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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Clinical laboratory testing and in vitro diagnostic test systems - Broth
micro-dilution reference method for testing the in vitro activity of
antimicrobial agents against yeast fungi involved in infectious diseases**

临床实验室检测和体外诊断系统 感染性疾病相关酵母样真菌抗微生物药物的体外
活性检测微量肉汤稀释参考方法

(English Translation)

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Appendix A (Informative) RPMI-1640 Culture Medium

A.1 Overview

Appendix B (Informative) 0.5 McFarland Barium Sulfate Turbidity Standard

Reference

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is equivalent to ISO 16256:2021 "Clinical laboratory testing and in vitro diagnostic systems for yeast-like fungi associated with infectious diseases".

Reference method for in vitro activity assay of antimicrobial drugs using microbroth dilution.

The following minimal editorial changes have been made to this document.

---Some notes have been added to facilitate understanding of the terms (see 4.7).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Medical Clinical Laboratory and In Vitro Diagnostic Systems (SAC/TC136).

Introduction

In vitro susceptibility testing of antimicrobial agents typically targets microorganisms that may cause disease, especially those considered resistant to commonly used antibiotics.

Microbial drug candidates may be able to identify microbial species that exhibit acquired resistance. This study is important for resistance monitoring and epidemiological studies of susceptibility.

It is also important to compare novel antimicrobial drugs with existing antimicrobial drugs.

Reference method for antifungal susceptibility testing. The MIC method is commonly used for resistance monitoring and for research and registration of new antimicrobial drugs.

Comparative studies, for microbial tests where results obtained by conventional methods are unreliable or where quantitative results are clinically required, to determine the effectiveness of routine testing.

Sensitivity to microorganisms that produce ambiguous results. In dilution assays, the susceptibility of microorganisms to antimicrobial activity is determined by detecting their activity at a series of dilution concentrations.

The MIC is determined by whether visible growth is produced on a series of agar plates (agar dilution method) or in broth (broth dilution method).

The MIC value of an antimicrobial drug refers to the ability of it to inhibit the growth of a specific microorganism under specified in vitro test conditions and within a specified time.

The lowest concentration of an antimicrobial agent whose growth is visible to the naked eye or optically measurable [in milligrams per liter (mg/L)]. MIC values provide...

Information on the susceptibility of microorganisms to antimicrobial drugs can guide clinicians in making appropriate treatment decisions. Because the methods used may affect the effectiveness of the drug...

To ensure the reproducibility of results both within and between laboratories, rigorous quality control and standardization are necessary. It is generally believed that the MIC value obtained by the broth dilution method should be within one serial dilution fraction above and below the true MIC endpoint (i.e., ± 1 well in the serial dilution series).

(or tube) is reproducible.

The broth dilution method involves adding equal volumes of broth containing an antimicrobial drug in progressively increasing (usually double) concentrations.

Techniques for identifying a known number of microorganisms.

The micro-broth dilution method refers to a broth dilution test performed on a micro-dilution plate.

The reference method described in this document is intended for the detection of pure cultures of yeast-like fungi. The method initially showed similar results to fluconazole.

The MIC of azole, if not completely identical, had a maximum difference within 2 mg/L [3]. Furthermore, the method showed that the two control strains of the approved antifungal drug were...

The MIC results given by the strains are similar, as described in this document, although the quality control results obtained by photometry may be slightly lower than those obtained by visual interpretation. It is hoped that...

Laboratories using this document for research on new antifungal drugs, or as a reference method for comparing MIC results with those given by diagnostic instruments, may...

The interpretation of MIC results is determined by whether to use visual observation (CLSI method) [5] or photometric method (EUCAST method) [2,10].

Which procedure option? In either case, the details of the selected procedure must be strictly followed. In ISO 16256:2012, the quality control report...

The test was conducted using a micro-broth dilution plate, and the manufacturer did not treat the plastic plate for visual or photometric methods in any way.

Clinical laboratory testing and in vitro diagnostic systems Infectious disease-associated yeast-like fungal antimicrobial in vitro activity assay of the drug using microbroth dilution Reference Method Warning---Use of this document may involve hazardous materials, operations, and equipment. This document is not intended to represent any risks associated with its use.

There are safety concerns. Before using this document, users are responsible for establishing appropriate safety and health measures and determining the applicability of regulatory restrictions.

1 Scope

This document describes a method for detecting the susceptibility of yeast-like fungi to antifungal agents, including *Candida* species and *Cryptococcus neoformans* that cause infection.

The reference methods described in this document have not been used in studies of the yeast phase of dimorphic fungi, such as *Blastomyces dermatitidis* and/or *Histoplasma capsulatum*.

Capsular variants. Several other issues not addressed in the standardization of filamentous fungi (molds) detection are also involved. These methods do not...

Within the scope of this document.

The micro-broth dilution reference method described in this document can be achieved through one of two approaches. One is by visually determining the MIC (CLSI).

The second approach is to determine the MIC using photometry (EUCAST method) [1,5]. MIC reflects the drug's performance under specified test conditions.

The activity of the drug should be considered, and other factors should be taken into account to explain its clinical management purpose, such as the pharmacology of the drug or its antifungal resistance mechanism. Additionally...

MIC distributions can be used to identify wild-type or non-wild-type fungal communities. The