DIN EN ISO 20776-2:2022-04 (E)

Clinical laboratory testing and in vitro diagnostic test systems - Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 2: Evaluation of performance of antimicrobial susceptibility test devices against reference broth micro-dilution (ISO 20776-2:20 21)

Contents

Page

European foreword ... **3**

Foreword ... **4**

Introduction ... **6**

1 Scope ... **7**

2 Normative references ... **7**

3 Terms and definitions ... **7**

4 Test methods ... **11**
4.1 General ... 11
4.2 Methods ... 11
4.2.1 Reference method ... 11
4.2.2 Strain selection ... 11
4.2.3 Quality control (QC) ... 12
4.2.4 Quality control (QC) of the reference method ... 12
4.2.5 Reproducibility testing of test device ... 12
4.2.6 Isolate testing protocol ... 13
4.2.7 Inoculum preparation ... 13
4.2.8 Discrepancy resolution testing ... 13
4.2.9 System under evaluation ... 13

5 Data analysis and acceptance criteria ... **14**
5.1 Accuracy of test device ... 14
5.1.1 General ... 14
5.1.2 MIC devices ... 14
5.1.3 Qualitative AST devices ... 14
5.2 Quality control (QC) of test device ... 14
5.3 Reproducibility of test device ... 14
5.4 Documents related to study ... 14

Annex A (informative) **Evaluating the performance of MIC tests** ... **15**

Annex B (informative) **Rationale for bias analysis** ... **18**

Annex C (informative) **Sensitivity and specificity analyses for qualitative tests** ... **20**

Bibliography ... **22**