



# 2021 CATALOG

# Global Laboratory Standards for a Healthier World

The Clinical and Laboratory Standards Institute (CLSI) is the global leader in the standardization of medical laboratory best practices that can help you deliver more accurate results and improved patient outcomes.

CLSI supports health care professionals, laboratorians, IVD manufacturers, pharmaceutical companies, and government laboratories who need to meet the highest expectations for quality, accreditation, and regulatory compliance. We provide the best access to the most timely laboratory practices and offer unsurpassed opportunities for our members.

In this catalog, you'll find our full listing of neutral consensus-based products that are easy to access, use, and enable everyone from medical technologists to quality control managers to improve the outcomes of their laboratory testing. CLSI documents and other products are offered in PDF, print, and/or subscription format.



# What's New?

**EP06** | *Evaluation of Linearity of Quantitative Measurement Procedure, 2nd Edition*

**EP43** | *Implementing a Laboratory Test Under Emergency Use Conditions, 1st Edition*

**C64** | *Quantitative Measurement of Proteins and Peptides by Mass Spectrometry, 1st Edition*

**GP42** | *Collection of Capillary Blood Specimens, 7th Edition*

**LQMS Certificate Program** | *Updated*

**M235** | *Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters, 1st Edition*

**M54** | *Principles and Procedures for Detection and Culture of Fungi in Clinical Specimens, 2nd Edition*

**M59** | *Epidemiological Cutoff Values for Antifungal Susceptibility Testing, 3rd Edition*

**M60** | *Performance Standards for Antifungal Susceptibility Testing of Yeasts, 2nd Edition*

**M61** | *Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi, 2nd Edition*

**M100** | *Performance Standards for Antimicrobial Susceptibility Testing, 31st Edition*

**MM13** | *Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods, 2nd Edition*

**NBS01** | *Dried Blood Spot Specimen Collection for Newborn Screening, 7th Edition*

**NBS09** | *Newborn Screening for X-Linked Adrenoleukodystrophy, 1st Edition*

**POCT05** | *Performance Metrics for Continuous Interstitial Glucose Monitoring, 2nd Edition*

**POCT14** | *Point-of-Care Coagulation Testing and Anticoagulation Monitoring, 2nd Edition*

**POCT15** | *Point-of-Care Testing for Infectious Diseases, 1st Edition*

**QMS05** | *Qualifying, Selecting, and Evaluating a Referral Laboratory, 3rd Edition*

**QMS20** | *The Cost of Quality in the Medical Laboratory, 2nd Edition*

**QMS26** | *Managing Laboratory Records, 1st Edition*

**VET01S** | *Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals, 5th Edition*

**VET02** | *Development of Quality Control Ranges, Breakpoints, and Interpretive Categories for Antimicrobial Agents Used in Veterinary Medicine, 4th Edition*

**VET03** | *Methods for Antimicrobial Broth Dilution and Disk Diffusion Susceptibility Testing of Bacteria Isolated From Aquatic Animals, 2nd Edition*

**VET03S (VET04)** | *Performance Standards for Antimicrobial Susceptibility Testing of Bacteria Isolated From Aquatic Animals, 3rd Edition*

**VET09** | *Understanding Susceptibility Test Data as a Component of Antimicrobial Stewardship in Veterinary Settings, 1st Edition*

## Coming Soon!

**MM24** | *Molecular Methods for Genotyping and Strain Typing of Infectious Organisms, 2nd Edition*

**AUTO17** | *Semantic Interoperability for In Vitro Diagnostic Systems, 1st Edition*

**EP39** | *Surrogate Sample Framework, 1st Edition*

**H62** | *Validation of Assays Performed by Flow Cytometry, 1st Edition*

For more details and up-to-date information visit [clsi.org/projects-in-progress](https://www.clsi.org/projects-in-progress).



## CLSI Documents Helpful for COVID-19 Testing

Throughout the catalog you'll see documents with a note in red that says "COVID-19 Related." These documents have been identified as helpful for the laboratory community's use during the COVID-19 pandemic. To learn more about how they can help with COVID-19 testing, visit [clsi.org/covid-19](https://www.clsi.org/covid-19).

# Automation and Informatics

## Document Pricing

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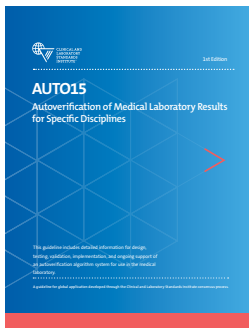
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## Featured Documents



### **AUTO15** | Autoverification of Medical Laboratory Results for Specific Disciplines, 1st Edition

This guideline includes detailed information for design, testing, validation, implementation, and ongoing support of an autoverification algorithm system for use in the medical laboratory.



### **AUTO16** | Next-Generation *In Vitro* Diagnostic Instrument Interface, 1st Edition

Laboratories and IVD manufacturers need to understand the connectivity challenges facing medical laboratories today. AUTO16 can help you improve interoperability and reduce connectivity installation cost and time.

**AUTO01\*** | Laboratory Automation: Specimen Container/Specimen Carrier, 1st Edition

**Item Order Code:** AUTO01AE

**AUTO02\*** | Laboratory Automation: Bar Codes for Specimen Container Identification, 2nd Edition

**Item Order Code:** AUTO02A2E

**AUTO03\*** | Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems, 2nd Edition

**Item Order Code:** AUTO03A2E

**AUTO04\*** | Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements, 1st Edition

**Item Order Code:** AUTO04AE

**AUTO05\*** | Laboratory Automation: Electromechanical Interfaces, 1st Edition

**Item Order Code:** AUTO05AE

**AUTO07\*** | Laboratory Automation: Data Content for Specimen Identification, 1st Edition

**Item Order Code:** AUTO07AE



**AUTO08\*** | Managing and Validating Laboratory Information Systems, 1st Edition  
**Item Order Code:** AUTO08AE

**AUTO09\*** | Remote Access to Clinical Laboratory Diagnostic Devices via the Internet, 1st Edition  
**Item Order Code:** AUTO09AE

**AUTO10\*** | Autoverification of Clinical Laboratory Test Results, 1st Edition  
**Item Order Code:** AUTO10AE

**AUTO11\*** | Information Technology Security of *In Vitro* Diagnostic Instruments and Software Systems, 2nd Edition  
**Item Order Code:** AUTO11A2E

**AUTO12** | Specimen Labels: Content and Location, Fonts, and Label Orientation, 1st Edition  
**Item Order Code:** AUTO12A

**AUTO13\*** | Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring, 2nd Edition  
**Item Order Code:** AUTO13A2E

**AUTO15** | Autoverification of Medical Laboratory Results for Specific Disciplines, 1st Edition  
**Item Order Code:** AUTO15Ed1

**AUTO16\*** | Next-Generation *In Vitro* Diagnostic Instrument Interface, 1st Edition  
**Item Order Code:** AUTO16Ed1

**LIS01\*** | Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems, 2nd Edition  
**Item Order Code:** LIS01A2E

**LIS02\*** | Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems, 2nd Edition  
**Item Order Code:** LIS02A2E



## Reminder

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# Clinical Chemistry and Toxicology

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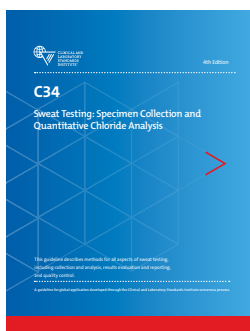
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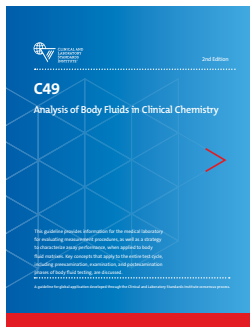
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## Featured Documents



### C34 | Sweat Testing: Sample Collection and Quantitative Chloride Analysis, 4th Edition

Ensuring your laboratory and clinical personnel are equipped to appropriately collect and analyze chloride sweat samples is the best way to provide your patients with high quality cystic fibrosis test results. Get your staff the resource they need with C34.



### C49 | Analysis of Body Fluids in Clinical Chemistry, 2nd Edition

Regulatory requirements for laboratories performing body fluid testing have changed. Medical laboratories need to determine appropriate fluid types for testing and understand performance limitations of testing methods.

**C24\*** | Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions, 4th Edition

**Item Order Code:** C24Ed4E

**C29\*** | Standardization of Sodium and Potassium Ion-Selective Electrode Systems to the Flame Photometric Reference Method, 2nd Edition

**Item Order Code:** C29A2E

**C31\*** | Ionized Calcium Determinations: Pre-collection Variables, Specimen Choice, Collection, and Handling, 2nd Edition

**Item Order Code:** C31A2E

**C34** | Sweat Testing: Sample Collection and Quantitative Chloride Analysis, 4th Edition

**Item Order Code:** C34Ed4

**C37\*** | Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures, 1st Edition

**Item Order Code:** C37AE

**C38\*** | Control of Preanalytical Variation in Trace Element Determinations, 1st Edition

**Item Order Code:** C38AE



**C39\*** | A Designated Comparison Method for the Measurement of Ionized Calcium in Serum, 1st Edition

**Item Order Code:** C39AE

**C40\*** | Measurement Procedures for the Determination of Lead Concentrations in Blood and Urine, 2nd Edition

**Item Order Code:** C40A2E

**C42\*** | Erythrocyte Protoporphyrin Testing, 1st Edition

**Item Order Code:** C42AE

**C43\*** | Gas Chromatography/Mass Spectrometry Confirmation of Drugs, 2nd Edition

**Item Order Code:** C43A2E

**C45\*** | Measurement of Free Thyroid Hormones, 1st Edition

**Item Order Code:** C45AE

**C46** | Blood Gas and pH Analysis and Related Measurements, 2nd Edition

**Item Order Code:** C46A2

**C48\*** | Application of Biochemical Markers of Bone Turnover in the Assessment and Monitoring of Bone Diseases, 1st Edition

**Item Order Code:** C48AE

**C49** | Analysis of Body Fluids in Clinical Chemistry, 2nd Edition

**Item Order Code:** C49Ed2

**C50\*** | Mass Spectrometry in the Clinical Laboratory: General Principles and Guidance, 1st Edition

**Item Order Code:** C50AE

**C52** | Toxicology and Drug Testing in the Clinical Laboratory, 3rd Edition

**Item Order Code:** C52Ed3

**C56\*** | Hemolysis, Icterus, and Lipemia/Turbidity Indices as Indicators of Interference in Clinical Laboratory Analysis, 1st Edition

**Item Order Code:** C56AE

**C56AQG** | Examples of Hemolyzed, Icteric, and Lipemic/Turbid Samples Quick Guide

**Item Order Code:** C56AEQG

**Nonmember Rate:** \$20.00

**C57\*** | Mass Spectrometry for Androgen and Estrogen Measurements in Serum, 1st Edition

**Item Order Code:** C57Ed1D

**C58\*** | Assessment of Fetal Lung Maturity by the Lamellar Body Count, 1st Edition

**Item Order Code:** C58AE

**C61\*** | Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation, 1st Edition

**Item Order Code:** C61AE

**C62\*** | Liquid Chromatography-Mass Spectrometry Methods, 1st Edition

**Item Order Code:** C62AE

**C63** | Laboratory Support for Pain Management Programs, 1st Edition

**Item Order Code:** C63Ed1

**C64** | Quantitative Measurement of Proteins and Peptides by Mass Spectrometry, 1st Edition

**Item Order Code:** C64Ed1

# General Laboratory

## Document Pricing

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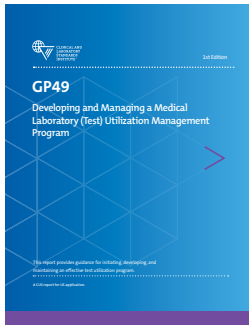
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## Featured Documents



### GP33 | Accuracy in Patient and Sample Identification, 2nd Edition

The processes required by regulatory bodies for ensuring accurate patient and specimen identification are covered in GP33. Invaluable guidance on bar-code system implementation and user training is included.



### GP49 | Developing and Managing a Medical Laboratory (Test) Utilization Management Program, 1st Edition

Eliminate unnecessary testing and focus on performing appropriate tests that improve quality and outcomes. Learn about implementing a test utilization management program in your lab with GP49.

### GP05\* | Clinical Laboratory Waste Management, 3rd Edition

Item Order Code: GP05A3E

### GP05A3CL\* | Waste Management Program – Audit Checklist

Item Order Code: GP05A3CLE

Nonmember Rate: \$20.00

### GP15\* | Cervicovaginal Cytology Based on the Papanicolaou Technique, 3rd Edition

Item Order Code: GP15A3E

### GP16 | Urinalysis, 3rd Edition

Item Order Code: GP16A3

### GP17 | Clinical Laboratory Safety, 3rd Edition

Item Order Code: GP17A3

COVID-19 Related

### GP20\* | Fine Needle Aspiration Biopsy (FNAB) Techniques, 2nd Edition

Item Order Code: GP20A2E

### GP23\* | Nongynecological Cytology Specimens: Preexamination, Examination, and Postexamination Processes, 2nd Edition

Item Order Code: GP23A2E

### GP33 | Accuracy in Patient and Sample Identification, 2nd Edition

Item Order Code: GP33Ed2

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**GP34** | Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection, 1st Edition

**Item Order Code:** GP34A

**GP36\*** | Planning for Laboratory Operations During a Disaster, 1st Edition

**Item Order Code:** GP36AE

**COVID-19 Related**

*Free for a limited time.*

**GP39\*** | Tubes and Additives for Venous and Capillary Blood Specimen Collection, 6th Edition

**Item Order Code:** GP39A6E

**GP40** | Preparation and Testing of Reagent Water in the Clinical Laboratory, 4th Edition

**Item Order Code:** GP40A4AMD

**GP41** | Collection of Diagnostic Venous Blood Specimens, 7th Edition

**Item Order Code:** GP41Ed7

**COVID-19 Related**

**GP41QG** | Quality Venipuncture Quick Guide

**Item Order Code:** GP41Ed7QG

**Nonmember Rate:** \$20.00

**GP42** | Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens, 6th Edition

**Item Order Code:** GP42A6

**GP42A6QG\*** | Technique for Skin Puncture in Adults and Older Children Quick Guide

**Item Order Code:** GP42A6QGE

**Nonmember Rate:** \$20.00

**GP44** | Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests, 4th Edition

**Item Order Code:** GP44A4

**COVID-19 Related**

**GP45\*** | Studies to Evaluate Patient Outcomes, 1st Edition

**Item Order Code:** GP45AE

**GP47** | Management of Critical- and Significant-Risk Results, 1st Edition

**Item Order Code:** GP47Ed1

**GP48** | Essential Elements of a Phlebotomy Training Program, 1st Edition

**Item Order Code:** GP48Ed1

**GP49** | Developing and Managing a Medical Laboratory (Test) Utilization Management Program, 1st Edition

**Item Order Code:** GP49Ed1



## Did you know?

Through our Partnerships program, CLSI provides international outreach services and hands-on support to laboratories throughout the world, helping them achieve sustainable quality with systems to better diagnose and treat patients with infectious diseases.

See where we work and how we can help your laboratory at [clsi.org/global-training](https://www.clsi.org/global-training).

# Hematology

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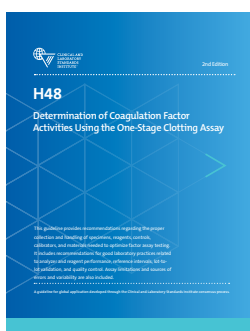
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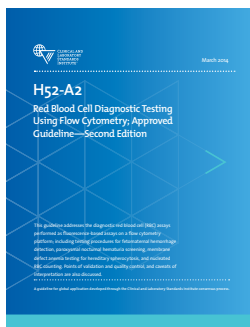
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## Featured Documents



### H48 | Determination of Coagulation Factor Activities Using the One-Stage Clotting Assay, 2nd Edition

Quantitative assays for measuring coagulant activity are important laboratory tools. Enhance the precision and accuracy of patient clotting factor assay results with H48.



### H52 | Red Blood Cell Diagnostic Testing Using Flow Cytometry, 2nd Edition

This guideline addresses the diagnostic red blood cell (RBC) assays performed as fluorescence-based assays on a flow cytometry platform. Points of validation and quality control, and caveats of interpretation are also discussed.

### H02\* | Procedures for the Erythrocyte Sedimentation Rate Test, 5th Edition

**Item Order Code:** H02A5E

### H07\* | Procedure for Determining Packed Cell Volume by the Microhematocrit Method, 3rd Edition

**Item Order Code:** H07A3E

### H15\* | Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood, 3rd Edition

**Item Order Code:** H15A3E

### H20\* | Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods, 2nd Edition

**Item Order Code:** H20A2E

### H21 | Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays, 5th Edition

**Item Order Code:** H21A5

### H21A5QG\* | H21-A5 Quick Guide

**Item Order Code:** H21A5QGE

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**H26\*** | Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, 2nd Edition

**Item Order Code:** H26A2

**H30\*** | Procedure for the Determination of Fibrinogen in Plasma, 2nd Edition

**Item Order Code:** H30A2E

**H42\*** | Enumeration of Immunologically Defined Cell Populations by Flow Cytometry, 2nd Edition

**Item Order Code:** H42A2E

**H43\*** | Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells, 2nd Edition

**Item Order Code:** H43A2E

**H44\*** | Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry and Supravital Dyes), 2nd Edition

**Item Order Code:** H44A2E

**H47\*** | One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test, 2nd Edition

**Item Order Code:** H47A2E

**H48** | Determination of Coagulation Factor Activities Using the One-Stage Clotting Assay, 2nd Edition

**Item Order Code:** H48Ed2

**H52** | Red Blood Cell Diagnostic Testing Using Flow Cytometry, 2nd Edition

**Item Order Code:** H52A2

**H54\*** | Procedures for Validation of INR and Local Calibration of PT/INR Systems, 1st Edition

**Item Order Code:** H54AE

**H56\*** | Body Fluid Analysis for Cellular Composition, 1st Edition

**Item Order Code:** H56AE

**H57\*** | Protocol for the Evaluation, Validation, and Implementation of Coagulometers, 1st Edition

**Item Order Code:** H57AE

**H58\*** | Platelet Function Testing by Aggregometry, 1st Edition

**Item Order Code:** H58AE

**H59\*** | Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease, 1st Edition

**Item Order Code:** H59AE

**H60** | Laboratory Testing for the Lupus Anticoagulant, 1st Edition

**Item Order Code:** H60A

**H60AQG1\*** | Algorithmic Approach to Lupus Anticoagulant Testing

**Item Order Code:** H60AQG1E

**Nonmember Rate:** \$20.00

**H60AQG2\*** | Criteria for the Laboratory Diagnosis of the Lupus Anticoagulant

**Item Order Code:** H60AQG2E

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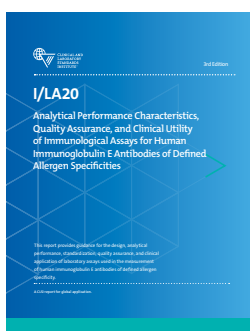
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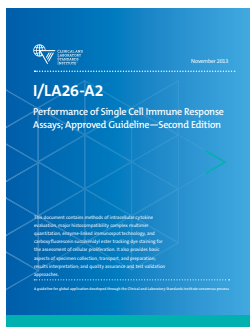
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## Featured Documents



### I/LA20 | Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities, 3rd Edition

Give your laboratory staff the guidance they need for the clinical application of laboratory assays used in the measurement of human IgE.



### I/LA26 | Performance of Single Cell Immune Response Assays, 2nd Edition

Learn about methods for intracellular cytokine evaluation, major histocompatibility complex multimer quantitation, and enzyme-linked immunospot technology for the assessment of cellular proliferation with I/LA26.

**I/LA02\*** | Quality Assurance of Laboratory Tests for Autoantibodies to Nuclear Antigens: (1) Indirect Fluorescence Assay for Microscopy and (2) Microtiter Enzyme Immunoassay Methods, 2nd Edition

**Item Order Code:** ILA02A2E

**I/LA20\*** | Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities, 3rd Edition

**Item Order Code:** ILA20Ed3E

**I/LA20S (I/LA37)\*** | Analytical Performance Characteristics and Clinical Utility of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies and Defined Allergen Specificities, 1st Edition

**Item Order Code:** ILA37Ed1E

**Nonmember Rate:** \$80.00

**I/LA21\*** | Clinical Evaluation of Immunoassays, 2nd Edition

**Item Order Code:** ILA21A2E



**I/LA23\*** | Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays, 1st Edition

**Item Order Code:** ILA23AE

**I/LA25\*** | Maternal Serum Screening, 2nd Edition

**Item Order Code:** ILA25A2E

**I/LA26\*** | Performance of Single Cell Immune Response Assays, 2nd Edition

**Item Order Code:** ILA26A2E

**I/LA28\*** | Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays, 2nd Edition

**Item Order Code:** ILA28A2E

**I/LA28A2QG\*** | Comparison of the Characteristics of Immunoassays Such as Enzyme-Linked Immunosorbent Assay and Immunohistochemistry Quick Guide

**Item Order Code:** ILA28A2QGE

**Nonmember Rate:** \$40.00

**I/LA30\*** | Immunoassay Interference by Endogenous Antibodies, 1st Edition

**Item Order Code:** ILA30AE

**I/LA33\*** | Validation of Automated Systems for Immunohematological Testing Before Implementation, 1st Edition

**Item Order Code:** ILA33AE

**I/LA34\*** | Design and Validation of Immunoassays for Assessment of Human Allergenicity of New Biotherapeutic Drugs, 1st Edition

**Item Order Code:** ILA34AE



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# Method Evaluation

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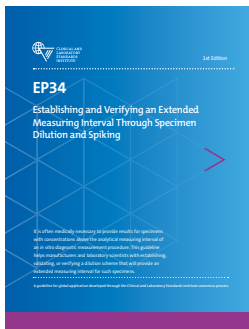
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## Featured Documents



### EP34 | Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking, 1st Edition

Establish, validate, or verify a dilution scheme that will provide an extended measuring interval for specimens with concentrations above the analytical measuring interval of an *in vitro* diagnostic measurement procedure.



### EP35 | Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures, 1st Edition

This guideline provides recommendations for assessing clinically equivalent performance for additional similar-matrix specimen types and suitable performance for dissimilar-matrix specimen types, such that the laboratory does not necessarily need to repeat the full measurement procedure validation for each specimen type. The recommendations in this guideline apply to both quantitative measurement procedures and qualitative examinations.

### EP05 | Evaluation of Precision of Quantitative Measurement Procedures, 3rd Edition

Item Order Code: EP05A3

**COVID-19 Related**

### EP06\* | Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach, 2nd Edition

Item Order Code: EP06Ed2E

**COVID-19 Related**

### EP07 | Interference Testing in Clinical Chemistry, 3rd Edition

Item Order Code: EP07Ed3

**COVID-19 Related**

### EP07S (EP37)\* | Supplemental Tables for Interference Testing in Clinical Chemistry, 1st Edition

Item Order Code: EP37Ed1E

Nonmember Rate: \$80.00

### EP09 | Measurement Procedure Comparison and Bias Estimation Using Patient Samples, 3rd Edition

Item Order Code: EP09Ed3c

### EP10 | Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures, 3rd Edition

Item Order Code: EP10A3AMD



**EP12\*** | User Protocol for Evaluation of Qualitative Test Performance, 2nd Edition

**Item Order Code:** EP12A2E **COVID-19 Related**

**EP14** | Evaluation of Commutability of Processed Samples, 3rd Edition

**Item Order Code:** EP14A3

**EP15** | User Verification of Precision and Estimation of Bias, 3rd Edition

**Item Order Code:** EP15A3

**EP17\*** | Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition

**Item Order Code:** EP17A2E **COVID-19 Related**

**EP18** | Risk Management Techniques to Identify and Control Laboratory Error Sources, 2nd Edition

**Item Order Code:** EP18A2 **COVID-19 Related**

**EP18A2EP23AWS\*** | Laboratory Quality Control Based on Risk Management; Worksheet Template

**Item Order Code:** EP18A2EP23AWSE

*Free document*

**EP19\*** | A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures, 2nd Edition

**Item Order Code:** EP19Ed2E **COVID-19 Related**

*Free report*

**EP21** | Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures, 2nd Edition

**Item Order Code:** EP21Ed2

**EP23™** | Laboratory Quality Control Based on Risk Management, 1st Edition

**Item Order Code:** EP23A **COVID-19 Related**

**EP23AQG\*** | EP23 Quick Reference Guide

**Item Order Code:** EP23AQGE

**Nonmember Rate:** \$50.00

**E23AWB\*** | Laboratory Quality Control Based on Risk Management; Electronic Workbook

**Item Order Code:** EP23AWBE

**Nonmember Rate:** \$100.00

**EP24\*** | Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves, 2nd Edition

**Item Order Code:** EP24A2E

**EP25** | Evaluation of Stability of *In Vitro* Diagnostic Reagents, 1st Edition

**Item Order Code:** EP25A **COVID-19 Related**

**EP26** | User Evaluation of Between-Reagent Lot Variation, 1st Edition

**Item Order Code:** EP26A

**EP27\*** | How to Construct and Interpret an Error Grid for Quantitative Diagnostic Assays, 1st Edition

**Item Order Code:** EP27AE

**EP28** | Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory, 3rd Edition

**Item Order Code:** EP28A3C

**EP29\*** | Expression of Measurement Uncertainty in Laboratory Medicine, 1st Edition

**Item Order Code:** EP29AE

**EP30\*** | Characterization and Qualification of Commutable Reference Materials for Laboratory Medicine, 1st Edition

**Item Order Code:** EP30AE

**EP31\*** | Verification of Comparability of Patient Results Within One Health Care System, 1st Edition (Interim Revision)

**Item Order Code:** EP31AIRE

**EP32\*** | Metrological Traceability and Its Implementation, 1st Edition

**Item Order Code:** EP32RE

**EP33** | Use of Delta Checks in the Medical Laboratory, 1st Edition

**Item Order Code:** EP33Ed1

**EP34** | Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking, 1st Edition

**Item Order Code:** EP34Ed1

# Method Evaluation

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*Access documents for free in eCLIPSE, included in some membership levels. Visit [clsi.org/eclipse](https://clsi.org/eclipse) for more information.*

**EP35** | Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures, 1st Edition

**Item Order Code:** EP35Ed1

**COVID-19 Related**

**EP36\*** | Harmonization of Symbology and Equations, 1st Edition

**Item Order Code:** EP36Ed1E

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**EP43\*** | Implementing a Laboratory Test Under Emergency Use Conditions, 1st Edition

**Item Order Code:** EP36Ed1E

**QSR LDT\*** | Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory

**Item Order Code:** QSRLDTE

**COVID-19 Related**

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# Microbiology

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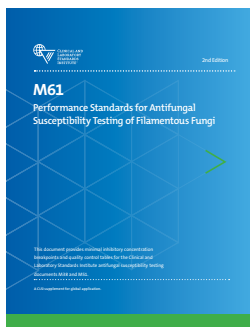
*Access documents for free in eCLIPSE, included in some membership levels. Visit [clsi.org/eclipse](https://clsi.org/eclipse) for more information.*

## Featured Documents



### **M60** | Performance Standards for Antifungal Susceptibility Testing of Yeasts, 2nd Edition

This document provides updated minimal inhibitory concentration, zone diameter, and quality control tables for the Clinical and Laboratory Standards Institute antifungal susceptibility testing documents M27 and M44.



### **M61** | Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi, 2nd Edition

This document provides minimal inhibitory concentration breakpoints and quality control tables for the Clinical and Laboratory Standards Institute antifungal susceptibility testing documents M38 and M51.

### **M02** | Performance Standards for Antimicrobial Disk Susceptibility Tests, 13th Edition

**Item Order Code:** M02Ed13

### **M02QG** | Disk Diffusion Reading Guide, 1st Edition

**Item Order Code:** M02QG

**Nonmember Rate:** \$20.00

### **M07** | Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, 11th Edition

**Item Order Code:** M07Ed11

### **M11** | Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria, 9th Edition

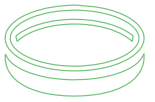
**Item Order Code:** M11Ed9

### **M15\*** | Laboratory Diagnosis of Blood-borne Parasitic Diseases, 1st Edition

**Item Order Code:** M15AE

### **M22** | Quality Control for Commercially Prepared Microbiological Culture Media, 3rd Edition

**Item Order Code:** M22A3



**M23\*** | Development of *In Vitro* Susceptibility Testing Criteria and Quality Control Parameters, 5th Edition

**Item Order Code:** M23Ed5E

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**M23S\*** | Procedure for Optimizing Disk Contents (Potencies) for Disk Diffusion Testing of Antimicrobial Agents Using Harmonized CLSI and EUCAST Criteria, 1st Edition

**Item Order Code:** M23SEd1E

*Free document*

**M23S2\*** | Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval, 1st Edition

**Item Order Code:** M23S2Ed1E

*Free document*

**M24** | Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes, 3rd Edition

**Item Order Code:** M24Ed3

**M24S (M62)** | Performance Standards for Susceptibility Testing of Mycobacteria, *Nocardia* spp., and Other Aerobic Actinomycetes, 1st Edition

**Item Order Code:** M62Ed1

**Nonmember Rate:** \$80.00

**M26\*** | Methods for Determining Bactericidal Activity of Antimicrobial Agents, 1st Edition

**Item Order Code:** M26AE

**M27\*** | Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts, 4th Edition

**Item Order Code:** M27Ed4E

**M28\*** | Procedures for the Recovery and Identification of Parasites From the Intestinal Tract, 2nd Edition

**Item Order Code:** M28A2E

**M29** | Protection of Laboratory Workers From Occupationally Acquired Infections, 4th Edition

**Item Order Code:** M29A4

**COVID-19 Related**

**M34\*** | Western Blot Assay for Antibodies to *Borrelia burgdorferi*, 1st Edition

**Item Order Code:** M34AE

**M35\*** | Abbreviated Identification of Bacteria and Yeast, 2nd Edition

**Item Order Code:** M35A2E

**M36\*** | Clinical Use and Interpretation of Serologic Tests for *Toxoplasma gondii*, 1st Edition

**Item Order Code:** M36AE

**M38** | Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi, 3rd Edition

**Item Order Code:** M38Ed3

**M39** | Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data, 4th Edition

**Item Order Code:** M39A4

**M39 QG\*** | Antibiograms: Developing Cumulative Reports for Your Clinicians

**Item Order Code:** M39A4QGE

**Nonmember Rate:** \$60.00

**M40** | Quality Control of Microbiological Transport Systems, 2nd Edition

**Item Order Code:** M40A2

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**M41\*** | Viral Culture, 1st Edition

**Item Order Code:** M41AE

**M43\*** | Methods for Antimicrobial Susceptibility Testing for Human Mycoplasmas, 1st Edition

**Item Order Code:** M43AE

**M44** | Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts, 3rd Edition

**Item Order Code:** M44Ed3

**M45** | Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria, 3rd Edition

**Item Order Code:** M45Ed3

**M47** | Principles and Procedures for Blood Cultures, 1st Edition

**Item Order Code:** M47A

# Microbiology

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**M48** | Laboratory Detection and Identification of Mycobacteria, 2nd Edition  
**Item Order Code:** M48Ed2

**M50\*** | Quality Control for Commercial Microbial Identification Systems, 1st Edition  
**Item Order Code:** M50AE

**M51\*** | Method for Antifungal Disk Diffusion Susceptibility Testing of Nondermatophyte Filamentous Fungi, 1st Edition  
**Item Order Code:** M51AE

**M52** | Verification of Commercial Microbial Identification and Antimicrobial Susceptibility Testing Systems, 1st Edition  
**Item Order Code:** M52Ed1

**M53\*** | Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection, 1st Edition  
**Item Order Code:** M53AE

**M54** | Principles and Procedures for Detection of Fungi in Clinical Specimens—Direct Examination and Culture, 2nd Edition  
**Item Order Code:** M54Ed2

**M56** | Principles and Procedures for Detection of Anaerobes in Clinical Specimens, 1st Edition  
**Item Order Code:** M56A

**M57** | Principles and Procedures for the Development of Epidemiological Cutoff Values for Antifungal Susceptibility Testing, 1st Edition  
**Item Order Code:** M57Ed1

**M58** | Methods for the Identification of Cultured Microorganisms Using Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry, 1st Edition  
**Item Order Code:** M58Ed1

**M59** | Epidemiological Cutoff Values for Antifungal Susceptibility Testing, 2nd Edition  
**Item Order Code:** M59Ed3  
**Nonmember Rate:** \$80.00

**M60** | Performance Standards for Antifungal Susceptibility Testing of Yeasts, 2nd Edition  
**Item Order Code:** M60Ed2  
**Nonmember Rate:** \$80.00

**M61** | Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi, 2nd Edition  
**Item Order Code:** M61Ed2  
**Nonmember Rate:** \$80.00

**M100** | Performance Standards for Antimicrobial Susceptibility Testing, 31st Edition  
**Item Order Code:** M100Ed31

# AST Resources

## Strengthen Your Antimicrobial Susceptibility Testing (AST) Results

For over 30 years, the microbiology community has relied upon our annually updated M100 document for the latest, most trusted AST breakpoint data. Now the reference you reach for is more easily accessible in a variety of new formats to help you identify and update AST breakpoints with confidence.



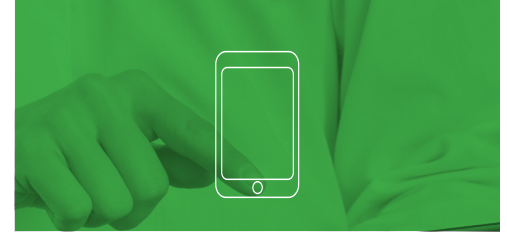
### M100 Document

The 31st edition of this document provides updated tables for the CLSI AST standards M02, M07, and M11, and is available as a downloadable PDF or printed document.



### M100 PLUS

Get full online access to M100, M02, M07, and M11 with added functionality and fast, easy data searching in an electronic format. Plus, you'll have the added benefit of quick access to related materials via an AST Resource Center. Learn more at [clsi.org/m100-plus](http://clsi.org/m100-plus).



### M100, M23, and M60 FREE

You can now quickly reference the most trusted AST breakpoints from anywhere with an Internet connection. M100, M60, and M23 are available online as convenient companions to the documents. Access today at [clsi.org/freeresources](http://clsi.org/freeresources).

## Free Rationale Documents

Using the CLSI voluntary consensus process, the Subcommittee on AST develops standards that promote accurate AST and appropriate reporting.

To meet this need, CLSI has published free rationale documents that provide the scientific reasons behind the subcommittee's decisions, along with documentation of the standardized data and methods used to determine breakpoints. Access all Rationale Documents at [clsi.org/rationale](http://clsi.org/rationale).



**MR01 | Polymyxin Breakpoints for Enterobacterales, *Pseudomonas aeruginosa*, and *Acinetobacter* spp., 2nd Edition**  
**Item Order Code:** MR01Ed2E

**MR02 | Fluoroquinolone Breakpoints for *Enterobacteriaceae* and *Pseudomonas aeruginosa*, 1st Edition**  
**Item Order Code:** MR02Ed1E

**MR03 | Meropenem Breakpoints for *Acinetobacter* spp., 1st Edition**  
**Item Order Code:** MR03Ed1E

**MR04 | Azithromycin Breakpoint for *Neisseria gonorrhoeae*, 1st Edition**  
**Item Order Code:** MR04Ed1E

**MR05 | Ceftaroline Breakpoints for *Staphylococcus aureus*, 1st Edition**  
**Item Order Code:** MR05Ed1E

**MR06 | Daptomycin Breakpoints for Enterococci, 1st Edition**  
**Item Order Code:** MR06Ed1E

**MR07 | Cefazolin Breakpoints for Enterobacterales (Systemic Infections), 1st Edition**  
**Item Order Code:** MR07Ed1E

**MR08 | Cefazolin Breakpoints for Enterobacterales (Uncomplicated Urinary Tract Infections), 1st Edition**  
**Item Order Code:** MR08Ed1E

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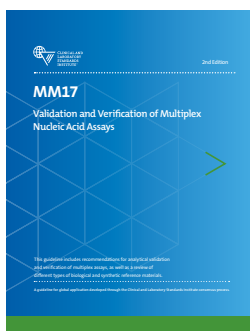
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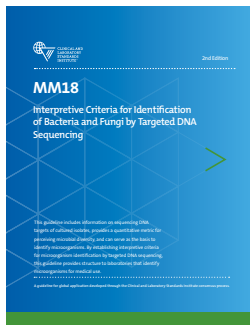
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## Featured Documents



### MM17 | Validation and Verification of Multiplex Nucleic Acid Assays, 2nd Edition

Nucleic acid testing is one of the fastest growing fields in laboratory medicine. This guideline includes recommendations for analytical validation and verification of multiplex assays, with a review of biological and synthetic reference materials.



### MM18 | Interpretive Criteria for Identification of Bacteria and Fungi by Targeted DNA Sequencing, 2nd Edition

This guideline includes the most current information for microbial classification by targeted DNA sequencing, with particular emphasis on interpreting and reporting results.

### MM01\* | Molecular Methods for Clinical Genetics and Oncology Testing, 3rd Edition

Item Order Code: MM01A3E

### MM03\* | Molecular Diagnostic Methods for Infectious Diseases, 3rd Edition

Item Order Code: MM03Ed3E **COVID-19 Related**

### MM05\* | Nucleic Acid Amplification Assays for Molecular Hematopathology, 2nd Edition

Item Order Code: MM05A2E

### MM06 | Quantitative Molecular Methods for Infectious Diseases, 2nd Edition

Item Order Code: MM06A2 **COVID-19 Related**

### MM07\* | Fluorescence *In Situ* Hybridization Methods for Clinical Laboratories, 2nd Edition

Item Order Code: MM07A2E

### MM09 | Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine, 2nd Edition

Item Order Code: MM09A2 **COVID-19 Related**

### MM11\* | Molecular Methods for Bacterial Strain Typing, 1st Edition

Item Order Code: MM11AE

### MM12\* | Diagnostic Nucleic Acid Microarrays, 1st Edition

Item Order Code: MM12AE



**MM13\*** | Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods, 2nd Edition

**Item Order Code:** MM13Ed2E **COVID-19 Related**

**MM14\*** | Design of Molecular Proficiency Testing/ External Quality Assessment, 2nd Edition

**Item Order Code:** MM14A2E **COVID-19 Related**

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**MM17** | Validation and Verification of Multiplex Nucleic Acid Assays, 2nd Edition

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**MM18** | Interpretive Criteria for Identification of Bacteria and Fungi by Targeted DNA Sequencing, 2nd Edition

**Item Order Code:** MM18Ed2

**MM19\*** | Establishing Molecular Testing in Clinical Laboratory Environments, 1st Edition

**Item Order Code:** MM19AE **COVID-19 Related**

**MM20\*** | Quality Management for Molecular Genetic Testing, 1st Edition

**Item Order Code:** MM20AE

**MM21\*** | Genomic Copy Number Microarrays for Constitutional Genetic and Oncology Applications, 1st Edition

**Item Order Code:** MM21Ed1\*

**MM22\*** | Microarrays for Diagnosis and Monitoring of Infectious Diseases, 1st Edition

**Item Order Code:** MM22AE **COVID-19 Related**

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**MM23\*** | Molecular Diagnostic Methods for Solid Tumors (Nonhematological Neoplasms), 1st Edition

**Item Order Code:** MM23Ed1E



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# Newborn Screening

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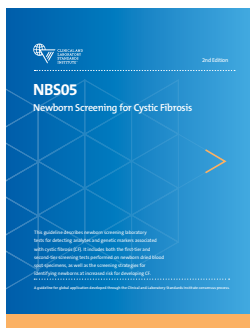
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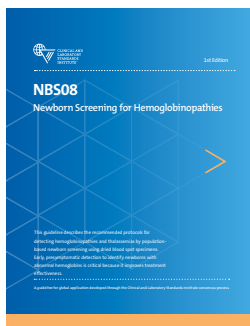
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## Featured Documents



### NBS05 | Newborn Screening for Cystic Fibrosis, 2nd Edition

NBS05 provides essential information about newborn screening laboratory tests for detecting analytes and genetic markers associated with cystic fibrosis.



### NBS08 | Newborn Screening for Hemoglobinopathies, 1st Edition

NBS08 describes the recommended protocols for detecting hemoglobinopathies and thalassemias. Early, presymptomatic detection to identify newborns with abnormal hemoglobins is critical.

### NBS01 | Blood Collection on Filter Paper for Newborn Screening Programs, 7th Edition

**Item Order Code:** NBS01Ed7

### NBS02\* | Newborn Screening Follow-up, 2nd Edition

**Item Order Code:** NBS02A2E

### NBS02A2QG\* | Newborn Screening Follow-up Process Quick Guide

**Item Order Code:** NBS02A2QGE

**Nonmember Rate:** \$20.00

### NBS03 | Newborn Screening for Preterm, Low Birth Weight, and Sick Newborns, 2nd Edition

**Item Order Code:** NBS03Ed2

### NBS04 | Newborn Screening by Tandem Mass Spectrometry, 2nd Edition

**Item Order Code:** NBS04Ed2

### NBS05 | Newborn Screening for Cystic Fibrosis, 2nd Edition

**Item Order Code:** NBS05Ed2

### NBS06\* | Newborn Blood Spot Screening for Severe Combined Immunodeficiency by Measurement of T-cell Receptor Excision Circles, 1st Edition

**Item Order Code:** NBS06AE



**NBS06AQG1\*** | Generic Flow Chart for Assays to Measure T-cell Receptor Excision Circles in Newborn Dried Blood Spot Specimens

**Item Order Code:** NBS06AQG1E

**Nonmember Rate:** \$20.00

**NBS06AQG2\*** | Schematic for Preparing Dried Blood Spot Reference Materials Quick Guide

**Item Order Code:** NBS06AQG2E

**Nonmember Rate:** \$20.00

**NBS07** | Newborn Blood Spot Screening for Pompe Disease by Lysosomal Acid  $\alpha$ -Glucosidase Activity Assays, 1st Edition

**Item Order Code:** NBS07Ed1

**NBS08** | Newborn Screening for Hemoglobinopathies, 1st Edition

**Item Order Code:** NBS08Ed1

**NBS09** | Newborn Screening for X-Linked Adrenoleukodystrophy, 1st Edition

**Item Order Code:** NBS09Ed1



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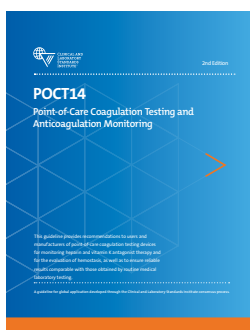
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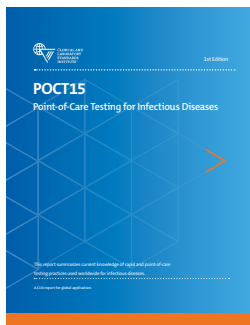
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## Featured Documents



### **POCT14** | Point-of-Care Coagulation Testing and Anticoagulation Monitoring, 2nd Edition

This guideline provides recommendations to users and manufacturers of point-of-care coagulation testing devices for monitoring heparin and vitamin K antagonist therapy and for the evaluation of hemostasis, as well as to ensure reliable results comparable with those obtained by routine medical laboratory testing.



### **POCT15** | Point-of-Care Testing for Infectious Diseases, 1st Edition

This report summarizes current knowledge of rapid and point-of-care testing practices used worldwide for infectious diseases.

### **POCT01\*** | Point-of-Care Connectivity, 2nd Edition

**Item Order Code:** POCT01A2E

### **POCT01QG\*** | CLSI Vendor Code Registry, 1st Edition

**Item Order Code:** POCT01QGE1E

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### **POCT02\*** | Implementation Guide of POCT01 for Healthcare Providers, 1st Edition

**Item Order Code:** POCT02AE

### **POCT04** | Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Edition

**Item Order Code:** POCT04Ed3

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### **POCT05\*** | Performance Metrics for Continuous Interstitial Glucose Monitoring, 2nd Edition

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### **POCT06\*** | Effects of Different Sample Types on Glucose Measurements, 1st Edition

**Item Order Code:** POCT06Ed1E

### **POCT07\*** | Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition

**Item Order Code:** POCT07AE

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**POCT07RG** | Addressing Errors in Point-of-Care Testing, 1st Edition  
**Item Order Code:** POCT07RDEd1

**POCT08\*** | Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers, 1st Edition  
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**POCT08AQG1\*** | Corrective Action Quick Guide  
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**POCT08AQG2\*** | Quality Control Troubleshooting Flow Chart  
**Item Order Code:** POCT08AQG2E  
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**POCT08AQG3\*** | Quality Control Log Sheet Quick Guide  
**Item Order Code:** POCT08AQG3E  
**Nonmember Rate:** \$20.00

**POCT09\*** | Selection Criteria for Point-of-Care Testing Devices, 1st Edition  
**Item Order Code:** POCT09AE

**POCT09AWS\*** | Instrument Selection Worksheet  
**Item Order Code:** POCT09AWSE  
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**POCT10\*** | Physician and Nonphysician Provider-Performed Microscopy Testing, 2nd Edition  
**Item Order Code:** POCT10A2E

**POCT12\*** | Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities, 3rd Edition  
**Item Order Code:** POCT12A3

**POCT13\*** | Glucose Monitoring in Settings Without Laboratory Support, 3rd Edition  
**Item Order Code:** POCT13Ed3cE

**POCT14** | Point-of-Care Monitoring of Anticoagulation Therapy, 2nd Edition  
**Item Order Code:** POCT14Ed2

**POCT15** | POCT for Infectious Diseases, 1st Edition  
**Item Order Code:** POCT15Ed1E **COVID-19 Related**

**POCT17\*** | Use of Glucose Meters for Critically Ill Patients, 1st Edition  
**Item Order Code:** POCT17Ed1E

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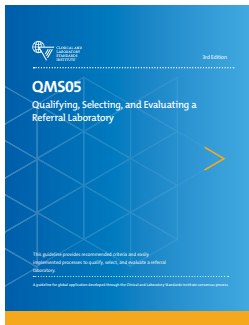
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## Featured Documents



### QMS01 | Quality Management System: A Model for Laboratory Services, 5th Edition

Reduce nonconformances and help your lab pass and maintain accreditation with QMS01. This document will show you how to develop and implement a quality management system that fits your lab's unique needs.



### QMS05 | Qualifying, Selecting, and Evaluating a Referral Laboratory, 3rd Edition

This guideline provides recommended criteria and easily implemented processes to qualify, select, and evaluate a referral laboratory.

### QMS01 | Quality Management System: A Model for Laboratory Services, 5th Edition

**Item Order Code:** QMS01Ed5

### QMS01CL\* | Gap Analysis Checklists, 1st Edition

**Item Order Code:** QMS01CLE

**Nonmember Rate:** \$30.00

### QMS02 | Quality Management System: Development and Management of Laboratory Documents, 6th Edition

**Item Order Code:** QMS02A6

### QMS02QG\* | Ten Rules for Laboratory Document Management Quick Guide

**Item Order Code:** QMS02A6

**Nonmember Rate:** \$20.00

### QMS03 | Training and Competence Assessment, 4th Edition

**Item Order Code:** QMS03Ed4

**COVID-19 Related**

### QMS04 | Laboratory Design, 3rd Edition

**Item Order Code:** QMS04Ed3



**QMS05** | Quality Management System: Qualifying, Selecting, and Evaluating a Referral Laboratory, 3rd Edition

**Item Order Code:** QMS05Ed3

**QMS06** | Quality Management System: Continual Improvement, 3rd Edition

**Item Order Code:** QMS06A3

**QMS11** | Nonconforming Event Management, 2nd Edition

**Item Order Code:** QMS11Ed2

**QMS12** | Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality, 2nd Edition

**Item Order Code:** QMS12Ed2

**QMS13\*** | Quality Management System: Equipment, 1st Edition

**Item Order Code:** QMS13AE

**QMS14** | Quality Management System: Leadership and Management Roles and Responsibilities, 1st Edition

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*QMS14 Executive Summary included with purchase*

**QMS15** | Assessments: Laboratory Internal Audit Program, 1st Edition

**Item Order Code:** QMS15A

**QMS16\*** | Laboratory Personnel Management, 1st Edition

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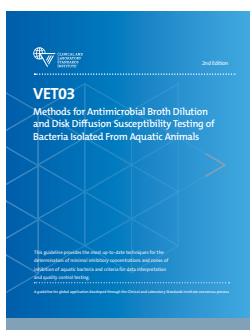
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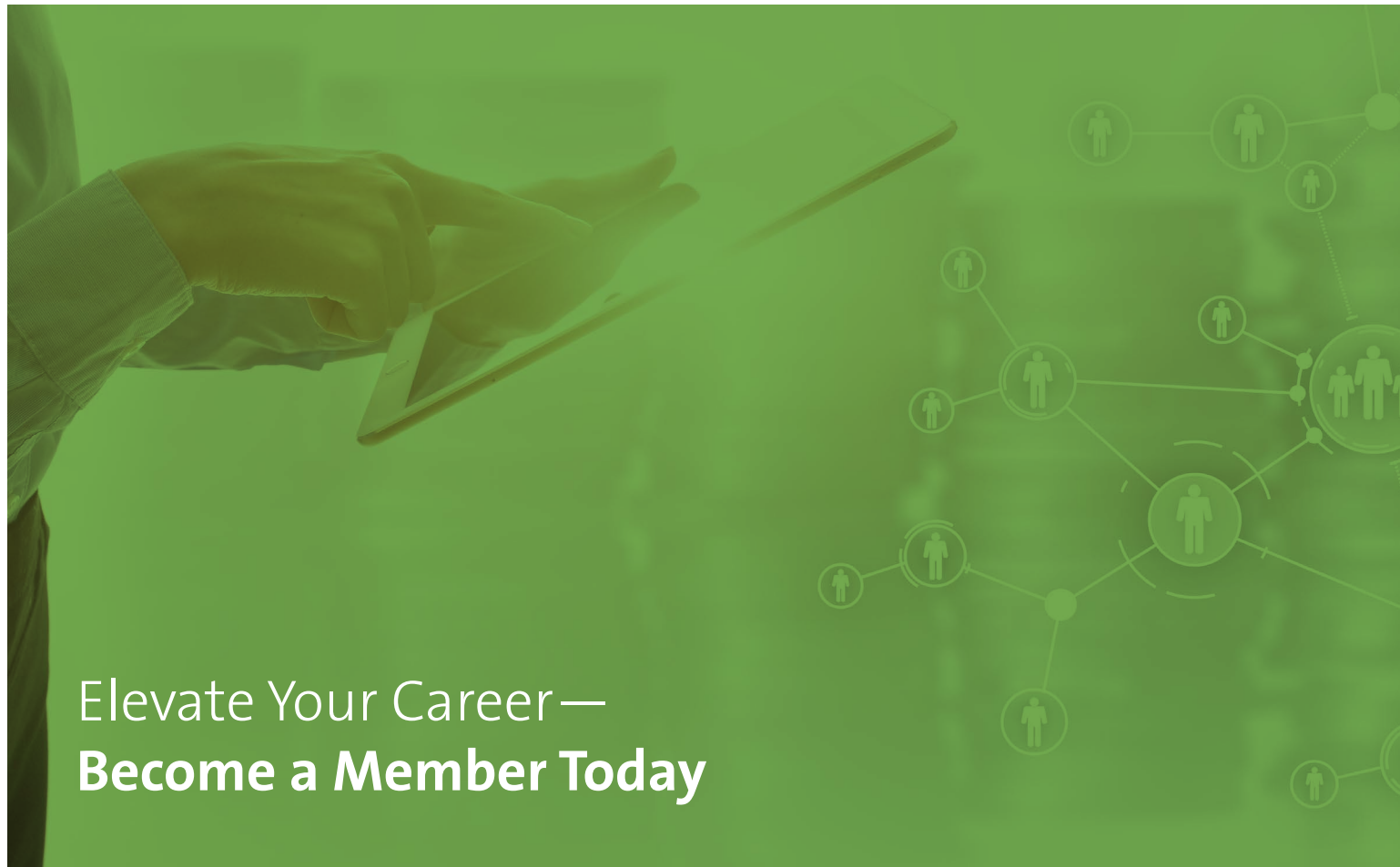
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