INTERNATIONAL STANDARD

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Second edition
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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

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

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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.