CLINICAL AND LABORATORY STANDARDS INSTITUTE®

3rd Edition

M27M44S

Performance Standards for Antifungal Susceptibility Testing of Yeasts

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.

A CLSI supplement for global application.

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Performance Standards for Antifungal Susceptibility Testing of Yeasts

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Abstract

Clinical and Laboratory Standards Institute document M27M44S—*Performance Standards for Antifungal Susceptibility Testing of Yeasts* includes minimal inhibitory concentration, zone diameter, and quality control tables developed following the guidance in CLSI documents M27[1] and M44.[2] The data in the tables are valid only when the methodologies in CLSI documents M27[1] and M44[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 methods for antifungal susceptibility testing of yeasts described in CLSI documents M27[1] and M44.[2] These reference methods may be used for:

- Routine antifungal testing of patient isolates to guide therapy
- 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 commercial 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.

However, CLSI breakpoints may differ from breakpoints approved by various regulatory organizations for many reasons, including:

- Database differences
- Data interpretation
- Dosage amounts used in different parts of the world
- Public health policies

Differences also exist because CLSI proactively evaluates the need for changing breakpoints. The reasons that breakpoints may change, as well as the manner in which CLSI evaluates data and determines breakpoints, are described in CLSI document M23.[3]

When CLSI decides to change an existing breakpoint, regulatory organizations may review data to determine how the changes may affect antimicrobial agent safety and effectiveness for the approved indications. When a regulatory authority changes breakpoints, commercial device manufacturers may have to conduct a clinical trial, submit the data to the regulatory organization, and await review and approval. For these reasons, there might be a delay of one or more years if a device manufacturer decides to implement a breakpoint change. Some regulatory and accreditation requirements permit laboratories using cleared or approved testing devices to use existing regulatory organization breakpoints. Either the regulatory approved breakpoints or CLSI breakpoints may be acceptable to laboratory accreditation organizations**, depending on the method used for susceptibility testing.** Other regulatory and accreditation requirements vary. Each laboratory should consult its susceptibility test system manufacturer for additional information on the breakpoints used in its system software. Laboratories should be aware of their specific regulatory and accreditation requirements for using CLSI breakpoints.