CLINICAL AND LABORATORY STANDARDS INSTITUTE®

3rd Edition

M38M51S

Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi

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

A CLSI supplement for global application.

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Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi

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Abstract

Clinical and Laboratory Standards Institute document M38M51S—*Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi* includes minimal inhibitory concentration and quality control tables developed following the guidance in CLSI documents M38[1] and M51.[2] The data in the tables are valid only when the methodologies in CLSI documents M38[1] and M51[2] 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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Contents

Foreword

The breakpoints and interpretive categories provided in this document are generated using the reference method for antifungal susceptibility testing of filamentous fungi described in CLSI documents M38[1] **and M51.**[2] These methods may be used for:

- Routine antifungal testing of patient isolates to guide therapy and classify isolates as susceptible or resistant to antifungal agents for which clinical breakpoints have been established
- 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 those described in 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 those generated using reference methods for the organisms and antimicrobial agents described in the device manufacturer's approved package insert.

NOTE: Fungal taxonomy has undergone major changes in recent years. The dual (asexual and sexual stages) nomenclature has been abolished, and fungal species are constantly being reclassified and renamed according to improved molecular characterization.[3] Species names listed in CLSI documents M38[1] **and M51**[2] were revised to reflect the most recent taxonomic changes (at the time of publication), based on classification by DNA bar coding. Information on updated fungal species classification is publicly available.[4-7]

NOTE: When serial twofold dilution 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 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.