CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

M24S

Performance Standards for Susceptibility Testing of Mycobacteria, *Nocardia* spp., and Other Aerobic Actinomycetes

This document includes updated breakpoint and quality control tables for the Clinical and Laboratory Standards Institute susceptibility testing standard M24.

A CLSI supplement for global application.

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Performance Standards for Susceptibility Testing of Mycobacteria, *Nocardia* spp., and Other Aerobic Actinomycetes

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Abstract

Clinical and Laboratory Standards Institute document M24S—*Performance Standards for Susceptibility Testing of Mycobacteria,* Nocardia *spp., and Other Aerobic Actinomycetes* includes the minimal inhibitory concentrations and QC ranges developed following the standards described in CLSI document M24.[1] The data in the tables are valid only when the methodology in CLSI document M24[1] is followed.

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Table 1. Broth Microdilution Breakpoints and Interpretive Categories for MTBC Tested in Middlebrook 7H9 Broth Supplemented With OADC Using MIC Panels[1-3]

QC Recommendation (see Table 10 for acceptable QC ranges)

Routine QC strain:
- *Mycobacterium tuberculosis* ATCC® 27294 (H37Rv)

General Comments

(1) ATCC® is a registered trademark of the American Type Culture Collection.

(2) This table contains updated information and notifies laboratories of important changes among published versions of CLSI document M24.[4]

(3) The breakpoints in Table 1 were established using lyophilized MIC panels incubated in 5% to 10% CO_2. Incubating tests in ambient air may result in erroneous MICs because MTBC grow more slowly in ambient air. If preparing in-house MIC panels, care should be taken to match the manufacturer's formulation because the use of polysorbate or glycerol in the broth may affect the MIC values obtained.

(4) This antimicrobial susceptibility testing system is not regulatory organization cleared.

NOTE: Information in black boldface type is new or modified since the previous edition.

Antimicrobial Agent	MIC Breakpoints, µg/mL			Comments
	S	Inconclusive[3]	R	
Ethambutol	≤ 2	4	≥ 8	(5) Inconclusive MIC for ethambutol. An MIC of 4 µg/mL obtained by broth microdilution using **lyophilized panels** does not correlate with either a susceptible or resistant result in commercial automated, short-incubation broth systems, and there are no clinical data correlating such a result with ethambutol treatment response. **NOTE:** Repeat testing **using an alternative broth method (eg, critical concentration) or genotypic method** may determine whether the isolate in question is susceptible or resistant.

Table 6. Antimicrobial Agents and Breakpoints for Testing Rapidly Growing Mycobacteria

QC Recommendations (see Table 13 for acceptable QC ranges)

Routine QC strain:
- *Mycobacterium peregrinum* ATCC® 700686

Supplemental QC strains:
- *Staphylococcus aureus* ATCC® 29213
- *Enterococcus faecalis* ATCC® 29212 and/or *Pseudomonas aeruginosa* ATCC® 27853 may also be used, if desired.

General Comment

(1) ATCC® is a registered trademark of the American Type Culture Collection.

NOTE: Information in black boldface type is new or modified since the previous edition.

Antimicrobial Agent	MIC, µg/mL			Comments
	S	I	R	
Amikacin (IV)	≤ 16	32	≥ 64	(2) If *Mycobacterium abscessus* isolates have an MIC ≥ 64 µg/mL, they should be retested. The amikacin mutation **in the *rrs* gene** may be **detected** in isolates with higher MICs. If the repeat result is ≥ 64 µg/mL, the MIC should be reported with the comment, "The MIC is greater than expected for this species; if the drug is being considered for therapy, the laboratory should be notified so the isolate can be sent to a referral laboratory for confirmation of resistance."
Cefoxitin	≤ 16	32-64	≥ 128	
Ciprofloxacin	≤ 1	2	≥ 4	(3) Ciprofloxacin and levofloxacin are interchangeable. Both are less active *in vitro* than the newer 8-methoxy fluoroquinolones.
Clarithromycin	≤ 2	4	≥ 8	(4) Clarithromycin is the class representative for the newer macrolides (eg, azithromycin, clarithromycin, and roxithromycin). See CLSI document M24[1] for guidance regarding incubation period, molecular testing, and interpretation of clarithromycin results for rapidly growing mycobacteria.
Doxycycline	≤ 1	2-4	≥ 8	(5) Minocycline can be substituted.