DIN EN ISO 16256:2022-02 (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 in fectious diseases (ISO 16256:2021)

Contents

Page

European foreword 3

Foreword 4

Introduction 6

1 Scope 7

2 Normative references 7

3 Termsanddefinitions 7

4 Test procedures 9
4.1 General 9
4.1.1 Trays and method 9
4.1.2 Conditions for use of disposable micro-dilution trays 9
4.2 Medium 9
4.2.1 General 9
4.2.2 Visual reading pathway 9
4.2.3 Spectrophotometric reading pathway 10
4.3 Antifungal agents 10
4.3.1 General 10
4.3.2 Preparation of stock solutions 10
4.3.3 Preparation of working solutions 11
4.4 Preparation of broth micro-dilution trays 12
4.4.1 Preparation for tests read visually - Visual reading pathway 12
4.4.2 Preparation for tests read by spectrophotometer - Spectrophometric reading pathway 12
4.5 Storage of micro-dilution trays 12
4.6 Preparation of inoculum 13
4.6.1 General 13
4.6.2 Preparation of inoculum for visual test reading 13
4.6.3 Preparation of inoculum for spectrophotometric test reading 13
4.7 Inoculation of micro-dilution trays 13
4.8 Incubation of micro-dilution trays 14
4.8.1 General 14
4.8.2 Visual pathway 14
4.8.3 Spectrophotometric pathway 14
4.9 Reading MIC results 14
4.9.1 General 14
4.9.2 Visual reading method 14
4.9.3 Spectrophotometric reading methods 14
4.10 Interpretation of MICs 15

5 Quality Control (QC) 15

Annex A (informative) RPMI-1640 medium 18

Annex B (informative) McFarland 0,5 barium sulfate turbidity standard 20

Bibliography 21