



# CLSI Updates: Guidance, Documents, and Revisions

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Whitehat Communications Point of Care Webinars | September 7, 2023

# LEARNING OBJECTIVES

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**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



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# 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

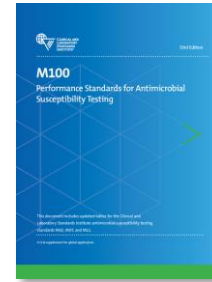
Cultivating best practices and fostering innovation through standards and training



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



**1985**  
 Designated WHO Collaborating Center for Clinical Laboratory Standards

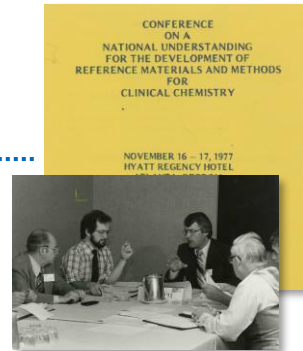


**1986**  
 First edition of M100—Performance Standards for Antimicrobial Susceptibility Testing

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



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



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

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



**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



Improve testing quality & consistency



Achieve or maintain accreditation



Bring products to market faster



Train & develop staff



Assess & diagnose more accurately

# 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

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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



International  
Organization for  
Standardization

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

## 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

## 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

## ASIA PACIFIC

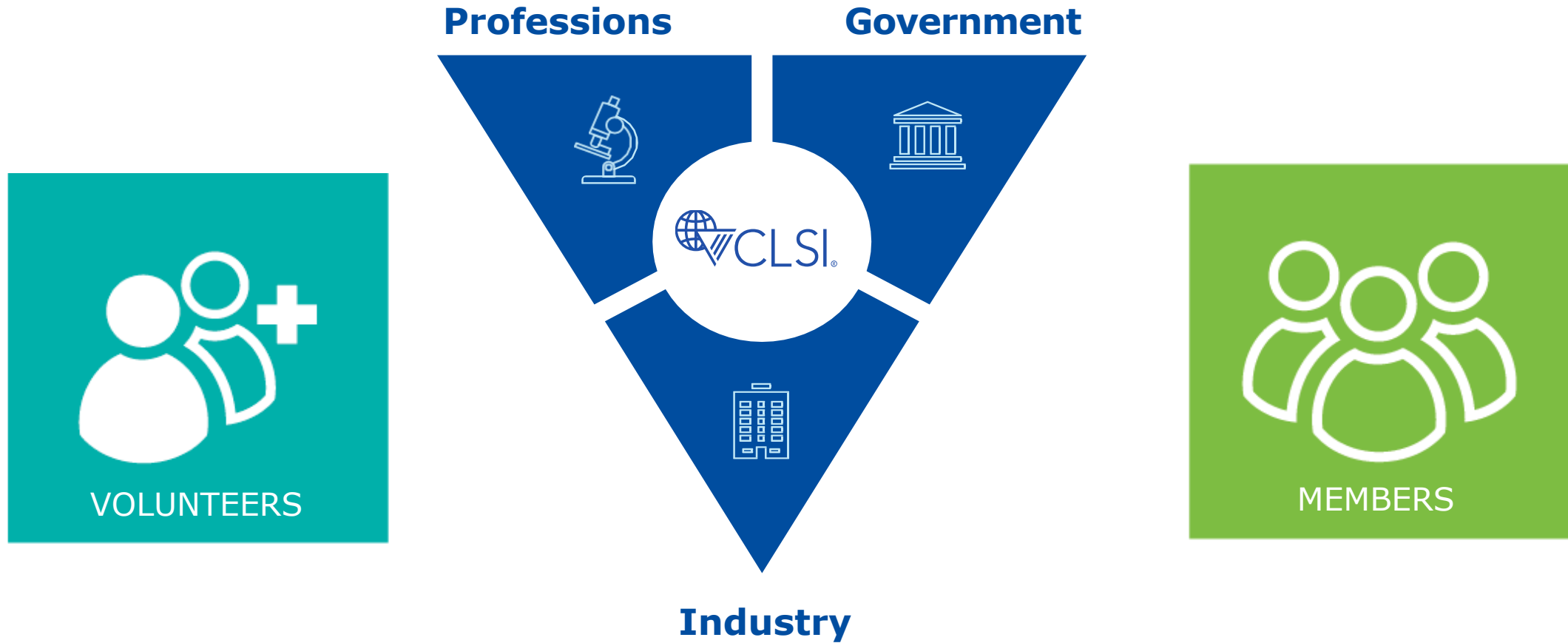
Australia, Bangladesh, Bhutan, Cambodia, China, East Timor, Guam, Hong Kong, India, Indonesia, Japan, Malaysia, Maldives, Micronesia, Mongolia, Myanmar, Nepal, New Zealand, Pakistan, Papua New Guinea, Philippines, Singapore, South Korea, Sri Lanka, Taiwan, Thailand, Vietnam

## 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

The screenshot shows the CLSI website's 'How to Volunteer' page. At the top, there is a navigation bar with the CLSI logo and links for Shop, Membership, Participate, Standards, Global Training, and About. Below the navigation bar, the page title 'How to Volunteer' is centered. The main content is organized into four numbered steps:

- 1. Create an Online Account or Log in**  
It's easy, free, and takes only a few minutes. Already have an account? You can login here too.  
[Create Account or Log in](#)
- 2. Complete Your Volunteer Profile**  
Once you complete your profile, you'll receive updates about opportunities in your area of interest.  
[Complete Your Volunteer Profile >](#)
- 3. Apply for Current Opportunities**  
CLSI sends new volunteer opportunities every month via e-mail. You can also check back here or in your [CLSI Exchange account](#) to view opportunities.
- 4. Get Notified About Your Application**  
If selected, you'll be notified about your committee position and start date via e-mail. You can learn more about the volunteer process at our [Standards Development Process](#) page.

# CLSI STANDARDS – How to Access?

The screenshot shows the CLSI website interface. At the top left is the CLSI logo. To the right is a navigation menu with the following items: Shop, Membership, Participate, Standards, Global Training, About, and a search icon. A blue arrow points to the 'Shop' link. Below the navigation is a banner image of laboratory workers in white coats and blue gloves working with petri dishes. On the left side, there is a 'Quick Links' section with a list of categories: New Products, Derivative Products, COVID-19 Testing Resources, Crosswalks, Free Resources, ISO Documents, Order Form, Catalog, & More, eLearning, Webinars, Packages, and Subscriptions. A blue arrow points to 'New Products'. Below this is a 'Specialty Areas' section with categories: Automation and Informatics, Clinical Chemistry and Toxicology, and General Laboratory. On the right side, there is a section titled 'CLSI Standards: Guidelines for Health Care Excellence'. It contains a paragraph about CLSI standards, a link to 'Browse our collection of consensus-based medical laboratory standards documents', and another link to 'Guide on Placing a Purchase Order'. Below this is a filter and sort section with 'Standards', 'Educational Programs', and 'Related Resources' tabs. The 'Standards' tab is selected. There are dropdown menus for 'Filter by' (set to 'All Subcategories') and 'Sort by' (set to 'Date (newest first)'). Below this are two product listings. The first is 'EP23 Laboratory Quality Control Based on Risk Management, 2nd Edition', published in 2023, with a member price of \$54.00 (reduced from \$170.00) and a nonmember price of \$200.00. A link 'Log in/sign up to see price and add to cart' is provided. The second listing is 'POCT18 Selection Process for CLIA-Waived Testing for SARS-CoV-2', with a member price of \$0.00 (reduced from \$0.00) and a nonmember price of FREE.

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

The screenshot displays the CLSI ECLIPSE Ultimate Access web interface. At the top, the logo and navigation links (Sign-Out, My Account, Help) are visible. A search bar with a magnifying glass icon and radio buttons for 'Document Number' and 'Text' is prominent. A left sidebar lists user-specific items like 'My Cloud', 'My Comments', and 'My Bookmarks', with 'COVID-19 Testing Documents' highlighted in red. The main content area includes sections for 'My Library' and 'Categories'.

Log in Here! ↑

**WELCOME TO CLSI**

**eCLIPSE**  
Ultimate Access™

With eCLIPSE Ultimate Access, we've made it even easier for your laboratory to access and use our invaluable resources for quality improvement—anytime, anywhere.



# 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

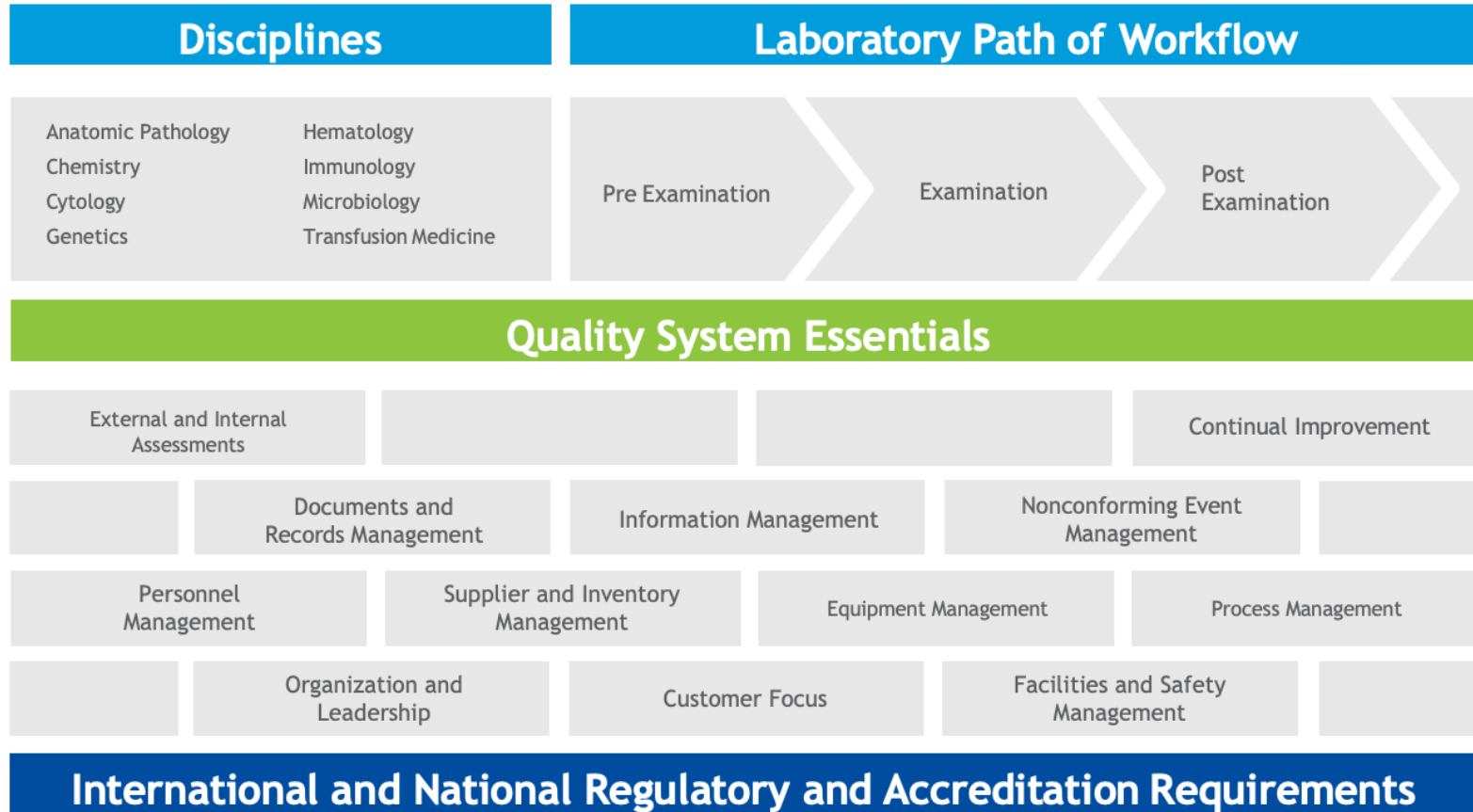
Selection Criteria for Point-of-Care Testing Devices, 1st Ed (2010)  
Instrument Selection Worksheet

# OTHER CLSI POCT STANDARDS & GUIDELINES

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- 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

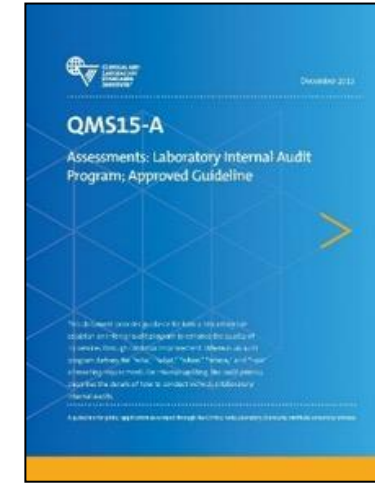
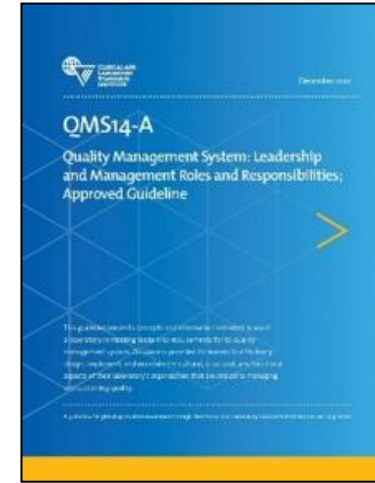


## Advantages of Utilizing QMS

- 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

CLSI AND LABORATORY STANDARDS INSTITUTE

2nd Edition

## EP23™

### Laboratory Quality Control Based on Risk Management

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

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

CLSI AND LABORATORY STANDARDS INSTITUTE

3rd Edition

## EP12

### Evaluation of Qualitative, Binary Output Examination Performance

This guideline includes descriptions of the types of qualitative, binary output examinations and procedures for evaluating their performance.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

CLSI AND LABORATORY STANDARDS INSTITUTE

2nd Edition

## EP25

### Evaluation of Stability of *In Vitro* Medical Laboratory Test Reagents

This guideline provides recommendations for establishing and verifying shelf-life and in-use stability claims for *in vitro* diagnostic medical laboratory test reagents such as reagent kits, calibrators, and control products.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

CLSI AND LABORATORY STANDARDS INSTITUTE

2nd Edition

## EP33

### Use of Delta Checks in the Medical Laboratory

This guideline provides approaches for selecting measurement for which delta checks are useful, establishing delta check limits, and rules for comparing current clinical reported results with previously reported results for a given patient, initiating delta check alerts in the laboratory information system, investigating patient samples with delta check alerts, and evaluating the effectiveness of the laboratory's delta check program.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

Implementing a Laboratory Test Under Emergency Use Conditions

CLSI

## EP43

### On-Demand Webinar

Tuesday, October 19, 2021

CLSI

## Verification of Comparability of Patient Results Within One Health Care System Implementation Guide

EP31-ED1:IG

**Introduction**  
This implementation guide describes the minimum procedures necessary for a medical laboratory to verify the comparability of patient results across a health care system. For additional information on verifying comparability of results, see CLSI document EP31.

**NOTE:** This verification process can be used only when the measurement procedure produces quantitative numerical results.

**IMPORTANT NOTE:** The study outlined in this implementation guide and described in CLSI document EP31 is not intended for use by a test developer to establish or validate comparability of results for the purpose of comparing different tests. Instead, test developers should consult CLSI document EP39 for guidance on establishing and validating measurement procedure comparisons. Laboratories and commercial manufacturers are collectively referred to as "developers" in this implementation guide.

**Why is it Important to Verify Comparability of Results?**  
Individual patients often have medical care appointments at multiple facilities within a health care system. For example, a patient scheduled for surgery might visit a primary care physician's office, a hospital, and a central laboratory. Testing can be done at any of these locations, and the results may be available to multiple providers in the health care system. The laboratory needs to ensure that providers are reviewing comparable results, regardless of where the testing was performed.

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CLSI AND LABORATORY STANDARDS INSTITUTE

October 2014

## EP05-A3

### Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition

This document provides guidance for evaluating the precision performance of quantitative measurement procedures. It is intended for manufacturers of quantitative measurement procedures and for laboratories that develop or modify such procedures.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

CLSI AND LABORATORY STANDARDS INSTITUTE

2nd Edition

## EP06

### Evaluation of Linearity of Quantitative Measurement Procedures

This guideline provides information for characterizing the linearity interval of measurement procedures, stating a linearity interval claim (to be performed by the manufacturer), and verifying an established linearity interval claim (to be performed by the end user).

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

CLSI AND LABORATORY STANDARDS INSTITUTE

4th Edition

## EP14

### Evaluation of Commutability of Processed Samples

This document provides guidance for evaluating the commutability of processed samples by determining if they behave differently than unprocessed patient samples when two quantitative measurement procedures are compared.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

CLSI AND LABORATORY STANDARDS INSTITUTE

Free

## EP36

### Harmonization of Symbology and Equations

This report provides a standardized symbology for use throughout CLSI documents. Use of these standardized symbols is expected to be of great benefit to the CLSI readership, volunteers participating in CLSI committees, and the scientific community in general.

A CLSI report for global application.

CLSI

## Passing-Bablok Regression On-Demand Webinar

Tuesday, October 6, 2020

CLSI

## Preliminary Evaluation of Quantitative Medical Laboratory Measurement Procedures Implementation Guide

EP10-ED3:IG

**Introduction**  
This implementation guide describes the minimum procedures necessary for a medical laboratory to make a preliminary decision about a new measurement procedure's acceptability before using the procedure for laboratory testing. This preliminary testing evaluation is conducted before verification testing and does not replace verification testing for the measurement procedure. The laboratory can also conduct this preliminary evaluation to help detect problems that may require immediate correction, referral to the developer, or expanded investigation. This implementation guide describes procedures for the preliminary evaluation of accuracy, proportional and constant bias, linear shift, sample coverage, and precision for quantitative measurement procedures. For additional information, see CLSI document EP10.

**IMPORTANT NOTE:** The study described in CLSI document EP10 is not intended for use by a test developer to establish performance for a new commercial test or laboratory-developed test. Instead, test developers should see CLSI document EP9 for more information on CLSI documents related to establishing measurement procedure performance. Laboratories and commercial manufacturers are collectively referred to as "developers" in this implementation guide.

**Accuracy: A Combination of Precision and Bias**  
Measurement procedures must be precise and have low bias to provide accurate results. The figure below uses three targets to show different degrees of precision and bias, with the leftmost target showing more precision and less bias than the other two targets.

Less bias, more precise. More bias, more precise. Less bias, less precise.

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# 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

Selection Process for CLIA-Waived Testing for SARS-CoV-2, Respiratory Syncytial Virus, and Influenza Viruses  
White Paper  
POCT18-Ed1  
August 2023  
Free

# 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](https://clsi.org/bit-toolkit) to learn more.





# KEY DOCUMENT CHANGES & UPDATES

## CLSI POCT18

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

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<sup>1</sup>. 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

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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

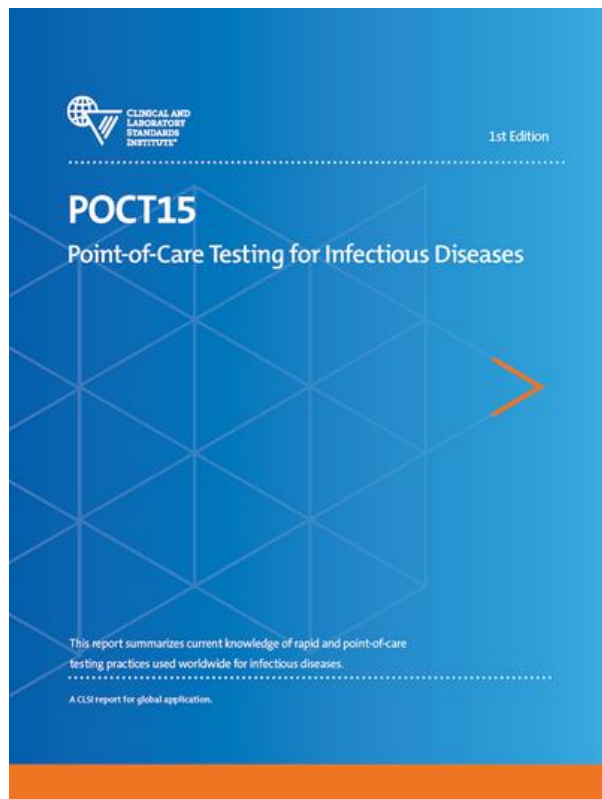
*Pre-examination Processes for Identification, Collection, Transport, and Handling of Medical Laboratory Specimens*

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

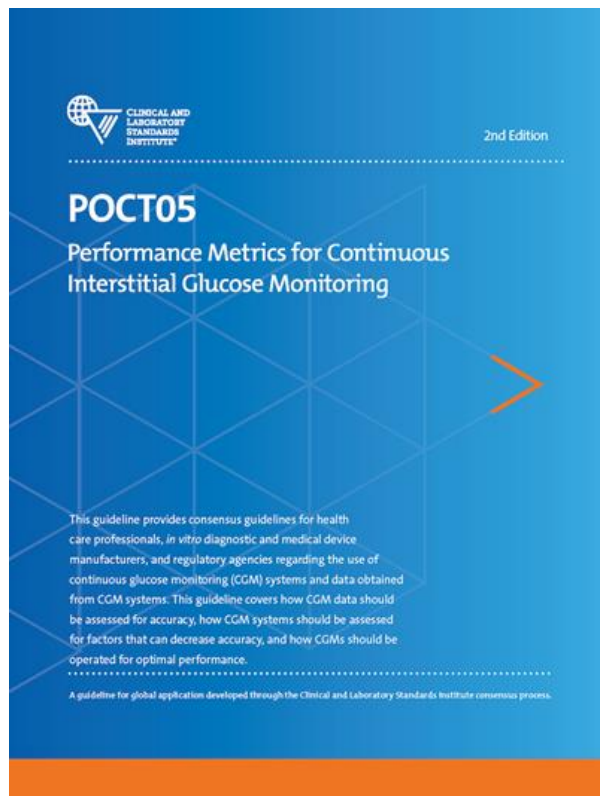


This report provides:

- 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

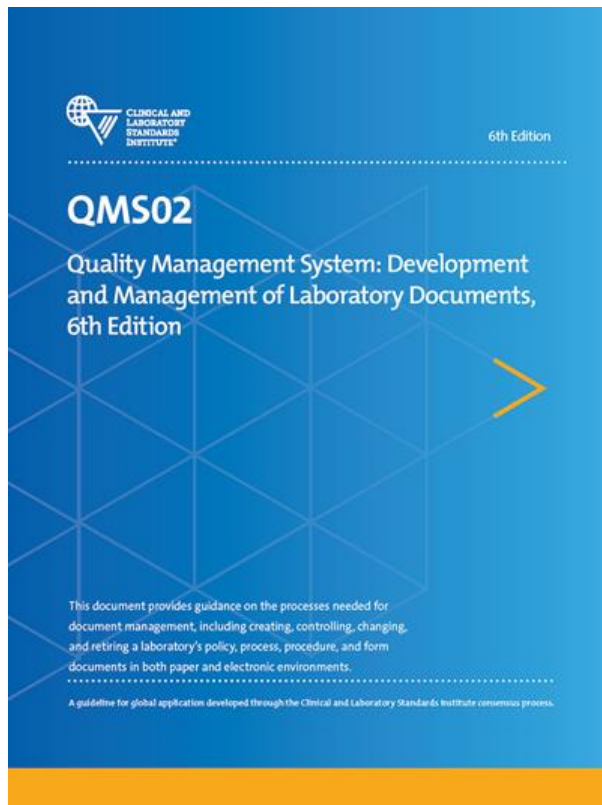
# CLSI EP23: Revision Changes to Expect

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- ✓ 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

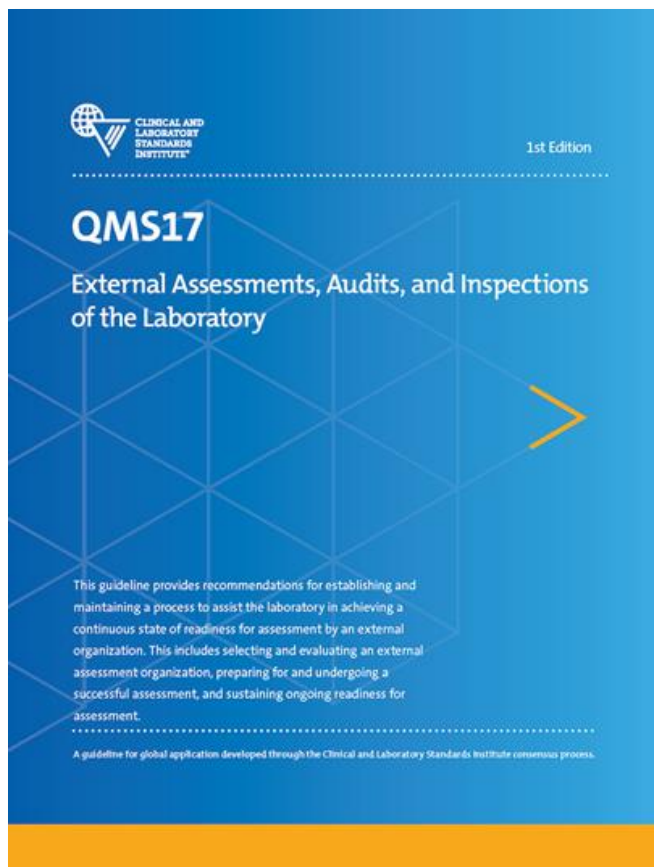


This guideline:

- 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





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# 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



# A COMMON GOAL: QUALITY HEALTH CARE





# Thank you

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# QUESTIONS?