

Setting the **Global**
Standard for Quality
in Laboratory Testing

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Dear customer,

In order to better classify our library of documents, the Clinical and Laboratory Standards Institute (CLSI) has expanded and color coded its document categories. The assigned colors are prominently displayed on each CLSI document cover.

The new document categories are:

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|---------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
|  Automation and Informatics |  Immunology and Ligand Assay |  Newborn Screening |
|  Clinical Chemistry and Toxicology |  Method Evaluation |  Point-of-Care Testing |
|  General Laboratory |  Microbiology |  Quality Management Systems |
|  Hematology |  Molecular Methods |  Veterinary Medicine |



As part of this initiative, some CLSI documents were assigned new codes to reflect their categories. See below for the complete list of affected documents, or visit www.clsi.org.

Sincerely,

CLSI Customer Service

Former Document Code	New Document Code	Document Title
Automation and Informatics		
GP19-A2	AUTO13-A2	Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition
Clinical Chemistry and Toxicology		
I/LA15-A	C59-A	Apolipoprotein Immunoassays: Development and Recommended Performance Characteristics; Approved Guideline
T/DM06-A	C60-A	Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline
H17-A	C61-A	Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation; Approved Standard
General Laboratory		
H01-A6	GP39-A6	Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition
C03-A4-AMD	GP40-A4-AMD	Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline—Fourth Edition
H03-A6	GP41-A6	Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition
H04-A6	GP42-A6	Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Sixth Edition
H11-A4	GP43-A4	Procedures for the Collection of Arterial Blood Specimens; Approved Standard—Fourth Edition
H18-A4	GP44-A4	Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition
HS06-A	GP45-A	Studies to Evaluate Patient Outcomes; Approved Guideline
X04-R	GP46-R	Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report

Former Document Code	New Document Code	Document Title
Method Evaluation		
C28-A3c	EP28-A3c	Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition
C51-A	EP29-A	Expression of Measurement Uncertainty in Laboratory Medicine; Approved Guideline
C53-A	EP30-A	Characterization and Qualification of Commutable Reference Materials for Laboratory Medicine; Approved Guideline
C54-A-IR	EP31-A-IR	Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline (Interim Revision)
X05-R	EP32-R	Metrological Traceability and Its Implementation; A Report
Microbiology		
X07-R	M55-R	Surveillance for Methicillin-Resistant <i>Staphylococcus aureus</i> : Principles, Practices, and Challenges; A Report
Newborn Screening		
LA04-A5	NBS01-A5	Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fifth Edition
I/LA27-A	NBS02-A	Newborn Screening Follow-up; Approved Guideline
I/LA31-A	NBS03-A	Newborn Screening for Preterm, Low Birth Weight, and Sick Newborns; Approved Guideline
I/LA32-A	NBS04-A	Newborn Screening by Tandem Mass Spectrometry; Approved Guideline
I/LA35-A	NBS05-A	Newborn Screening for Cystic Fibrosis; Approved Guideline
Point-of-Care Testing		
AST04-A2	POCT13-A2	Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline—Second Edition
H49-A	POCT14-A	Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline
Quality Management Systems		
GP26-A4	QMS01-A4	Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition
GP02-A6*	QMS02-A6	Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition
GP21-A3	QMS03-A3	Training and Competence Assessment; Approved Guideline—Third Edition
GP18-A2	QMS04-A2	Laboratory Design; Approved Guideline—Second Edition
GP09-A2	QMS05-A2	Quality Management System: Qualifying, Selecting, and Evaluating a Referral Laboratory; Approved Guideline—Second Edition
GP22-A3	QMS06-A3	Quality Management System: Continual Improvement; Approved Guideline—Third Edition
HS04-A2	QMS07-A2	Application of a Quality Management System Model for Respiratory Services; Approved Guideline—Second Edition
HS05-A2	QMS08-A2	Application of a Quality Management System Model for Medical Imaging Services; Approved Guideline—Second Edition
HS10-A2	QMS09-A2	Application of a Quality Management System Model for Inpatient Medication Use; Approved Guideline—Second Edition
HS11-A	QMS10-A	A Model for Managing Medical Device Alerts (Hazards and Recalls) for Healthcare Organizations; Approved Guideline
GP32-A	QMS11-A	Management of Nonconforming Laboratory Events; Approved Guideline
GP35-A	QMS12-A	Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline
GP37-A	QMS13-A	Quality Management System: Equipment; Approved Guideline
GP38-A	QMS14-A	Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline
GP38-AES	QMS14-AES	Quality Management System: Leadership and Management Roles and Responsibilities—Executive Summary
Veterinary Medicine		
M31-A3	VET01-A3	Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals; Approved Standard—Third Edition
M37-A3	VET02-A3	Development of <i>In Vitro</i> Susceptibility Testing Criteria and Quality Control Parameters for Veterinary Antimicrobial Agents; Approved Guideline—Third Edition
M42/M49-S1	VET03/VET04-S1	Performance Standards for Antimicrobial Susceptibility Testing of Bacteria Isolated From Aquatic Animals; First Informational Supplement
M42-A	VET03-A	Methods for Antimicrobial Disk Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline
M49-A	VET04-A	Methods for Broth Dilution Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline
X08-R	VET05-R	Generation, Presentation, and Application of Antimicrobial Susceptibility Test Data for Bacteria of Animal Origin; A Report

* GP02 was never officially published as GP02-A6. GP02-A5 was revised and published as QMS02-A6 in February 2013.