
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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Contents

	Page
Foreword	iv
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Test procedures	3
4.1 General.....	3
4.1.1 Trays and method.....	3
4.1.2 Conditions for use of disposable micro-dilution trays.....	3
4.2 Medium.....	3
4.2.1 General.....	3
4.2.2 Visual reading pathway.....	3
4.2.3 Spectrophotometric reading pathway.....	4
4.3 Antifungal agents.....	4
4.3.1 General.....	4
4.3.2 Preparation of stock solutions.....	4
4.3.3 Preparation of working solutions.....	5
4.4 Preparation of broth micro-dilution trays.....	6
4.4.1 Preparation for tests read visually – Visual reading pathway.....	6
4.4.2 Preparation for tests read by spectrophotometer - Spectrophotometric reading pathway.....	6
4.5 Storage of micro-dilution trays.....	6
4.6 Preparation of inoculum.....	7
4.6.1 General.....	7
4.6.2 Preparation of inoculum for visual test reading.....	7
4.6.3 Preparation of inoculum for spectrophotometric test reading.....	7
4.7 Inoculation of micro-dilution trays.....	7
4.8 Incubation of micro-dilution trays.....	8
4.8.1 General.....	8
4.8.2 Visual pathway.....	8
4.8.3 Spectrophotometric pathway.....	8
4.9 Reading MIC results.....	8
4.9.1 General.....	8
4.9.2 Visual reading method.....	8
4.9.3 Spectrophotometric reading methods.....	8
4.10 Interpretation of MICs.....	9
5 Quality Control (QC)	9
Annex A (informative) RPMI-1640 medium	12
Annex B (informative) McFarland 0,5 barium sulfate turbidity standard	14
Bibliography	15

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.

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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.