



CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE

4th Edition

CLSI M38M51S™

Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi

Sample

CLSI M38M51S includes minimal inhibitory concentration breakpoints and quality control tables for the Clinical and Laboratory Standards Institute antifungal susceptibility testing documents CLSI M38 and CLSI M51.

A CLSI supplement for global application.

Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi

Philippe J. Dufresne, PhD
Nathan P. Wiederhold, PharmD
Barbara D. Alexander, MD, MHS
David Andes, MD
Andrew Borman, BSc, PhD
Ryan Demkowicz, MD
Tanis Dingle, PhD, D(ABMM), FCCM
Hari Dwivedi, BVSc(DVM), MVSC, PhD

Julianne Kus, MSc, PhD, FCCM
Shawn R. Lockhart, PhD, D(ABMM), F(AAM)
Stephanie Mitchell, PhD, D(ABMM)
Chris Pillar, PhD
Amir Seyedmousavi, VMD, PhD, D(ABMM), FECMM
Paul E. Verweij, MD, FECMM
Sean Zhang, MD, PhD, D(ABMM)

Abstract

CLSI M38M51S—*Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi* includes minimal inhibitory concentration and quality control tables developed following the guidance in CLSI M38¹ and CLSI M51.² The data in the tables are valid only when the methodologies in CLSI M38¹ and CLSI M51² are followed. Users should replace previously published tables with these new tables. Changes in the tables since the previous edition was published appear in boldface type.

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Foreword

The breakpoints and interpretive categories provided in CLSI M38M51S are generated using the reference **broth dilution** method for antifungal susceptibility testing of filamentous fungi described in CLSI M38¹; **none exist at the moment for the standardized disk diffusion methodology of CLSI M51.²** The **broth dilution CLSI M38¹** method may be used for:

- Routine antifungal testing of patient isolates to guide therapy and classify isolates as susceptible or resistant to antifungal agents with established clinical breakpoints
- Evaluation of commercial devices that will be used in medical laboratories
- Testing of new agents or systems by drug or device manufacturers

Results generated by reference methods, such as **CLSI M38¹ or other** CLSI documents, may be used by regulatory authorities to evaluate commercial susceptibility testing device performance as part of the device approval process. Regulatory clearance indicates that the commercial susceptibility testing device provides 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.

NOTE 1: Fungal taxonomy has undergone **some** changes in recent years. The dual (asexual and sexual stages) nomenclature has been abolished, and **some** fungal species are constantly being reclassified and renamed according to **new molecular phylogeny changes.**³ Species names listed in CLSI M38¹ and CLSI M51² were **acknowledged** to reflect the most recent taxonomic changes (at the time of publication). Information on updated fungal species classification is publicly available.⁴⁻⁸

NOTE 2: When serial 2-fold dilution minimal inhibitory concentrations (MICs) are being prepared and tested, the actual dilution scheme is, eg, 128, 64, 32, 16, 8, 4, 2, 1, 0.5, 0.25, 0.125, 0.0625, 0.03125, 0.015625, 0.0078125, 0.0039063, 0.0019531 µg/mL, etc. For convenience only, and not because these are the actual concentrations tested, it was decided to use the following values in CLSI M38M51S: 128, 64, 32, 16, 8, 4, 2, 1, 0.5, 0.25, 0.12, 0.06, 0.03, 0.016, 0.008, 0.004, 0.002 µg/mL, etc. The values that appear in the tables are equivalent to the actual values tested (eg, 0.12 µg/mL = 0.125 µg/mL), and laboratories should report an MIC of ≤ 0.125 µg/mL as ≤ 0.12 µg/mL.

NOTE 3: Information in boldface type is new or modified since the previous edition.

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Overview of Changes

CLSI M38M51S-Ed4 replaces CLSI M38M51S-Ed3, published in 2022. Several changes were made in this edition, including:

Section/Table	Action	Change to:	Reason/Specific Change
Foreword	Revised	Foreword	Clarifying language regarding the reference broth dilution method
	Added	References	Supporting new fungal organism name changes
Table 1. Minimal Inhibitory Concentration Breakpoints for Select Antifungal Agents Against <i>Aspergillus fumigatus</i>	Added	MIC breakpoints for isavuconazole	<ul style="list-style-type: none"> • <i>A. fumigatus</i>
		Footnotes	<ul style="list-style-type: none"> • Regarding adoption of MIC interpretive categories for isavuconazole • Regarding the isavuconazole “I” category and surrogate testing prediction
	References	Regarding rationale determination of isavuconazole and voriconazole breakpoints	
Table 2. Recommended 24-Hour Minimal Inhibitory Concentration or Minimal Effective Concentration Limits for Quality Control and Reference Strains Using Broth Microdilution Antifungal Susceptibility Testing Procedures	Revised	Taxonomy	<i>Aspergillus terreus</i> ATCC® ^a MYA-3633
Table 3. Recommended 48-Hour Minimal Inhibitory Concentration or Minimal Effective Concentration Limits for Quality Control and Reference Strains Using Broth Microdilution Antifungal Susceptibility Testing Procedures	Revised	MIC/MEC range for micafungin	<i>Candida krusei</i> ATCC® 6258
		Taxonomy	<ul style="list-style-type: none"> • <i>A. terreus</i> ATCC® MYA-3633 • <i>Fusarium solani</i> ATCC® MYA-3636
Table 4. Recommended 48- to 96-Hour Minimal Inhibitory Concentration or Minimal Effective Concentration Limits for Quality Control and Reference Strains Using Broth Microdilution Antifungal Susceptibility Testing Procedures	Revised	Taxonomy	<i>Trichophyton mentagrophytes</i> MRL 1957 ATCC® MYA-4439
Table 5. Recommended Zone Diameter Limits for Quality Control and Reference Strains Using Disk Diffusion Antifungal Susceptibility Testing Procedures	Revised	Taxonomy	<i>A. terreus</i> ATCC® MYA-3633

Section/Table	Action	Change to:	Reason/Specific Change
Table 6. Solvents and Diluents for Preparation of Stock Solutions of Antifungal Agents	Added	Solvents and diluents	<ul style="list-style-type: none"> • Ibrexafungerp • Opelconazole
Appendix. Intrinsic Resistance for Molds	Added	Isavuconazole IR designation	<i>Lomentospora prolificans</i>
		Amphotericin B IR designation	<i>Scedosporium boydii</i>
		Footnotes	<ul style="list-style-type: none"> • Regarding IR designation for <i>L. prolificans</i> • Regarding isavuconazole not meeting CLSI IR criteria for <i>Scedosporium apiospermum</i> and <i>S. boydii</i>
		References	Supporting new footnote additions
Glossary. Antifungal Agent Abbreviations, Routes of Administration, and Drug Class	Added	New antifungal agents	<ul style="list-style-type: none"> • Ibrexafungerp • Opelconazole
		Drug class	Manogepix
	Deleted	IV route of administration	Olorofim

Abbreviations: ATCC[®], American Type Culture Collection; I, intermediate; IR, intrinsic resistance; IV, intravenous; MEC, minimal effective concentration; MIC, minimal inhibitory concentration.
^a ATCC[®] is a registered trademark of the American Type Culture Collection.

KEY WORDS

- antifungal agent
- azole
- breakpoint
- disk diffusion
- echinocandin
- filamentous fungi
- interpretive category
- microbroth dilution
- minimal inhibitory concentration
- quality control
- susceptibility testing

NOTE: The content of CLSI M38M51S is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

Abbreviations and Acronyms

- ATCC^{®a}** American Type Culture Collection
- DMSO** dimethyl sulfoxide
- I** intermediate

IR	intrinsic resistance
IV	intravenous
MEC	minimal effective concentration
MIC	minimal inhibitory concentration
N/A	not applicable
ND	not determined
QC	quality control
R	resistant
S	susceptible

Footnote

- a. ATCC® is a registered trademark of the American Type Culture Collection.

References

- ¹ CLSI. *Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi*. 3rd ed. CLSI standard M38. Clinical and Laboratory Standards Institute; 2017.
- ² CLSI. *Method for Antifungal Disk Diffusion Susceptibility Testing of Nondermatophyte Filamentous Fungi; Approved Guideline*. CLSI document M51-A. Clinical and Laboratory Standards Institute; 2010.
- ³ **de Hoog S, Walsh TJ, Ahmed SA, et al. A conceptual framework for nomenclatural stability and validity of medically important fungi: a proposed global consensus guideline for fungal name changes supported by ABP, ASM, CLSI, ECMM, ESCMID-EFISG, EUCAST-AFST, FDLC, IDSA, ISHAM, MMSA, and MSGERC. *J Clin Microbiol.* 2023;61(11):e0087323. doi:10.1128/jcm.00873-23**
- ⁴ **Borman AM, Johnson EM. Name changes for fungi of medical importance, 2020 to 2021. *J Clin Microbiol.* 2023;61(6):e0033022. doi:10.1128/jcm.00330-22**
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- ⁸ Warnock DW. Name changes for fungi of medical importance, 2016-2017. *J Clin Microbiol.* 2019;57(2):e01183-18. doi:10.1128/jcm.01183-18

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