Clinical and Laboratory Standards Institute

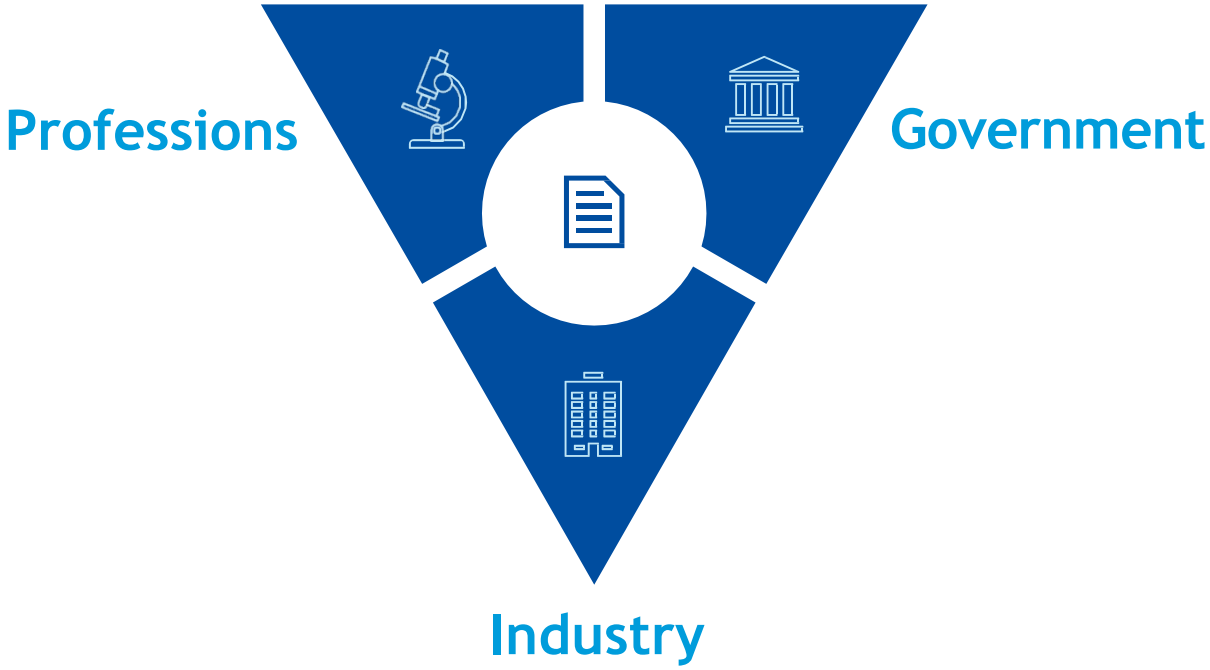
Objectives

- Who We Are
- CLSI & ISO/TC 212
- CLSI Standards
- Global Education

Who We Are

CLSI is a standards development organization that creates global best practices for medical laboratories.

- We develop standards using an open, transparent, consensus-based process.
- We aim to help medical laboratories meet accreditation, regulatory, and public health requirements.
- We strive to improve patient care through high quality medical laboratory testing.



CLSI Membership Profile

24,000+
Individuals with Membership From 75+ Different Countries

83+
Health Systems

45+
Government Organizations

1,200+
Volunteers

100+
Industry Organizations

1,400+
Hospitals and Independent Laboratory Organizations

400+
Individual Members

CLSI & ISO/TC 212

CLSI and ISO

- ISO Technical Committee 212 (ISO/TC 212) is responsible for international standardization and guidance in the field of laboratory medicine and *in vitro* diagnostic test systems.

Secretariat for ISO Technical Committee (TC) 212

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

ISO/TC 212

- 44 participating member countries, 29 observer countries
- Last met virtually on 5 October 2021
- Structure:
  - WG1, Quality and competence in the medical laboratory
  - WG2, Reference systems
  - WG3, *In vitro* diagnostic products
  - WG4, Microbiology and molecular diagnostics
  - WG5, Laboratory biorisk management
  - Joint ISO/TC 212 – ISO/TC 276 WG: Quality practice for detection of SARS-CoV-2
  - STTF: Spanish translation task force

ISO TC 212 Recent Publication

- **ISO 20776-2, Clinical laboratory testing and *in vitro* diagnostic test systems** — Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 2: Evaluation of performance of antimicrobial susceptibility test devices against reference broth micro-dilution

ISO/TC 212 Upcoming Publications

- **ISO/TS 5798, *In vitro* diagnostic test systems** — Requirements and recommendations for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods

- **ISO 17593, Clinical laboratory testing and *in vitro* medical devices** — Requirements for *in vitro* monitoring systems for self-testing of oral anticoagulant therapy

ISO/TC 212 Newly Approved Projects

- **ISO 5649**, Concepts and specifications for the design, development, production and use of in-house *in vitro* diagnostic medical devices (laboratory-developed tests)

- **ISO/TS 7552**, Parts 1-3, Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood. Part 1: Isolated RNA, Part 2: Isolated DNA, Part 3: Preparations for analytical CTC staining.

CLSI Standards

250+ Standards, Guidelines, Other Products

12 Specialty Areas:

- Automation and Informatics
- Clinical Chemistry and Toxicology
- Hematology
- Immunology and Ligand Assay
- Method Evaluation
- Microbiology
- Molecular Diagnostics
- Newborn Screening
- Point-of-Care Testing
- Preexamination Processes
- Quality Management Systems
- Veterinary Medicine

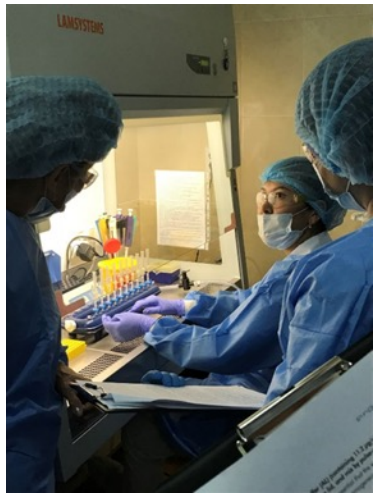
Recent Publications

Code	Document Name
CLSI M100-ED32	Performance Standards for Antimicrobial Susceptibility Testing, 32nd Edition
CLSI M39-ED5	Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data, 5th Edition
CLSI EP39-ED1	A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of *In Vitro* Medical Laboratory Tests, 1st Edition
CLSI H62-ED1	Validation of Assays Performed by Flow Cytometry, 1st Edition
CLSI MM24-ED1	Molecular Methods for Genotyping and Strain Typing of Infectious Organisms, 1st Edition
CLSI NBS09-ED1	Newborn Screening for X-Linked Adrenoleukodystrophy, 1st Edition
CLSI EP43-ED1	Implementing a Laboratory Test Under Emergency Use Conditions, 1st Edition
CLSI M23S2-ED1	Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval, 1st Edition
CLSI C64-ED1	Quantitative Measurement of Proteins and Peptides by Mass Spectrometry, 1st Edition
CLSI NBS01-ED7	Dried Blood Spot Specimen Collection for Newborn Screening, 7th Edition
CLSI QMS26-ED1	Managing Laboratory Records, 1st Edition
CLSI VET02-ED4	Development of Quality Control Ranges, Breakpoints, and Interpretive Categories for Antimicrobial Agents Used in Veterinary Medicine, 4th Edition
CLSI M54-ED2	Principles and Procedures for Detection and Culture of Fungi in Clinical Specimens, 2nd Edition

Global Education

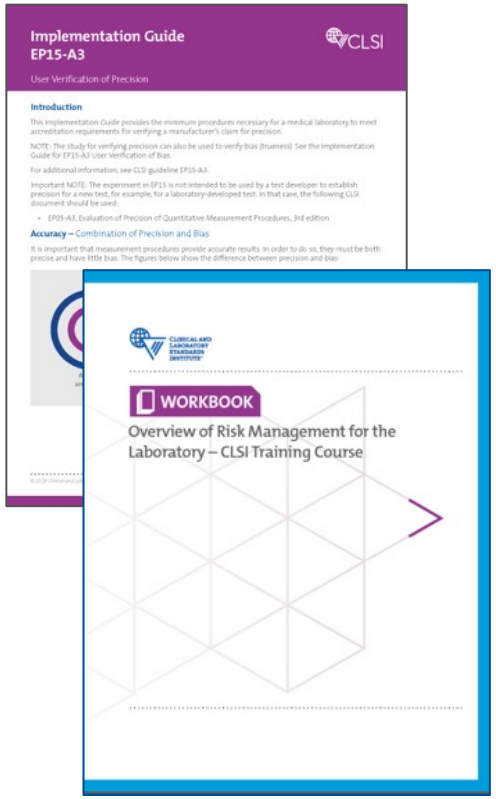
Targeted Trainings to Increase Competencies

- **QMS Implementation:** Documentation, Personnel, Process Management, EQA, etc.
- **Quality Control and Method Evaluation** across disciplines
- **Technical Skills:** Molecular Testing, POCT/Rapid Testing, Microbiology, and Recency Testing
- **ISO Standards Implementation**
- **Auditor/Mentor**



Integration at In-Service and Pre-Service Levels

Educational Products



- Laboratory Quality Management System (LQMS) Certificate Program
- Tools for Understanding Laboratory Risk Management
- Webinars
- NEW! Implementation Guides

New Implementation Guides

CLSI EP18-ED2IG	Risk Management Techniques to Identify and Control Laboratory Error Sources Implementation Guide
CLSI EP21-ED2IG	Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures Implementation Guide
CLSI EP15-ED3IG1	User Verification of Bias (Trueness) Implementation Guide, 1st Edition
CLSI EP15-ED3IG2	User Verification of Precision Implementation Guide, 1st Edition
CLSI EP17-ED2IG	Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures Implementation Guide

For More Information…

www.clsi.org

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