FDA-Recognized CLSI Consensus Standards

A **quick reference tool** for those seeking information on **FDA-recognized CLSI consensus standards.**

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FDA-Recognized CLSI Consensus Standards

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The US Food and Drug Administration (FDA) maintains a database of recognized consensus standards, which includes more than 100 CLSI consensus standards and guidelines. FDA-Recognized Consensus Standards is a quick reference tool for those seeking information on CLSI consensus standards recognized by the FDA.

If there are any discrepancies between the FDA-Recognized Consensus Standards and the FDA-Recognized Consensus Standards Database, the FDA database should be regarded as the definitive source.

FDA Recognized Consensus Standards Database:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm

Access FDA-Recognized CLSI Consensus Standards on the CLSI website:

clsi.org/standards/products/crosswalks/accreditation-crosswalks

Note: The FDA Publication Date is the date the FDA either recognized the document or made a change to the document's profile. It is not the CLSI publication date.

Number	Product Area	Title of Standard or Guideline	Reference Number	CLSI Code or Edition Changes	FDA Publication Date
Automation and Informatics					
13-10	Software/ Informatics	*Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard*	AUTO01-A		9/9/2008
13-9	Software/ Informatics	*Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition*	AUTO02-A2		9/9/2008
13-30	Software/ Informatics	*Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition*	AUTO03-A2		3/16/2012
13-12	Software/ Informatics	*Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard*	AUTO04-A		9/9/2008
13-13	Software/ Informatics	*Laboratory Automation: Electromechanical Interfaces; Approved Standard*	AUTO05-A		9/9/2008
13-37	Software/ Informatics	*Laboratory Automation: Data Content for Specimen Identification; Approved Standard*	AUTO07-A		8/5/2013
13-25	Software/ Informatics	*Managing and Validating Laboratory Information Systems; Approved Guideline*	AUTO08-A		3/18/2009
13-28	Software/ Informatics	*Remote Access to Clinical Laboratory Diagnostic Devices via the Internet; Approved Standard*	AUTO09-A		3/18/2009
13-26	Software/ Informatics	*Autoverification of Clinical Laboratory Test Results; Approved Guideline*	AUTO10-A		3/18/2009
13-27	Software/ Informatics	*IT Security of* In Vitro *Diagnostic Instruments and Software Systems; Approved Standard --Second Edition*	AUTO11-A2		3/18/2009
13-31	Software/ Informatics	*Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard*	AUTO12-A		8/20/2012
13-15	Software/ Informatics	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition*	AUTO13-A2		7/9/2014
13-29	Software/ Informatics	*Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition*	LIS01-A2		9/8/2009
13-17	Software/ Informatics	*Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition*	LIS02-A2		9/9/2008

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Number	Product Area	Title of Standard or Guideline	Reference Number	CLSI Code or Edition Changes	FDA Publication Date
Clinical Chemistry and Toxicology					
7-267	*In Vitro* Diagnostics	*Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition*	C24-A3	C24-ED4*	12/23/2016
7-86	*In Vitro* Diagnostics	*Standardization of Sodium and Potassium Ion-Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard—Second Edition*	C29-A2		3/8/2004
7-87	*In Vitro* Diagnostics	*Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling; Approved Guideline—Second Edition*	C31-A2		3/8/2004
7-211	*In Vitro* Diagnostics	*Sweat Testing: Sample Testing: Sample Collection and Quantitative Chloride Analysis; Approved Guideline—Third Edition*	C34-A3	C34-ED4*	10/4/2010
7-88	*In Vitro* Diagnostics	*Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline*	C37-A		3/8/2004
7-89	*In Vitro* Diagnostics	*A Designated Comparison Method for the Measurement of Ionized Calcium in Serum; Approved Standard*	C39-A		3/8/2004
7-21	*In Vitro* Diagnostics	*Erythrocyte Protoporphyrin Testing; Approved Guideline*	C42-A		9/9/2008
7-242	*In Vitro* Diagnostics	*Hemolysis, Icterus, and Lipemia/Turbidity Indices as Indicators of Interference in Clinical Laboratory Analysis; Approved Guideline*	C56-A		8/6/2013
7-272	*In Vitro* Diagnostics	*Mass Spectrometry for Androgen and Estrogen Measurements in Serum--First Edition*	C57-ED1		8/21/2017
7-265	*In Vitro* Diagnostics	*Liquid Chromatography-Mass Spectrometry Methods, First Edition*	C62-A		9/21/2016
General Laboratory					
7-207	*In Vitro* Diagnostics	*Urinalysis; Approved Guideline—Third Edition*	GP16-A3		5/5/2010
7-166	*In Vitro* Diagnostics	*Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition*	GP20-A2		3/16/2012
7-259	*In Vitro* Diagnostics	*Nongynecological Cytology Specimens: Preexamination, Examination, and Postexamination Processes; Approved Guideline—Second Edition*	GP23-A2		4/4/2016
7-225	*In Vitro* Diagnostics	*Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline*	GP34-A		3/16/2012
7-221	*In Vitro* Diagnostics	*Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition*	GP39-A6		7/9/2014

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7-201	*In Vitro* Diagnostics	*Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition*	GP41-A6	GP41-ED7*	9/17/2018
7-203	*In Vitro* Diagnostics	*Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Sixth Edition*	GP42-A6		7/9/2014
7-213	*In Vitro* Diagnostics	*Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*	GP44-A4		7/9/2014
Hematology					
7-104	*In Vitro* Diagnostics	*Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard—Third Edition*	H07-A3		10/04/2004
7-71	*In Vitro* Diagnostics	*Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard—Third Edition*	H15-A3		3/18/2009
7-165	*In Vitro* Diagnostics	*Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition*	H20-A2		3/16/2012
7-159	*In Vitro* Diagnostics	*Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition*	H21-A5		9/9/2008
7-210	*In Vitro* Diagnostics	*Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard—Second Edition*	H26-A2		1/30/2014
7-105	*In Vitro* Diagnostics	*Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline—Second Edition*	H30-A2		10/04/2004
7-145	*In Vitro* Diagnostics	*Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline—Second Edition*	H42-A2		3/18/2009
7-150	*In Vitro* Diagnostics	*Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline—Second Edition*	H43-A2		3/16/2012
7-205	*In Vitro* Diagnostics	*One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline—Second Edition*	H47-A2		5/5/2010
7-163	*In Vitro* Diagnostics	*Body Fluid Analysis for Cellular Composition; Approved Guideline*	H56-A		9/9/2008
7-220	*In Vitro* Diagnostics	*Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline*	H59-A		1/30/2014

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Immunology and Ligand Assay					
7-136	*In Vitro* Diagnostics	*Quality Assurance of Laboratory Tests for Autoantibodies to Nuclear Antigens: (1) Indirect Fluorescence Assay for Microscopy and (2) Microtiter Enzyme Immunoassay Methods; Approved Guideline—Second Edition*	I/LA02-A2		9/9/2008
7-270	*In Vitro* Diagnostics	*Analytical Performance Characteristics and Clinical Utility of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies and Defined Allergen Specificities; Approved Guideline—Second Edition*	I/LA20-A2	I/LA20-ED3*	8/21/2017
7-170	*In Vitro* Diagnostics	*Clinical Evaluation of Immunoassays; Approved Guideline—Second Edition*	I/LA21-A2		3/18/2009
7-113	*In Vitro* Diagnostics	*Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guideline*	I/LA23-A		11/8/2005
7-219	*In Vitro* Diagnostics	*Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays; Approved Guideline—Second Edition*	I/LA28-A2		8/2/2011
7-176	*In Vitro* Diagnostics	*Immunoassay Interference by Endogenous Antibodies; Approved Guideline*	I/LA30-A		3/18/2009
Method Evaluation					
7-251	*In Vitro* Diagnostics	*Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*	EP05-A3		8/14/2015
7-193	*In Vitro* Diagnostics	*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*	EP06-A		1/30/2014
7-127	*In Vitro* Diagnostics	*Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*	EP07-A2	EP07-ED3*	9/17/2018
7-245	*In Vitro* Diagnostics	*Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*	EP09-A3		1/30/2014
7-152	*In Vitro* Diagnostics	*User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition*	EP12-A2		1/30/2014
7-252	*In Vitro* Diagnostics	*Evaluation of Commutability of Processed Samples; Approved Guideline—Third Edition*	EP14-A3		8/14/2015
7-253	*In Vitro* Diagnostics	*User Verification of Precision and Estimation of Bias; Approved Guideline—Third Edition*	EP15-A3		8/14/2015
7-233	*In Vitro* Diagnostics	*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*	EP17-A2		1/15/2013

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Number	Product Area	Title of Standard or Guideline	Reference Number	CLSI Code or Edition Changes	FDA Publication Date
7-212	*In Vitro* Diagnostics	*Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition*	EP18-A2		10/4/2010
7-266	*In Vitro* Diagnostics	*A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures, Second Edition*	EP19-ED2		9/21/2016
7-268	*In Vitro* Diagnostics	*Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline*	EP21-A	EP21-ED2*	1/15/2013
7-234	*In Vitro* Diagnostics	*Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline—Second Edition*	EP24-A2		8/6/2013
7-235	*In Vitro* Diagnostics	*Evaluation of Stability of* In Vitro *Diagnostic Reagents; Approved Guideline*	EP25-A		1/15/2013
7-291	*In Vitro* Diagnostics	*How to Construct and Interpret an Error Grid for Quantitative Diagnostic Assays, First Edition*	EP27-A		7/15/2019
7-224	*In Vitro* Diagnostics	*Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition*	EP28-A3c		1/30/2014
7-239	*In Vitro* Diagnostics	*Metrological Traceability and Its Implementation; A Report*	EP32-R		1/30/2014
7-290	*In Vitro* Diagnostics	*Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking, First Edition*	EP34-ED1		7/15/2019
7-284	*In Vitro* Diagnostics	*Supplemental Tables for Interference Testing in Clinical Chemistry, First Edition*	EP37-ED1		9/17/2018
Microbiology					
7-258	*In Vitro* Diagnostics	*Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standards—Twelfth Edition*	M02-A12	M02-ED13*	9/17/2018
7-279	*In Vitro* Diagnostics	*Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard—Eleventh Edition*	M07-ED11		9/17/2018
7-228	*In Vitro* Diagnostics	*Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard—Eighth Edition*	M11-A8	M11-ED9*	1/14/2019
7-76	*In Vitro* Diagnostics	*Laboratory Diagnosis of Blood-borne Parasitic Diseases; Approved Guideline*	M15-A		8/20/2012
7-178	*In Vitro* Diagnostics	*Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition*	M22-A3		1/14/2019
7-261	*In Vitro* Diagnostics	*Development of* In Vitro *Susceptibility Testing Criteria and Quality Control Parameters, Fourth Edition*	M23-ED4	M23-ED5*	1/14/2019

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7-288	*In Vitro* Diagnostics	*Susceptibility Testing of Mycobacteria, Nocardiae, and other Aerobic Actinomycetes; Approved Standard—Second Edition*	M24-A2	M24-ED3*	7/15/2019
7-278	*In Vitro* Diagnostics	*Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard—Third Edition*	M27-A3	M27-ED4*	9/17/2018
7-148	*In Vitro* Diagnostics	*Procedures for the Recovery and Identification of Parasites From the Intestinal Tract; Approved Guideline—Second Edition*	M28-A2		8/20/2012
7-180	*In Vitro* Diagnostics	*Western Blot Assay for Antibodies to* Borrelia burgdorferi; *Approved Guideline*	M34-A		3/18/2009
7-197	*In Vitro* Diagnostics	*Abbreviated Identification of Bacteria and Yeast; Approved Guideline—Second Edition*	M35-A2		8/20/2012
7-182	*In Vitro* Diagnostics	*Clinical Use and Interpretation of Serologic Tests for* Toxoplasma gondii; *Approved Guideline*	M36-A		3/18/2009
7-171	*In Vitro* Diagnostics	*Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi; Approved Standard—Second Edition*	M38-A2	M38-ED3*	9/17/2018
7-250	*In Vitro* Diagnostics	*Quality Control of Microbiological Transport Systems; Approved Standard—Second Edition*	M40-A2		1/27/2015
7-185	*In Vitro* Diagnostics	*Viral Culture; Approved Guideline*	M41-A		3/18/2009
7-236	*In Vitro* Diagnostics	*Methods for Antimicrobial Susceptibility Testing for Human Mycoplasmas; Approved Guideline*	M43-A		1/15/2013
7-215	*In Vitro* Diagnostics	*Method for Antifungal Disk Diffusion Susceptibility Testing of Yeast; Approved Guideline—Second Edition*	M44-A2	M44-ED3*	1/14/2019
7-217	*In Vitro* Diagnostics	*Zone Diameter Interpretive Standards, Corresponding Minimal Inhibitory Concentration (MIC) Interpretive Breakpoints, and Quality Control Limits for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Third Informational Supplement*	M44-S3	M60-ED1	8/5/2013
7-262	*In Vitro* Diagnostics	*Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria, Third Edition*	M45-ED3		1/14/2019
7-189	*In Vitro* Diagnostics	*Principles and Procedures for Blood Cultures; Approved Guideline*	M47-A		3/18/2009
7-200	*In Vitro* Diagnostics	*Laboratory Detection and Identification of Mycobacteria; Approved Guideline*	M48-A	M48-ED2*	1/14/2019
7-190	*In Vitro* Diagnostics	*Quality Control for Commercial Microbial Identification Systems; Approved Guideline*	M50-A		3/18/2009

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7-243	*In Vitro* Diagnostics	*Method for Antifungal Disk Diffusion Susceptibility Testing of Nondermatophyte Filamentous Fungi; Approved Guideline*	M51-A		8/6/2013
7-292	*In Vitro* Diagnostics	*Performance Standards for Susceptibility Testing of Mycobacteria, Nocardia spp., and Other Aerobic Actinomycetes, First Edition*	M52-ED1		7/15/2019
7-227	*In Vitro* Diagnostics	*Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection; Approved Guideline*	M53-A		3/6/2012
7-257	*In Vitro* Diagnostics	*Principles and procedures for Detection of Anaerobes in Clinical Specimens; Approved Guideline*	M56-A		8/14/2015
7-273	*In Vitro* Diagnostics	*Methods for the Identification of Cultured Microorganisms Using Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry, First Edition*	M58-ED1		8/21/2017
7-217	*In Vitro* Diagnostics	*Performance Standards for Antifungal Susceptibility Testing of Yeasts, First Edition*	M60-ED1		9/17/2019
7-281	*In Vitro* Diagnostics	*Performance Standards for Antimicrobial Susceptibility Testing, Twenty-Eighth Edition*	M100-ED28	M100-ED29*	9/17/2018
Molecular Methods					
7-237	*In Vitro* Diagnostics	*Molecular Methods for Clinical Genetics and Oncology Testing; Approved Guideline—Third Edition*	MM01-A3		1/15/2013
7-260	*In Vitro* Diagnostics	*Molecular Diagnostic Methods for Infectious Diseases, Third Edition*	MM03-ED3		4/4/2016
7-232	*In Vitro* Diagnostics	*Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline—Second Edition*	MM05-A2		1/14/2019
7-238	*In Vitro* Diagnostics	*Quantitative Molecular Methods for Infectious Diseases; Approved Guideline—Second Edition*	MM06-A2		1/14/2019
7-255	*In Vitro* Diagnostics	*Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline*	MM09-A	MM09-A2*	08/14/2015
7-191	*In Vitro* Diagnostics	*Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline*	MM13-A		3/18/2009
7-274	*In Vitro* Diagnostics	*Verification and Validation of Multiplex Nucleic Acid Assays, Second Edition*	MM17-ED2		7/15/2019
7-192	*In Vitro* Diagnostics	*Interpretive Criteria for Identification of Bacteria and Fungi by DNA Target Sequencing; Approved Guideline*	MM18-A	MM18-ED2*	3/18/2009

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7-264	*In Vitro* Diagnostics	*Genomic Copy Number Microarrays for Constitutional Genetic and Oncology Applications, First Edition*	MM21-ED1		6/27/2016
7-269	*In Vitro* Diagnostics	*Molecular Diagnostic Methods for Solid Tumors (Nonhematological Neoplasms), First Edition*	MM23-ED1		1/14/2019
Newborn Screening					
7-244	*In Vitro* Diagnostics	*Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Sixth Edition*	NBS01-A6		1/30/2014
Point-of-Care Testing					
13-14	Software/ Informatics	*Point-of-Care Connectivity; Approved Standard—Second Edition*	POCT01-A2		9/9/2008
7-283	Software/ Informatics	*Essential Tools for Implementation and Management of a Point-of-Care Testing Program, Third Edition*	POCT04-ED3		9/17/2018
7-209	*In Vitro* Diagnostics	*Performance Metrics for Continuous Interstitial Glucose Monitoring; Approved Guideline*	POCT05-A		5/5/2010
7-112	*In Vitro* Diagnostics	*Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline*	POCT14-A		7/9/2014
Quality Management Systems					
7-226	*In Vitro* Diagnostics	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*	QMS01-A4	QMS01-ED5*	1/30/2014
7-223	*In Vitro* Diagnostics	*Quality Management System: Continual Improvement; Approved Guideline—Third Edition*	QMS06-A3		1/30/2014
7-139	*In Vitro* Diagnostics	*Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality, Third Edition*	QMS24-ED3		1/14/2019

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