ICS 11.100.10 SLOVENSKÁ TECHNICKÁ NORMA Január 2022

STN	**Klinické laboratórne skúšanie a diagnostické skúšobné systémy in vitro Referenčná metóda mikroriedenia bujónu na skúšanie in vitro aktivity antimikrobiálnych činidiel proti kvasinkovým hubám pôsobiacim pri infekčných ochoreniach (ISO 16256: 2021)**	**STN EN ISO 16256** 85 1022

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 (ISO 16256:2021)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/21

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16256

October 2021

ICS 11.100.10

Supersedes EN ISO 16256:2012

English Version

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 (ISO 16256:2021)

Laboratoires d'analyses de biologie médicale et systèmes de diagnostic in vitro - Méthode de référence de microdilution en milieu liquide pour soumettre à essai l'activité in vitro des agents antimicrobiens par rapport aux levures impliquées dans les maladies infectieuses (ISO 16256:2021)

Labormedizinische Untersuchungen und In-vitro-Diagnostika-Systeme - Referenzmethode zur Testung der In-vitro-Aktivität von antimikrobiellen Substanzen gegen Pilze, die Infektionskrankheiten verursachen (ISO 16256:2021)

This European Standard was approved by CEN on 2 August 2021.

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European foreword

This document (EN ISO 16256:2021) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2022, and conflicting national standards shall be withdrawn at the latest by October 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 16256:2012.

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The text of ISO 16256:2021 has been approved by CEN as EN ISO 16256:2021 without any modification.

INTERNATIONAL STANDARD

ISO 16256

Second edition
2021-10

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

Laboratoires d'analyses de biologie médicale et systèmes de diagnostic in vitro — Méthode de référence de microdilution en milieu liquide pour soumettre à essai l'activité in vitro des agents antimicrobiens par rapport aux levures impliquées dans les maladies infectieuses

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 16256:2012), which has been technically revised.

The main changes are as follows:

— addition of “broth micro-dilution” to the title;

— removal of 48 h reading for *Candida* species by the visual reading method;

— removal of definitions for susceptibility and resistance that are beyond the scope of this test performance document;

— inclusion of considerations for antifungal testing of yeast species with micro-dilution trays “treated” by manufacturers of the trays prior to use in the tests;

— updating of viable count testing methods for visual and spectrophotometer test pathways.

— addition of new antifungals (isavuconazole, rezafungin) to the testing and quality control range tables;

— detailed characterization of the components of one formulation of RPMI-1640 known to provide reproducible results of antifungal susceptibility tests for *Candida* species and *Cryptococcus neoformans*;

— reassigning of annexes;

— update of bibliography to more relevant information about performance of antifungal susceptibility testing for yeast fungi.

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Introduction

In vitro susceptibility tests are performed on microorganisms suspected of causing disease, particularly if the organism is thought to belong to a species that can exhibit acquired resistance to frequently used antimicrobial agents. The tests are also important in resistance surveillance, epidemiological studies of susceptibility and in comparisons of new and existing agents.

Dilution procedures are used to determine the minimum inhibitory concentrations (MICs) of antimicrobial agents and represent the reference method for antifungal susceptibility testing. MIC methods are used in resistance surveillance, comparative testing of new agents for research or registration purposes, to establish the susceptibility of organisms that give equivocal results in routine tests, for tests with organisms where routine tests can be unreliable and when a quantitative result is needed for clinical management. In dilution tests, microorganisms are tested for their ability to produce discernible growth on a series of agar plates (agar dilution) or in broth (broth dilution) containing serial dilutions of the antimicrobial agent.

The lowest concentration of an antimicrobial agent (in mg/l) that, under defined in vitro test conditions, reduces visible or optically measurable growth of a microorganism within a defined period of time is known as the MIC. The MIC is a guide for the clinician to the susceptibility of the organism to the antimicrobial agent and aids treatment decisions. Careful control and standardization are required for intra- and inter-laboratory reproducibility, as results can be influenced by the method used. It is generally accepted that broth MIC tests are reproducible to within one doubling dilution of the true end point (i.e. ±1 well or tube in a doubling dilution series).

Broth dilution is a technique in which containers holding identical volumes of broth with antimicrobial agent solutions in incrementally (usually two-fold) increasing concentrations are inoculated with a known number of microorganisms.

Broth micro-dilution denotes the performance of the broth dilution test in micro-dilution trays.

The reference methods described in this document are intended for the testing of pure cultures of yeast fungi. The broth micro-dilution methods described in this document are the same as those described by the Clinical and Laboratory Standards Institute (CLSI)[1][5] and by the European Committee on Antimicrobial Susceptibility Testing (EUCAST)[2][10]. These methods were initially shown to provide MICs of fluconazole that were similar, if not identical up to 2 mg/l[3]. Further the methods have been shown to provide MICs for two quality control strains of licensed antifungal agents that are similar as described in this document although quality control results for the spectrophotometer can trend slightly lower than for the visual reading method. The laboratory that wishes to use this document for conducting studies of newer antifungal agents, or as a reference method for comparison to MICs generated by a diagnostic device, can select which of the procedure options to use based upon the choice of MIC reading determined by visual inspection (CLSI method)[5] or by use of a spectrophotometer (EUCAST method)[2][10]. In either case, the procedural details for that option should be followed explicitly. In the first edition of this document, i.e. ISO 16256:2012, the reported quality control tests were performed using broth micro-dilution trays that were not treated in some way by the manufacturers of the plastic trays for either the visual or spectrophotometer method.

In this document the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— ”may” indicates a permission;

— “can” indicates a possibility or a capability.

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INTERNATIONAL STANDARD ISO 16256:2021(E)

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

WARNING — The use of this document can involve hazardous materials, operations and equipment. This document does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this document to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

1 Scope

This document describes a method for testing the susceptibility to antifungal agents of yeasts, including *Candida* spp. and *Cryptococcus neoformans*, that cause infections. The reference method described here has not been used in studies of the yeast forms of dimorphic fungi, such as *Blastomyces dermatitidis* and/or *Histoplasma capsulatum* variety capsulatum. Moreover, testing filamentous fungi (moulds) introduces several additional problems in standardization not addressed by the current procedure. Those methods are beyond the scope of this document.

This document describes the broth micro-dilution reference method, which can be implemented by either of two pathways. One pathway involves visual determination of MICs (CLSI method)[1][5]; the second pathway involves spectrophotometric determination of MICs (EUCAST method)[2][10]. The MIC reflects the activity of the drug under the described test conditions and can be interpreted for clinical management purposes by taking into account other factors, such as drug pharmacology or antifungal resistance mechanisms. In addition, MIC distributions can be used to define wild type or non-wild type fungal populations. Clinical interpretation of the MIC value is beyond the scope of this document; interpretive category breakpoints specific to the CLSI- and EUCAST-derived methods can be found by consulting the latest interpretive tables provided by the organizations[5][15]. Routine susceptibility testing methods or diagnostic test devices can be compared with this reference method in order to ensure comparable and reliable results for validation or registration purposes.

2 Normative references

There are no normative references in this document.

koniec náhľadu – text ďalej pokračuje v platenej verzii STN

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