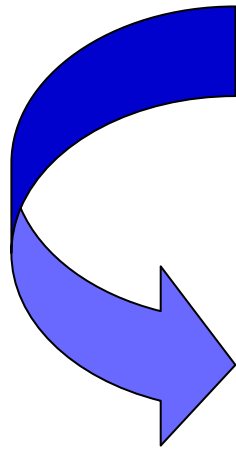


# Effective 1 January 2005



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# CLSI Membership

- Organizational Memberships
- Multiple membership categories:
  - Active (187)
  - Associate Active (205)
  - Corresponding (1,500)
  - Education (50)



**CLINICAL AND  
LABORATORY  
STANDARDS  
INSTITUTE** <sup>TM</sup>

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# Active Member Organizations

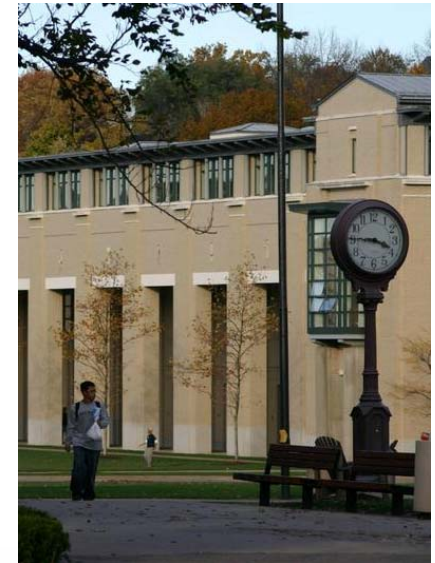
- 29 Professional Societies
- 22 Government Agencies
- 2 Trade Organizations
- 6 Startup Companies
- 52 Industry Organizations (Gross Sales up to US\$50 Million)
- 20 Industry Organizations (Gross Sales over US\$50 Million)
- 15 Multiple Sites
- 21 Consultants



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# Associate Active, Corresponding, and Education Members

- 150 Healthcare Delivery Systems
- 1,733 Hospitals and Laboratories
- 50 Educational Institutions



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# CLSI Volunteers

- Over 2,000 strong
- 2 Broad Categories
  - Board and Board Committees
  - Documents generation and revisions
- Strong educational and scientific backgrounds
- Thought leaders in their disciplines



# 2005 Catalog: 170 Documents

January 2005

## Performance Standards for Antimicrobial Susceptibility Testing; Fifteenth Informational Supplement

M100-S15  
Vol. 25 No. 1  
Replaces M100-S14  
Vol. 24 No. 1

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### Performance Standards for Antimicrobial Susceptibility Testing; Fifteenth Informational Supplement

Volume 25 Number 1

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This document provides up-to-date information for the Institute (CLSI)/NCCLS and M7-A6.

An informational supplement to the Performance Standards for Antimicrobial Susceptibility Testing, Fifteenth Informational Supplement.



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# 10 Area Committees

- Automation and Informatics
- Clinical Chemistry and Toxicology
- Evaluation Protocols
- General Laboratory Practices
- Healthcare Services
- Hematology
- Immunology and Ligand Assay
- Microbiology
- Molecular Methods
- Point-of-Care Testing



# The CLSI Consensus Process

- Balanced Board and committee representation from:
  - Government
  - Industry
  - Professions
- Is the heart of CLSI's reputation, credibility and value in the marketplace
- Jealously guarded and monitored in all we do





# CLSI as a Global Organization

- CLSI participants: non-US



- Active members: 35%

- Corresponding members: 24%

- Volunteers: 20%



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# X5-R

- ***Metrological Traceability and Its Implementation; A Report***
  - ***Guidance to manufacturers for establishing and reporting metrological traceability.***

***In cooperation with the IFCC***



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# X5-R Provides:

- Guidance on establishing traceability of the chemical calibration step in clinical laboratory measurements



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# X5-R Specifically Addresses

- traceability of the chemical calibration of a routine measurement procedure to the highest order reference, which is available for a measurand.

# C53

- ***Validate and Implement Reference Materials***

# C-53 Scope:

- recommendations for the characterization and assessment of reference materials in a patient sample matrix
  - CRMs
  - Materials without a certificate but are used to assess the trueness of methods
  - EQAS materials used to assess trueness

# C-53 Provides:

- Integrates standards and guidelines with new recommendations and will include recommendations for:
  - The evaluation of the commutability of a material
  - Assignment of analyte content or activity values
  - Additional attributes such as homogeneity, etc.



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# C-51

- ***Measurement Uncertainty***



# C-51

- Provides recommendations to medical laboratories attempting to estimate measurement uncertainty
  - To comply with ISO 15189
  - As a tool to assist with the validation of methods used by the laboratory

# C-51 Includes:

- Guidance as to how to estimate the uncertainty of a measurement method
  - The unique difficulties of estimating uncertainty in a clinical laboratory
  - Estimation of the uncertainty of a large number of patient results
  - Where to find data about influence quantities and how to integrate it
  - Examples

# ISO/TC 212

- International Organization for Standardization Technical Committee 212 (ISO/TC 212): *Clinical laboratory testing and in-vitro diagnostic test systems*



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# ISO/TC 212

- Founded in 1995
- CLSI has served as the Secretariat since its inception
- Scope: “Standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems,” including “quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance.”



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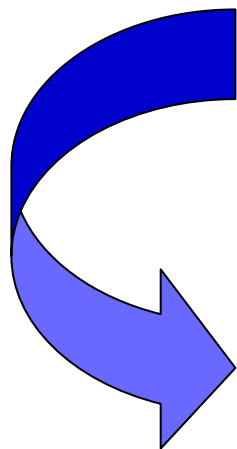
# 4 Working Groups

- Quality and competence in the clinical laboratory (WG 1)
- Reference systems (WG2)
- In vitro diagnostic products (WG3), and
- Antimicrobial susceptibility testing (WG4)

# Thank You



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