M100-S21
Vol. 31 No. 1
Replaces M100-S20 and M100-S20-U
Vol. 30 No. 1 and Vol. 30 No. 15

January 2011

Performance Standards for Antimicrobial Susceptibility Testing; Twenty-First Informational Supplement

This document provides updated tables for the Clinical and Laboratory Standards Institute antimicrobial susceptibility testing standards M02-A10 and M07-A8.

An informational supplement for global application developed through the Clinical and Laboratory Standards Institute consensus process.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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Advancing Quality in Health Care Testing

The Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related health care issues. Our process is based on the principle that consensus is an effective and cost-effective way to improve patient testing and health care services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, we provide an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

A document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

CONSENSUS PROCESS

The CLSI voluntary consensus process is a protocol establishing formal criteria for

- The authorization of a project
- The development and open review of documents
- The revision of documents in response to comments by users
- The acceptance of a document as a consensus standard or guideline

Most documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate consensus level.

Proposed A consensus document undergoes the first stage of review by the health care community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Approved An approved standard or guideline has achieved consensus within the health care community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (ie, that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

Our standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following CLSI's established consensus procedures. Provisions in CLSI standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are addressed by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any document. Address comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Health care professionals in all specialties are urged to volunteer for participation in CLSI projects. Please contact us at customerservice@clsi.org or +610.688.0100 for additional information on committee participation.

Performance Standards for Antimicrobial Susceptibility Testing; Twenty-First Informational Supplement

Abstract

The supplemental information presented in this document is intended for use with the antimicrobial susceptibility testing procedures published in the following Clinical and Laboratory Standards Institute (CLSI)–approved standards: M02-A10—*Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard—Tenth Edition*; and M07-A8—*Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard—Eighth Edition*. The standards contain information about both disk (M02) and dilution (M07) test procedures for aerobic bacteria.

Clinicians depend heavily on information from the clinical microbiology laboratory for treatment of their seriously ill patients. The clinical importance of antimicrobial susceptibility test results requires that these tests be performed under optimal conditions and that laboratories have the capability to provide results for the newest antimicrobial agents.

The tabular information presented here represents the most current information for drug selection, interpretation, and quality control using the procedures standardized in M02 and M07. Users should replace the tables published earlier with these new tables. (Changes in the tables since the most current edition appear in boldface type.)

Clinical and Laboratory Standards Institute. *Performance Standards for Antimicrobial Susceptibility Testing; Twenty-First Informational Supplement.* CLSI document M100-S21 (ISBN 1-56238-742-1). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2011.

The data in the interpretive tables in this supplement are valid only if the methodologies in M02-A10—*Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard—Tenth Edition*; and M07-A8—*Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard—Eighth Edition* are followed.

Suggested Citation

CLSI. *Performance Standards for Antimicrobial Susceptibility Testing; Twenty-First Informational Supplement.* CLSI document M100-S21. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Twenty-First Informational Supplement
January 2011

Twentieth Informational Supplement (Update)
June 2010

Twentieth Informational Supplement
January 2010

Nineteenth Informational Supplement
January 2009

Eighteenth Informational Supplement
January 2008

Seventeenth Informational Supplement
January 2007

Sixteenth Informational Supplement
January 2006

Fifteenth Informational Supplement
January 2005

Fourteenth Informational Supplement
January 2004

Thirteenth Informational Supplement
January 2003

Twelfth Informational Supplement
January 2002

Eleventh Informational Supplement
January 2001

Tenth Informational Supplement
January 2000

Ninth Informational Supplement
January 1999

ISBN 1-56238-742-1
ISSN 0273-3099

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Summary of Major Changes in This Document

This list includes the "major" changes in this document. Other minor or editorial changes were made to the general formatting and to some of the table footnotes and comments. Changes to the tables since the previous edition appear in boldface type.

Additions, Changes, and Deletions

The following table indicates renaming, renumbering, and/or relocating of various tables or appendixes.

Previous Designation	New M100-S21 Designation and/or Location
• Table 1. Groupings of Antimicrobial Agents for Routine Testing and Reporting (Nonfastidious Organisms)	• Table 1A. Groupings of Antimicrobial Agents for Routine Testing and Reporting (Nonfastidious Organisms)
• Table 1A. Groupings of Antimicrobial Agents for Routine Testing and Reporting (Fastidious Organisms)	• Table 1B. Groupings of Antimicrobial Agents for Routine Testing and Reporting (Fastidious Organisms)
• Table 3. Disk Diffusion Testing—Acceptable Limits (mm) for Quality Control Strains Used to Monitor Accuracy; Nonfastidious Organisms Using Mueller-Hinton Medium Without Blood or Other Supplements	• Table 3A. Disk Diffusion: Quality Control Ranges for Nonfastidious Organisms (Unsupplemented Mueller-Hinton Medium)
• Table 3A. Disk Diffusion Testing—Acceptable Limits (mm) for Quality Control Strains Used to Monitor Accuracy; Fastidious Organisms	• Table 3B. Disk Diffusion: Quality Control Ranges for Fastidious Organisms
• Table 3B. Disk Diffusion Testing—Reference Guide to Quality Control Testing Frequency	• Table 3C. Disk Diffusion: Reference Guide to Quality Control Frequency
• Table 3C. Disk Diffusion Quality Control Troubleshooting Guide	• Table 3D. Disk Diffusion: Troubleshooting Guide
• Table 4. MIC Testing—Acceptable Limits (μg/mL) for Quality Control Strains Used to Monitor Accuracy; Nonfastidious Organisms Using Mueller-Hinton Medium (Cation-Adjusted if Broth) Without Blood or Other Nutritional Supplements	• Table 4A. MIC: Quality Control Ranges for Nonfastidious Organisms (Unsupplemented Mueller-Hinton Medium [Cation-Adjusted if Broth])
• Table 4A. MIC Testing—Acceptable Limits (μg/mL) for Quality Control Strains Used to Monitor Accuracy; Fastidious Organisms Using Dilution Methods	• Table 4B. MIC: Quality Control Ranges for Fastidious Organisms (Broth Dilution Methods)
• Table 4B. MIC Testing—Acceptable Limits (μg/mL) for Quality Control Strains Used to Monitor Accuracy; Fastidious Organisms Using Agar Dilution	• Table 4C. MIC: Quality Control for *Neisseria gonorrhoeae* (Agar Dilution Method)
• Table 4E. MIC Testing—Reference Guide to Quality Control Testing Frequency	• Table 4F. MIC: Reference Guide to Quality Control Frequency
• Table 4F. MIC Testing Quality Control Troubleshooting Guide	• Table 4G. MIC: Troubleshooting Guide
• Table 5. Solvents and Diluents for Preparation of Stock Solutions of Antimicrobial Agents	• Table 5A. Solvents and Diluents for Preparation of Stock Solutions of Antimicrobial Agents

Summary of Major Changes in This Document (Continued)

• Table 5A. Preparation of Stock Solutions for Antimicrobial Agents Provided With Activity Expressed as Units	• Table 5B. Preparation of Stock Solutions for Antimicrobial Agents Provided With Activity Expressed as Units
• Table 5B. Preparation of Solutions and Media Containing Combinations of Antimicrobial Agents	• Table 5C. Preparation of Solutions and Media Containing Combinations of Antimicrobial Agents
• Table 6. Scheme for Preparing Dilutions of Antimicrobial Agents to Be Used in Agar Dilution Susceptibility Tests	• Table 6A. Scheme for Preparing Dilutions of Antimicrobial Agents to Be Used in Agar Dilution Susceptibility Tests
• Table 7. Scheme for Preparing Dilutions of Antimicrobial Agents to Be Used in Broth Dilution Susceptibility Tests	• Table 7A. Scheme for Preparing Dilutions of Antimicrobial Agents to Be Used in Broth Dilution Susceptibility Tests
• Table 7A. Scheme for Preparing Dilutions of Water-Insoluble Agents to Be Used in Broth Dilution Susceptibility Tests	• Table 7B. Scheme for Preparing Dilutions of Water-Insoluble Agents to Be Used in Broth Dilution Susceptibility Tests
• Appendix B. Quality Control Strains for Antimicrobial Susceptibility Tests	• Appendix C. Quality Control Strains for Antimicrobial Susceptibility Tests
• Appendix C. Cumulative Antimicrobial Susceptibility Report for *Bacteroides fragilis* Group Organisms	• Appendix D. Cumulative Antimicrobial Susceptibility Report for *Bacteroides fragilis* Group Organisms

The following are additions or changes unless otherwise noted as a "***deletion.***"

Introduction to Tables 1 and 2

Deleted in Warning Table the listing for Table 2A ESBL-producing *K. pneumoniae, K. oxytoca, E. coli*, and *P. mirabilis* now that revised cephalosporin breakpoints have been published.

Deleted in Warning Table the listing for Table 2K *Yersinia pestis,* because this table was deleted from M100 and moved to CLSI document M45.

Tables 1A, 1B, and 1C—Drugs Recommended for Testing and Reporting

Enterobacteriaceae:
Added information on testing chloramphenicol on extraintestinal isolates of *Salmonella* spp. (p. 30).

Staphylococcus spp.:
Added minocycline to Test Report Group B (p. 30).

Haemophilus spp.:
Deleted footnote for meropenem.

Streptococcus spp. β-hemolytic Group:
Added information that routine testing of penicillin and ampicillin is not necessary (pp. 36 and 39).

Deleted Table 1B. Agents Tested and Reported on Potential Bacterial Agents of Bioterrorism and moved to CLSI document M45.

Anaerobes:
Suggested Groupings of Antimicrobial Agents to Be Considered for Testing Anaerobes (New) Table 1C (p. 40).

Summary of Major Changes in This Document (Continued)

Tables 2A Through 2J—Interpretive Criteria (Breakpoints)

All Tables: Revised the statement regarding boldface type to explain that bolded information is new or modified since the previous edition.

***Enterobacteriaceae* (Table 2A):**
Added information on the dosage regimens listed for some antimicrobial agents and recommendations for reporting when implementing new breakpoints (p. 42).

New (revised) breakpoints for cefazolin with dosage regimen on which the breakpoints are based (p. 43).

***Pseudomonas aeruginosa* (Table 2B-1):**
Added information on the dosage regimens listed for some antimicrobial agents and recommendations for reporting when implementing new breakpoints (p. 60).

Added dosage regimens for ceftazidime, cefepime, and aztreonam (p. 61).

Deleted ceftizoxime, cefoperazone, moxalactam, ceftriaxone, and cefotaxime, because several of these agents are no longer available or have limited indications for *P. aeruginosa.*

***Staphylococcus* spp. (Table 2C):**
Clarified "relevant cephems" in comment (9) (p. 70).

Clarified performance of induced β-lactamase testing on *S. aureus* isolates (p. 70).

Added information on not reporting daptomycin for isolates from the lower respiratory tract (p. 74).

***Enterococcus* spp. (Table 2D):**
Added information on not reporting daptomycin for isolates from the lower respiratory tract (p. 85).

***Haemophilus influenzae* and *Haemophilus parainfluenzae* (Table 2E):**
Clarified that recommendations in Table 2E are specifically for *H. influenzae* and *H. parainfluenzae* (p. 88).

***Streptococcus* spp. β-Hemolytic Group (Table 2H-1):**
Incorporated recommendations from comment (7) for nonsusceptible penicillin and ampicillin isolates being sent to a public health laboratory into revised comment (3) (p. 100). Comment (7) was then ***deleted***.

Added information on not reporting daptomycin for isolates from the lower respiratory tract (p. 101).

Added new supplemental table for screening for inducible clindamycin resistance at the end of Table 2H-1 (p. 103).

Deleted Table 2I, Zone Diameter and MIC Interpretive Standards for *Vibrio cholerae* and moved to CLSI document M45.

Deleted Table 2K. MIC Interpretive Standards (µg/mL) for Potential Agents of Bioterrorism: *Bacillus anthracis, Yersinia pestis, Burkholderia mallei, Burkholderia pseudomallei, Francisella tularensis,* and *Brucella* spp. and moved to CLSI document M45.

Summary of Major Changes in This Document (Continued)

Anaerobes:
MIC Interpretive Standards for Anaerobes (New) Table 2J (p. 112).

Deleted Table 2L, MIC Interpretive Standards for *Helicobacter pylori* and moved to CLSI document M45.

Tables 3 and 4—Quality Control

Table 3A:

Recommendations added for QC when testing β-lactam/β-lactamase inhibitors with *Escherichia coli* ATCC® 35218 (p. 114).

S. aureus QC recommendations added to razupenem/*S. aureus* ATCC® 25923 (p. 115).

Table 4A:
QC range added for ceftaroline/*E. faecalis* ATCC® 29212 (p. 122).

Recommendations added for QC when testing β-lactam/β-lactamase inhibitors with *Escherichia coli* ATCC® 35218 (p. 123).

Table 4B:

Separate column made for *Neisseria meningitidis* testing conditions (p. 125).

Deleted QC ranges and testing conditions for *Helicobacter pylori* and moved to CLSI document M45.

Previous Tables 4C and 4D:

Deleted QC ranges for QC strains used for potential agents of bioterrorism (previous Tables 4C and 4D) and moved them to CLSI document M45.

Table 4D:

MIC: Quality Control Ranges for Anaerobes (Agar Dilution Method) added as new Table 4D (p. 127).

Table 4E:

MIC: Quality Control Ranges for Anaerobes (Broth Microdilution Method) added as new Table 4E (p. 128).

Table 5A:

Added: Amoxicillin-clavulanic acid (p. 134)
Nitazoxanide (p. 135)
Ramoplanin (p. 135)
Rifaximin (p. 135)
Ticarcillin-clavulanic acid (p. 136)
Tinidazole (p. 136)
Tizoxanide (p. 136)

Summary of Major Changes in This Document (Continued)

Revised solvent for ceftaroline (p. 134).

Added information for the final concentration of dimethyl sulfoxide (DMSO) (p. 136).

Appendixes and Glossaries

Updated Appendix A and included an additional category (III) for organisms that may be common but are generally considered of epidemiological concern (p. 144).

Intrinsic Resistance—*Enterobacteriaceae* (New) Appendix B (p. 147).

Updated Appendix D to include more current data (p. 151).

Cumulative Antimicrobial Susceptibility Report for Various Anaerobic Organisms (New) Appendix E (p. 152).

Glossaries I and II—Added fidaxomicin to a new antimicrobial class (pp. 155 and 157).

Glossary II – Added metronidazole (p. 157)

Summary of CLSI Processes for Establishing Interpretive Criteria and Quality Control Ranges

The Clinical and Laboratory Standards Institute (CLSI) is an international, voluntary, nonprofit, interdisciplinary, standards-developing, and educational organization accredited by the American National Standards Institute (ANSI) that develops and promotes use of consensus-developed standards and guidelines within the health care community. These consensus standards and guidelines are developed to address critical areas of diagnostic testing and patient health care, and are developed in an open and consensus-seeking forum. CLSI is open to anyone or any organization that has an interest in diagnostic testing and patient care. Information about CLSI can be found at www.clsi.org.

The CLSI Subcommittee on Antimicrobial Susceptibility Testing (AST) reviews data from a variety of sources and studies (eg, *in vitro,* pharmacokinetics/pharmacodynamics, and clinical studies) to establish antimicrobial susceptibility test methods, interpretive criteria, and quality control (QC) parameters. The details of the data required to establish interpretive criteria, QC parameters, and how the data are presented for evaluation are described in CLSI document M23—*Development of* In Vitro *Susceptibility Testing Criteria and Quality Control Parameters.*

Over time, a microorganism's susceptibility to an antimicrobial agent may decrease, resulting in a lack of clinical efficacy and/or safety. In addition, microbiological methods and QC parameters may be refined to ensure more accurate and better performance of susceptibility test methods. Because of this, CLSI continually monitors and updates information in its documents. Although CLSI standards and guidelines are developed using the most current information and thinking available at the time, the field of science and medicine is ever changing; therefore, standards and guidelines should be used in conjunction with clinical judgment, current knowledge, and clinically relevant laboratory test results to guide patient treatment.

Additional information, updates, and changes in this document are found in the meeting summary minutes of the Subcommittee on Antimicrobial Susceptibility Testing at www.clsi.org (from homepage: Committees → Microbiology → S/C Antimicrobial Susceptibility Testing).

CLSI Reference Methods vs Commercial Methods and CLSI vs FDA Breakpoints (interpretive criteria)

It is important for users of M02-A10, M07-A8, and the M100 Informational Supplement to recognize that the standard methods described in CLSI documents are reference methods. These methods may be used for routine AST of clinical isolates, for evaluation of commercial devices that will be used in clinical laboratories, or by drug or device manufacturers for testing of new agents or systems. Results generated by reference methods, such as those contained in CLSI documents, may be used by regulatory authorities to evaluate the performance of commercial susceptibility testing devices as part of the approval process. Clearance by a regulatory authority indicates that the commercial susceptibility testing device provides susceptibility results that are substantially equivalent to results generated using reference methods for the organisms and antimicrobial agents described in the device manufacturer's approved package insert.

CLSI breakpoints may differ from those approved by various regulatory authorities for many reasons, including the following: different databases, differences in interpretation of data, differences in doses used in different parts of the world, and public health policies. Differences also exist because CLSI proactively evaluates the need for changing breakpoints. The reasons why breakpoints may change and the manner in which CLSI evaluates data and determines breakpoints are outlined in CLSI document M23—*Development of* In Vitro *Susceptibility Testing Criteria and Quality Control Parameters*.

Following a decision by CLSI to change an existing breakpoint, regulatory authorities may also review data in order to determine how changing breakpoints may affect the safety and effectiveness of the antimicrobial agent for the approved indications. If the regulatory authority changes breakpoints, commercial device manufacturers may have to conduct a clinical laboratory trial, submit the data to the regulatory authority, and await review and approval. For these reasons, a delay of one or more years may be required if an interpretive breakpoint change is to be implemented by a device manufacturer. In the United States, laboratories that use Food and Drug Administration (FDA)–approved susceptibility testing devices are allowed to use existing FDA interpretive breakpoints. Either FDA or CLSI susceptibility interpretive breakpoints are acceptable to clinical laboratory accrediting bodies. Policies in other countries may vary.

Following discussions with appropriate stakeholders, such as infectious disease practitioners and the pharmacy department, as well as the Pharmacy and Therapeutics and Infection Control committees of the medical staff, newly approved or revised breakpoints may be implemented by clinical laboratories. CLSI disk diffusion test breakpoints may be implemented as soon as they are published in M100. If a device includes antimicrobial test concentrations sufficient to allow interpretation of susceptibility and resistance to an agent using the CLSI breakpoints, a laboratory could, after appropriate validation, choose to interpret and report results using CLSI breakpoints.

Subcommittee on Antimicrobial Susceptibility Testing Mission Statement

The Subcommittee on Antimicrobial Susceptibility Testing is composed of representatives from the professions, government, and industry, including microbiology laboratories, government agencies, health care providers and educators, and pharmaceutical and diagnostic microbiology industries. Using the CLSI voluntary consensus process, the subcommittee develops standards that promote accurate antimicrobial susceptibility testing and appropriate reporting.

The mission of the Subcommittee on Antimicrobial Susceptibility Testing is to:

- Develop standard reference methods for antimicrobial susceptibility tests.
- Provide QC parameters for standard test methods.
- Establish interpretive criteria for the results of standard antimicrobial susceptibility tests.
- Provide suggestions for testing and reporting strategies that are clinically relevant and cost-effective.
- Continually refine standards and optimize detection of emerging resistance mechanisms through development of new or revised methods, interpretive criteria, and QC parameters.
- Educate users through multimedia communication of standards and guidelines.
- Foster a dialog with users of these methods and those who apply them.

The ultimate purpose of the subcommittee's mission is to provide useful information to enable laboratories to assist the clinician in the selection of appropriate antimicrobial therapy for patient care. The standards and guidelines are meant to be comprehensive and to include all antimicrobial agents for which the data meet established CLSI guidelines. The values that guide this mission are quality, accuracy, fairness, timeliness, teamwork, consensus, and trust.

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI document HS01—*A Quality Management System Model for Health Care.* The quality management system approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any health care service's path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The QSEs are:

Documents and Records	Equipment	Information Management	Process Improvement
Organization	Purchasing and Inventory	Occurrence Management	Customer Service
Personnel	Process Control	Assessments—External and Internal	Facilities and Safety

M100-S21 addresses the QSEs indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Documents and Records	Organization	Personnel	Equipment	Purchasing and Inventory	Process Control	Information Management	Occurrence Management	Assessments—External and Internal	Process Improvement	Customer Service	Facilities and Safety
M07					M02 M07 M11 M23 M27 M31 M37 M39 M45						

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care*.

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow, which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

M100-S21 addresses the clinical laboratory path of workflow steps indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				**Examination**			**Postexamination**	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
					X	X	X	
				M02	M02	M02	M02	
				M07	M07	M07	M07	
					M11	M11	M11	
				M27	M27	M27	M27	M27
				M31	M31	M31	M31	

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care*.

Related CLSI Reference Materials*

M02-A10 **Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard—Tenth Edition (2009).** This standard contains the current Clinical and Laboratory Standards Institute-recommended methods for disk susceptibility testing, criteria for quality control testing, and updated tables for interpretive zone diameters.

M07-A8 **Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard—Eighth Edition (2009).** This document addresses reference methods for the determination of minimal inhibitory concentrations (MICs) of aerobic bacteria by broth macrodilution, broth microdilution, and agar dilution.

M11-A7 **Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard—Seventh Edition (2007).** This standard provides reference methods for the determination of minimal inhibitory concentrations (MICs) of anaerobic bacteria by broth microdilution and agar dilution.

M23-A3 **Development of *In Vitro* Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline—Third Edition (2008).** This document addresses the required and recommended data needed for the selection of appropriate interpretive criteria and quality control ranges for antimicrobial agents.

M27-A3 **Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard—Third Edition (2008).** This document addresses the selection and preparation of antifungal agents; implementation and interpretation of test procedures; and quality control requirements for susceptibility testing of yeasts that cause invasive fungal infections.

M31-A3 **Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals; Approved Standard—Third Edition (2008).** This document provides the currently recommended techniques for antimicrobial agent disk and dilution susceptibility testing, criteria for quality control testing, and interpretive criteria for veterinary use.

M37-A3 **Development of *In Vitro* Susceptibility Testing Criteria and Quality Control Parameters for Veterinary Antimicrobial Agents; Approved Guideline—Third Edition (2008).** This document addresses the required and recommended data needed for selection of appropriate interpretive standards and quality control guidance for new veterinary antimicrobial agents.

M39-A3 **Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline—Third Edition (2009).** This document describes methods for recording and analysis of antimicrobial susceptibility test data, consisting of cumulative and ongoing summaries of susceptibility patterns of clinically significant microorganisms.

M45-A2 **Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline—Second Edition (2010).** This document provides guidance to clinical microbiology laboratories for standardized susceptibility testing of infrequently isolated or fastidious bacteria that are not presently included in CLSI documents M02 or M07. The tabular information in this document presents the most current information for drug selection, interpretation, and quality control for the infrequently isolated or fastidious bacterial pathogens included in this guideline.

*CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

NOTES

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Bio-Rad Laboratories, Inc. - France
Bio-Reference Laboratories
Bioanalyse, Ltd.
BioDevelopment S.r.l.
Biohit Oyj.
Biomedia Laboratories SDN BHD
bioMérieux, Inc.
Blaine Healthcare Associates, Inc.
The Clinical Microbiology Institute
BRI Consultants Limited
Calloway Laboratories
Canon U.S. Life Sciences, Inc.
Cempra Pharmaceuticals, Inc.
Cepheid
The Clinical Microbiology Institute
Compliance Insight, Inc.
Constitution Medical Inc
Controllab
Copan Diagnostics Inc.
Crescendo Bioscience
Cubist Pharmaceuticals, Inc.
Dahl-Chase Pathology Associates PA
Diagnostica Stago
Docro, Inc.
DX Assays Pte Ltd.
Eiken Chemical Company, Ltd.
Elanco Animal Health
Elkin Simson Consulting Services
Emika Consulting
Enigma Diagnostics
Eurofins Medinet
Evidia Biosciences Inc.
Gen-Probe
Genzyme Diagnostics
GlaxoSmithKline
Greiner Bio-One Inc.
Habig Regulatory Consulting
HandyLab Inc.
Himedia Labs Ltd
HistoGenex N.V.
Icon Laboratories, Inc.
Innovotech, Inc.
Instrumentation Laboratory
Integrated BioBank
IntelligentMDx, Inc.
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Japan Assn. of Clinical Reagents Industries
Johnson & Johnson Pharmaceutical Research & Develop., L.L.C.
Kaiser Permanente
KoreaBIO
Krouwer Consulting
Lab PMM
Laboratory Specialists, Inc.
LifeLabs
LifeScan, Inc.
Liofilchem SRL
LipoScience, Inc.
Maine Standards Company, LLC
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Medical Device Consultants, Inc.
The Medicines Company
Merck & Company, Inc.
Merial Limited
Micromyx, LLC
Nanosphere, Inc.
Nihon Kohden Corporation
Nissui Pharmaceutical Co., Ltd.
NJK & Associates, Inc.
NorDx - Scarborough Campus
NovaBiotics
Novartis Institutes for Biomedical Research
OncoMethylome Sciences S.a.
Optimer Pharmaceuticals, Inc.
Ortho-Clinical Diagnostics, Inc.
Ortho-McNeil, Inc.
Paratek Pharmaceuticals, Inc.
PathCare Pathology Laboratory
PerkinElmer Genetics, Inc
Pfizer Animal Health
Pfizer Inc
Pfizer Italia Srl
Phadia AB
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PPD
ProteoGenix, Inc.
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Therapeutic Monitoring Services, LLC
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Baptist Memorial Hospital East (TN)
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Changhua Christian Hospital (Taiwan)
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CHC Labs (FL)
Chester County Hospital (PA)
Children's Healthcare of Atlanta (GA)
Childrens Hosp.- Kings Daughters (VA)
Children's Hospital & Research Center At Oakland (CA)
Childrens Hospital Los Angeles (CA)
Children's Hospital Medical Center (OH)
Children's Hospital of Central California (CA)
Children's Hospital of Philadelphia (PA)
Childrens Hospital of Wisconsin (WI)
Children's Hospitals and Clinics (MN)
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Children's Memorial Hospital (IL)
The Children's Mercy Hospital (MO)
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Clearstone Central Laboratories (ON, Canada)
Cleveland Clinic (OH)
Cleveland Heartlab, LLC (OH)
Clinical Hospital Merkur (Croatia)
Clinical Labs of Hawaii (HI)
Clinton Memorial Hospital (OH)
Colchester East Hants Health Authority (NS, Canada)
Colegio De Tecnologos Medicos De Puerto (PR)
College of Physicians and Surgeons of Alberta (AB, Canada)
Collingwood General & Marine Hospital (ON, Canada)
Columbia Regional Hospital (MO)
Commonwealth of Virginia (DCLS) (VA)
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Community Hospital of the Monterey Peninsula (CA)
Community Medical Center (NJ)
Community Memorial Hospital (WI)
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Consultants Laboratory of WI LLC (WI)
Contra Costa Regional Medical Center (CA)
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The Cooley Dickinson Hospital, Inc. (MA)
Corniche Hospital (United Arab Emirates)
Cornwall Community Hospital (ON, Canada)
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Covance CLS (IN)
The Credit Valley Hospital (ON, Canada)
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Creighton University Medical Center (NE)
Crozer-Chester Medical Center (PA)
Cumberland Medical Center (TN)
Darwin Library NT Territory Health Services (NT, Australia)
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Daviess Community Hospital (IN)
Deaconess Hospital Laboratory (IN)
Dean Medical Center (WI)
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Dynacare Laboratory (WI)
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DynaLIFE (AB, Canada)
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Eastern Health - Health Sciences Centre (NL, Canada)
Eastern Health Pathology (Victoria, Australia)
Easton Hospital (PA)
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Effingham Hospital (GA)
Eliza Coffee Memorial Hospital (AL)
Elmhurst Hospital Center (NY)
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Evangelical Community Hospital (PA)
Evans Army Community Hospital (CO)
Exeter Hospital (NH)
Exosome Diagnostics, Inc. (MN)
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Florida Hospital (FL)
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Fort St. John General Hospital (BC, Canada)
Forum Health Northside Medical Center (OH)
Fox Chase Cancer Center (PA)
Franciscan Skemp Medical Center (WI)
Fraser Health Authority Royal Columbian Hospital Site (BC, Canada)
Fresenius Medical Care/Spectra East (NJ)
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Garfield Medical Center (CA)
Gaston Memorial Hospital (NC)
Geisinger Medical Center (PA)
Genesis Healthcare System (OH)
George Washington University Hospital (DC)
Ghent University Hospital (Belgium)
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Good Shepherd Medical Center (TX)
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Grey Bruce Regional Health Center (ON, Canada)
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Harrison Medical Center (WA)
Hartford Hospital (CT)
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Heartland Health (MO)
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Holy Spirit Hospital (PA)
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Hopital Maisonneuve-Rosemont (PQ, Canada)
Hopital Santa Cabrini Ospedale (PQ, Canada)
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John Muir Health (CA)
Johns Hopkins Medical Institutions (MD)
Johns Hopkins University (MD)
Johnson City Medical Center Hospital (TN)
JPS Health Network (TX)
Kailos Genetics (AL)
Kaiser Permanente (MD)
Kaiser Permanente (OH)
Kaiser Permanente Medical Care (CA)
Kaleida Health Center for Laboratory Medicine (NY)
Kantonsspital Aarau AG (AG) Switzerland
Kenora-Rainy River Reg. Lab. Program (ON, Canada)
King Abdulaziz Hospital, Al Ahsa Dept. of Pathology & Laboratory Medicine (Al-hasa, Saudi Arabia)
King Abdulaziz Medical City - Jeddah National Guard Health Affairs (WR, Saudi Arabia)
King Fahad National Guard Hospital KAMC - NGHA (Saudi Arabia)
King Fahad Specialist Hospital-Dammam, K.S.A. (Eastern Region) Saudi Arabia
King Faisal Specialist Hospital (MD)
King Faisal Specialist Hospital & Research Center (Saudi Arabia)
King Hussein Cancer Center (Jordan)
Kings County Hospital Center (NY)
King's Daughters Medical Center (KY)
Kingston General Hospital (ON, Canada)
Lab Medico Santa Luzia LTDA (Brazil)
Labette Health (KS)
Laboratory Alliance of Central New York (NY)
Laboratory Corporation of America (NJ)
LabPlus Auckland District Health Board (New Zealand)
LAC/USC Medical Center (CA)
Lafayette General Medical Center (LA)
Lakeland Regional Medical Center (FL)
Lancaster General Hospital (PA)
Landstuhl Regional Medical Center (AE)
Langley Air Force Base (VA)
Laredo Medical Center (TX)
LeBonheur Children's Medical Center (TN)
Legacy Laboratory Services (OR)
Lewis-Gale Medical Center (VA)
L'Hotel-Dieu de Quebec (PQ, Canada)
Licking Memorial Hospital (OH)
LifeLabs Medical Laboratory Services (BC, Canada)
Loma Linda University Medical Center (LLUMC) (CA)
Long Beach Memorial Medical Center-LBMMC (CA)
Long Island Jewish Medical Center (NY)
Louisiana Office of Public Health Laboratory (LA)
Louisiana State University Medical Ctr. (LA)
Lourdes Hospital (KY)
Lower Columbia Pathologists, P.S. (WA)
Maccabi Medical Care and Health Fund (Israel)
Madigan Army Medical Center (WA)
Mafraq Hospital (United Arab Emirates)
Magnolia Regional Health Center (MS)
Main Line Clinical Laboratories, Inc. (PA)
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Martha Jefferson Hospital (VA)
Martin Luther King, Jr.-Harbor Hospital (CA)
Martin Memorial Health Systems (FL)
Mary Hitchcock Memorial Hospital (NH)
Mary Imogene Bassett Hospital (NY)
Mary Washington Hospital (VA)
Massachusetts General Hospital (MA)
Mater Health Services - Pathology (Australia)
Maxwell Air Force Base (AL)
Mayo Clinic (MN)
MCG Health (GA)
Meadows Regional Medical Center (GA)
Medecin Microbiologiste (Quebec, Canada)
Medical Center Hospital (TX)
Medical Center of Louisiana At NO-Charity (LA)
Medical Centre Ljubljana (Slovenia)
Medical College of Virginia Hospital (VA)
Medical University of South Carolina (SC)
Memorial Hermann Healthcare System (TX)
Memorial Hospital at Gulfport (MS)
Memorial Medical Center (PA)
Memorial Medical Center (IL)
Memorial Regional Hospital (FL)
Mercy Franciscan Mt. Airy (OH)
Mercy Hospital & Medical Center (IL)
Methodist Dallas Medical Center (TX)
Methodist Hospital (PA)
Methodist Hospital (TX)
Methodist Hospital Park Nicollet Health Services (MN)
Methodist Hospital Pathology (NE)
MetroHealth Medical Center (OH)
Metropolitan Hospital Center (NY)
Metropolitan Medical Laboratory, PLC (IA)
Miami Children's Hospital (FL)
The Michener Inst. for Applied Health Sciences (ON, Canada)
Middelheim General Hospital (Belgium)
Middlesex Hospital (CT)
Minneapolis Medical Research Foundation (MN)
Mississippi Baptist Medical Center (MS)
Mississippi Public Health Lab (MS)
Monongalia General Hospital (WV)
Montreal General Hospital (Quebec, Canada)
Mt. Carmel Health System (OH)
Mt. Sinai Hospital (ON, Canada)
Mt. Sinai Hospital - New York (NY)
Naples Community Hospital (FL)
Nassau County Medical Center (NY)
National B Virus Resource Laboratory (GA)
National Cancer Center (Republic of Korea)
National Institutes of Health, Clinical Center (MD)
National Naval Medical Center (MD)
National University Hospital Department of Laboratory Medicine (Singapore)
National University of Ireland, Galway (NUIG) (Ireland)
Nationwide Children's Hospital (OH)
Nationwide Laboratory Services (FL)
Naval Hospital Great Lakes (IL)
The Naval Hospital of Jacksonville (FL)
Naval Medical Center Portsmouth (VA)
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NB Department of Health (NB, Canada)
The Nebraska Medical Center (NE)
New England Baptist Hospital (MA)
New Lexington Clinic (KY)
New York City Department of Health and Mental Hygiene (NY)
New York Presbyterian Hospital (NY)
New York University Medical Center (NY)
Newark Beth Israel Medical Center (NJ)
Nor-Lea General Hospital (NM)
North Carolina Baptist Hospital (NC)
North District Hospital (China)
North Mississippi Medical Center (MS)
North Shore Hospital Laboratory (New Zealand)
North Shore-Long Island Jewish Health System Laboratories (NY)
Northridge Hospital Medical Center (CA)
Northside Hospital (GA)
Northwest Texas Hospital (TX)
Northwestern Memorial Hospital (IL)
Norton Healthcare (KY)
Ochsner Clinic Foundation (LA)
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Ohio Valley Medical Center (WV)
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Orebro University Hospital (Sweden)
Orlando Regional Healthcare System (FL)
Ospedale Casa Sollievo Della Sofferenza - IRCCS (Italy)
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Our Lady's Hospital For Sick Children (Ireland)
Palmetto Baptist Medical Center (SC)
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Pathlab (IA)
Pathology and Cytology Laboratories, Inc. (KY)
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Peace River Regional Health Center (FL)
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Pennsylvania Hospital (PA)
The Permanente Medical Group (CA)

Peterborough Regional Health Centre (ON, Canada)
Piedmont Hospital (GA)
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Prairie Lakes Hospital (SD)
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Prince County Hospital (PE, Canada)
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Providence Alaska Medical Center (AK)
Providence Health Care (BC, Canada)
Providence Health Services, Regional Laboratory (OR)
Providence Medford Medical Center (OR)
Provincial Health Services Authority (BC, Canada)
Provincial Laboratory for Public Health (AB, Canada)
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Queen Elizabeth Hospital (China)
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Quest Diagnostics JV (OH)
Quest Diagnostics, Incorporated (CA)
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Redington-Fairview General Hospital (ME)
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River Valley Health-Chalmers Regional Hospital (NB, Canada)
Riverside County Regional Medical Center (CA)
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Samsung Medical Center (Republic of Korea)
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Seattle Children's Hospital/Children's Hospital and Regional Medical Center (WA)
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Seoul St. Mary's Hospital (Republic of Korea)
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Singapore General Hospital (Singapore)
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St. Barnabas Medical Center (NJ)
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St. Elizabeth Community Hospital (CA)
St. Eustache Hospital (Quebec, Canada)
St. Francis Hospital (SC)
St. John Hospital and Medical Center (MI)
St. John's Hospital & Health Ctr. (CA)
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St. John's Regional Health Center (MO)
St. Joseph Hospital (IN)
St. Joseph Mercy Hospital (MI)
St. Joseph's Medical Center (CA)
St. Joseph's Regional Medical Center (NJ)
St. Jude Children's Research Hospital (TN)
St. Luke's Hospital (PA)
St. Luke's Hospital (IA)
St. Mary Medical Center (CA)
St. Mary of Nazareth Hospital (IL)
St. Mary's Hospital (WI)
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State of Washington Public Health Labs (WA)
Stillwater Medical Center (OK)
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Sunnybrook Health Sciences Centre (ON, Canada)
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Touro Infirmary (LA)
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Trident Medical Center (SC)
Trinity Medical Center (AL)
Tripler Army Medical Center (HI)
Tuen Mun Hospital, Hospital Authority (China)
Tufts Medical Center Hospital (MA)
Tulane Medical Center Hospital & Clinic (LA)
Turku University Central Hospital (Finland)
Twin Lakes Regional Medical Center (KY)
UCI Medical Center (CA)
UCLA Medical Center Clinical Laboratories (CA)
UCSD Medical Center (CA)
UCSF Medical Center China Basin (CA)
UMC of El Paso-Laboratory (TX)
UMC of Southern Nevada (NV)
UNC Hospitals (NC)
Union Clinical Laboratory (Taiwan)
United Christian Hospital (Kowloon, Hong Kong)
United Clinical Laboratories (IA)
United Medical Center (DC)
United States Air Force School of Aerospace Medicine / PHE (TX)
Unity HealthCare (IA)
Univ. of Pennsylvania Health System (PA)
Università Campus Bio - Medico Di Roma (IT) Italy
Universitair Ziekenhuis Antwerpen (Belgium)
University College Hospital (Ireland)
University Hospital (GA)
University Hospital Center Sherbrooke (CHUS) (Quebec, Canada)
University Medical Center At Princeton (NJ)
University of Alabama Hospital Lab (AL)
University of Chicago Hospitals Laboratories (IL)
University of Colorado Health Sciences Center (CO)
University of Colorado Hospital (CO)
University of Illinois Medical Center (IL)
University of Iowa Hospitals and Clinics (IA)
University of Kentucky Med. Ctr. (KY)
University of Maryland Medical System (MD)
University of Medicine & Dentistry of New Jersey (UMDNJ) (NJ)
University of Minnesota Medical Center-Fairview (MN)
University of Missouri Hospital (MO)
University of MS Medical Center (MS)
University of Pittsburgh Medical Center (PA)
University of So. Alabama Children's and Women's Hospital (AL)
University of Texas Health Center (TX)
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University of the Ryukyus (Japan)
University of Virginia Medical Center (VA)
UPMC Bedford Memorial (PA)
UZ-KUL Medical Center (Belgium)
VA (Asheville) Medical Center (NC)
VA (Bay Pines) Medical Center (FL)
VA (Central Texas) Veterans Health Care System (TX)
VA (Chillicothe) Medical Center (OH)
VA (Cincinnati) Medical Center (OH)
VA (Dayton) Medical Center (OH)
VA (Decatur) Medical Center (GA)
VA (Durham) Medical Center (NC)
VA (Hampton) Medical Center (VA)
VA (Indianapolis) Medical Center (IN)
VA (San Diego) Medical Center (CA)
VA (Tampa) Hospital (FL)
Valley Health / Winchester Medical Center (VA)
Vancouver Coastal Health Regional Laboratory (BC, Canada)
Vancouver Island Health Authority (SI) (BC, Canada)
Vanderbilt University Medical Center (TN)
Via Christi Regional Medical Center (KS)
Virginia Beach General Hospital (VA)
Virginia Regional Medical Center (MN)
Virtua - West Jersey Hospital (NJ)
WakeMed (NC)
Walter Reed Army Medical Center (DC)
Warren Hospital (NJ)
Washington Hospital Center (DC)
Waterbury Hospital (CT)
Waterford Regional Hospital (Ireland)
Wayne Memorial Hospital (NC)
Weirton Medical Center (WV)
West China Second University Hospital, Sichuan University (China)
West Jefferson Medical Center (LA)
West Penn Allegheny Health System-Allegheny General Hospital (PA)
West Shore Medical Center (MI)
West Valley Medical Center Laboratory (ID)
Westchester Medical Center (NY)
Western Baptist Hospital (KY)
Western Healthcare Corporation (NL, Canada)
Wheaton Franciscan Laboratories (WI)
Wheeling Hospital (WV)
Whitehorse General Hospital (YT, Canada)
William Beaumont Army Medical Center (TX)
William Beaumont Hospital (MI)
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Winchester Hospital (MA)
Winn Army Community Hospital (GA)
Wishard Health Sciences (IN)
Womack Army Medical Center Department of Pathology (NC)
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