

M100

Performance Standards for Antimicrobial Susceptibility Testing

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.

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 M02,¹ M07,² and M11³ are followed. These standards contain information about disk diffusion (M02¹) and dilution (M07² and M11³) test procedures for aerobic and anaerobic bacteria. 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 M02,¹ M07,² and M11.³ 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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Overview of Changes

M100, 30th ed. replaces the previous edition of the supplement, M100, 29th ed., published in 2019. The major changes in M100, 30th ed., are listed below. 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. The following are additions or changes unless otherwise noted as a “*deletion*.”

Users of M100, 30th ed. should note recent and new formatting changes to Tables 2, including:

- Intermediate ranges denoted with a “^” for the applicable antimicrobial agents in the drug groups in Tables 2 are based on the known ability of these agents to concentrate in the urine; some agents may also have the potential to concentrate at other anatomical sites (ie, epithelial lining).

M100 is updated and reviewed annually as new data and new agents become available. Use of outdated documents is strongly discouraged.

Section/Table	Change(s)
General	
Throughout the document	Replaced: <ul style="list-style-type: none"> • “Coagulase-negative staphylococci (CoNS)” with “other <i>Staphylococcus</i> spp.” • The term “infection control” with “infection prevention”
	Clarified: <ul style="list-style-type: none"> • Methicillin and oxacillin terminology for <i>Staphylococcus</i> spp.
	Updated: <ul style="list-style-type: none"> • Genera formerly included in the family <i>Enterobacteriaceae</i> reorganized to an order (Enterobacterales) containing seven families: <i>Budviciaceae</i>, <i>Enterobacteriaceae</i>, <i>Erwiniaceae</i>, <i>Hafniaceae</i>, <i>Morganellaceae</i>, <i>Pectobacteriaceae</i>, <i>Yersiniaceae</i>⁴ • Nomenclature for <i>Salmonella</i> Typhi to <i>Salmonella</i> enterica ser. Typhi • Nomenclature for <i>Salmonella</i> Paratyphi to <i>Salmonella</i> enterica ser. Paratyphi

CLSI Breakpoint Additions/Revisions Since 2010 (Continued)

Antimicrobial Agent	Date of Addition/Revision* (M100 edition)	Comments
Other Non-Enterobacterales		
Norfloxacin	January 2020 (M100, 30th ed.)	Reinstated breakpoints deleted from M100, 29th ed.
<i>Staphylococcus</i> spp.		
Ceftaroline	January 2013 (M100-S23)	NPBP
	January 2019 (M100, 29th ed.)	Disk diffusion and MIC breakpoints were revised to include an SDD interpretive category.
Dalbavancin	January 2018 (M100, 28th ed.)	NPBP
Norfloxacin	January 2020 (M100, 30th ed.)	Reinstated breakpoints deleted from M100, 29th ed.
Oritavancin	January 2016 (M100S, 26th ed.)	NPBP
Tedizolid	January 2016 (M100S, 26th ed.)	NPBP
Telavancin	January 2016 (M100S, 26th ed.)	NPBP
<i>Enterococcus</i> spp.		
Dalbavancin	January 2018 (M100, 28th ed.)	NPBP
Daptomycin	January 2019 (M100, 29th ed.)	MIC breakpoints for <i>E. faecium</i> only were added. MIC breakpoints for <i>Enterococcus</i> spp. other than <i>E. faecium</i> were revised.
	January 2020 (M100, 30th ed.)	
Norfloxacin	January 2020 (M100, 30th ed.)	Reinstated breakpoints deleted from M100, 29th ed.
Oritavancin	January 2016 (M100S, 26th ed.)	NPBP
Tedizolid	January 2016 (M100S, 26th ed.)	NPBP
Telavancin	January 2016 (M100S, 26th ed.)	NPBP
<i>Haemophilus influenzae</i> and <i>Haemophilus parainfluenzae</i>		
Ceftaroline	January 2013 (M100-S23)	NPBP
<i>Neisseria gonorrhoeae</i>		
Azithromycin	January 2019 (M100, 29th ed.)	NPBP, previously assigned an ECV
<i>Streptococcus pneumoniae</i>		
Ceftaroline	January 2013 (M100-S23)	NPBP
Doxycycline	January 2013 (M100-S23)	NPBP
Tetracycline	January 2013 (M100-S23)	
<i>Streptococcus</i> spp. β-Hemolytic Group		
Ceftaroline	January 2013 (M100-S23)	NPBP
Dalbavancin	January 2018 (M100, 28th ed.)	NPBP
Oritavancin	January 2016 (M100S, 26th ed.)	NPBP
Telavancin	January 2016 (M100S, 26th ed.)	NPBP

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

Group A: Includes antimicrobial agents considered appropriate for inclusion in a routine, primary testing panel, as well as for routine reporting of results for the specific organism group.			
Enterobacterales	<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus</i> spp.	<i>Enterococcus</i> spp. ⁿ
Ampicillin ^d	Ceftazidime	Azithromycin ^b or clarithromycin ^b or erythromycin ^b	Ampicillin ^o Penicillin ^p
Cefazolin ^e	Gentamicin Tobramycin		
Gentamicin ^d Tobramycin ^d	Piperacillin-tazobactam	Clindamycin ^b	
		Oxacillin ^{l,l,t,t,s}	
		Cefoxitin ^{l,l,t} (surrogate test for oxacillin)	
		Penicillin ^l	
		Trimethoprim-sulfamethoxazole	
Group B: Includes antimicrobial agents that may warrant primary testing but may be reported only selectively, such as when the organism is resistant to agents of the same antimicrobial class in Group A. ^c			
Amikacin ^d	Amikacin	Ceftaroline ^l	Daptomycin ^{k,*}
Amoxicillin-clavulanate Ampicillin-sulbactam	Aztreonam	Daptomycin ^{k,*}	Linezolid Tedizolid ^q
Ceftazidime-avibactam	Cefepime	Linezolid Tedizolid ^l	Vancomycin
Ceftolozane-tazobactam	Ceftazidime-avibactam		
Meropenem-vaborbactam	Ceftolozane-tazobactam		
Piperacillin-tazobactam			
Cefuroxime	Ciprofloxacin Levofloxacin	Doxycycline Minocycline ^b	
Cefepime	Doripenem	Tetracycline ^a	
Cefotetan Cefoxitin	Imipenem Meropenem	Vancomycin [*]	
Cefotaxime ^{d,e} or Ceftriaxone ^{d,e}			
Ciprofloxacin ^d Levofloxacin ^d		Rifampin ^h	
Doripenem Ertapenem Imipenem Meropenem			
Trimethoprim-sulfamethoxazole ^d			

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.
- M02QG** **M02 Disk Diffusion Reading Guide. 1st ed., 2018.** The Disk Diffusion Reading Guide provides photographic examples of the proper method for reading disk diffusion susceptibility testing results.
- 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. 9th ed., 2018.** This standard provides reference methods for determining 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.

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

SAMPLE



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