

Program Index of CLSI Standards and Guidelines

Code	Document Title	Date
Antifungal Susceptibility Testing		
M27-A3	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard – Third Edition (Vol.28, No.14)	April 2008
M27-S3	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Third Informational Supplement (Vol.28, No.15)	April 2008
M38-A2	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi; Approved Standard – Second Edition (Vol.38, No.2)	April 2008
M44-A2	Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guideline — Second Edition (Vol.29, No.17)	August 2009
M44-S3	Zone Diameter Interpretive Standards, Corresponding Minimal Inhibitory Concentration (MIC) Interpretive Breakpoints, and Quality Control Limits for Antifungal Disk Diffusion Susceptibility Testing of Yeasts	August 2009
M51-A	Method for Antifungal Disk Diffusion Susceptibility Testing of Nondermatophyte Filamentous Fungi; Approved Guideline (Vol.30, No.11)	May 2010
Automation		
AUTO2-A2	Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard – Second Edition (Vol.25, No.29)	December 2005
AUTO03-A2	Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard — Second Edition (Vol.29, No.21)	September 2009
AUTO7-A	Laboratory Automation: Data Content for Specimen Identification; Approved Standard (Vol.24, No.20)	June 2004
AUTO8-A	Managing and Validating Laboratory Information Systems; Approved Guideline (Vol.26, No.36)	December 2006
AUTO9-A	Remote Access to Clinical Laboratory Diagnostic Devices via the Internet; Approved Standard (Vol.26, No.11)	March 2006
AUTO 10-A	Autoverification of Clinical Laboratory Test Results; Approved Guidelines (Vol.26, No.32)	October 2006
AUTO 11-A	IT Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard (Vol.26, No.33)	October 2006
AUTO12-A	Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard (Vol.31, No.7)	April 2011
GP19-A2	Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation and Monitoring; Approved Guideline – Second Edition (Vol.23, No.4)	March 2003

Program Index of CLSI Standards and Guidelines

Code	Document Title	Date
Chemistry		
C3-A4	Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline – Fourth Edition (Vol.24, No.22)	June 2006
C24-A3	Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline – Third Edition (Vol.26, No.25)	June 2006
C28-A3	Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition (Vol.28, No.30)	November 2008
C30-A2	Point of Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Second Edition	September 2002
C31-A2	Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling; Approved Guideline – Second Edition	June 2001
C34-A3	Sweat Testing: Sample Collection and Quantitative Chloride Analysis; Approved Guideline — Third Edition (Vol.20, No.27)	December 2009
C37-A	Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline	November 1999
C38-A	Control of Preanalytical Variation in Trace Element Determinations; Approved Guideline	September 1997
C39-A	A Designated Comparison Method for the Measurement of Ionized Calcium in Serum; Approved Standard	May 2000
C40-P	Analytical Procedures for the Determination of Lead in Blood and Urine; Proposed Guideline (Vol.18, No.4)	April 1998
C42-A	Erythrocyte Protoporphyrin Testing; Approved Guideline (Vol.16, No.8)	November 1996
C43-A2	Gas Chromatography/Mass Spectrometry (GC/MS) Confirmation of Drugs (Vol.30, No.6)	March 2010
C44-A	Harmonization of Glycohemoglobin Measurements; Approved Guideline (Vol.22, No.25)	January 2003
C45-A	Measurement of Free Thyroid Hormones; Approved Guideline (Vol.24 No.31)	October 2004
C46-A2	Blood Gas and pH Analysis and Related Measurements; Approved Guideline — Second Edition (Vol.29, No.8)	February 2009
C48-A	Application of Biochemical Markers of Bone Turnover in the Assessment and Monitoring of Bone Diseases: Approve Guideline (Vol.24, No.22)	July 2004
C49-A	Analysis of Body Fluids in Clinical Chemistry; Approved Guideline (Vol.27, No.14)	April 2007
C50-A	Mass Spectrometry in the Clinical Laboratory: General Principles and Guidance; Approved Guideline (Vol.27, No.24)	October 2007
C54-A	Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline (Vol.28, No.19)	May 2008
C58-A	Assessment of Fetal Lung Maturity by the Lamellar Body Count; Approved Guideline (Vol.31, No.20)	<i>November 2011</i>

Program Index of CLSI Standards and Guidelines

Code	Document Title	Date
H17-A	Determination of Serum Iron, Total Iron-Binding Capacity, and Percent Transferrin Saturation; Approved Standard (Vol.18, No.19)	December 1998
Coagulation (Hemostasis)		
H21-A5	Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline – Fifth Edition (Vol.28, No.5)	January 2008
H30-A2	Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline – Second Edition (Vol.21, No.18)	January 2002
H45-A2	Performance of the Bleeding Time Test; Approved Guideline – Second Edition (Vol.25, No.15)	June 2005
H47-A2	One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline — Second Edition (Vol.28, No.20)	May 2008
H48-A	Determination of Factor Coagulant Activities; Approved Guideline (Vol.17, No.4)	April 1997
H49-A	Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline (Vol.24, No.23)	July 2004
H51-A	Assays of von Willebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline (Vol.22, No.20)	September 2002
H58-A	Platelet Function Testing by Aggregometry; Approved Guideline (Vol.28, No.31)	November 2008
H59-A	Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline (Vol.31, No.6)	March 2011
Cytology and Histology		
GP15-A3	Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline—Third Edition (Vol.28, No.28)	November 2008
GP20-A2	Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline – Second Edition (Vol.23, No.27)	October 2003
GP23-A	Nongynecologic Cytologic Specimens: Collection and Cytopreparatory Techniques; Approved Guideline (Vol.19, No.14)	August 1999
GP28-A	Microwave Device Use in the Histology Laboratory; Approved Guideline (Vol.25, No.7)	February 2005
Flow Cytometry		
H42-A2	Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline – Second Edition (Vol.27, No.16)	May 2007
H43-A2	Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline – Second Edition (Vol.27, No.11)	April 2007
H44-A2	Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes); Approved Guideline – Second Edition (Vol.24, No.8)	February 2004
H52-A	Fetal Red Cell Detection; Approved Guideline (Vol.21, No.26)	March 2002

Program Index of CLSI Standards and Guidelines

Code	Document Title	Date
I/LA26-A	Performance of Single Cell Immune Response Assays; Approved Guideline (Vol.24, No.29)	October 2004
Hematology		
H02-A5	Procedures for the Erythrocyte Sedimentation Rate Test; Approved Standard — Fifth Edition (Vol.31, No.11)	May 2011
H7-A3	Procedure for Determining Packed Cell Volume by the Microhematocrit Method – Approved Standard – Third Edition (Vol.20, No.18)	November 2000
H8-A2	Detection of Abnormal Hemoglobin Using Cellulose Acetate Electrophoresis – Second Edition; Approved Standard (Vol.14, No.10)	September 1994
H9-A	Chromatographic (Microcolumn) Determination of Hemoglobin A2, Approved Standard (Vol.9, No.17)	December 1989
H10-A2	Solubility Test to Confirm the Presence of Sickling Hemoglobins – Second Edition; Approved Standard (Vol.15, No.7)	August 1995
H13-A	Quantitative Measurement of Fetal Hemoglobin Using the Alkali Denaturation Method, Approved Guideline (Vol.9, No.18)	December 1989
H15-A3	Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard – Third Edition (Vol.20, No.28)	March 2001
H20-A2	Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard – Second Edition (Vol.27, No.4)	January 2007
H22-P	Histochemical Method for Leukocyte Alkaline Phosphatase, Proposed Standard (Vol.4, No.14)	October 1984
H23-T	Citrate Agar Electrophoresis for Confirming the Identification of Variant Hemoglobins, Tentative Guideline (Vol.8, No.6)	September 1988
H26-A2	Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard -- Second Edition (Vol.30, No.14)	June 2010
H33-P	Algorithm for the Identification of Hemoglobin Variants; Proposed Guideline (Vol.17, No.8)	May 1997
H39-P	Determination of von Willebrand Factor Antigen; Proposed Guideline (Vol.13, No.29)	December 1993
H41-P	Assay for Ristocetin Cofactor; Proposed Guideline (Vol.13, No.30)	December 1993
H56-A	Body Fluid Analysis for Cellular Composition; Approved Guideline (Vol.26, No.26)	June 2006
Immunology		
DI1-A2	Glossary and Guidelines for Immunodiagnostic Procedures, Reagents and Reference Materials – Second Edition, Approved Guideline (Vol.12, No.9)	July 1992
DI2-A2	Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials – Second Edition, Approved Guideline (Vol.13, No.14)	October 1993
DI3-A	Agglutination Analyses: Antibody Characteristics, Methodology, Limitations, and Clinical Validation; Approved Guideline (Vol.13, No.15)	October 1993

Program Index of CLSI Standards and Guidelines

Code	Document Title	Date
DI4-T	Enzyme and Fluorescence Immunoassays, Tentative Guideline (Vol.6, No.11)	August 1986
I/LA2-A2	Quality Assurance of Laboratory Tests for Autoantibodies to Nuclear Antigens: (1) Indirect Fluorescence Assay for Microscopy and (2) Microtiter Enzyme Immunoassay Methods: Approved Guideline—Second Edition	March 2006
I/LA6-A	Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling and Use of Test Products in the Clinical Laboratory; Approved Guideline (Vol.17, No.17)	October 1997
I/LA9-T	A Candidate Reference Method for Serum Digoxin: A Model for Radioimmunoassay Reference Methods; Tentative Guideline (Vol.16, No.1)	May 1996
I/LA10-A	Choriogonadotropin Testing: Nomenclature, Reference Preparations, Assay Performance, and Clinical Application; Approved Guideline (Vol.16, No.14)	December 1996
I/LA13-A	Human Immunodeficiency Virus Type 1 Reference Material Specifications, Approved Guideline (Vol.11, No.21)	December 1991
I/LA15-A	Apolipoprotein Immunoassays: Development and Recommended Performance Characteristics; Approved Guideline (Vol.17, No.12)	September 1997
I/LA17-A	Assessing the Quality of Systems for Alpha-Fetoprotein (AFP) Assays Used in Prenatal Screening and Diagnosis of Open Neural Tube Defects; Approved Guideline (Vol.17, No.5)	April 1997
I/LA18-A2	Specifications for Immunological Testing for Infectious Diseases; Approved Guideline – Second Edition (Vol.21, No.15)	October 2001
I/LA19-A	Primary Reference Preparations Used to Standardize Calibration of Immunochemical Assays for Serum Prostate Specific Antigen (PSA); Approved Guideline (Vol.17, No.6)	June 1997
I/LA20-A2	Analytical Performance Characteristics and Clinical Utility of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies and Defined Allergen Specificities; Approved Guideline — Second Edition (Vol.29, No.9)	March 2009
I/LA21-A2	Clinical Evaluation of Immunoassays; Approved Guideline — Second Edition (Vol.28, No.22)	August 2008
I/LA23-A	Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guideline (Vol.24, No.16)	May 2004
I/LA24-A	Fluorescence Calibration and Quantitative Measurement of Fluorescence Intensity; Approved Guideline (Vol.24, No.26)	August 2004
I/LA25-A2	Maternal Serum Screening; Approved Standard – Second Edition (Vol.31, No.8)	April 2011
I/LA27-A	Newborn Screening Follow-up; Approved Guideline (Vol.26, No.18)	May 2006
I/LA28-A2	Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays; Approved Guideline — Second Edition (Vol.31, No.4)	January 2011
I/LA29-A	Detection of HLA-Specific Alloantibody by Flow Cytometry and Solid Phase Assays; Approved Guidelines (Vol.28, No.24)	August 2008

Program Index of CLSI Standards and Guidelines

Code	Document Title	Date
I/LA30-A	Immunoassay Interference by Endogenous Antibodies; Approved Guideline (Vol.28, No.6)	February 2008
I/LA31-A	Newborn Screening for Preterm, Low Birth Weight, and Sick Newborns; Approved Guideline (Vol.29, No.24)	October 2009
I/LA32-A	Newborn Screening by Tandem Mass Spectrometry; Approved Guideline (Vol.30, No.16)	July 2010
IL/A33-A	Validation of Automated Systems for Immunohematological Testing Before Implementation; Approved Guideline (Vol.29, No.28)	December 2009
IL/A34-A	Design and Validation of Immunoassays for Assessment of Human Allergenicity of New Biotherapeutic Drugs; Approved Guideline (Vol.31, No.12)	June 2011
I/LA35-A	Newborn Screening for Cystic Fibrosis; Approved Guideline (Vol.31, No.22)	<i>November 2011</i>
LA1-A2	Assessing the Quality of Radioimmunoassay Systems – Second Edition; Approved Guideline (Vol.14, No.17)	December 1994
LA4-A5	Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard – Fifth Edition (Vol.27, No.20)	July 2007

Laboratory

GP2-A5	Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition (Vol.26, No.12)	March 2006
GP05-A3	Clinical Laboratory Waste Management (Vol.31, No.3)	January 2011
GP6-A	Inventory Control Systems for Laboratory Supplies; Approved Guideline (Vol.14, No.3)	February 1994
GP9-A	Selecting and Evaluating a Referral Laboratory, Approved Guideline (Vol.18, No.15)	November 1998
GP11-A	Basic Cost Accounting for Clinical Services; Approved Guideline (Vol.18, No.14)	November 1998
GP14-A	Labeling of Home-Use In Vitro Testing Products; Approved Guideline (Vol.16, No.2)	June 1996
GP17-A2	Clinical Laboratory Safety; Approved Guideline – Second Edition (Vol.24, No.13)	April 2004
GP18-A2	Laboratory Design; Approved Guideline – Second Edition (Vol.27, No.7)	February 2007
GP31-A	Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline (Vol.29, No.11)	April 2009
GP34-A	Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline (Vol.30, No.25)	December 2010
I2-A2	Temperature Calibration of Water Baths, Instruments and Temperature Sensors – Second Edition, Approved Standard (Vol.10, No.3)	April 1990
I8-P	Determining Performance of Volumetric Equipment, Proposed Guideline (Vol.4, No.6)	May 1984
I16-T	Temperature Monitoring and Recording in Blood Banks (Vol.6, No.19)	November 1986

Program Index of CLSI Standards and Guidelines

Code	Document Title	Date
M29-A3	Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Third Edition (Vol.25, No.10)	March 2005
NRSCL8-A	Terminology and Definitions For Use in NCCLS Documents; Approved Standard (Vol.18, No.16)	November 1998
NRSCL12-P	Sourcebook of Reference Methods, Materials and Related Information for the Clinical Laboratory; Proposed Guideline (Vol.14, No.1)	January 1994
NRSCL13-A	The Reference System for the Clinical Laboratory: Criteria for Development and Credentialing of Methods and Materials for Harmonization of Results; Approved Guideline (Vol.20, No.21)	January 2001
X3-R	Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory; A Report (Vol.22, No.4)	March 2002
X4-R	Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report (Vol.23, No.29)	October 2003

Laboratory Information Systems (LIS)

LIS01-A2	Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard – Second Edition (Vol.28, No.13)	April 2008
LIS2-A2	Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard – Second Edition (Vol.24, No.33)	October 2004
LIS3-A	Standard Guide for Selection of a Clinical Laboratory Information Management System (Vol.23, No.9)	April 2003
LIS4-A	Standard Guide for Documentation of Clinical Laboratory Computer Systems (Vol.23, No.10)	April 2003
LIS5-A	Standard Specification for Transferring Clinical Observations Between Independent Computer Systems (Vol.23, No.11)	April 2003
LIS6-A	Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems (Vol.23, No.12)	April 2003
LIS7-A	Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory (Vol.23, No.13)	April 2003
LIS8-A	Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems (Vol.23, No.14)	April 2003
LIS9-A	Standard Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures (Vol.23, No.15)	April 2003

Method Evaluation

C53-A	Characterization and Qualification of Commutable Reference Materials for Laboratory Medicine; Approved Guideline (Vol.30, No.12)	May 2010
EP5-A2	Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition (Vol.24, No.25)	August 2004

Program Index of CLSI Standards and Guidelines

Code	Document Title	Date
EP6-A	Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (Vol.23, No.16)	April 2003
EP7-A2	Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition (Vol.25, No.27)	November 2005
EP9-A2	Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition (Vol.22, No.19)	September 2002
EP10-A3	Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guidelines – Third Edition (Vol.26, No.34)	November 2006
EP11-P	Uniformity of Claims For In Vitro Diagnostic Tests; Proposed Guideline (Vol.16, No.4)	July 1996
EP12-A2	User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition (Vol.28, No.3)	January 2008
EP13-R	Laboratory Statistics – Standard Deviation; A Report (Vol.15, No.8)	August 1995
EP14-A2	Evaluation of Matrix Effects; Approved Guideline – Second Edition (Vol.25, No.4)	January 2005
EP15-A2	User Verification of Performance for Precision and Trueness; Approved Guideline – Second Edition (Vol.25, No.17)	June 2005
EP17-A	Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline (Vol.24, No.34)	October 2004
EP18-A2	Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline — Second Edition (Vol.29, No.26)	November 2009
EP21-A	Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline (Vol.23 No.20)	April 2003
EP23-A	Laboratory Quality Control Based on Risk Management; Approved Guideline (Vol.31, No.18)	<i>October 2011</i>
EP24-A2	Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline - Second Edition (Vol.31, No.23)	<i>November 2011</i>
EP25-A	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline (Vol.29, No.20)	September 2009

Microbiology

M02-A10	Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard — Tenth Edition (Vol.29, No.1)	January 2009
M6-A2	Protocols for Evaluating Dehydrated Mueller-Hinton Agar; Approved Standard—Second Edition (Vol.26, No.6)	January 2006
M07-A8	Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard — Eighth Edition (Vol.29, No.2)	January 2009
M11-A7	Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard – Seventh Edition (Vol.27, No.2)	January 2007

Program Index of CLSI Standards and Guidelines

Code	Document Title	Date
M11-S1	Performance Standards for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Informational Supplement	September 2009
M15-A	Laboratory Diagnosis of Blood-borne Parasitic Diseases; Approved Guideline (Vol.20, No.12)	June 2000
M21-A	Methodology for the Serum Bactericidal Test; Approved Guideline (Vol.19, No.17)	September 1999
M22-A3	Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard – Third Edition (Vol.24, No.19)	June 2004
M23-A3	Development of _In Vitro_ Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline — Third Edition (Vol.28, No.27)	October 2008
M24-A2	Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard – Second Edition (Vol.31, No.5)	March 2011
M25-A	Fetal Bovine Serum; Approved Guideline (Vol.15, No.9)	October 1995
M26-A	Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline (Vol.19, No.18)	September 1999
M28-A2	Procedures for the Recovery and Identification of Parasites From the Intestinal Tract; Approved Guideline – Second Edition (Vol.25, No.16)	June 2005
M33-A	Antiviral Susceptibility Testing: Herpes Simplex Virus by Plaque Reduction Assay; Approved Standard (Vol.24, No.7)	February 2004
M34-A	Western Blot Assay for Antibodies to Borrelia burgdorferi; Approved Guideline (Vol.20, No.20)	January 2001
M35-A2	Abbreviated Identification of Bacteria and Yeast; Approved Guideline—Second Edition (Vol.28, No.29)	November 2008
M36-A	Clinical Use and Interpretation of Serologic Tests for Toxoplasma gondii; Approved Guideline (Vol.24, No.6)	February 2004
M39-A3	Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline – Second Edition (Vol.29, No.6)	February 2009
M40-A	Quality Control of Microbiological Transport Systems; Approved Standard (Vol.23, No.34)	December 2003
M41-A	Viral Culture; Approved Guideline	November 2006
M43-A	Methods for Antimicrobial Susceptibility Testing for Human Mycoplasmas; Approved Guideline (Vol.31, No.19)	<i>October 2011</i>
M45-A2	for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline (Vol.30, No.18)	August 2010
M47-A	Principles and Procedures for Blood Cultures; Approved Guideline (Vol.27, No.17)	May 2007
M48-A	Laboratory Detection and Identification of Mycobacteria; Approved Guideline (Vol.28, No.17)	May 2008
M50-A	Quality Control for Commercial Microbial Identification Systems; Approved Guideline (Vol.28, No.23)	August 2008

Program Index of CLSI Standards and Guidelines

Code	Document Title	Date
M53-A	Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection; Approve Guideline (Vol.31, No.13)	June 2011
M100-S13 (M7)	MIC Testing Supplemental Tables	January 2003
M100-S21	Performance Standards for Antimicrobial Susceptibility Testing; Twenty-First Informational Supplement (Vol.31, No.1)	December 2010

Molecular Methods

MM1-A2	Molecular Diagnostic Methods for Genetic Diseases; Approved Guidelines – Second Edition (Vol.26, No.27)	June 2006
MM2-A2	Immunoglobulin and T-Cell Receptor Gene Rearrangement Assays; Approved Guideline – Second Edition (Vol.22, No.12)	September 2002
MM3-A2	Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline—Second Edition (Vol.26, No.8)	February 2006
MM5-A	Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline (Vol.23, No.17)	April 2003
MM06-A2	Quantitative Molecular Methods for Infectious Diseases; Approved Guideline — Second Edition (Vol.30, No.22)	November 2010
MM7-A	Fluorescence In Situ Hybridization (FISH) Methods for Medical Genetics; Approved Guideline (Vol.24, No.5)	January 2004
MM9-A	Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline (Vol.24, No.40)	December 2004
MM10-A	Genotyping for Infectious Diseases: Identification and Characterization; Approved Guideline (Vol.26, No.9)	February 2006
MM11-A	Molecular Methods for Bacterial Strain Typing; Approved Guidelines (Vol.27, No.10)	April 2007
MM12-A	Diagnostic Nucleic Acid Microarrays; Approved Guideline (Vol.26, No.20)	May 2006
MM13-A	Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline (Vol.25, No.31)	December 2005
MM14-A	Proficiency Testing (External Quality Assessment) for Molecular Methods; Approved Guideline (Vol.25, No.27)	August 2005
MM16-A	Use of External RNA Controls in Gene Expression Assays; Approved Guideline (Vol.26, No.29)	August 2006
MM17-A	Verification and Validation of Multiplex Nucleic Acid Assays; Approved Guideline (Vol.29, No.9)	March 2008
MM18-A	Interpretive Criteria for Identification of Bacteria and Fungi by DNA Target Sequencing; Approved Guideline (Vol.28, No.12)	April 2008
MM19-A	Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline (Vol.31, No.21)	<i>November 2011</i>

Program Index of CLSI Standards and Guidelines

Code	Document Title	Date
Point-of-Care Testing		
AST3-A	Wellness Testing Using IVD Devices; Approved Guideline (Vol.19, No.4)	February 1999
AST4-A2	Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline – Second Edition (Vol.25, No.12)	May 2005
HS2-A	Provider-Performed Microscopy Testing; Approved Guideline (Vol.23, No.5)	March 2003
POCT2-A	Implementation Guide of POCT01 for Health Care Providers; Approved Guideline (Vol.28, No.18)	May 2008
POCT4-A2	Point-of-Care In Vitro Diagnostic (IVD) Testing; Approved Guideline – Second Edition (Vol.26, No.30)	August 2006
POCT05-A	Performance Metrics for Continuous Interstitial Glucose Monitoring; Approved Guideline (Vol.28, No.33)	December 2008
POCT07-A	Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline (Vol.30, No.20)	October 2010
POCT08-A	Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline (Vol.30, No.23)	December 2010
POCT09-A	Selection Criteria for Point-of-Care Testing Devices; Approved Guideline (Vol.30, No.8)	April 2010
POCT11-A2	Pulse Oximetry; Approved Guideline – Second Edition (Vol.31, No.9)	April 2011
Quality Assurance		
GP22-A3	Quality Management System: Continual Improvement; Approved Guideline — Third Edition (Vol.31, No.14)	June 2011
GP27-A2	Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Second Edition (Vol.27, No.8)	February 2007
GP29-A2	Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline — Second Edition (Vol.28, No.21)	August 2008
Quality Management Systems		
GP21-A3	Training and Competence Assessment; Approved Guideline — Third Edition (Vol.29, No.3)	February 2009
GP26-A4	Quality Management System: A Model for Laboratory Services; Approved Guideline — Fourth Edition	June 2011
GP32-A	Management of Nonconforming Laboratory Events; Approved Guideline (Vol.27, No.27)	November 2007
GP33-A	Accuracy in Patient and Sample Identification (Vol.30, No.7)	March 2010
GP35-A	Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline (Vol.30, No.24)	December 2010
GP37-A	Quality Management System: Equipment; Approved Guideline (Vol.31, No.16)	<i>August 2011</i>

Program Index of CLSI Standards and Guidelines

Code	Document Title	Date
HS4-A2	Application of a Quality Management System Model for Respiratory Services; Approved Guidelines – Second Edition (Vol.22, No.23)	May 2006
HS5-A2	Application of a Quality Management System Model for Medical Imaging Services; Approved Guidelines – Second Edition (Vol.22, No.24)	May 2006
HS6-A	Studies to Evaluate Patient Outcomes; Approved Guideline (Vol.24, No.32)	October 2004
HS10-A2	Application of a Quality Management System Model for Inpatient Medication Use; Approved Guideline – Second Edition (Vol.26, No.17)	May 2006
HS11-A	A Model for Managing Medical Device Alerts (Hazards and Recalls) for Healthcare Organizations; Approved Guideline (Vol.25, No.30)	December 2005

Specimen Collection and Handling

GP16-A3	Urinalysis; Approved Guideline — Third Edition (Vol.29, No.4)	February 2009
H01-A6	Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard — Sixth Edition (Vol.30, No.26)	December 2010
H3-A6	Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard — Sixth Edition	October 2007
H04-A6	Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard — Sixth Edition (Vol.28, No.25)	September 2008
H5-A3	Procedures for the Handling and Transport of Diagnostic Specimens and Etiologic Agents – Third Edition; Approved Standard (Vol.14, No.7)	May 1994
H18-A4	Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline -- Fourth Edition (Vol.30, No.10)	May 2010
H31-P	Collection Containers for Specimens for Toxicological Analysis, Proposed Guideline (Vol.6, No.4)	July 1986

Toxicology

C52-A2	Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline – Second Edition (Vol.27, No.15)	April 2007
T/DM6-A	Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline (Vol.17, No.14)	September 1997

Veterinary Microbiology

M31-A3	Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals; Approved Standard — Third Edition (Vol.28, No.8)	February 2008
M37-A3	Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters for Veterinary Antimicrobial Agents; Approved Guideline — Third Edition (Vol.28, No.7)	February 2008
M42-A	Methods for Antimicrobial Disk Susceptibility Testing of Bacteria Isolated from Aquatic Animals; Approved Guidelines (Vol.26, No.23)	June 2006
M49-A	Methods for Broth Dilution Susceptibility Testing of Bacteria Isolated from Aquatic Animals; Approved Guideline (Vol.26, No.24)	June 2006