Vision and Mission

Vision
Quality practices for better health

Mission
Develop clinical and laboratory practices and promote their use worldwide.
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

Ideation
New project ideas can be proposed by anyone, including individuals from our vast member base, and from the specialty leaders serving on Expert Panels.

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

Recruitment
Recruitment is a collaborative effort between the Expert Panel, the Consensus Council, and CLSI Staff.

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

Development
The project’s Development Groups, with oversight from the Consensus Council, work to draft the standard, looking to Expert Panels for technical input as needed.

Kickoff
Once a Development Group is formed, the project is presented to the Consensus Council for final review and approval. Development begins.

Commenting
Expert Panels and the General Public are 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, who confirms that the consensus process was followed, and approves it for publication.

Publication
Standards Library
150+ Publications

Specialty Areas
- Microbiology
- Automation and Informatics
- Clinical Chemistry and Toxicology
- Point-of-Care Testing
- Molecular Methods
- Evaluation Protocols
- Hematology and Immunology and Ligand Assay
- Newborn Screening
- Quality Management Systems
- Pre-examination Processes
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

Abbreviation: ANSI, American National Standards Institute
How Do I Get Involved?

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?

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