



The Clinical and Laboratory Standards Institute

Standards Alliance Medical Device Workshop - INVIMA

Vision and Mission

Vision

Quality practices for better health

Mission

Develop clinical and laboratory practices and promote their use worldwide.



**Celebrating
50 Years of
Standards
Development**

CLSI's presence has dramatically improved the **quality** of medical laboratory testing over the last **50 years**.





Not-for-profit



Volunteer
Membership
Organization

Global Organization

- CLSI members come from 60+ countries. Members include:
 - 1,400+ Organizations
 - 1,100+ Hospitals and Independent Laboratories
 - 400+ Individuals
 - 100+ Industry Organizations
 - 50+ Health Systems
 - 45 Government Agencies
- CLSI standards are written by 2500+ volunteers from 60+ countries.
- CLSI standards have been purchased from over 100 different countries, including 17 countries in Latin America.

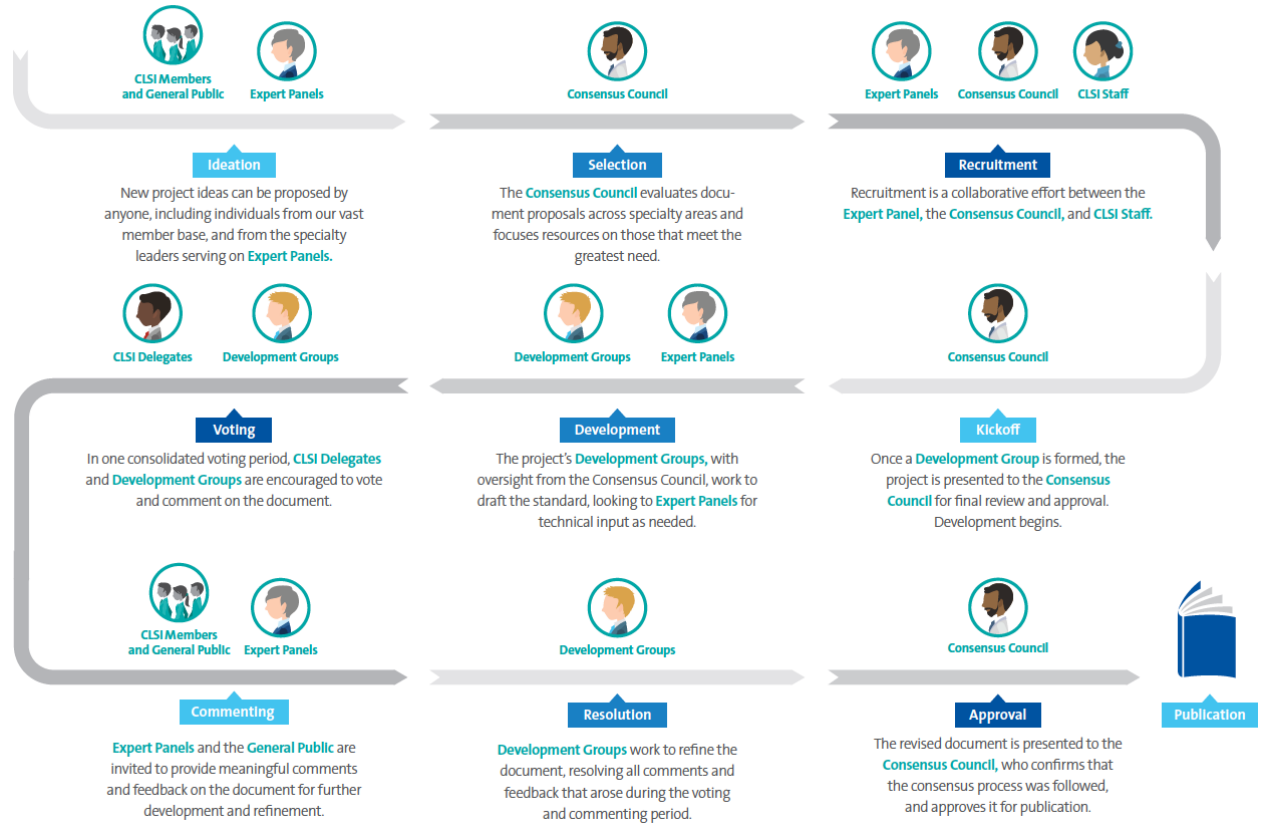
What Do We Do?

- CLSI helps laboratories deliver standardized high-quality test results.
- Our consensus process brings together experts from industry, government, and health care professions to develop timely and useful standards.
- Our standards are recognized by laboratories, industry, accreditors, and regulators as the way to improve testing.

Benefits of Using CLSI Standards

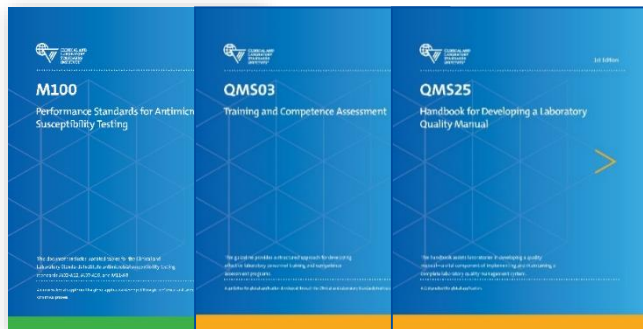
- Developed using an open, inclusive, and transparent consensus process
- The authors include:
 - Accrediting organizations.
 - Government agencies charged with laboratory oversight.
 - Practicing laboratory professionals providing expertise and real world experience.
 - *In vitro* diagnostic industries.
 - Professional societies.

Our Process

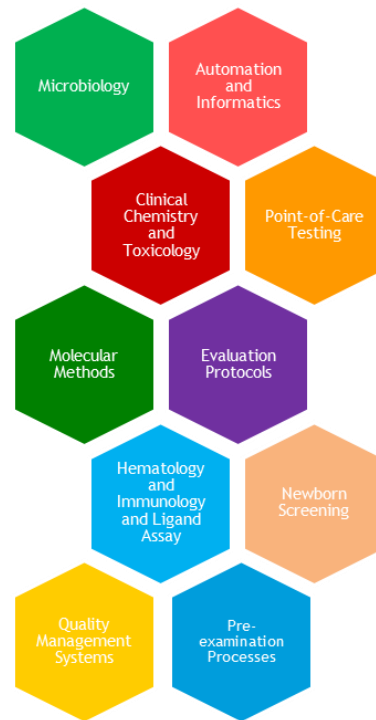


Standards Library

150+ Publications



Specialty Areas



CLSI Standards Committees for the Medical Technology Industry

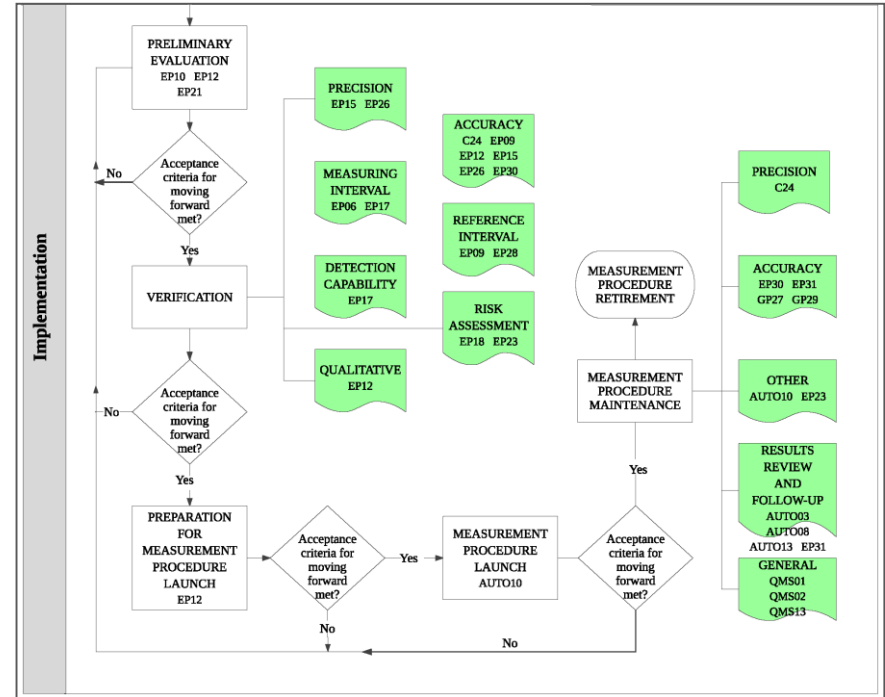
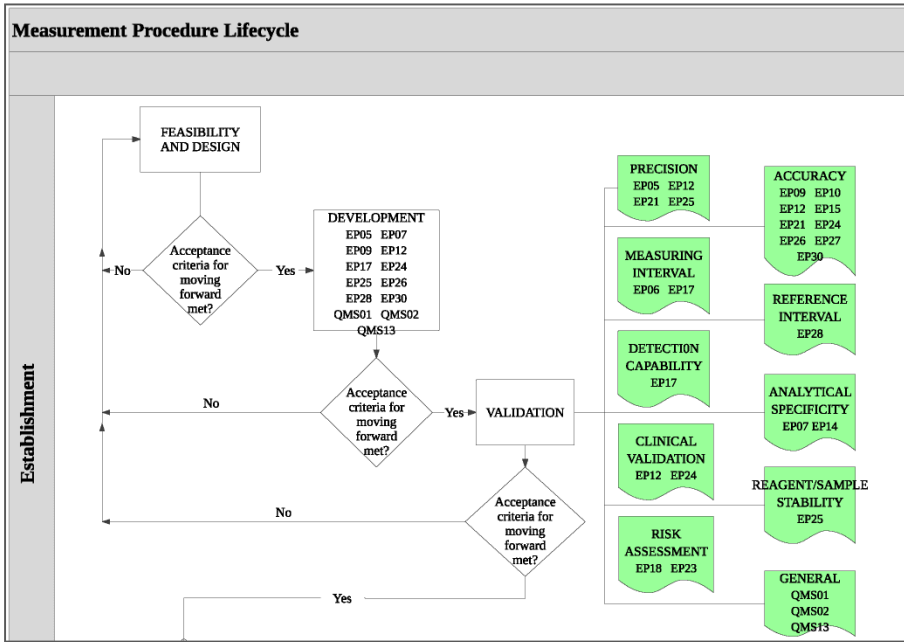
CLSI members from the medical technology industry serve on document development committees that help us develop standards related to:

- Automation and Informatics
- Clinical Chemistry and Toxicology
- Evaluation Protocols
- Point-of-Care Testing

CLSI Evaluation Protocols Standards

- Precision
- Linearity
- Interference testing
- Method comparison
- Matrix effects
- Total analytical error
- Evaluating qualitative tests
- Verification of claims
- Limits of detection
- Risk management
- QC based on risk management
- Stability

A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures (EP19)



ISO Standards



CLSI is the Secretariat
for
ISO Technical
Committee (TC) 212

CLSI is the
Administrator of ANSI-
accredited US Technical
Advisory Group to
ISO/TC 212

How Do I Get Involved?

CLSI

News About Login

Standards Education Membership Volunteer Resources Partnerships

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Volunteering with CLSI

Why Volunteer?

- Play an active role in improving public health across the globe.
- Take part in developing the best practice standards that affect the work you do each day.
- Directly impact and improve quality in laboratory medicine by sharing your expertise.
- Enrich your career and résumé through your contributions.
- Gain recognition from CLSI, your organization, your colleagues, and your community.

[Explore Volunteer Opportunities](#)

Help shape the standards that impact your day-to-day work.

Don't just follow the gold standard. Set it. CLSI offers unmatched opportunity to maximize your voice in the global laboratory and health care community. Work alongside colleagues and experts from diverse sectors to improve patient care worldwide.

By volunteering with CLSI, you'll have a seat at the table with many influential members of the health care community and a chance to contribute your own expertise to the development of world-respected medical laboratory testing standards.

Current Volunteers:

[Log in to Access CLSI Exchange](#)

clsi.org/volunteer

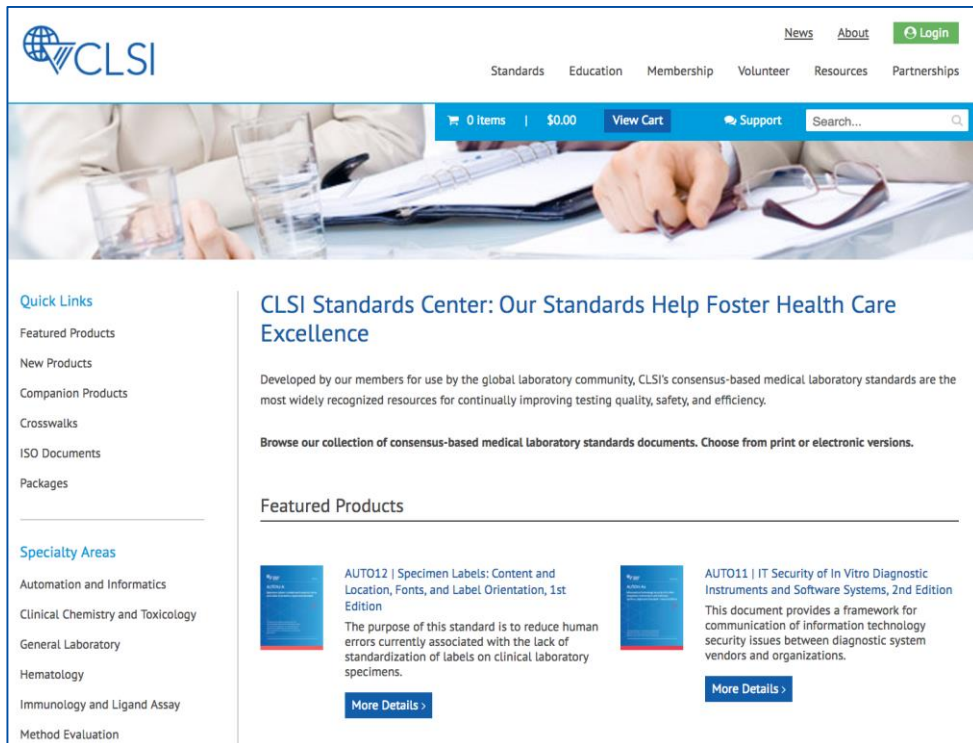
Membership

CLSI membership can help your organization develop innovative products by using globally recognized standards.

Through CLSI membership, industry organizations and commercial laboratories have access to standards for their organization and employees are able to volunteer to participate on document development committees.

To find out more about membership, contact membership@clsi.org.

How Do I Find Standards?



The screenshot shows the CLSI Standards Center website. At the top left is the CLSI logo. The top navigation bar includes links for News, About, and Login. Below this is a secondary navigation bar with links for Standards, Education, Membership, Volunteer, Resources, and Partnerships. A blue banner below the navigation contains a shopping cart icon with '0 Items | \$0.00', a 'View Cart' button, a 'Support' link, and a search bar. The main content area features a large image of a person writing in a notebook. Below the image, the page title is 'CLSI Standards Center: Our Standards Help Foster Health Care Excellence'. The text describes the standards as developed by members for the global laboratory community. A section titled 'Browse our collection of consensus-based medical laboratory standards documents. Choose from print or electronic versions.' is followed by a 'Featured Products' section. Two products are highlighted: AUTO12 | Specimen Labels: Content and Location, Fonts, and Label Orientation, 1st Edition, and AUTO11 | IT Security of In Vitro Diagnostic Instruments and Software Systems, 2nd Edition. Each product has a 'More Details >' button.

Quick Links

- Featured Products
- New Products
- Companion Products
- Crosswalks
- ISO Documents
- Packages

Specialty Areas


- Automation and Informatics
- Clinical Chemistry and Toxicology
- General Laboratory
- Hematology
- Immunology and Ligand Assay
- Method Evaluation

CLSI Standards Center: Our Standards Help Foster 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.


Featured Products



AUTO12 | Specimen Labels: Content and Location, Fonts, and Label Orientation, 1st Edition

The purpose of this standard is to reduce human errors currently associated with the lack of standardization of labels on clinical laboratory specimens.

[More Details >](#)



AUTO11 | IT Security of In Vitro Diagnostic Instruments and Software Systems, 2nd Edition

This document provides a framework for communication of information technology security issues between diagnostic system vendors and organizations.

[More Details >](#)

clsi.org/standards

Summary

- CLSI is a global, consensus-based, standards development organization with 150+ standards and related products.
- CLSI standards are invaluable tools used by government agencies, health care professions, and industry organizations.
- Ways to access CLSI standards, volunteering opportunities, and membership information were provided.

Global Laboratory Standards for a Healthier World



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