



CLINICAL AND  
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INSTITUTE®

28th Edition

# M100

## Performance Standards for Antimicrobial Susceptibility Testing

SAMPLE

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

A CLSI supplement for global application.

# Clinical and Laboratory Standards Institute

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# Performance Standards for Antimicrobial Susceptibility Testing

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## Abstract

The data in the tables are valid only if the methodologies in CLSI documents M02,<sup>1</sup> M07,<sup>2</sup> and M11<sup>3</sup> are followed. These standards contain information about broth disk (M02<sup>1</sup>) and dilution (M07<sup>2</sup> and M11<sup>3</sup>) test procedures for aerobic and anaerobic bacteria, respectively.

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

The tables presented in M100 represent the most current information for drug selection, interpretation, and quality control using the procedures standardized in M02,<sup>1</sup> M07,<sup>2</sup> and M11.<sup>3</sup> Users should replace previously published tables with these new tables. Changes in the tables since the previous edition appear in boldface type.

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**Contents**

Abstract.....	i
Committee Membership.....	iii
Overview of Changes.....	xiv
Summary of CLSI Processes for Establishing Breakpoints and Quality Control Ranges.....	xxvii
CLSI Reference Methods vs Commercial Methods and CLSI vs US Food and Drug Administration Breakpoints.....	xxviii
CLSI Breakpoint Additions/Revisions Since 2010.....	xxix
CLSI Epidemiological Cutoff Value Additions/Revisions Since 2015.....	xxxii
CLSI Archived Resources.....	xxxii
Subcommittee on Antimicrobial Susceptibility Testing Mission Statement.....	xxxiii
Instructions for Use of Tables.....	1
Table 1A. Suggested Groupings of Antimicrobial Agents Approved by the US Food and Drug Administration for Clinical Use That Should Be Considered for Testing and Reporting on Nonfastidious Organisms by Microbiology Laboratories in the United States.....	16
Table 1B. Suggested Groupings of Antimicrobial Agents Approved by the US Food and Drug Administration for Clinical Use That Should Be Considered for Testing and Reporting on Fastidious Organisms by Microbiology Laboratories in the United States.....	22
Table 1C. Suggested Groupings of Antimicrobial Agents Approved by the US Food and Drug Administration for Clinical Use That Should Be Considered for Testing and Reporting on Anaerobic Organisms by Microbiology Laboratories in the United States.....	28
Table 2A. Zone Diameter and MIC Breakpoints for <i>Enterobacteriaceae</i> .....	30
Table 2B-1. Zone Diameter and MIC Breakpoints for <i>Pseudomonas aeruginosa</i> .....	38
Table 2B-2. Zone Diameter and MIC Breakpoints for <i>Acinetobacter</i> spp.....	42

## Contents (Continued)

Table 2B-3. Zone Diameter and MIC Breakpoints for <i>Burkholderia cepacia</i> complex.....	46
Table 2B-4. Zone Diameter and MIC Breakpoints for <i>Stenotrophomonas maltophilia</i> .....	48
Table 2B-5. MIC Breakpoints for Other Non- <i>Enterobacteriaceae</i> (Refer to General Comment 1).....	50
Table 2C. Zone Diameter and MIC Breakpoints for <i>Staphylococcus</i> spp.....	54
Table 2D. Zone Diameter and MIC Breakpoints for <i>Enterococcus</i> spp.....	64
Table 2E. Zone Diameter and MIC Breakpoints for <i>Haemophilus influenzae</i> and <i>Haemophilus parainfluenzae</i> .....	68
Table 2F. Zone Diameter and MIC Breakpoints for <i>Neisseria gonorrhoeae</i> .....	72
Table 2G. Zone Diameter and MIC Breakpoints for <i>Streptococcus pneumoniae</i> .....	76
Table 2H-1. Zone Diameter and MIC Breakpoints for <i>Streptococcus</i> spp. $\beta$ -Hemolytic Group.....	82
Table 2H-2. Zone Diameter and MIC Breakpoints for <i>Streptococcus</i> spp. Viridans Group.....	86
Table 2I. Zone Diameter and MIC Breakpoints for <i>Neisseria meningitidis</i> .....	90
Table 2J. MIC Breakpoints for Anaerobes.....	94
Table 3A. Tests for Extended-Spectrum $\beta$ -Lactamases in <i>Klebsiella pneumoniae</i> , <i>Klebsiella oxytoca</i> , <i>Escherichia coli</i> , and <i>Proteus mirabilis</i> ...	98
Introduction to Tables 3B and 3C. Tests for Carbapenemases in <i>Enterobacteriaceae</i> and <i>Pseudomonas aeruginosa</i> .....	102
Table 3B. CarbaNP Test for Suspected Carbapenemase Production in <i>Enterobacteriaceae</i> and <i>Pseudomonas aeruginosa</i> .....	104
Table 3B-1. Modifications of Table 3B When Using MIC Breakpoints for Carbapenems Described in M100-S20 (January 2010).....	108
Table 3C. Modified Carbapenem Inactivation Methods for Suspected Carbapenemase Production in <i>Enterobacteriaceae</i> and <i>P. aeruginosa</i> ....	112
Table 3C-1. Modifications of Table 3C When Using MIC Breakpoints for Carbapenems Described in M100-S20 (January 2010).....	124

**Contents (Continued)**

Table 3D. Test for Detection of $\beta$ -Lactamase Production in <i>Staphylococcus</i> spp.....	126
Table 3E. Test for Detection of Methicillin Resistance (Oxacillin Resistance) in <i>Staphylococcus</i> spp., Except <i>Staphylococcus pseudintermedius</i> and <i>Staphylococcus schleiferi</i> .....	130
Table 3F. Vancomycin Agar Screen for <i>Staphylococcus aureus</i> and <i>Enterococcus</i> spp.....	134
Table 3G. Test for Detection of Inducible Clindamycin Resistance in <i>Staphylococcus</i> spp., <i>Streptococcus pneumoniae</i> , and <i>Streptococcus</i> spp. $\beta$ -Hemolytic Group.....	136
Table 3H. Test for Detection of High-Level Mupirocin Resistance in <i>Staphylococcus aureus</i> .....	140
Table 3I. Test for Detection of High-Level Aminoglycoside Resistance in <i>Enterococcus</i> spp. (Includes Disk Diffusion).....	142
Table 4A-1. Disk Diffusion QC Ranges for Nonfastidious Organisms and Antimicrobial Agents Excluding $\beta$ -Lactam Combination Agents.....	144
Table 4A-2. Disk Diffusion QC Ranges for Nonfastidious Organisms and $\beta$ -Lactam Combination Agents.....	148
Table 4B. Disk Diffusion QC Ranges for Fastidious Organisms.....	150
Table 4C. Disk Diffusion: Reference Guide to QC Frequency.....	154
Table 4D. Disk Diffusion: Troubleshooting Guide.....	156
Table 5A-1. MIC QC Ranges for Nonfastidious Organisms and Antimicrobial Agents Excluding $\beta$ -Lactam Combination Agents.....	160
Table 5A-2. MIC QC Ranges for Nonfastidious Organisms and $\beta$ -Lactam Combination Agents.....	166
Table 5B. MIC QC Ranges for Fastidious Organisms (Broth Dilution Methods).....	170
Table 5C. MIC QC Ranges for <i>Neisseria gonorrhoeae</i> (Agar Dilution Method).....	174
Table 5D. MIC QC Ranges for Anaerobes (Agar Dilution Method).....	176
Table 5E. MIC QC Ranges for Anaerobes (Broth Microdilution Method).....	178

## Contents (Continued)

Table 5F. MIC Reference Guide to QC Frequency .....	180
Table 5G. MIC: Troubleshooting Guide.....	182
Table 6A. Solvents and Diluents for Preparation of Stock Solutions of Antimicrobial Agents .....	186
Table 6B. Preparation of Stock Solutions for Antimicrobial Agents Provided With Activity Expressed as Units.....	192
Table 6C. Preparing Solutions and Media Containing Combinations of Antimicrobial Agents .....	194
Table 7. Preparing Dilutions of Antimicrobial Agents to Be Used in Agar Dilution Susceptibility Tests.....	198
Table 8A. Preparing Dilutions of Antimicrobial Agents to Be Used in Broth Dilution Susceptibility Tests.....	200
Table 8B. Preparing Dilutions of Water-Insoluble Antimicrobial Agents to Be Used in Broth Dilution Susceptibility Tests.....	202
References.....	203
Appendix A. Suggestions for Confirming Resistant, Intermediate, or Nonsusceptible Antimicrobial Susceptibility Test Results and Organism Identification .....	204
Appendix B. Intrinsic Resistance.....	210
Appendix C. QC Strains for Antimicrobial Susceptibility Tests .....	216
Appendix D. Cumulative Antimicrobial Susceptibility Report for Anaerobic Organisms.....	222
Appendix E. Dosage Regimens Used to Establish Susceptible or Susceptible-Dose Dependent Breakpoints .....	228
Appendix F. Cefepime Breakpoint Change for <i>Enterobacteriaceae</i> and Introduction of the Susceptible-Dose Dependent Interpretive Category .....	232
Appendix G. Epidemiological Cutoff Values.....	236
Glossary I (Part 1). $\beta$ -Lactams: Class and Subclass Designations and Generic Name.....	242



**Contents (Continued)**

Glossary I (Part 2). Non- $\beta$ -Lactams: Class and Subclass Designations and Generic Name.....	244
Glossary II. Antimicrobial Agent Abbreviation(s), Route(s) of Administration, and Drug Class.....	248
Glossary III. List of Identical Abbreviations Used for More Than One Antimicrobial Agent in US Diagnostic Products.....	254
The Quality Management System Approach.....	256
Related CLSI Reference Materials.....	257

SAMPLE

## Instructions for Use of Tables

### These instructions apply to:

- **Tables 1A and 1B:** suggested groupings of antimicrobial agents that should be considered for testing and reporting by microbiology laboratories. These guidelines are based on antimicrobial agents approved by the US Food and Drug Administration (FDA) for clinical use in the United States. In other countries, placement of antimicrobial agents in Tables 1A and 1B should be based on available drugs approved for clinical use by relevant regulatory organizations.
- **Tables 2A through 2I:** tables for each organism group that contain:
  - Recommended testing conditions
  - Routine QC recommendations (also see Chapter 4 in M02<sup>1</sup> and M07<sup>2</sup>)
  - General comments for testing the organism group and specific comments for testing particular agent/organism combinations
  - Suggested agents that should be considered for routine testing and reporting by medical microbiology laboratories, as specified in Tables 1A and 1B (test/report groups A, B, C, U)
  - Additional drugs that have an approved indication for the respective organism group but would generally not warrant routine testing by a medical microbiology laboratory in the United States (test/report group O for “other”; test/report group Inv. for “investigational” [not yet FDA approved])
  - Zone diameter and minimal inhibitory concentration (MIC) breakpoints
- **Tables 1C and 2J:** tables containing specific recommendations for testing and reporting results on anaerobes and some of the information listed in the bullets above
- **Tables 3A to 3I:** tables describing tests to detect particular resistance types in specific organisms or organism groups

### I. Selecting Antimicrobial Agents for Testing and Reporting

- A. Selecting the most appropriate antimicrobial agents to test and report is a decision best made by each laboratory in consultation with the **infectious diseases and pharmacy practitioners**, the pharmacy and therapeutics and infection control committees of the medical staff, **and the antimicrobial stewardship team**. The recommendations for each organism group include agents of proven efficacy that show acceptable *in vitro* test performance. Considerations in the assignment of agents to specific test/report groups include clinical efficacy, prevalence of resistance, minimizing emergence of resistance, cost, FDA clinical indications for use, and current consensus recommendations for first-choice and alternative drugs. Tests of selected agents may be useful for infection control purposes.

- 2
- B. Drugs listed together in a single box are agents for which interpretive categories (susceptible, intermediate, or resistant) and clinical efficacy are similar. Within each box, an “or” between agents indicates agents for which cross-resistance and cross-susceptibility are nearly complete. Results from one agent connected by an “or” can be used to predict results for the other agent. For example, *Enterobacteriaceae* susceptible to cefotaxime can be considered susceptible to ceftriaxone. The results obtained from testing cefotaxime could be reported along with a comment that the isolate is also susceptible to ceftriaxone. For drugs connected with an “or,” combined major and very major errors are fewer than 3%, and minor errors are fewer than 10%, based on a large population of bacteria tested (see CLSI document M23<sup>4</sup> for description of error types). In addition, to qualify for an “or,” at least 100 strains with resistance to the agents in question must be tested, and a result of “resistant” must be obtained with all agents for at least 95% of the strains. “Or” is also used for comparable agents when tested against organisms for which “susceptible-only” breakpoints are provided (eg, cefotaxime or ceftriaxone with *H. influenzae*). When no “or” connects agents within a box, testing of one agent cannot be used to predict results for another, owing either to discrepancies or insufficient data.
- C. Test/Report Groups
1. As listed in Tables 1A, 1B, and 1C, agents in **group A** are considered appropriate for inclusion in a routine, primary testing panel, as well as for routine reporting of results for the specific organism groups.
  2. **Group B** includes antimicrobial agents that may warrant primary testing, but they may be reported only selectively, such as when the organism is resistant to agents of the same antimicrobial class, as in group A. Other indications for reporting the result might include a selected specimen source (eg, a third-generation cephalosporin for enteric bacilli from CSF or trimethoprim-sulfamethoxazole for urinary tract isolates); a polymicrobial infection; infections involving multiple sites; cases of patient allergy, intolerance, or failure to respond to an antimicrobial agent in group A; or for infection control purposes.
  3. **Group C** includes alternative or supplemental antimicrobial agents that may necessitate testing in those institutions that harbor endemic or epidemic strains resistant to several of the primary drugs (especially in the same class, eg,  $\beta$ -lactams); for treatment of patients allergic to primary drugs; for treatment of unusual organisms (eg, chloramphenicol for extraintestinal isolates of *Salmonella* spp.); or for reporting to infection control as an epidemiological aid.
  4. **Group U (“urine”)** includes certain antimicrobial agents (eg, nitrofurantoin and certain quinolones) that are used only or primarily for treating UTIs. These agents should not be routinely reported against pathogens recovered from other infection sites. An exception to this rule is for *Enterobacteriaceae* in Table 1A, in which cefazolin is listed as a surrogate agent for oral cephalosporins. Other antimicrobial agents with broader indications may be included in group U for specific urinary pathogens (eg, *Enterococcus* and ciprofloxacin).
  5. **Group O (“other”)** includes antimicrobial agents that have a clinical indication for the organism group but are generally not candidates for routine testing and reporting in the United States.

## The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system (QMS) approach in the development of standards and guidelines that facilitates project management, defines a document structure using a template, and provides a process to identify needed documents. The QMS 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:

Organization	Personnel	Process Management	Nonconforming Event Management
Customer Focus	Purchasing and Inventory	Documents and Records	Assessments
Facilities and Safety	Equipment	Information Management	Continual Improvement

M100 covers the QSE indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
						X EP23 M02 M07 M11 M23 M39 M45 M52 M60					

### Path of Workflow

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver their services, namely quality laboratory information.

M100 covers the medical laboratory path of workflow processes indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section.

Preexamination				Examination			Postexamination	
Examination ordering	Sample collection	Sample transport	Sample receipt and processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
				EP23 M02 M07 M11	X EP23 M02 M07 M11  M45 M60	X EP23 M02 M07 M11  M45 M60	X M02 M07 M11 M39 M45 M60	

## Related CLSI Reference Materials\*

- EP23™**      **Laboratory Quality Control Based on Risk Management. 1st ed., 2011.** This document provides guidance based on risk management for laboratories to develop quality control plans tailored to the particular combination of measuring system, laboratory setting, and clinical application of the test.
- M02**        **Performance Standards for Antimicrobial Disk Susceptibility Tests. 13th ed., 2018.** This standard covers the current 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 ed., 2018.** This standard covers reference methods for determining minimal inhibitory concentrations of aerobic bacteria by broth macrodilution, broth microdilution, and agar dilution.
- M11**        **Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria. 8th ed., 2012.** This standard provides reference methods for the determination of minimal inhibitory concentrations of anaerobic bacteria by agar dilution and broth microdilution.
- M23**        **Development of *In Vitro* Susceptibility Testing Criteria and Quality Control Parameters. 5th ed., 2018.** This guideline discusses the necessary and recommended data for selecting appropriate breakpoints and quality control ranges for antimicrobial agents.
- M39**        **Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data. 4th ed., 2014.** 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**        **Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria. 3rd ed., 2016.** This guideline informs clinical, public health, and research laboratories on susceptibility testing of infrequently isolated or fastidious bacteria that are not included in CLSI documents M02, M07, or M100. Antimicrobial agent selection, test interpretation, and quality control are addressed.
- M52**        **Verification of Commercial Microbial Identification and Antimicrobial Susceptibility Testing Systems. 1st ed., 2015.** This guideline includes recommendations for verification of commercial US Food and Drug Administration–cleared microbial identification and antimicrobial susceptibility testing systems by clinical laboratory professionals to fulfill regulatory or quality assurance requirements for the use of these systems for diagnostic testing.
- M60**        **Performance Standards for Antifungal Susceptibility Testing of Yeasts. 1st ed., 2017.** This document includes updated minimal inhibitory concentration, zone diameter, and quality control tables for the Clinical and Laboratory Standards Institute antifungal susceptibility testing documents M27 and M44.

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