CLSI Updates: Guidance, Documents, and Revisions

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Whitehat Communications Point of Care Webinars | September 7, 2023

LEARNING OBJECTIVES

Explain CLSI, the importance of standards, and opportunities to participate in the standards development process

Discuss available CLSI standards and guidelines

Describe new projects in process and changes to updated editions

OVERVIEW OF TODAY'S WEBINAR

CLSI Overview & History

Consensus Standards Development Process

Domain Areas of Expertise

Participation

POCT Tools & Resources

Q&A

1 PACE® continuing education credit is offered for completion of this program

ABOUT CLSI

Clinical and Laboratory Standards Institute (CLSI)

CLSI MISSION

Develop clinical and laboratory practice guidelines and promote their use worldwide

OFFERING

1. Global consensus-based standards development
2. Lab training and implementation guidance
3. Public education and advocacy

55 YEARS OF LABORATORY LEADERSHIP

Cultivating best practices and fostering innovation through standards and training


from the Laboratory Program

ESTABLISHMENT OF A PROVISIONAL NATIONAL COMMITTEE ON CLINICAL LABORATORY STANDARDS

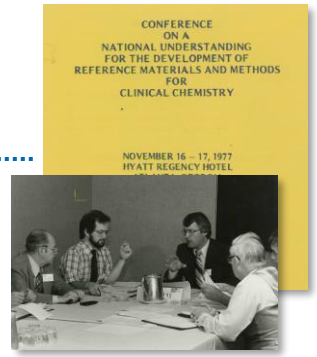
1967
Founding of the National Committee on Clinical Laboratory Standards (NCCLS)


PATHOLOGIST

THE ROLE OF PROFESSIONAL ORGANIZATIONS IN THE ESTABLISHMENT OF STANDARDS AND THE EVOLUTION OF THE NCCLS

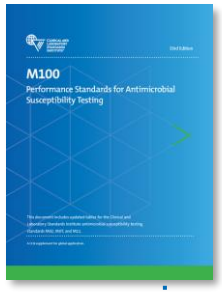
1969
First standard published: *Preparation of Manuals for Installation, Operation, and Repair of Laboratory Instruments*

1985
Designated WHO Collaborating Center for Clinical Laboratory Standards


CONFERENCE ON A NATIONAL UNDERSTANDING FOR THE DEVELOPMENT OF REFERENCE MATERIALS AND METHODS FOR CLINICAL CHEMISTRY

NOVEMBER 16 – 17, 1977
HYATT REGENCY HOTEL

1977
Accredited by *American National Standards Institute (ANSI)* as voluntary consensus standards organization


M100
Performance Standards for Antimicrobial Susceptibility Testing

1986
First edition of M100—*Performance Standards for Antimicrobial Susceptibility Testing*

1997
International Organization for Standardization (ISO) Technical Committee 212 (ISO/TC 212) established with NCCLS as the Secretariat

2005
NCCLS becomes *Clinical and Laboratory Standards Institute (CLSI)* and launches Global Health Partnerships


EXECUTIVE DIRECTORS QUALITY SYSTEMS MANAGEMENT TRAINING - MOROGORO
FACILITATED BY CLSI 11SEPT2011

Today
More than 250 standards, and 25,000 members, supporting users in 140 countries

FACILITATING INNOVATION, IMPROVING CARE

Better diagnostic tools & methods to improve health and prevent the spread of disease

GLOBAL CONSENSUS-BASED STANDARDS

Bringing constituencies together through balanced, inclusive, and participatory processes

Professions

- Hospital & Clinical Laboratories
- Research & Reference Laboratories
- Colleges & Universities
- Pharmacies

Government

- Public Health Agencies
- Public Health Ministries
- Regulatory Bodies
- Accreditors

Industry

- *In Vitro* & Medical Device Manufacturers
- Pharmaceutical Manufacturing
- Commercial & Clinical Trial Laboratories
- MedTech & Testing Companies

WHY STANDARDS MATTER: POTENTIAL FOR ERROR

Preanalytical
46-48%

- Incorrect test request
- Incorrect analysis ordered
- Patient identification error
- Patient preparation error
- Mislabeling of the test tube
- Sample collection error
- Incorrect sample handling
- Transport error

Analytical
7-13%

- Sample lost
- Sample mix up
- Equipment failure
- Analytical error

Postanalytical
19-47%

- Test result lost
- Turnaround time
- Transcription error
- Incorrect interpretation

THE CLSI CONSENSUS PROCESS

Ideation

New project ideas can be proposed by anyone, including the laboratory community at large and CLSI's vast member base.

Selection

The Consensus Council evaluates document proposals across specialty areas and focuses resources on those that meet the greatest need.

Recruitment

Subject matter experts are assembled and assigned to Committees to participate in document development.

Development

Committee Members meet regularly—in person and via Zoom—throughout the development process to:

- Review the draft document
- Discuss and resolve issues related to the document's content
- Ensure the committee is on schedule with respect to the document development timeline

Voting and Commenting

In one consolidated voting period, CLSI Delegates, Development Groups, and Expert Panels are encouraged to vote and comment on the document.

The general public is invited to provide meaningful comments and feedback on the document for further development and refinement.

Resolution

Development Groups work to refine the document, resolving all comments and feedback that arose during the voting and commenting period.

Approval

The revised document is presented to the Consensus Council, which confirms that the consensus process was followed, and approves the document for publication.

11 SPECIALTY AREAS, 250+ STANDARDS AND PRODUCTS

Automation and Informatics

Clinical Chemistry and Toxicology

General Laboratory

Preexamination

Hematology

Immunology and Ligand Assay

Method Evaluation

Microbiology

Molecular Methods

Newborn Screening

Point-of-Care Testing

Quality Management Systems

Veterinary Medicine

EXPERTISE RECOGNIZED AROUND THE GLOBE

Collaborating with and supporting regulatory and public health agencies worldwide

CLSI ALSO SERVES AS ISO SECRETARIAT

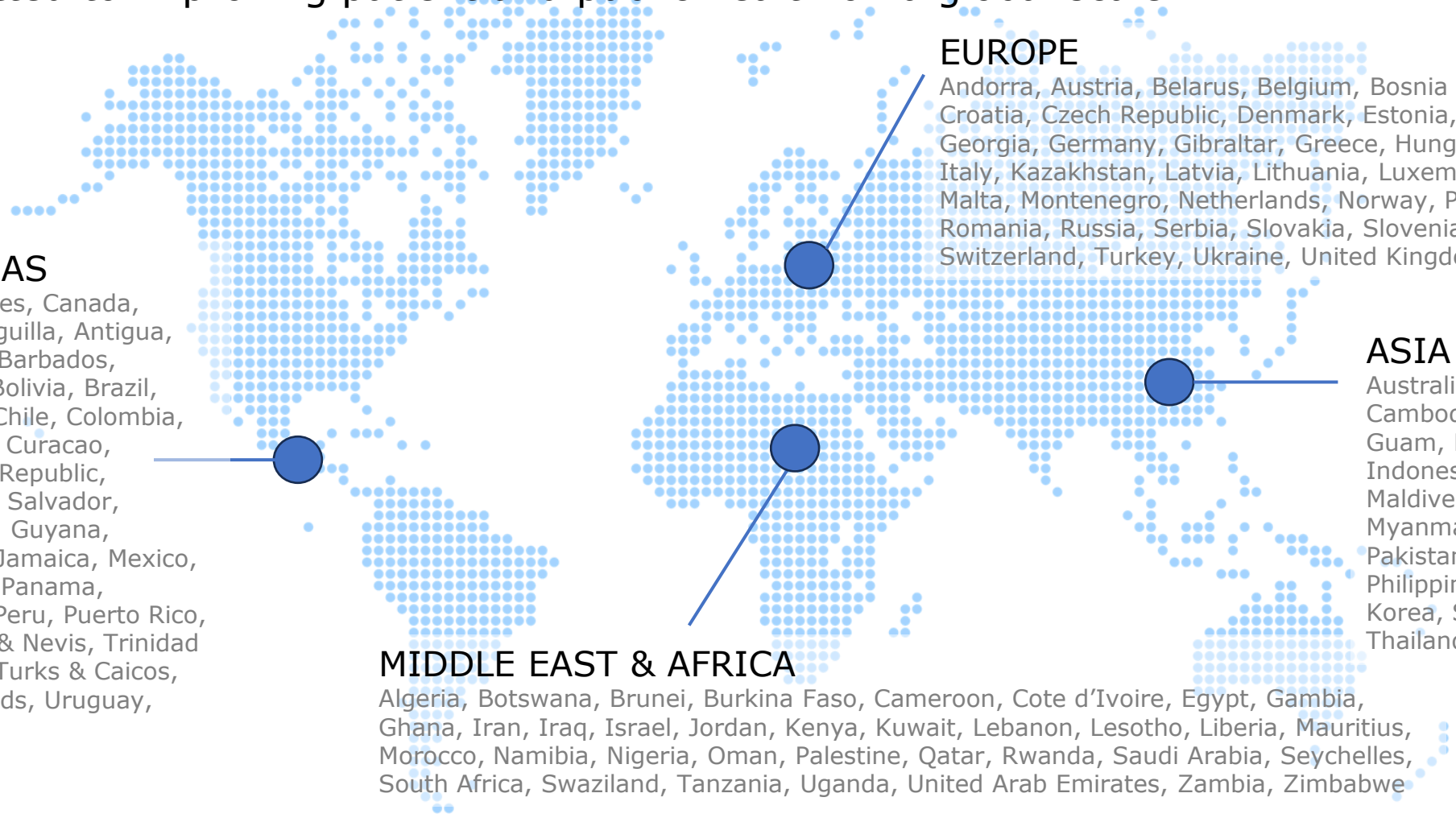
Providing guidance for *how* to implement regulatory requirements

Secretariat for ISO Technical Committee 212 (Clinical Laboratory Testing and *In Vitro* Diagnostic Test Systems)

Working Group 1: Quality and competence in the medical laboratory
Working Group 2: Reference systems
Working Group 3: *In vitro* diagnostic products
Working Group 4: Microbiology and molecular diagnostics
Working Group 5: Laboratory biorisk management

SUPPORTING USERS IN 140 COUNTRIES

Committed to improving patient and public health on a global scale



EUROPE

Andorra, Austria, Belarus, Belgium, Bosnia & Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Gibraltar, Greece, Hungary, Iceland, Ireland, Italy, Kazakhstan, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, Uzbekistan

AMERICAS

United States, Canada, Mexico, Anguilla, Antigua, Argentina, Barbados, Bermuda, Bolivia, Brazil, Caymans, Chile, Colombia, Costa Rica, Curacao, Dominican Republic, Ecuador, El Salvador, Guatemala, Guyana, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Puerto Rico, Saint Kitts & Nevis, Trinidad & Tobago, Turks & Caicos, Virgin Islands, Uruguay, Venezuela

ASIA PACIFIC

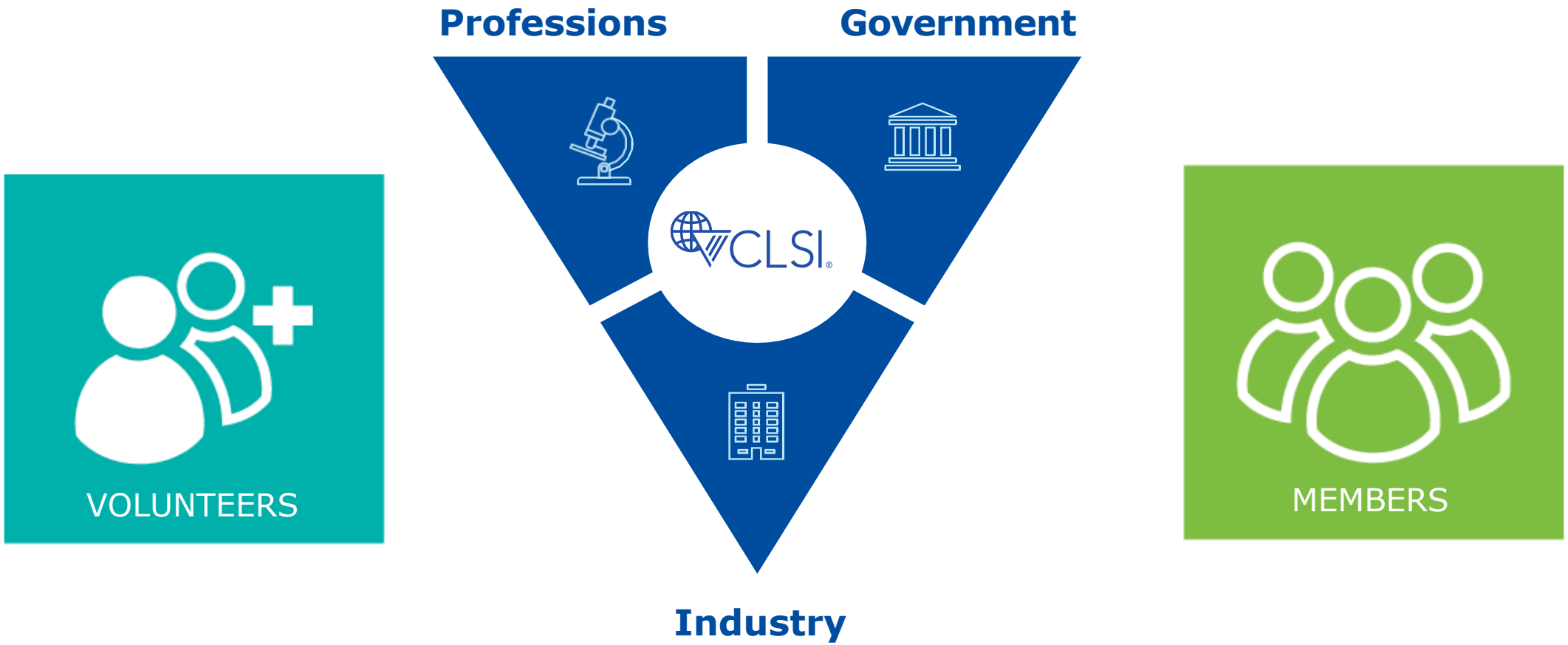
Australia, Bangladesh, Bhutan, Cambodia, China, East Timor, Guam, Hong Kong, India, Indonesia, Japan, Malaysia, Maldives, Micronesia, Mongolia, Myanmar, Nepal, New Zealand, Pakistan, Papua New Guinea, Philippines, Singapore, South Korea, Sri Lanka, Taiwan, Thailand, Vietnam

MIDDLE EAST & AFRICA

Algeria, Botswana, Brunei, Burkina Faso, Cameroon, Cote d'Ivoire, Egypt, Gambia, Ghana, Iran, Iraq, Israel, Jordan, Kenya, Kuwait, Lebanon, Lesotho, Liberia, Mauritius, Morocco, Namibia, Nigeria, Oman, Palestine, Qatar, Rwanda, Saudi Arabia, Seychelles, South Africa, Swaziland, Tanzania, Uganda, United Arab Emirates, Zambia, Zimbabwe

2200 ACTIVE VOLUNTEERS & 25K MEMBERS

Active and engaged constituency participating and benefitting as well as networking



PARTNERING TO BUILD CAPABILITIES

Capacity-building for labs around the world

- Quality Management Systems Implementation and Training
- Accreditation Preparedness and Maintenance
- HIV Rapid Test and Viral Load Scale-Up
- Biosafety and Biosecurity Training

CLSI MEMBERSHIP – Why join?

- ✓ Stay current and informed
- ✓ Network with other leaders
- ✓ Grow and learn with CLSI training
- ✓ Participate in standards development
- ✓ Contribute your expertise
- ✓ Influence the evolution of laboratory medicine!

CLSI VOLUNTEER OPPORTUNITIES

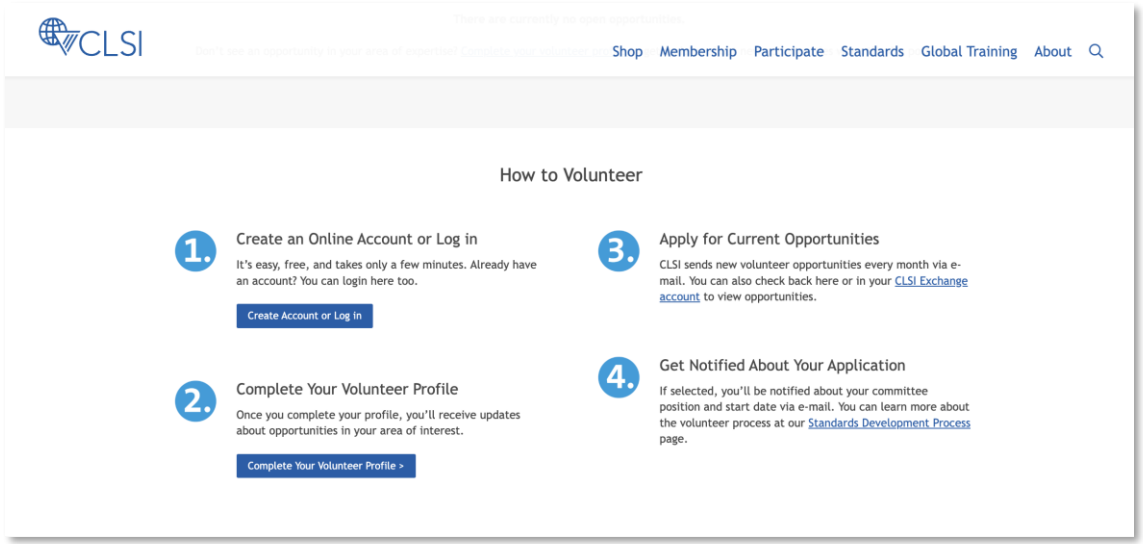
Why Participate?

- ✓ Assist with new documents & document revisions
- ✓ Be an advisor on expert panel or governance committee
- ✓ Collaborate with industry leaders to shape standards and ensure guidance is designed for optimal implementation
- ✓ Advance career and receive recognition as a thought leader

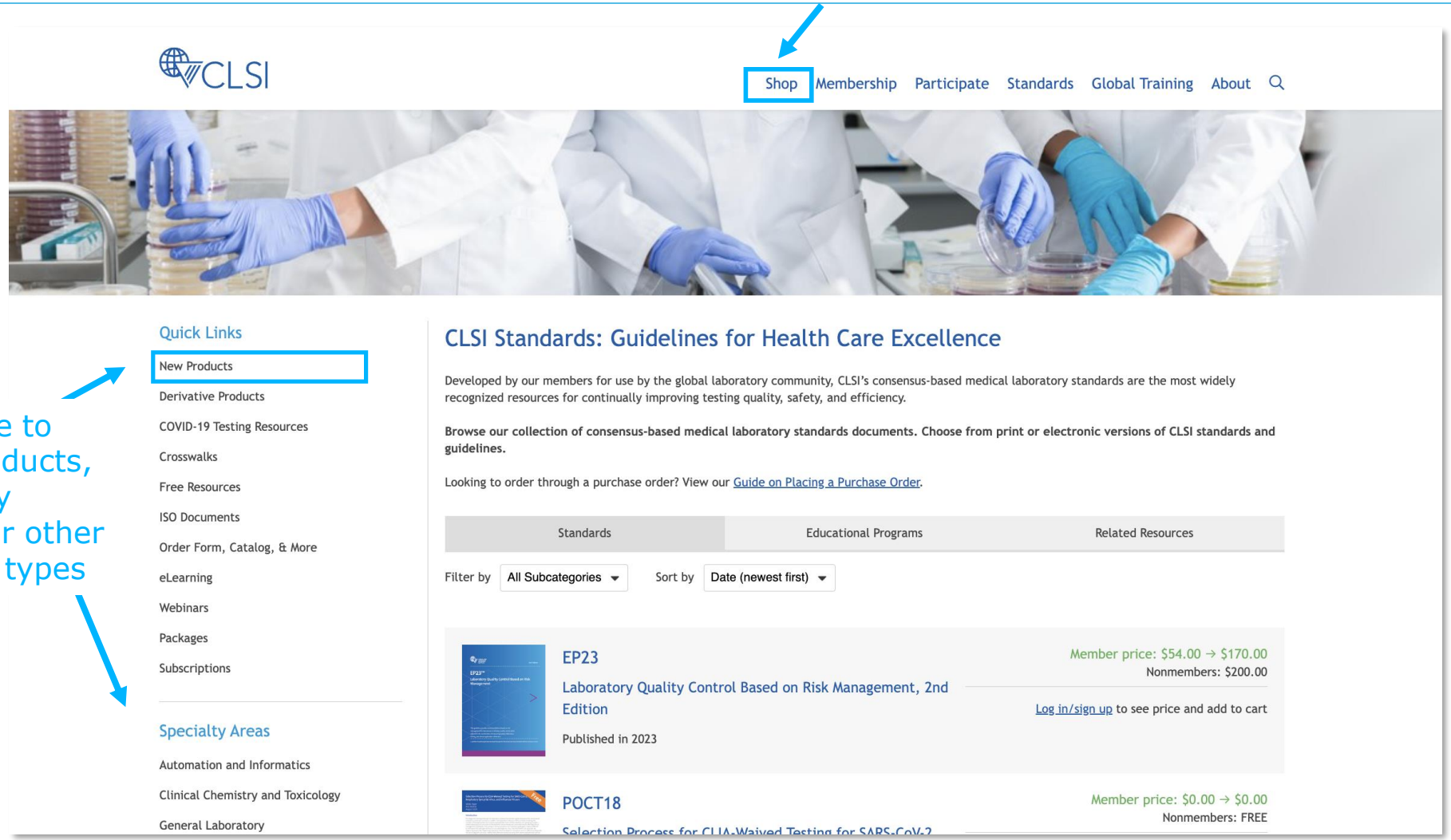
HOW TO GET INVOLVED?

More than 2200 subject matter experts contribute their expertise in many capacities

- Working Groups
- Subcommittees
- Document Development Committees
- Board of Directors
- Expert Panels
- Consensus Council



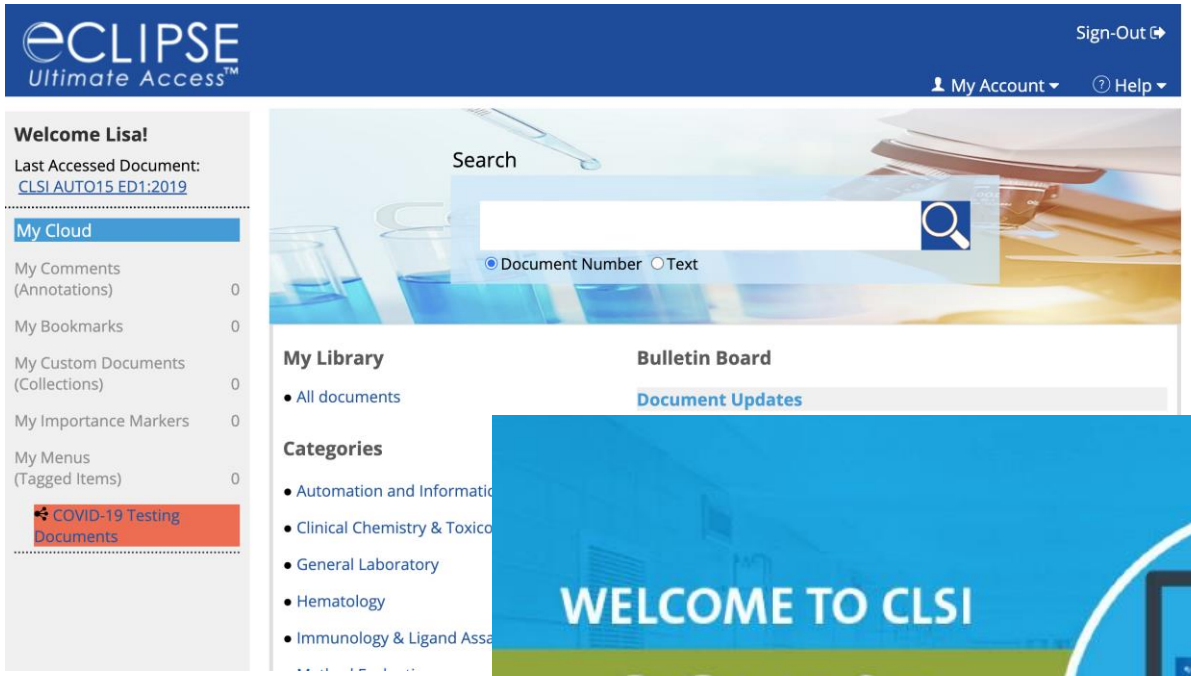
CLSI STANDARDS – How to Access?



Navigate to new products, specialty areas, or other product types

CLSI ECLIPSE – Digital Library Access

- Unlimited 24/7 access
- Full library of current standards
- Easily search-and-find related content
- Bookmarks and annotate functionality
- Custom collections that can be shared with colleagues
- Advanced printing options



CLSI POCT Resources

FEATURED POCT STANDARDS

CLSI POCT05

Performance Metrics for Continuous Interstitial Glucose Monitoring, 2nd Edition (2020)

CLSI POCT15

Point-of-Care Testing for Infectious Disease (2020)

CLSI POCT01
CLSI POC02

Point-of-Care Connectivity, 2nd Edition (2006)

Implementation Guide of POCT01 for Health Care Providers, 1st Ed (2008)

CLSI POCT07

Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition (2010)

CLSI POCT09
CLSI POCT09 AW

Selection Criteria for Point-of-Care Testing Devices, 1st Ed (2010)

Instrument Selection Worksheet

OTHER CLSI POCT STANDARDS & GUIDELINES

POCT01 Point-of-Care Connectivity, 2nd Ed (2006)

POCT02 Implementation Guide of POCT01 for Health Care Providers, 1st Ed (2008)

POCT04 Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Ed (2016)

POCT06 Effects of Different Sample Types on Glucose Measurements, 1st Ed (2015)

POCT08 Quality Practices in Non-instrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers, 1st Ed (2010)

POCT10 Physician and Nonphysician Provider-Performed Microscopy Testing, 2nd Ed (2011)

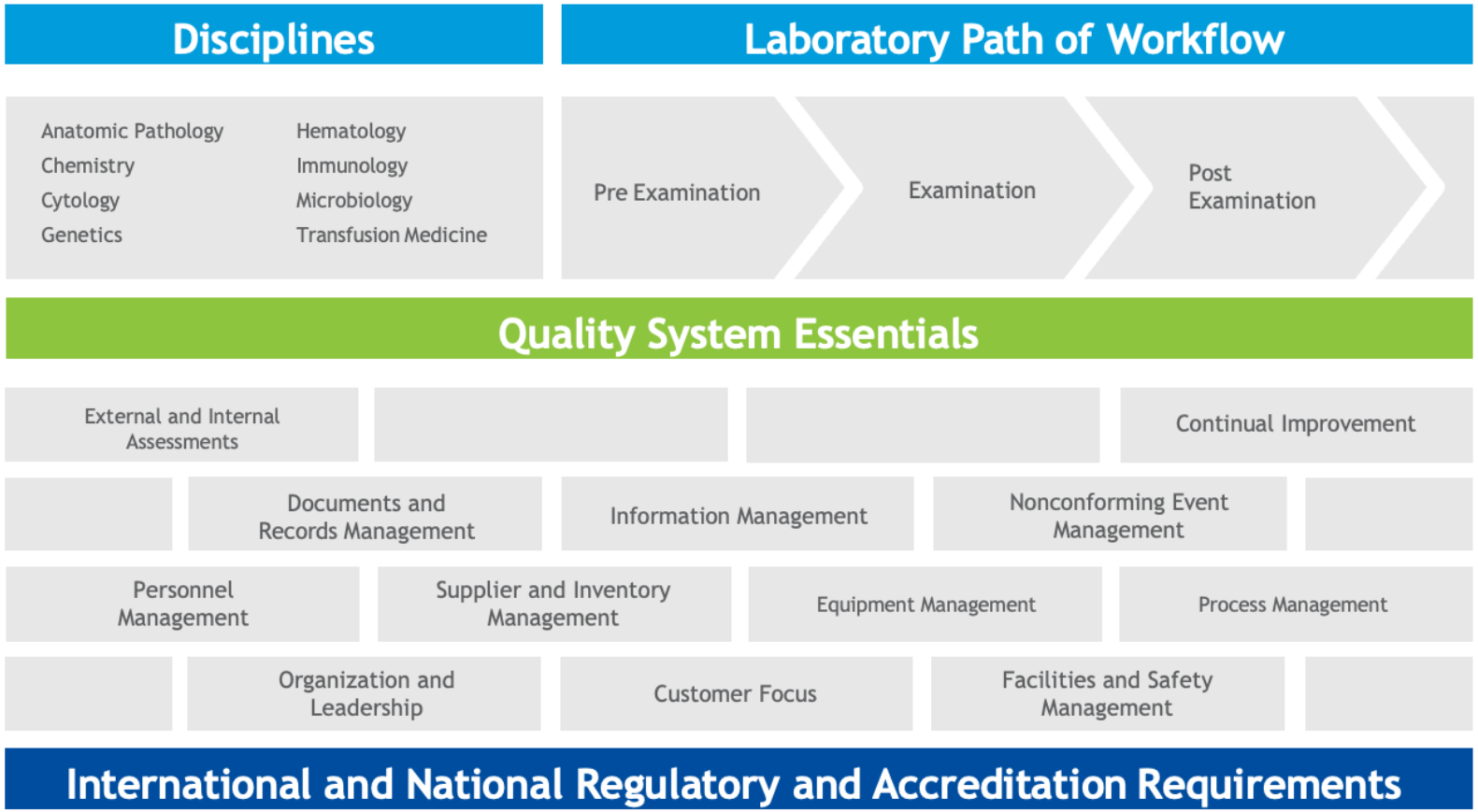
POCT12 Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities, 3rd Ed (2013)

POCT13 Glucose Monitoring in Settings Without Laboratory Support, 3rd Edition (2018)

POCT14 Point-of-Care Coagulation Testing and Anticoagulation Monitoring, 2nd Edition (2020)

POCT17 Use of Glucose Meters for Critically Ill Patients, 1st Edition (2016)

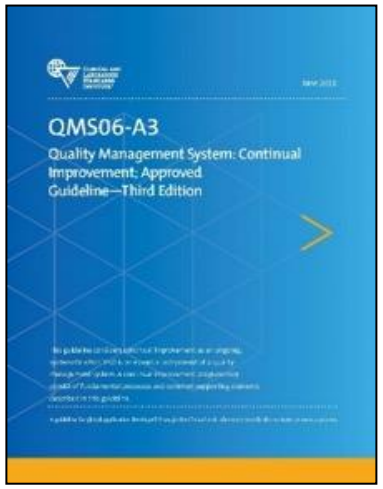
CLSI QUALITY MANAGEMENT MODEL

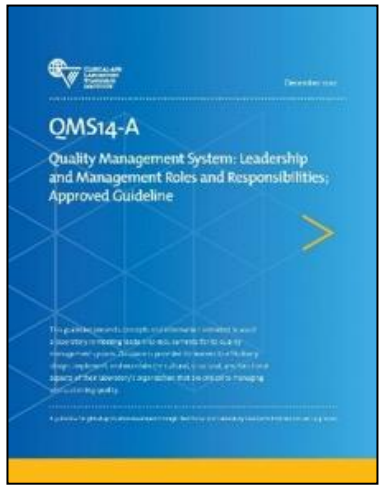


Advantages of Utilizing QMS

- Meet all requirements
- Improve patient safety
- Realize the cost of quality
- Obtain competitive advantage
- Achieve laboratory quality services

THE BEST OF CLSI'S QUALITY COLLECTION





BENEFITS OF IMPLEMENTING A QMS

Better ability to reduce or eliminate error.

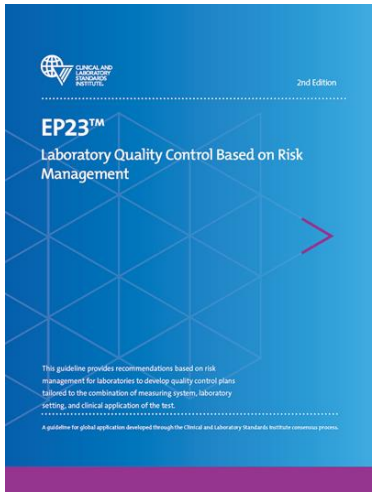
Higher likelihood of meeting customer expectations.

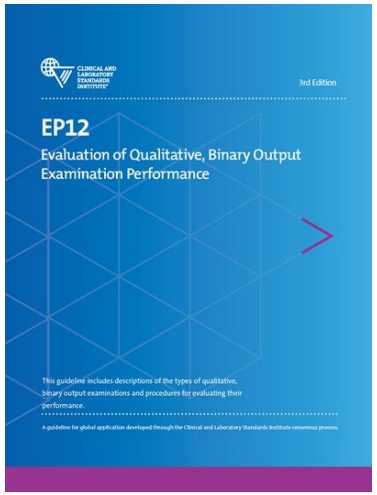
More effective and efficient operations.

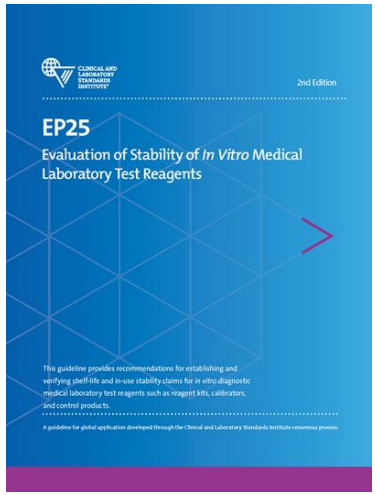
Greater potential for successful governmental and accreditation assessments.

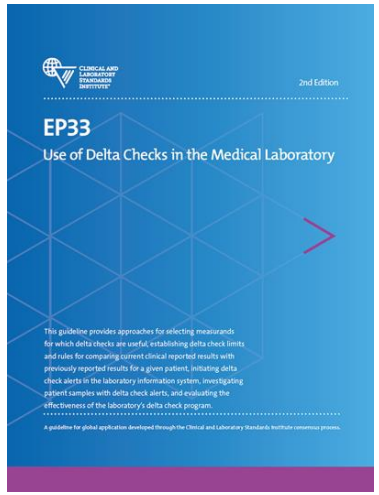
Allows for sustainable attainment of quality objectives.

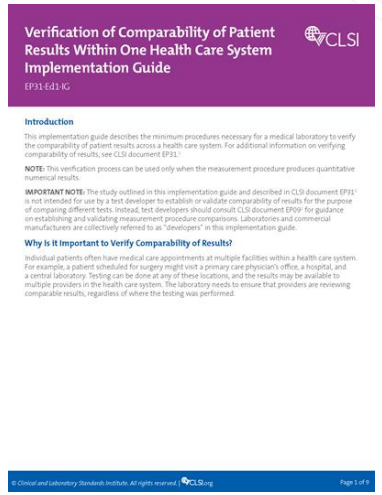
THE BEST OF CLSI'S EP TOOLS

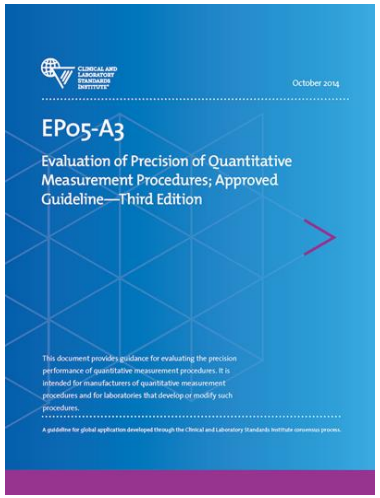


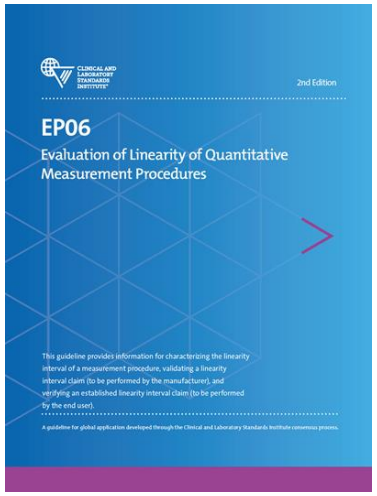


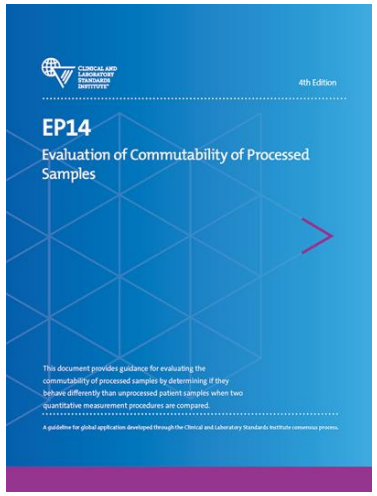


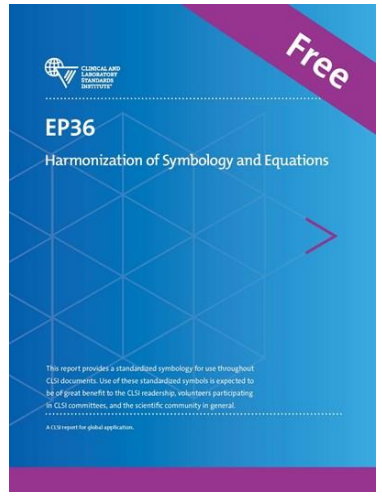


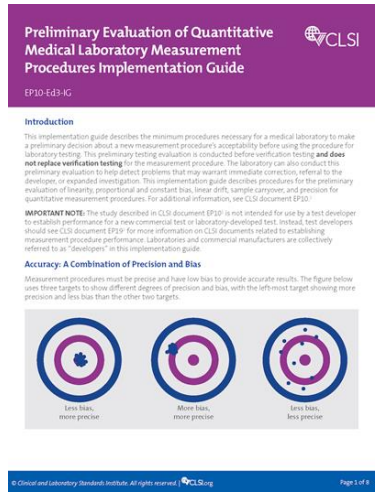












Recently Published Guidance Documents

NEW

Recently Published Documents

PRE04-Ed1
Procedures for Handling, Transport, and Processing of Blood Specimens for Common Laboratory Tests, 1st Ed

AUTO17-Ed1
Semantic Interoperability for In Vitro Diagnostic Systems, 1st Ed

EP33-Ed2
Use of Delta Checks in the Medical Laboratory, 2nd Ed

MM01-Ed4
Molecular Testing for Heritable Genetics and Specimen Identification, 4th Ed

QMS18-Ed2
Process Management, 2nd Ed

NEW

Newly Released Documents

CLSI POCT18 | Selection Process for CLIA-Waived Testing for SARS-CoV-2, Respiratory Syncytial Virus, and Influenza Viruses, 1st Edition

CLSI EP23 | Laboratory Quality Control Based on Risk Management, 2nd Edition

CLSI PRE04 | Handling, Transport, Processing, and Storage of Blood Specimens for Routine Laboratory Examinations, 1st Edition

CLSI M23 | Development of *In Vitro* Susceptibility Test Methods, Breakpoints, and Quality Control Parameters, 6th Edition

KEY CHANGES & UDPATES

NEW

Breakpoint Implementation Toolkit

CLSI, APHL, ASM, and CAP have jointly developed a toolkit to assist clinical laboratories in updating minimal inhibitory concentration (MIC) breakpoints.

Visit clsi.org/bit-toolkit to learn more.

KEY DOCUMENT CHANGES & UPDATES

CLSI POCT18


Free

Selection Process for CLIA-Waived Testing for SARS-CoV-2, Respiratory Syncytial Virus, and Influenza Viruses

White Paper
POCT18-Ed1
August 2023

Introduction

The diagnostic testing landscape for respiratory diseases has evolved rapidly because of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. Because of this increase in testing, the number of testing facilities has increased substantially. Some of these facilities are operating outside a central laboratory and are closer to the patient to ensure timely and actionable results affecting clinical management of patients. The overlap in clinical symptoms for respiratory pathogens makes it difficult to distinguish the pathogen without an accurate diagnosis; thus, very few health care providers are diagnosing empirically. Diagnosing respiratory infections based on symptoms alone is difficult and typically has poor diagnostic accuracy.[1] Additionally, there are several use cases that require asymptomatic testing or screening. This white paper provides guidance on selecting tests that can be used at the point of care (POC) under a Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver to detect SARS-CoV-2, respiratory syncytial virus (RSV), and influenza A and B viruses. There are two common testing modalities: rapid antigen tests and rapid molecular tests. Considerations based on testing location, patient population, and appropriate use of tests are discussed.

POCT18 includes information on different testing platforms, interpreting the manufacturer's stated performance, and choosing the best test for the user's needs. An explanation of emergency use authorization (EUA) is included. The intended users may lack specific laboratory training to perform tests in outpatient settings such as physician offices, urgent care facilities, and pharmacies.

The following topics are not discussed in detail:

- Specific information related to appropriate coding of laboratory tests
- Verification of performance specifications (accuracy and precision) for instruments or tests for SARS-CoV-2, RSV, or influenza viruses
- Specimen pooling strategies for testing
- Reporting laboratory test results and data to public health agencies
- Cost and reimbursement considerations
- Patient self-testing (at home or in other locations)
- Patient education
- Immune response testing
- Antibody tests for detecting past SARS-CoV-2 infections

This white paper provides:

- Explanation of emergency use authorization (EUA)
- Information to guide the selection and implementation of CLIA-waived tests for SARS-CoV-2, RSV, and influenza viruses in POCT sites
- Interpreting the manufacturer's stated performance

KEY DOCUMENT CHANGES & UPDATES

CLSI PRE01

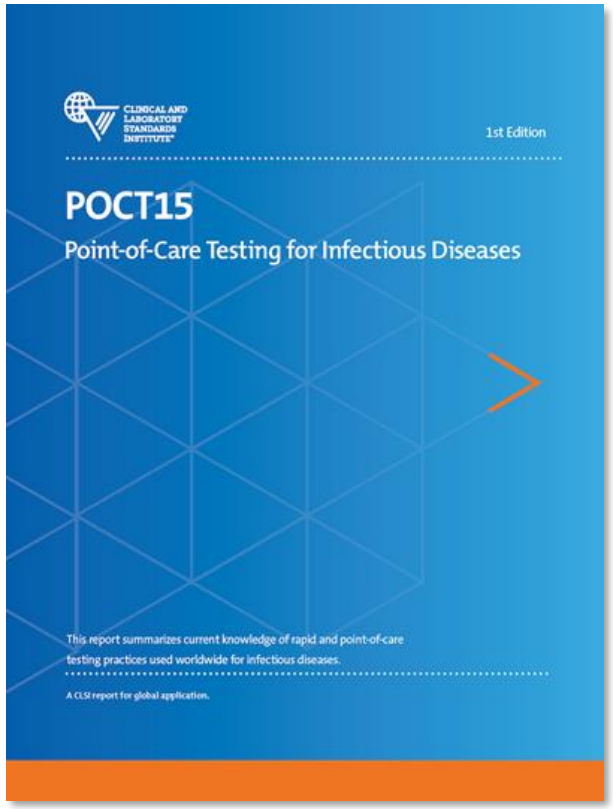
Pre-examination Processes for Identification, Collection, Transport, and Handling of Medical Laboratory Specimens

This standard:

- Discusses the critical need for accuracy in examination ordering, patient registration, patient & specimen ID, and specimen labeling throughout all phases of the lab's path of workflow
- Serves as a single-source document for pre-examination practices, which are common to many different specimen types
- Harmonizes patient & specimen ID processes wherever blood and nonblood specimens are collected and identified

KEY DOCUMENT CHANGES & UPDATES

CLSI POCT15

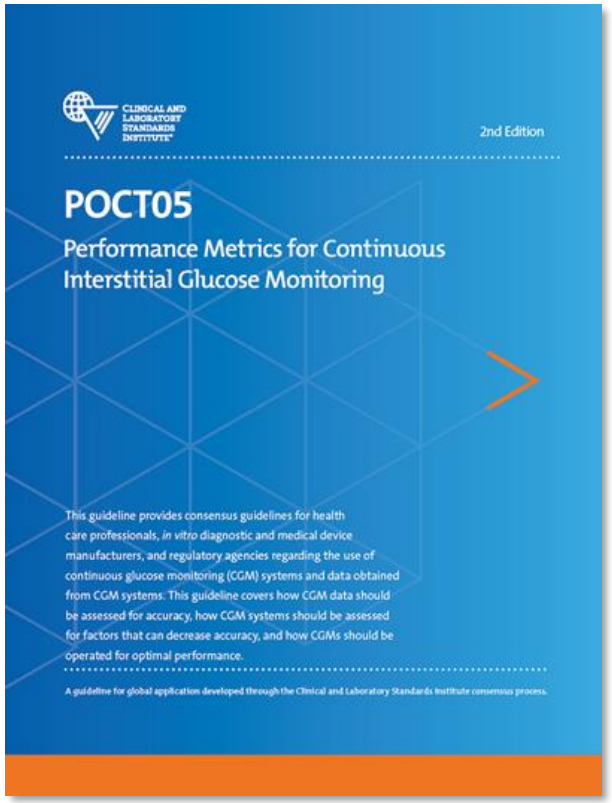


This report provides:

- Recommendations for assessing, implementing, performing, and using point-of-care tests to improve management of infectious diseases
- Information on indications, limitations, appropriate use, and reporting and interpretation for the major POC tests available
- Potential uses of POC tests in community outreach and public health testing and in resource-limited settings

KEY DOCUMENT CHANGES & UPDATES

CLSI POCT05 – Ed2



This guideline provides recommendations for methods used to determine analytical and clinical performance of continuous glucose monitoring (CGM).

Several changes were made in this edition, including:

- CGM device use cases
- Cybersecurity for CGM devices
- CGM device labeling

KEY DOCUMENT CHANGES & UPDATES

CLSI EP23 – Ed2

This guideline provides recommendations based on risk management for laboratories to develop quality control plans tailored to the combination of measuring system, laboratory setting, and clinical application of the test.

CLSI EP23 introduces industrial risk management principles to the clinical laboratory

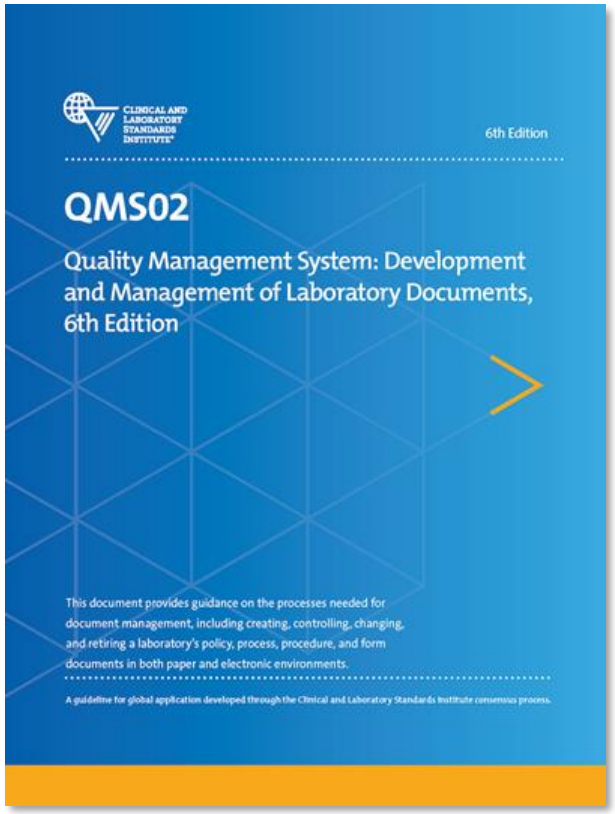
Provides guidance to select the right control processes and frequency of controls to minimize risk of error to a clinically acceptable levels

CLSI EP23: Revision Changes to Expect

- ✓ Aligns CLSI EP23 with ISO 22367 and ISO 14971
- ✓ Incorporates detectability in the risk assessment
- ✓ Replaces “Glucose Concentration Measurement on an Automated Measuring System” example with real-world examples of quality control plans for:
  - Non-instrumented, single-use device
  - Instrumented, single-use device; and
  - Exempt microbiological media
- ✓ Updates references

KEY DOCUMENT CHANGES & UPDATES

CLSI QMS02 - Ed7



This guideline:

- Presents the elements of a program for managing laboratory documents in both paper-based and electronic document management systems
- Describes an evidence-based process for preparing different types of laboratory documents from the time a need is recognized for a new or revised document, through the document's use and control, until the time it is retired

KEY DOCUMENT CHANGES & UPDATES

CLSI QM17 - Ed2

This guideline provides recommendations for establishing and maintaining a process to assist the laboratory in achieving a continuous state of readiness for assessment by an external organization, including:

- Selecting and evaluating an external assessment organization
- Preparing for an undergoing a successful assessment
- Improving laboratory processes to achieve and sustain positive assessment outcomes
- Sustaining ongoing readiness for assessment

PROJECTS IN PROGRESS

PROJECTS IN PROGRESS – 2023/Early 2024

Projects below are in final stages of development; however, timing may be subject to change

CLSI M53	Criteria for Laboratory Testing. Diagnosis of Human Immunodeficiency Virus Infection, Ed2
CLSI QMS17	External Assessments, Audits, and Inspections of the Laboratory, Ed2
CLSI QMS02	Quality Management System: Development & Management of Laboratory Documents, Ed7
CLSI PRE01	Preexamination Processes for Identification, Collection, Transport & Handling of Medical Laboratory Specimens
CLSI M100	Performance Standards for Antimicrobial Susceptibility Testing, Ed34
CLSI QMS29	Conducting Effective Management Reviews
CLSI M02	Performance Standards for Antimicrobial Susceptibility Tests, Ed14
CLSI M07	Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, Ed12
CLSI QMS27	Decontamination of Laboratory Instrumentation
CLSI POCT16	Emergency and Disaster Point-of-Care Testing

Visit **clsi.org/standards** for latest

A COMMON GOAL: QUALITY HEALTH CARE








Thank you

james.h.nichols@vumc.org

QUESTIONS?