SLOVENSKI STANDARD
SIST EN ISO 16256:2013

01-marec-2013

Klinično laboratorijsko preskušanje ter dignostični preskusni sistemi in vitro - Referenčna metoda za preskušanje aktivnosti in vitro antimikrobnih snovi proti gobam kvasovkam, ki povzročajo infekcijske bolezni (ISO 16256:2012)

Clinical laboratory testing and in vitro diagnostic test systems - Reference method for testing the in vitro activity of antimicrobial agents against yeast of fungi involved in infectious diseases (ISO 16256:2012)

Labormedizinische Untersuchungen und In-vitro-Diagnostika-Systeme - Referenzmethode zur Testung der In-vitro-Aktivität von antimikrobiellen Substanzen gegen Pilze, die Infektionskrankheiten verursachen (ISO 16256:2012)

Essais de laboratoire clinique et systèmes de diagnostic in vitro - Méthode de référence pour soumettre à essai l'activité in vitro des agents antimicrobiens par rapport aux levures impliquées dans les maladies infectieuses (ISO 16256:2012)

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11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

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Clinical laboratory testing and in vitro diagnostic test systems - Reference method for testing the in vitro activity of antimicrobial agents against yeast of fungi involved in infectious diseases (ISO 16256:2012)

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Foreword

This document (EN ISO 16256:2012) 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of an identical text or by endorsement, at the latest by June 2013, and conflicting national standards shall be withdrawn at the latest by December 2015.

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The text of ISO 16256:2012 has been approved by CEN as a EN ISO 16256:2012 without any modification.

INTERNATIONAL STANDARD

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Clinical laboratory testing and in vitro diagnostic test systems — Reference method for testing the in vitro activity of antimicrobial agents against yeast fungi involved in infectious diseases

Essais de laboratoire clinique et systèmes de diagnostic in vitro — Méthode de référence 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 16256 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

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 may 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 may 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 is required for intra- and inter-laboratory reproducibility, as results may 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 twofold) increasing concentrations are inoculated with a known number of microorganisms.

Broth microdilution denotes the performance of the broth dilution test in microdilution trays.

The reference methods described in this International Standard are intended for the testing of pure cultures of yeast fungi. The broth microdilution methods described in this part of this International Standard are essentially the same as those described by the Clinical and Laboratory Standards Institute (CLSI)[1] and by the European Committee on Antimicrobial Susceptibility Testing (EUCAST)[2]. These methods have been shown to provide MICs of fluconazole that are essentially the same, if not identical up to 2 mg/l[3]. Studies with various other antifungal agents are planned or under way. The laboratory that wishes to use this International Standard for conducting studies of newer antifungal agents, or as a reference method for comparison to MICs generated by a diagnostic device, should select which of the procedure options to use based upon the choice of MIC reading determined by visual inspection (CLSI method) or by use of a spectrophotometer (EUCAST method). In either case, the procedural details for that option are to be followed explicitly.