

# CLSI CATALOG | Setting the standard in laboratory medicine for a healthier world.



# 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?

**C62** | *Liquid Chromatography-Mass Spectrometry Methods, 2nd Edition*

**EP27** | *Constructing and Interpreting an Error Grid for Quantitative Measurement Procedures, 2nd Edition*

**QMS15** | *Laboratory Internal Audit Program, 2nd Edition*

**M47** | *Principles and Procedures for Blood Cultures, 2nd Edition*

**EP26** | *User Evaluation of Acceptability of a Reagent Lot Change, 2nd Edition*

**M100** | *Performance Standards for Antimicrobial Susceptibility Testing, 32nd Edition*

**M39** | *Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data, 5th Edition*

**EP39** | *A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests, 1st Edition*

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

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

**MM24** | *Molecular Methods for Genotyping and Strain Typing of Infectious Organisms, 1st Edition*

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

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

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

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

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

## Coming Soon!

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

**EP14** | *Evaluation of Commutability of Processed Samples, 4th Edition*

**EP19** | *A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures, 3rd Edition*

**EP33** | *Use of Delta Checks in the Medical Laboratory, 2nd Edition*

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



 **M100**  
Educational Program

### Free Online Course

## Using M100: Performance Standards for Antimicrobial Susceptibility Testing

Improve your lab's antimicrobial susceptibility testing (AST) by using this self-paced, online learning program. This interactive program will teach you how to navigate the many tables found in CLSI's document **M100—Performance Standards for Antimicrobial Susceptibility Testing, 32nd Edition**.

Learn more at [clsi.org/using-m100](https://clsi.org/using-m100).

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### Table of Contents

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### Advanced Print Options

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### Access is included for all employees at organizations with the following memberships:

- Health System
- Level I Industry

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- Level I Government
- Level II Industry

Is your membership level not included? Contact us at [membership@clsi.org](mailto:membership@clsi.org) to learn about how to get access to eCLIPSE.

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**Coming Soon!**



## **METHOD** Navigator

### **If you develop laboratory tests, you need Method Navigator!**

As a manufacturer or laboratory in the *in vitro* diagnostics community, your test methods are subject to a myriad of regulatory requirements. Often, it is difficult to stay up-to-date with the pertinent requirements. CLSI's new Method Navigator, a comprehensive subscription resource, was built to help make your job easier.

Learn to identify, understand, and meet requirements and gain guidance to help document your efforts. Applicable to any test developer — manufacturers, laboratories, research labs, medical devices for humans — CLSI's new Method Navigator subscription pulls together specific guidance from CLSI documents that will help your lab fulfill FDA, CLIA, ISO, and other requirements, quickly and easily.

Method Navigator also includes downloadable checklists that you can fill out to make sure that you have met all the requirements with objective evidence, and that you know where to find that evidence should you need to locate it for an audit or inspection.

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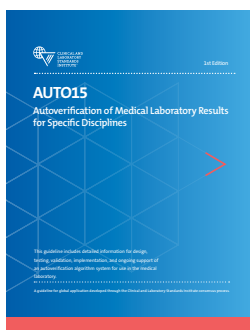
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Access documents for free in eCLIPSE, included in some membership levels. Visit [clsi.org/eclipse](https://clsi.org/eclipse) for more information.

## Featured Documents



### **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:** AUTO12AE

**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:** AUTO16Ed1E

**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

Join our e-mail list to be the first to learn about new documents and volunteer opportunities. Sign up today at [clsi.org/email](http://clsi.org/email).

# Clinical Chemistry and Toxicology

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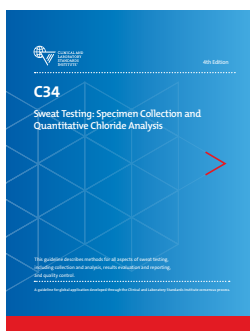
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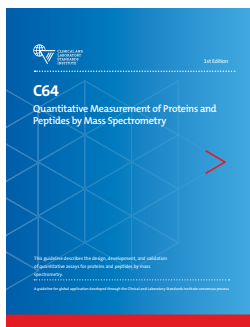
Access documents for free in eCLIPSE, included in some membership levels. Visit [clsi.org/eclipse](https://www.clsi.org/eclipse) for more information.

## 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.



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

This guideline describes the design, development, and validation of quantitative assays for proteins and peptides by mass spectrometry.

### 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:** C46A2E

**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:** C56AEQGE

**Nonmember Rate:** \$20.00

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

**Item Order Code:** C57Ed1E

**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, 2nd Edition

**Item Order Code:** C62Ed2

**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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## 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.



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

This standard provides procedures for collection of capillary blood specimens. Specifications for collection sites, puncture depth, and disposable devices used to collect, process, and transfer capillary blood specimens are also included.

**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:** GP16A3E

**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

**COVID-19 Related**



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

**Item Order Code:** GP34AE

**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:** GP40A4AMDE

**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, 7th Edition

**Item Order Code:** GP42Ed7

**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:** GP44A4E

**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:** GP47Ed1E

**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.

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# Hematology

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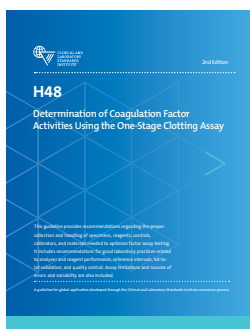
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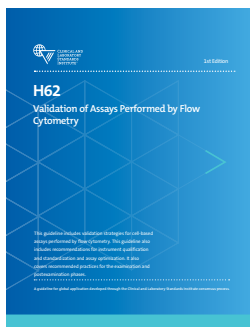
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## Featured Documents



### 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.



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

This guideline includes validation strategies for cell-based assays performed by flow cytometry. This guideline also includes recommendations for instrument qualification and standardization and assay optimization. It also covers recommended practices for the examination and postexamination phases.

### 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:** H21A5E

### H21A5QG | H21-A5 Quick Guide

**Item Order Code:** H21A5QGE

**Nonmember Rate:** \$20.00



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

**Item Order Code:** H26A2E

**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:** H48Ed2E

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

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**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:** H60AE

**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

**Nonmember Rate:** \$20.00

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

**Item Order Code:** H62Ed1

 **METHOD** *Coming soon! If you develop laboratory tests, you need Method Navigator!*  
**Navigator**

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# Immunology and Ligand Assay

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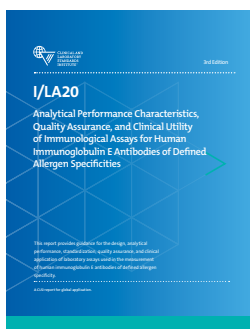
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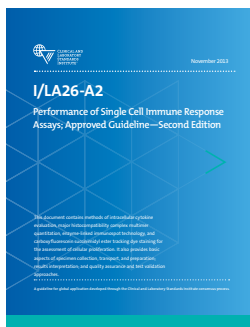
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## Featured Documents



### 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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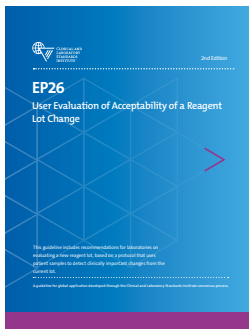
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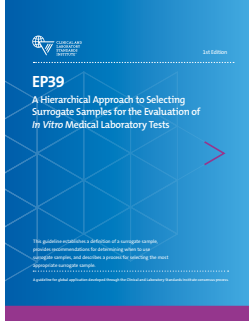
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## Featured Documents



### EP26 | User Evaluation of Acceptability of a Reagent Lot Change, 2nd Edition

This guideline includes recommendations for laboratories on evaluating a new reagent lot, based on a protocol that uses patient samples to detect clinically important changes from the current lot.



### EP39 | A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of *In Vitro* Medical Laboratory Tests, 1st Edition

This guideline establishes a definition of a surrogate sample, provides recommendations for determining when to use surrogate samples, and describes a process for selecting the most appropriate surrogate sample.

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

Item Order Code: EP05A3E

**COVID-19 Related**

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

Item Order Code: EP06Ed2

**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

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

Item Order Code: EP09Ed3cE

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

Item Order Code: EP10A3AMDE



**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:** EP15A3E

**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:** EP18A2E **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**

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**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

**EP23AWB** | 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:** EP25AE **COVID-19 Related**

**EP26\*** | User Evaluation of Between-Reagent Lot Variation, 2nd Edition

**Item Order Code:** EP26Ed2

**EP27** | Constructing and Interpreting an Error Grid for Quantitative Measurement Procedures, 2nd Edition

**Item Order Code:** EP27Ed2E

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

**Item Order Code:** EP28A3CE

**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:** EP33Ed1E

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

**Item Order Code:** EP34Ed1

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

**Item Order Code:** EP35Ed1

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

**Item Order Code:** EP36Ed1E

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**EP39\*** | A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of *In Vitro* Medical Laboratory Tests, 1st Edition

**Item Order Code:** EP39Ed1

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

**Item Order Code:** EP43Ed1E

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

**Item Order Code:** QSRLDTE

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**EP26IG | User Evaluation of Acceptability of a Reagent Lot Change Implementation Guide, 2nd Edition**

**EP15IG1 | User Verification of Precision Implementation Guide, 1st Edition**

**EP28IG | Verification of Reference Intervals in the Medical Laboratory Implementation Guide, 1st Edition**

**EP15IG2 | User Verification of Bias (Trueness) Implementation Guide, 1st Edition**

**EP34IG | Verification of an Extended Measuring Interval Implementation Guide, 1st Edition**

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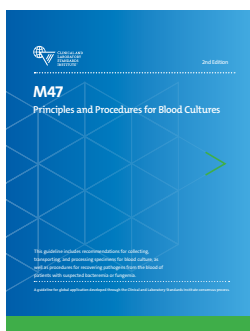
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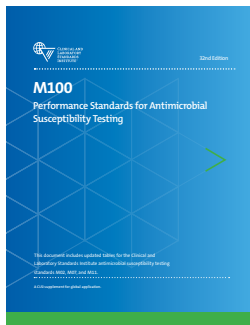
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## Featured Documents



### M47 | Principles and Procedures for Blood Cultures, 2nd Edition

This guideline includes recommendations for collecting, transporting, and processing specimens for blood culture, as well as procedures for recovering pathogens from the blood of patients with suspected bacteremia or fungemia.



### M100 | Performance Standards for Antimicrobial Susceptibility Testing, 32nd Edition

This document includes updated tables for the Clinical and Laboratory Standards Institute antimicrobial susceptibility testing standards M02, M07, and M11.

### 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

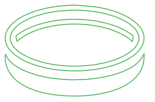
**Item Order Code:** M11Ed9

### 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

*Free document*

**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

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**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:** M24Ed3E

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

**Item Order Code:** M62Ed1E

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**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:** M29A4E

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**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, 5th Edition

**Item Order Code:** M39Ed5

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

**Item Order Code:** M40A2E

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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:** M44Ed3E

**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, 2nd Edition

**Item Order Code:** M47Ed2

**M48** | Laboratory Detection and Identification of Mycobacteria, 2nd Edition

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**M50** | Quality Control for Commercial Microbial Identification Systems, 1st Edition

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# Microbiology

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**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:** M56AE

**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

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**Item Order Code:** M59Ed3

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

**Item Order Code:** M60Ed2

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

**Item Order Code:** M61Ed2

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**M100\*** | Performance Standards for Antimicrobial Susceptibility Testing, 32nd Edition

**Item Order Code:** M100Ed32



# 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 32nd 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

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## Free Rationale Documents

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

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**MR01** | Polymyxin Breakpoints for Enterobacteriales, *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 Enterobacteriales (Systemic Infections), 1st Edition

**Item Order Code:** MR07Ed1E

**MR08** | Cefazolin Breakpoints for Enterobacteriales (Uncomplicated Urinary Tract Infections), 1st Edition

**Item Order Code:** MR08Ed1E

**MR14** | Piperacillin-Tazobactam Breakpoints for Enterobacteriales, 1st Edition

**Item Order Code:** MR14Ed1E

# Molecular Methods

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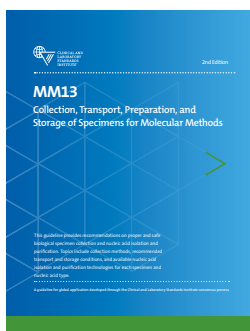
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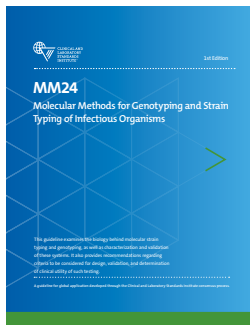
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## Featured Documents



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

This guideline provides recommendations on proper and safe biological specimen collection and nucleic acid isolation and purification. Topics include collection methods, recommended transport and storage conditions, and available nucleic acid isolation and purification technologies for each specimen and nucleic acid type.



### MM24 | Molecular Methods for Genotyping and Strain Typing of Infectious Organisms, 1st Edition

This guideline examines the biology behind molecular strain typing and genotyping, as well as characterization and validation of these systems. It also provides recommendations regarding criteria to be considered for design, validation, and determination of clinical utility of such testing.

### 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: MM06A2E **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: MM09A2E **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:** MM13Ed2 **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

**Item Order Code:** MM17Ed2E **COVID-19 Related**

**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:** MM21Ed1E

**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

**MM24\*** | Molecular Methods for Genotyping and Strain Typing of Infectious Organisms, 1st Edition

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# Newborn Screening

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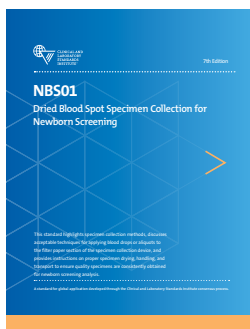
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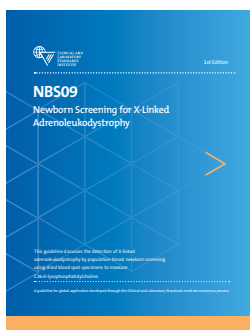
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## Featured Documents



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

This standard highlights specimen collection methods, discusses acceptable techniques for applying blood drops or aliquots to the filter paper section of the specimen collection device, and provides instructions on proper specimen drying, handling, and transport to ensure quality specimens are consistently obtained for newborn screening analysis.



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

This guideline discusses the detection of X-linked adrenoleukodystrophy by population-based newborn screening using dried blood spot specimens to measure C26:0-lysophosphatidylcholine.

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

**Item Order Code:** NBS01Ed7

### **NBS01Ed7QG\*** | Specimen Collection and Specimen Quality for Newborn Screening Quick Guide, 7th Edition

**Item Order Code:** NBS01Ed7QG

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

**Item Order Code:** NBS02A2E

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

**Item Order Code:** NBS02A2QGE

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

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### **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

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

**Item Order Code:** NBS07Ed1

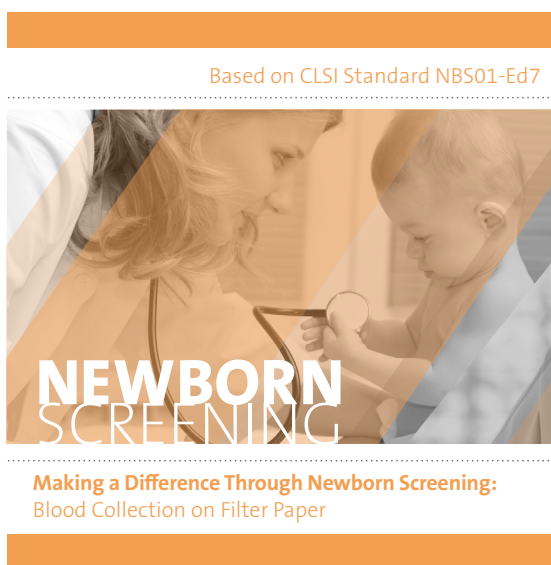
**NBS08\*** | Newborn Screening for Hemoglobinopathies, 1st Edition

**Item Order Code:** NBS08Ed1

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

**Item Order Code:** NBS09Ed1

## Online Course: Making a Difference Through Newborn Screening: Blood Collection on Filter Paper



**This video demonstrates how to:**

- Prepare for specimen collection.
- Collect blood specimens using the recommended heelstick technique.
- Handle specimens properly and maintain appropriate records.
- Transfer specimens to the screening lab in a timely manner.
- Prevent testing problems that can delay the newborn's diagnosis and treatment.

**Nonmembers:** \$100

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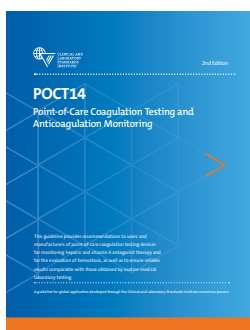
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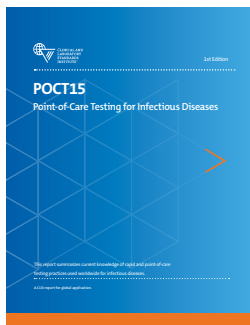
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## Featured Documents



### **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

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**POCT08** | Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers, 1st Edition  
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**POCT08AQG3** | Quality Control Log Sheet Quick Guide  
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**POCT13** | Glucose Monitoring in Settings Without Laboratory Support, 3rd Edition  
**Item Order Code:** POCT13Ed3cE

**POCT14\*** | Point-of-Care Monitoring of Anticoagulation Therapy, 2nd Edition  
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**POCT15\*** | POCT for Infectious Diseases, 1st Edition  
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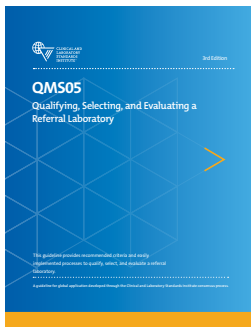
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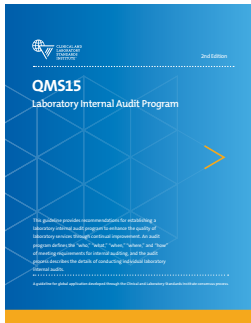
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## Featured Documents



### 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.



### QMS15 | Laboratory Internal Audit Program, 2nd Edition

This guideline provides recommendations for establishing a laboratory internal audit program to enhance the quality of laboratory services through continual improvement. An audit program defines the “who,” “what,” “when,” “where,” and “how” of meeting requirements for internal auditing, and the audit process describes the details of conducting individual laboratory internal audits.

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

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

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**Item Order Code:** QMS02A6E

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

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

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### QMS04 | Laboratory Design, 3rd Edition

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

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- Assessment services
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### Partnering With Us

If you or your organization is interested in a partnership opportunity, CLSI is ready to work with you on a site-specific plan. Simply e-mail us at [ghp@clsi.org](mailto:ghp@clsi.org) to get started.

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

This guideline discusses the necessary and recommended data for selecting appropriate quality control ranges, breakpoints, and interpretive categories for antimicrobial agents for veterinary use.

**VET01\*** | Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals, 5th Edition

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**VET05** | Generation, Presentation, and Application of Antimicrobial Susceptibility Test Data for Bacteria of Animal Origin, 1st Edition

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**VET06** | Methods for Antimicrobial Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria Isolated From Animals, 1st Edition

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