



CLSI Update

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AMDM IVD Focus Meeting| October 19, 2023

OVERVIEW OF TODAY'S WEBINAR



CLSI Overview and History



**Consensus Standards
Development Process
Participation**



**CLSI Method
Evaluation Resources**



Q&A



About CLSI

Clinical and Laboratory Standards Institute (CLSI)

CLSI MISSION

Develop clinical and laboratory practices and promote their use worldwide

OFFERING

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

Cultivating best practices and fostering innovation through standards and training

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



World Health Organization

Designated WHO
Collaborating
Center for
Clinical
Laboratory
Standards.



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

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



EXECUTIVE DIRECTORS QUALITY SYSTEMS MANAGEMENT TRAINING - MOROGORO
FACILITATED BY CISI 21/SEPT/02/11



Today

More than 250 standards,
25000 members and
standards in practice in
more than xxx countries

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



THE ROLE OF PROFESSIONAL ORGANIZATIONS IN THE ESTABLISHMENT OF

With such scientific, technical, and legislative needs, the need for workable standards in the field of laboratory medicine is clearly evident to the patient care, business review, and public interest. These standards obviously involve the interests of the individual, the community, and the national agencies. Hence, an organization representing all three of these could clearly be in a position of possible leadership to identify and solve the problems that this need has created. If it is, therefore, appropriate to review the current status of the National Committee for Clinical Laboratory

Seven professional organizations were invited to participate in the development of the guidelines prior to the formation of MOCCLA. Such organizations included the American Society of Professional Engineers, the American Association of Chemical Engineers, the American Nuclear Society, the American Society of Mechanical Engineers, the American Association for Clinical Chemistry, the American Society of Heating, Refrigerating and Air Conditioning Engineers, which participated in the establishment of a crystallographic committee, and the American Council of the National Academy of Sciences and the American Chemical Society.

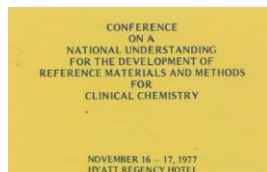
Other organizations, such as the Cybernetics Institute, the American Society of Mechanical Engineers, and the American Nuclear Society have also been quite active for several years in the development of the guidelines. The American Nuclear Society, in addition to the Cybernetics Institute, has been instrumental in the development of the American Society of Mechanical Engineers' ASME standards in cooperation with other organizations. The American Society of Mechanical Engineers, the American Nuclear Society, and the American Chemical Society have been instrumental in the development of the American Society of Mechanical Engineers' ASME standards in cooperation with other organizations.

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The Founding of NCCLS

The idea for the NCCLS began on October 21, 1967, when, with the total commitment and support of the CAP, a meeting was arranged including a large number of representatives of professional organizations interested in the setting of standards for clinical laboratories. This meeting

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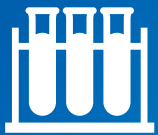
Accredited by
American
National
Standards
Institute (ANSI)
as voluntary
consensus
standards
organization

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



FACILITATING INNOVATION, IMPROVING CARE

Bettering 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* Device Manufacturers
- Pharmaceutical Manufacturing
- Commercial & Clinical Trial Laboratories
- Testing Companies



Consensus Document Development Process and Participation in CLSI

THE CLSI CONSENSUS PROCESS



11 SPECIALTY AREAS, 250+ STANDARDS & 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



Recognized CLSI Standards

 **U.S. FOOD & DRUG**
ADMINISTRATION

Follow FDA | En Español

SEARCH

HomeFoodDrugsMedical DevicesRadiation-Emitting ProductsVaccines, Blood & BiologicsAnimal & VeterinaryCosmeticsTobacco Products

Recognized Consensus Standards: Medical Devices

FDA HomeMedical DevicesDatabases

1 to 59 of 59 Results
Standards Designation Number: EP

Results per Page 100

New SearchExport To ExcelStandardsSearchAssistance

Date of Entry	Specialty Task Group Area	Recognition Number	Extent of Recognition	Standards Developing Organization	Standard Designation Number and Date	Title of Standard
05/29/2023	InVitro Diagnostics	7-315	Complete	CLSI	EP12 3rd Edition	Evaluation of Qualitative, Binary Output Examination Performance
12/19/2022	InVitro Diagnostics	7-313	Complete	CLSI	EP27 2nd Edition	Constructing and Interpreting an Error Grid for Quantitative Measurement Procedures
12/20/2021	InVitro Diagnostics	7-311	Complete	CLSI	EP39, 1st Edition	A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests
06/07/2021	InVitro Diagnostics	7-306	Complete	CLSI	EP06 2nd Edition	Evaluation of the Linearity of Quantitative Measurement Procedures
12/21/2020	Dental/ ENT	4-270	Complete	ANSI ADA	Technical Report No. 146-2018	CAD/CAM Abutments in Dentistry
07/06/2020	InVitro Diagnostics	7-296	Partial	CLSI	EP09c 3rd Edition	Measurement Procedure Comparison and Bias Estimation Using Patient Samples

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm>

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

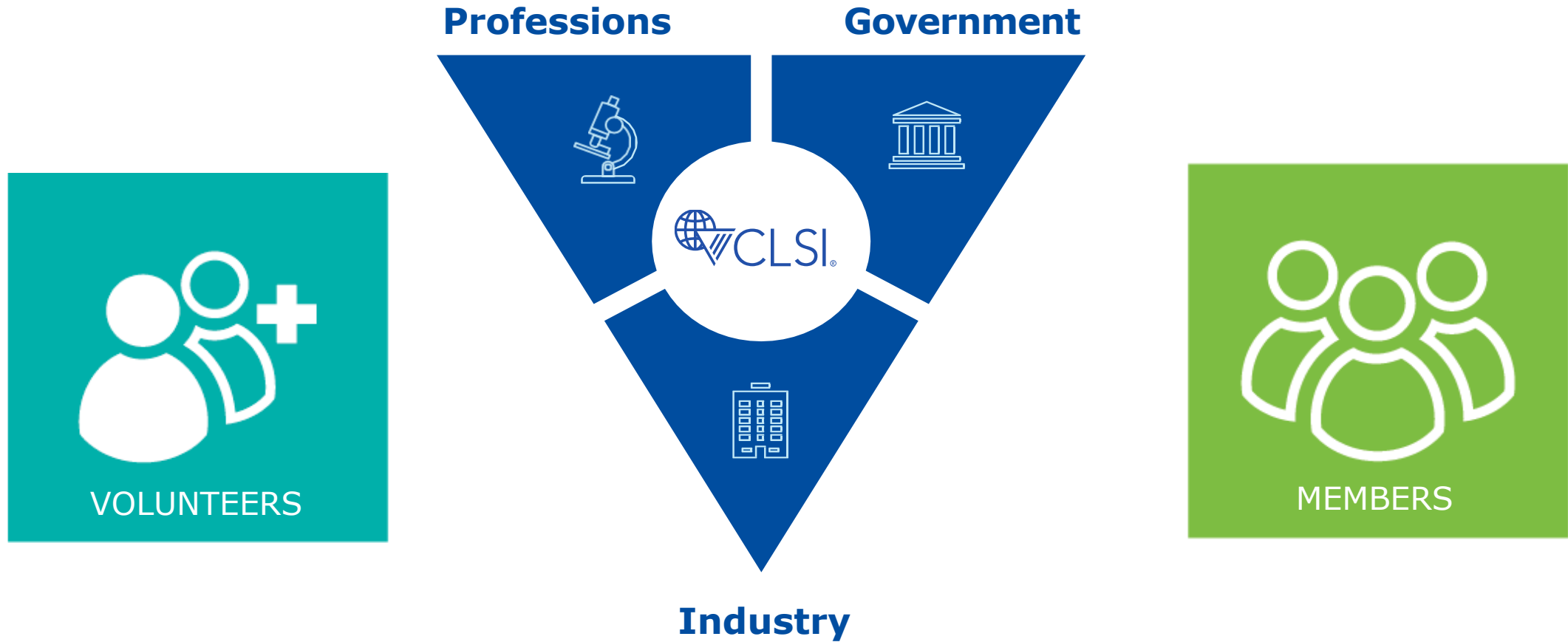
Australia, Bangladesh, Bhutan, Cambodia, China, East Timor, Guam, Hong Kong, India, Indonesia, Japan, Malaysia, Maldives, Micronesia, Mongolia, Myanmar, Nepal, New Zealand, Pakistan, Papua New Guinea, Philippines, Singapore, South Korea, Sri Lanka, Taiwan, Thailand, Vietnam

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



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
- ✓ Participate 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

Board of Directors

Consensus Council

Expert Panels

Document
Development
Committees

Subcommittees

Working Groups



There are currently no open opportunities.

Don't see an opportunity in your area of expertise? [Complete your volunteer profile](#) [Shop](#) [Membership](#) [Participate](#) [Standards](#) [Global Training](#) [About](#) [Q](#)

How to Volunteer

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 displays the CLSI website interface. At the top, the CLSI logo is on the left, and a navigation bar on the right includes links for Shop, Membership, Participate, Standards, Global Training, and About. A blue arrow points to the 'Shop' link. Below the navigation bar is a large banner image showing laboratory technicians in white coats and blue gloves working with petri dishes. On the left side of the page, a 'Quick Links' section lists various resources, with 'New Products' highlighted by a blue box and a blue arrow. Below this is a 'Specialty Areas' section. The main content area on the right is titled 'CLSI Standards: Guidelines for Health Care Excellence' and contains descriptive text about the standards. Below the text are tabs for 'Standards', 'Educational Programs', and 'Related Resources'. A filter and sort section allows users to filter by 'All Subcategories' and sort by 'Date (newest first)'. Two product listings are shown: 'EP23 Laboratory Quality Control Based on Risk Management, 2nd Edition' and 'POCT18 Selection Process for CLIA-Waived Testing for SARS-CoV-2'. Each listing includes a cover image, title, publication date, and pricing for members and nonmembers. A blue arrow points from the 'New Products' link to the 'EP23' product listing.

Quick Links

- New Products
- Derivative Products
- COVID-19 Testing Resources
- Crosswalks
- Free Resources
- ISO Documents
- Order Form, Catalog, & More
- eLearning
- Webinars
- Packages
- Subscriptions

Specialty Areas

- Automation and Informatics
- Clinical Chemistry and Toxicology
- General Laboratory

CLSI Standards: Guidelines for Health Care Excellence

Developed by our members for use by the global laboratory community, CLSI's consensus-based medical laboratory standards are the most widely recognized resources for continually improving testing quality, safety, and efficiency.

Browse our collection of consensus-based medical laboratory standards documents. Choose from print or electronic versions of CLSI standards and guidelines.

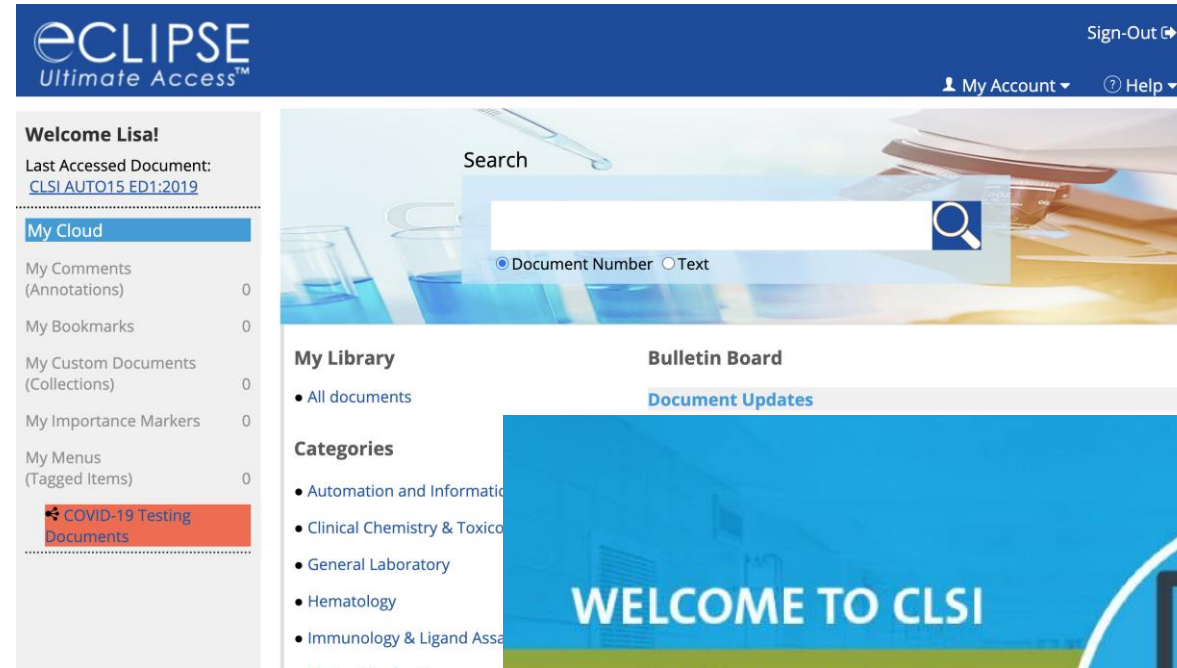
Looking to order through a purchase order? View our [Guide on Placing a Purchase Order](#).

Standards	Educational Programs	Related Resources
<p>Filter by All Subcategories Sort by Date (newest first)</p> <p>EP23 Laboratory Quality Control Based on Risk Management, 2nd Edition Published in 2023</p> <p>POCT18 Selection Process for CLIA-Waived Testing for SARS-CoV-2</p>		<p>Member price: \$54.00 → \$170.00 Nonmembers: \$200.00</p> <p>Log in/sign up to see price and add to cart</p> <p>Member price: \$0.00 → \$0.00 Nonmembers: FREE</p>

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

CLSI ECLIPSE – Digital Library Access

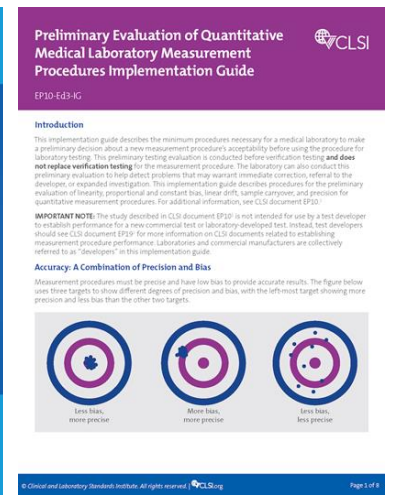
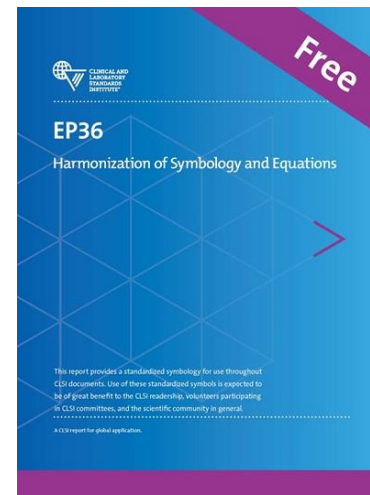
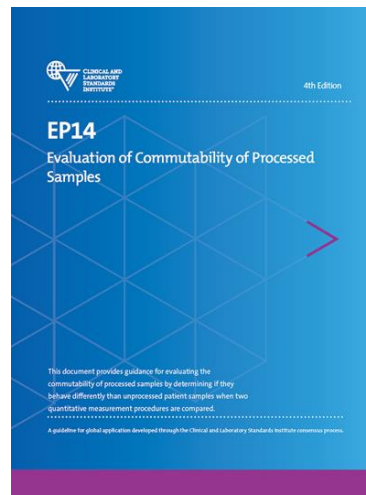
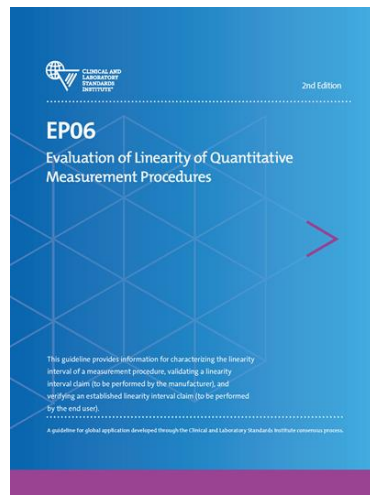
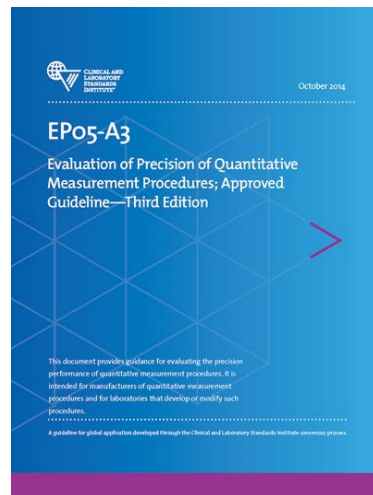
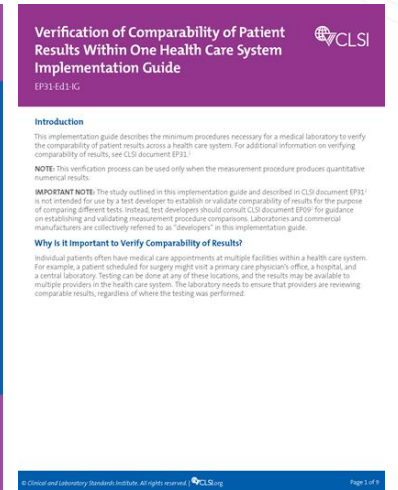
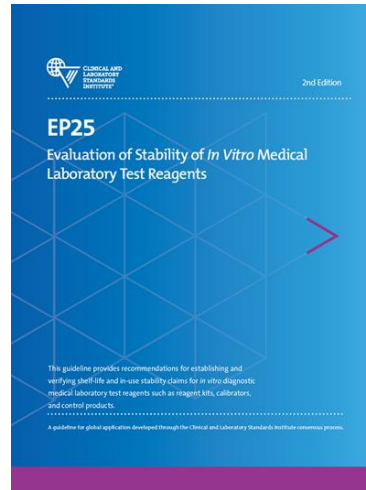
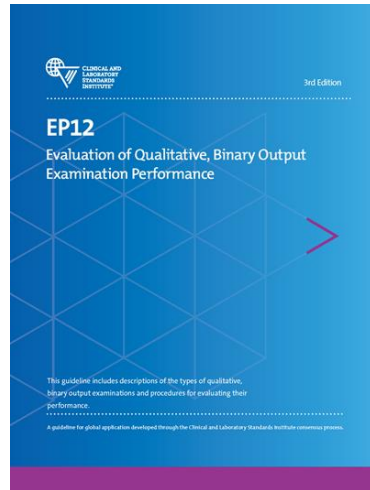
- › Unlimited 24/7 access
- › Full library of current standards
- › Easily search and find related content
- › Bookmarks and annotate
- › Create custom collections and share with colleagues
- › Advanced printing options





CLSI Method Evaluation Resources

THE BEST OF CLSI'S EP TOOLS

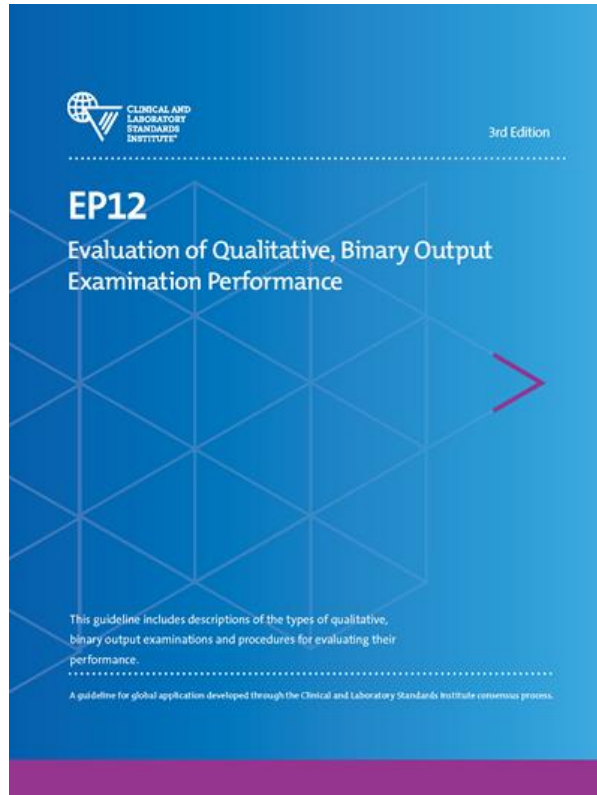




Key changes & updates

KEY DOCUMENT CHANGES & UPDATES

CLSI EP12 – Ed3



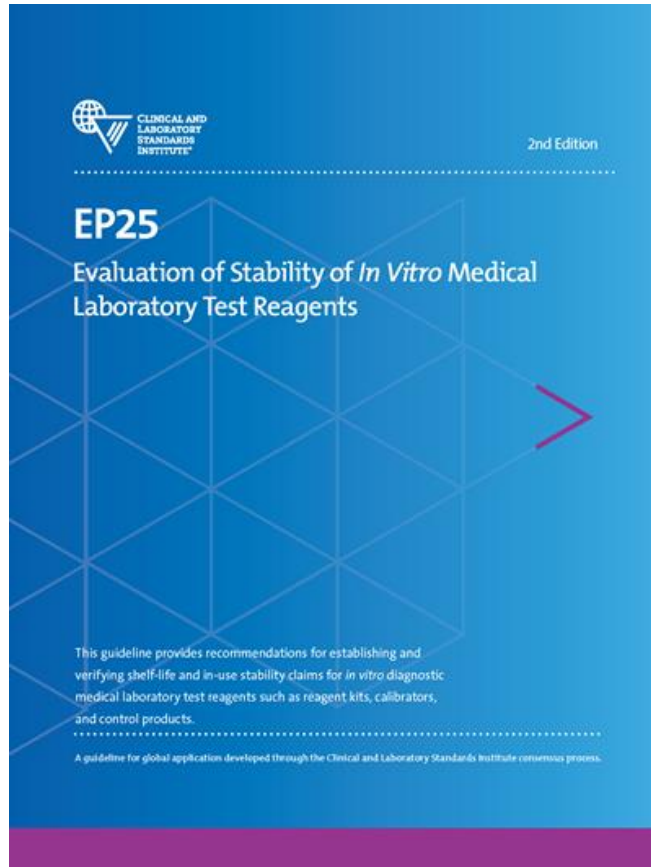
This guideline describes the categories of qualitative, binary output examinations and covers their performance evaluations for imprecision, clinical performance (sensitivity and specificity), and stability and interferences.

Several changes were made including:

- Expanding the types of procedures covered to reflect ongoing advances in laboratory medicine
- Adding protocols to be used by developers during examination procedure design as well as for validation and verification
- Adding topics such as stability and interferences to the existing coverage of the assessment of precision and clinical performance (or examination agreement)

KEY DOCUMENT CHANGES & UPDATES

CLSI EP25 – Ed2



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.

Several changes were made including:

- Revising the approach to statistical power analysis for planning studies to assume there will be some drift in reagent performance
- Eliminating the custom of using the t-test of regression slope results ($P > 0.05$) as a rationale for passing a stability assessment
- Eliminating the requirement for a confidence interval within the acceptance criteria as a basis for stating claims
- Expanding the practices for transport simulation stability testing
- Expanding the use and practices for accelerated stability testing

KEY DOCUMENT CHANGES & UPDATES

CLSI EP23 – Ed2



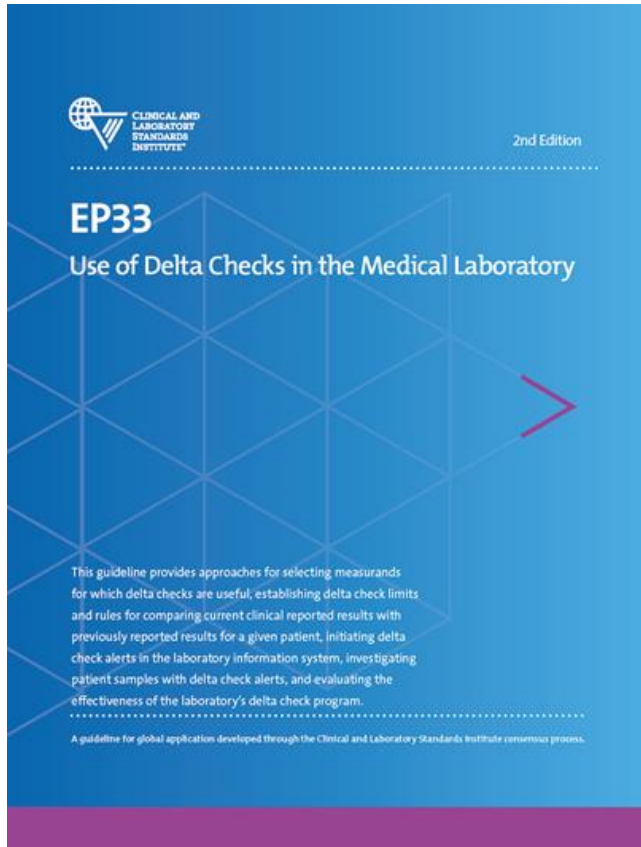
This guideline provides recommendations based on risk management for laboratories to develop quality control plans tailored to the combination of measuring system, laboratory setting, and clinical application of the test. CLSI EP23 aligns with the application of risk management requirements of ISO 22367 (medical laboratories) and ISO 14971 (medical devices).

Several changes were made including:

- Incorporating detectability in the risk assessment
- Adding real-world examples of QC plans for a
 - Noninstrumented single-use device
 - Instrumented single-use device, and
 - Exempt microbiological media

KEY DOCUMENT CHANGES & UPDATES

CLSI EP33 – Ed2



This guideline provides approaches for selecting measurands 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.

Several changes were made including:

- Emphasizing validation of the methods and published results for estimates of biological variation, which are important in setting limits for EP33
- Aligning this guideline with recommendations of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM),³ which uses a strict methodology to assess the validity of published biological variation estimates



What's New?

Implementation Guides and Workbooks

User Verification of Linearity
Implementation Guide

EP06-Ed2-IG

CLSI

Introduction

This implementation guide describes the minimum procedures necessary for a medical laboratory to verify a developer's linearity interval claim. For additional information on verifying linearity, see CLSI document EP06.¹

NOTE: This verification of linearity 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 Chapter 4 of CLSI document EP06¹ is not intended for use by a test developer to establish or validate the linearity interval for a new commercial test or laboratory-developed test. Instead, test developers should consult Chapters 2 and 3 of CLSI document EP06¹ for guidance on establishing and validating a linearity interval. Laboratories and commercial manufacturers are collectively referred to as "developers" in this implementation guide.

What Is Linearity?

A measurement procedure is linear throughout a given interval when the results, on average, are proportional to the true values of the samples. In the graph below, both test 1 (orange line) and test 2 (blue line) are linear and proportional but give very different values. Each line can be depicted in the following equations:

- Test 1: $Y = X$
- Test 2: $Y = 2X$

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Page 1 of 9

User Verification of Linearity Workbook						
EP06-Ed2-WB						
Instructions:						
1) Select "Reset Data" to start verification process.						
2) Enter numerical values into blue cells (top to bottom).						
3) Review resultant precision profile in yellow cells.						
<div>Reset Data</div>						
Allowable deviation from linearity (ADL)						
Constant (fixed) deviation in units:			Units	Laboratory: Laboratory name		
Relative (proportional) deviation (0 to 100):			%	Measurand: Measurand name		
				Units: Units		
				Measurement system: Measurement system name		
Note on ADL:			Date:			
ADL can be entered as constant, relative, or both.						
If both are entered, the ADL for any sample is the one that provides the greatest deviation.						
Known sample values:						
Sample number (low to high): 1 2 3 4 5 6						
Concentration values (1-5 or 1-6):						
Constant ADL: 0.00 0.00 0.00 0.00 0.00 0.00						
Relative ADL: 0.00 0.00 0.00 0.00 0.00 0.00						
Note on sample concentration values:						
If only 5 samples are available, enter the requested values in the first 5 columns from lowest to highest.						
If a low sample is to be mixed proportionally with a high sample then:						
1) Determine the values of the low and high samples (use best estimate).						
2) Compute the intermediate values based on the proportion of high vs low sample used.						
3) Enter the computed values; proportional accuracy is more important than exact value.						
Study results:						
Sample number (low to high): 1 2 3 4 5 6						
First measured replicate:						
Second measured replicate:						
Mean:						
Measured SD:						

Instructions

Data Entry

Linearity

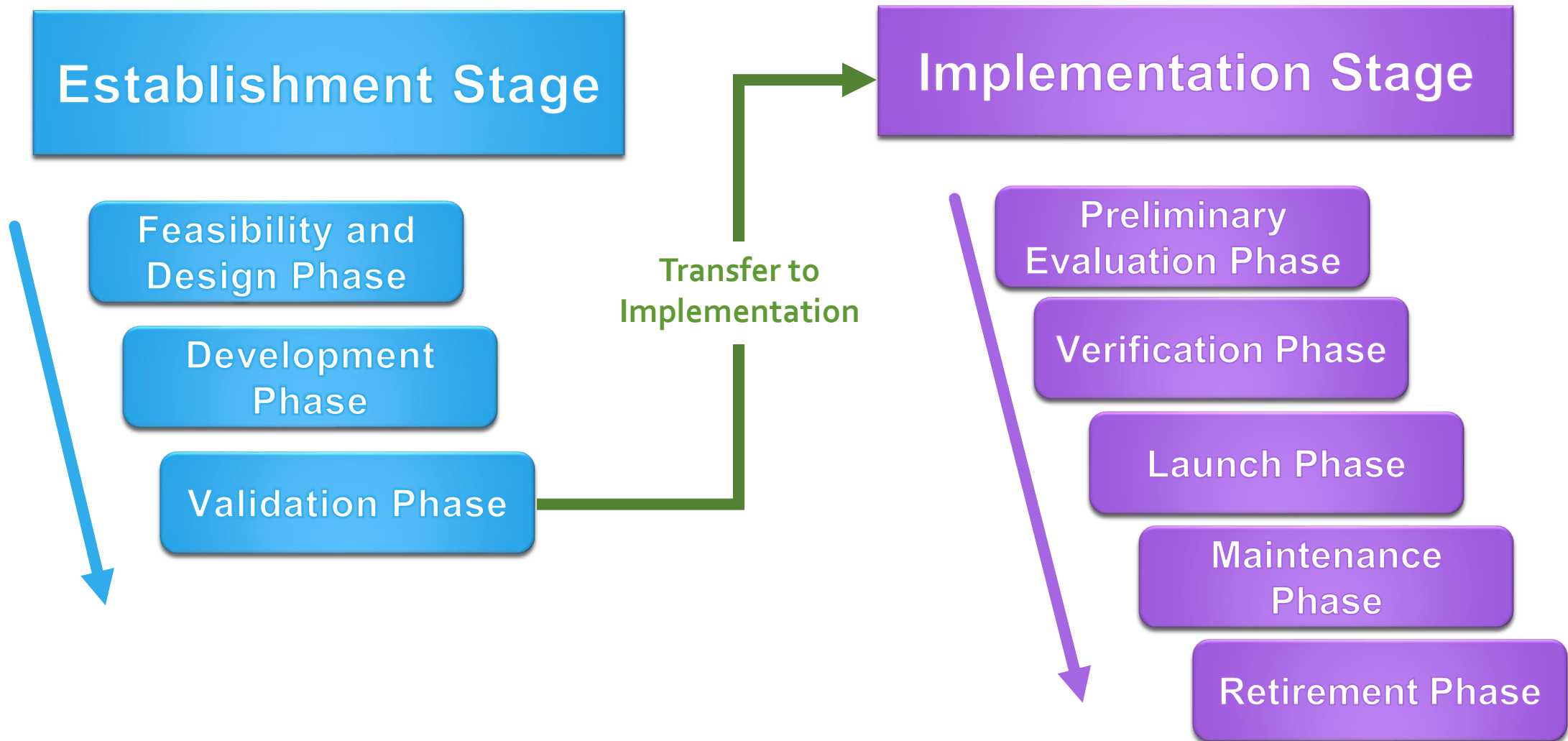
Reference

Method Navigator

- NEW electronic subscription product from CLSI
- Helps you meet applicable regulatory and accreditation requirements
- For establishing and implementing LDTs or implementing an FDA-cleared test method
- Helps provide guidance on the necessary documents and records



Test Life Phases Model



Why Use Method Navigator?



- › Reproducible outline for any new test method
- › Easily create needed documents and records as you develop
- › Helps your laboratory meet requirements
- › Contributes to good quality laboratory results and improves patient safety



Projects in Progress & Recent Publications

PROJECTS IN PROGRESS – 2023 – early 2024

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

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

CLSI QMS27 Decontamination of Laboratory Instrumentation

CLSI POCT16 Emergency and Disaster Point-of-Care Testing



Visit
clsi.org/standards
for latest

Recently Published Documents

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

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

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

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

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

CLSI QMS18, Process Management, 2nd Ed

CLSI M53, Criteria for Laboratory Testing. Diagnosis of Human Immunodeficiency Virus Infection, Ed2

CLSI QMS17, External Assessments, Audits, and Inspections of the Laboratory



QUESTIONS?

A COMMON GOAL: QUALITY HEALTH CARE





Thank you

Jennifer K. Adams | jadams@clsi.org