Recently Published Documents

**NBS04 | Newborn Screening by Tandem Mass Spectrometry, 2nd Edition**
This guideline serves as a reference for the multiple activities related to operating a tandem mass spectrometry laboratory as part of public and private newborn screening programs.

*Published: May 2017  Item Order Code: NBS04-ED2*

This guideline includes performance, reporting, and quality assurance recommendations for the identification of cultured microorganisms by medical laboratory professionals using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry. Recommendations for end-user verification and workflow integration are also included.

*Published: April 2017  Item Order Code: M58-ED1*

**GP41 | Collection of Diagnostic Venous Blood Specimens, 7th Edition**
This standard provides procedures for the collection of diagnostic venous blood specimens, including line draws, blood culture collection, and venipuncture in children.

*Published: April 2017  Item Order Code: GP41-ED7*

**GP48 | Essential Elements of a Phlebotomy Training Program, 1st Edition**
This guideline is a resource for health care professionals and educators for development and implementation of curricula for phlebotomy training programs and courses.

*Published: April 2017  Item Order Code: GP48-ED1*

**NBS07 | Newborn Blood Spot Screening for Pompe Disease by Lysosomal Acid α-Glucosidase Activity Assays, 1st Edition**
This report discusses the detection of Pompe disease (PD) by population-based newborn screening using dried blood spot specimens to measure acid α-glucosidase enzyme activity. Classic infantile-onset PD is a lethal disorder that is not evident at birth, and therapy effectiveness is improved by presymptomatic detection.

*Published: March 2017  Item Order Code: NBS07-ED1*

**C52 | Toxicology and Drug Testing in the Medical Laboratory, 3rd Edition**
This guideline provides an overview of drug testing by medical laboratories, including testing for drugs of abuse. It discusses the preexamination, examination, and postexamination considerations for specimen collection, methods of analysis, and the reporting and interpretation of results.

*Published: January 2017  Item Order Code: C52-ED3*
M100 | Performance Standards for Antimicrobial Susceptibility Testing, 27th Edition
This document provides updated tables for the Clinical and Laboratory Standards Institute antimicrobial susceptibility testing standards M02-A12, M07-A10, and M11-A8.
Published: January 2017  Item Order Code: M100-S27

QMS21 | Purchasing and Inventory Management, 1st Edition
This guideline describes effective purchasing and inventory management processes, which ensure availability of the appropriate equipment, instruments, reagents, consumable materials, other products, and services procured from external sources needed for providing quality laboratory services.
Published: November 2016  Item Order Code: QMS21-ED1

VET06 | Methods for Antimicrobial Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria Isolated From Animals, 1st Edition
This document provides guidance for antimicrobial agent disk and dilution susceptibility testing, criteria for quality control testing, and breakpoints for fastidious and infrequently tested bacteria for veterinary use.
Published: January 2017  Item Order Code: VET06-ED1

This report provides guidance for the design, analytical performance, standardization, quality assurance, and clinical application of laboratory assays used in the measurement of human immunoglobulin E antibodies of defined allergen specificity.
Published: October 2016  Item Order Code: I/LA20-ED3

This handbook assists laboratories in developing a quality manual—a vital component of implementing and maintaining a complete laboratory quality management system.
Published: January 2017  Item Order Code: QMS25-ED1

I/LA37 | Supplemental Data for Allergen Specificity for IgE Antibody Autoanalyzers
This database provides a harmonized listing of the allergen codes currently used by immunoglobulin E antibody assay manufacturers, along with their common name, Latin name, and allergen grouping.
Published: October 2016  Item Order Code: I/LA37

QMS03 | Training and Competence Assessment, 4th Edition
This guideline provides a structured approach for developing effective laboratory personnel training and competence assessment programs.
Published: December 2016  Item Order Code: QMS03-ED4

QMS24 | Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality, 3rd Edition
This guideline describes a complete proficiency testing (PT) process to assist laboratories in using PT as a quality improvement tool.
Published: September 2016  Item Order Code: QMS24-ED3
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CLSI Upcoming Publications

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This report provides guidance for initiating, developing, and maintaining an effective test utilization program.

**QMS17 | External Assessments, Audits, and Inspections of the Laboratory, 1st Edition**
This guideline provides recommendations for establishing and maintaining a process to assist the laboratory in achieving a continuous state of readiness for assessment by an external organization. This includes selecting and evaluating an external assessment organization, preparing and undergoing a successful assessment, and sustaining ongoing readiness for assessment.

**C49 | Analysis of Body Fluids in Clinical Chemistry, 2nd Edition**
This guideline provides information for the medical laboratory for evaluating measurement procedures, as well as a strategy to characterize assay performance, when applied to body fluid matrixes. Key concepts that apply to the entire test cycle, including preexamination, examination, and postexamination phases of body fluid testing are discussed.

**QMS19 | Customer Focus in a Quality Management System, 1st Edition**
This guideline provides useful information for how laboratories can develop and maintain a customer focus and meet the regulatory and accreditation requirements for managing external and internal customers.

**2018 AST Package**

**M100 | Performance Standards for Antimicrobial Susceptibility Testing, 28th 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**
This standard contains the currently recommended methods for disk susceptibility testing and criteria for quality control testing.

**M07 | Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, 11th Edition**
This standard contains reference methods for the determination of minimal inhibitory concentrations of aerobic bacteria by broth macrodilution, broth microdilution, and agar dilution.

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<th>Cost per Site</th>
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<table>
<thead>
<tr>
<th>Item Order Code</th>
<th>Document Title</th>
<th>Edition</th>
<th>Pricing</th>
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<tbody>
<tr>
<td>H02-A5</td>
<td>Procedures for the Erythrocyte Sedimentation Rate Test</td>
<td>5th</td>
<td>Level II Members: $56</td>
</tr>
<tr>
<td>H07-A3</td>
<td>Procedure for Determining Packed Cell Volume by the Microhematocrit Method</td>
<td>3rd</td>
<td>Level III Members: $70</td>
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<tr>
<td>H15-A3</td>
<td>Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood</td>
<td>3rd</td>
<td>Individual Full Members: $105</td>
</tr>
<tr>
<td>H20-A2</td>
<td>Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods</td>
<td>2nd</td>
<td>Individual Associate Members: $119</td>
</tr>
<tr>
<td>H21-A5</td>
<td>Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays</td>
<td>5th</td>
<td>Nonmembers: $140</td>
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<tr>
<td>H26-A2</td>
<td>Validation, Verification, and Quality Assurance of Automated Hematology Analyzers</td>
<td>2nd</td>
<td>Level I Members: $42</td>
</tr>
<tr>
<td>H30-A2</td>
<td>Procedure for the Determination of Fibrinogen in Plasma</td>
<td>2nd</td>
<td>Level II Members: $56</td>
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<tr>
<td>H42-A2</td>
<td>Enumeration of Immunologically Defined Cell Populations by Flow Cytometry</td>
<td>2nd</td>
<td>Level III Members: $70</td>
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<tr>
<td>H43-A2</td>
<td>Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells</td>
<td>2nd</td>
<td>Individual Full Members: $105</td>
</tr>
<tr>
<td>H47-A2</td>
<td>One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test</td>
<td>2nd</td>
<td>Individual Associate Members: $119</td>
</tr>
<tr>
<td>H48-ED2</td>
<td>Determination of Coagulation Factor Activities Using the One-Stage Clotting Assay</td>
<td>2nd</td>
<td>Nonmembers: $140</td>
</tr>
<tr>
<td>H52-A2</td>
<td>Red Blood Cell Diagnostic Testing Using Flow Cytometry</td>
<td>2nd</td>
<td>Level I Members: $42</td>
</tr>
<tr>
<td>H54-A</td>
<td>Procedures for Validation of INR and Local Calibration of PT/INR Systems</td>
<td>1st</td>
<td>Level II Members: $56</td>
</tr>
<tr>
<td>H56-A</td>
<td>Body Fluid Analysis for Cellular Composition</td>
<td>1st</td>
<td>Level III Members: $70</td>
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<tr>
<td>H57-A</td>
<td>Protocol for the Evaluation, Validation, and Implementation of Coagulometers</td>
<td>1st</td>
<td>Individual Full Members: $105</td>
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<td>H58-A</td>
<td>Platelet Function Testing by Aggregometry</td>
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