for staining in biology.

Members \$105 Nonmembers \$140

Clinical laboratory testing and *in vitro* diagnostic test systems – Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices (ISO 20776) 2006

Part 1: Reference method for testing the *in vitro* activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases

This part of ISO 20776 describes one reference method, broth microdilution, for determination of MICs.

Members \$250 Nonmembers \$450

To get interpretive criteria and updated QC ranges purchase ISO 20776 Part 1 with M100-S17.

Bundled price: Members \$300 Nonmembers \$600

Part 2: Evaluation of performance of antimicrobial susceptibility test devices

This standard will provide acceptable performance criteria for antimicrobial susceptibility test (AST) devices that are used for determining minimum inhibitory concentrations (MIC) and/or interpretive category determinations (Susceptible, Intermediate, Resistant, SIR) of bacteria to antimicrobial agents in medical laboratories. It will be developed as a joint activity of ISO/TC 212 and CEN/TC 140.

Members \$100 Nonmembers \$135

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

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

Members \$65 Nonmembers \$85

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 \$105 Nonmembers \$145

Point-of-care testing (POCT) – Requirements for quality and competence (ISO 22870) 2006

This International Standard gives specific requirements applicable to point-of-care testing and is intended to be used in conjunction with ISO 15189. The requirements of this standard apply when POCT is carried out in a hospital, clinic or healthcare organization providing ambulatory care.

Members \$90 Nonmembers \$125

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

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 40.

**Visit the online store at:
www.clsi.org**

Projects in Development

NOTE:

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

Clinical Chemistry and Toxicology

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.

Laboratory Quality Control Protocols Based on Manufacturer's Risk Mitigation Information and the Laboratory's Environment (EP23)

This guideline is primarily intended for users of moderate complexity/point-of-care (POC) test systems; however, all laboratories will find the manufacturer's test limitations and risk mitigation information useful. All laboratories will receive clear, concise scientific guidance to develop QC processes and procedures to 1) reduce the potential negative impact of the test system's limitations, while considering certain laboratory environmental factors like personnel competency, temperature, etc.; and 2) monitor immediate and extended test performance. Nonwaived (moderate and high complexity) laboratories will receive guidance that will enable them to develop effective, cost-efficient QC protocols that will ensure consistent and appropriate application of CLIA QC regulatory requirements based on the technologies selected by the laboratory and reflective of that laboratory's unique environmental aspects. This document will cross refer to EP22, the Risk Management guidance document.

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

Hematology

Protocol for the Evaluation of Coagulometers (H57)

This guideline will set out the various levels of evaluation and give guidance on how to plan and execute the evaluation of a laboratory coagulometer. It will cover the assessment of safety, carryover, precision, bias, linearity, and comparability.

Chairholder: Chris Gardiner
University College London Hospitals

Platelet Function Testing (H58)

This guideline will provide recommendations for specimen collection, patient preparation, sample processing, testing, and quality control in relation to platelet function testing. It will address anticoagulants, specimen storage, and transport temperatures; sample selection for various methodologies; establishment of reference intervals; result reporting; assay validation; and troubleshooting.

Chairholder: Douglas J. Christie, PhD, FAHA
Dade Behring, Inc

Immunology and Ligand Assay

Optimizing Detection of HLA-Specific Alloantibody by Flow Cytometry for Solid Organ and Stem Cell Transplantation (I/LA29)

This guideline will describe criteria for optimizing the detection of HLA alloantibody by cytometric methods. The methodologies addressed include the flow cytometric crossmatch as well as microparticle detection of HLA alloantibody in conventional and multiplexed platforms. Specific areas include the use of standardized instrument setup and staining procedures, reporting formats, interpretation, and multicenter quality assurance.

Chairholder: Robert A. Bray, PhD
Emory University Hospital

Interference with Immunoassay Results by Heterophile Antibodies and Other Binders (I/LA30)

This guideline will describe various types of interferences by heterophile antibodies and other binders as well as their effect on patient results. Methods to identify and characterize the interferences will be addressed along with assessment of these methods and their effectiveness in eliminating interference. This guideline will also create appropriate language for test manufacturers to use in package inserts to describe test limitations caused by endogenous interfering substances in human specimens. This language can then be used by clinical laboratorians to communicate results to test-ordering medical care professionals. The guideline will not address other types of immunoassay interferences such as hemolysis, cross-reacting substances, and drug interference except when the drug is an antibody.

Chairholder: Joan H. Howanitz, MD
SUNY Brooklyn

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/FCC 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

Quality Control for Commercial Microbial Identification Systems (M50)

This guideline will provide information on Quality Control (QC) to manufacturers, distributors, and users of commercial Microbial Identification Systems (MIS). The intent of the document is to define necessary QC for those MIS of proven reliability. It will address the QC responsibilities of the manufacturer, distributor, and user; identify the types of MIS qualifying for reduced QC; and propose general QC procedures for MIS.

Chairholder: Nancy L. Anderson, MMSc, MT(ASCP)
Centers for Disease Control and Prevention

Molecular Methods

Verification and Validation of Multiplex Nucleic Acid Assays (MM17)

This guideline will cover the verification and validation of multiplex nucleic acid tests. Topics covered will include defining and acquiring test samples, approaches for defining assay performance characteristics, i.e., sensitivity, specificity, accuracy and reproducibility, and methods of statistical analysis. Discussion of how to address reporting of results, when one or more of the multiplex assays may be invalid or wrong. This document is intended for manufacturers of multiplex assays/equipment, laboratory professionals who develop and/or perform multiplex assays, clinicians who use the results to diagnose or manage patients, and agencies that regulate the use of multiplex assays/equipment.

Co-Chairholders: Jean Amos Wilson, PhD, FACMG
Focus Diagnostics, and Michael A. Zoccoli, PhD,
Celera Diagnostics

Interpretive Criteria for Microorganism Identification by Gene Sequencing (MM18)

This document will address the importance of quality control, selection of appropriate reference sequences/databases, quality scores for sequencing results, identity scores for sequence analysis, interpretive criteria for specific groups of microorganisms, and limitations of gene sequencing method. The final identification of a microorganism is greatly influenced by: (1) nucleotide sequence length, (2) quality of generated sequence (ambiguous bases, intracellular polymorphisms), (3) identity scores which are unique for defining specific genera and species (for clinical purposes only), (4) intergenus, intragenus, interspecies, and intraspecies variability, and (5) reference databases. This document will establish guidelines for interpretive criteria to ensure intralaboratory and interlaboratory reproducibility, and will enable laboratories to report meaningful results to clinicians that directly impact patient management.

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

Point-of-Care Testing

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.

Performance Metrics for Continuous Interstitial Glucose Monitoring (POCT5)

This guideline will address the comparison of continuous glucose monitoring (CGM) devices, define good agreement given the time lag between blood and interstitial fluid levels, and explain how to display and interpret the data produced by CGM in a common fashion. Terminology will be defined for interstitial fluid glucose and its relationship to blood glucose levels, and the degree of agreement for acceptable technical performance will be defined to allow assessment of method comparability. It will also present recommendations for clinical interpretation of CGM for utilization in patient care.

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

Method Comparison of Point-of-Care Glucose Methodologies with Different Sample Types (POCT6)

This guideline will assist the clinical and point-of-care staff in method comparisons between glucose tests when the sample type is different. It will include considerations for the various sample types used in hospitals, i.e. finger-stick, venous, arterial, interstitial, etc. This guideline will also address factors that influence result variation such as methodology, calibration and transportation and testing intervals between test comparisons.

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

ISO/TC 212

ISO/AWI 25680

Laboratory Medicine – Estimation and reporting of measurement uncertainty

This standard will outline the principles of estimating measurement uncertainty for quantity values obtained in medical laboratories, based on data obtained from metrological experience, publications, manufacturers' information, and supplementary experiments – all necessary ingredients during the validation of any measurement procedure. It will be developed as a joint activity of ISO/TC 212 and CEN/TC 140.



TOOLKITS

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

Improving procedure writing in the clinical laboratory

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 pdf 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)

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 pdf file 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. A pdf file 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

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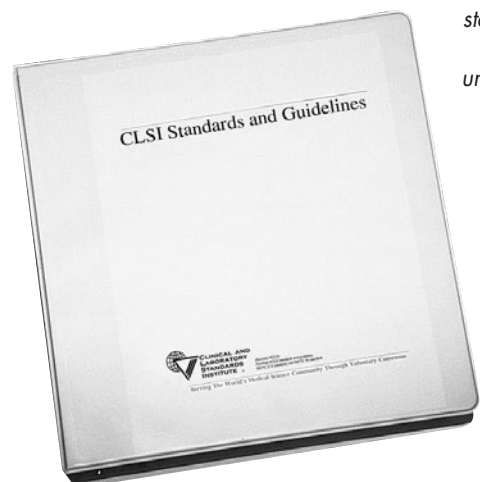
More than 180 standards and guidelines across the patient-testing disciplines help healthcare professionals achieve quality performance and safety.

Automation documents (AUTO 1-5) are included.



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For the Electronic Library, see Infobase™ 2007 on page three.

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.

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Antimicrobial Susceptibility Testing Searchable CD-ROM*

NEW

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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.



Members \$65 Nonmembers \$150

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

Metrological Traceability and Its Implementation; A Report (X5-R)

This document provides guidance to manufacturers for establishing and reporting metrological traceability. A CLSI-IFCC joint project.

Members \$65 Nonmembers \$150

Working Group on Metrological Traceability:

Marc I. Salit, PhD, National Institute of Standards and Technology

Dr. Thomas Ciesiolka, Roche Diagnostics GmbH

Neil Greenberg, PhD, Ortho-Clinical Diagnostics, Inc.

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

W. Gregory Miller, PhD, Virginia Commonwealth University

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

Professor Mauro Panteghini, MD, Azienda Ospedaliera "Spedali Civili"

Privatdozent Dr. Gerhard Schumann, PhD, Medizinische Hochschule Hannover

Professor Dr. Lothar Siekmann, University of Bonn

David Sogin, PhD, Abbott Laboratories

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.

Members \$15 Nonmembers \$25

QC for the Future Workshop Sponsoring Organizations:

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American Clinical Laboratory Association

American Medical Technologists

American Society for Clinical Laboratory Science

American Society for Clinical Pathology

American Society for Microbiology

Advanced Medical Technology Association (AdvaMed)

Centers for Disease Control and Prevention

Centers for Medicare & Medicaid Services

College of American Pathologists

CLMA

Clinical and Laboratory Standards Institute (CLSI)

COLA

Joint Commission on Accreditation of Healthcare Organizations

U.S. Food and Drug Administration

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- H4-A3-V**, Quality Microcollection
Members \$95 Nonmembers \$175
- LA4-A3-V**, Newborn Screening
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- M29-A2-V or DVD**, Preventing
Blood-borne Pathogen Infection
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AUTO3-A, Communications with
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M44-S1, Zone Diameter Interpretive Standards and Corresponding MIC Interpretive Breakpoints
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Healthcare Information and Management Systems Society (HIMSS) Annual Conference and Exhibition

25 February - 1 March 2007
New Orleans, Louisiana USA

CLSI Booth #7427

CLMA ThinkLab '07

24 - 27 March 2007
Houston, Texas USA

Plan to participate in the CLSI Edutrack at CLMA

Topics include:

- Laboratory Documents
- Occurrence Management
- Risk Management
- Proficiency Testing
- Quality Laboratory Specimens

XXth International Symposium on Technological Innovations in Laboratory Hematology (ISLH)

8-11 May 2007

Doral Golf Resort and Spa
Miami, Florida USA

American Society for Microbiology (ASM) 107th General Meeting

22-24 May 2007

Toronto, Ontario Canada

CLSI Booth #102

2007 AACC Annual Meeting & Clinical Lab Expo

15-19 July 2007

San Diego, California USA

**For more information, check out our website at www.clsi.org
or contact CLSI at +610.688.0100 or toll free at 877.447.1888.**



**CLINICAL AND
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(Formerly NCCLS)

940 West Valley Road, Suite 1400

Wayne, PA 19087-1898 USA

Phone: +610.688.0100

Fax: +610.688.0700

E-Mail: customerservice@clsi.org

Website: www.clsi.org

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