INTERNATIONAL STANDARD

ISO 20776-2

Second edition
2021-12

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 microdilution

Systèmes d'essais en laboratoire et de diagnostic in vitro — Sensibilité in vitro des agents infectieux et évaluation des performances des dispositifs pour antibiogrammes —

Partie 2: Évaluation des performances des dispositifs pour antibiogrammes par rapport à une méthode de référence de microdilution en bouillon

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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 20776-2:2007), which has been technically revised.

The main changes are as follows:

— Revision in the title of this document to better align with the intended information.

— Addition of an Introduction (not present in the first edition).

— Revised Clause 3 as follows:

  — Removed definitions for category agreement, susceptible, intermediate, resistant, non-susceptible, major discrepancy, minor discrepancy, very major discrepancy, breakpoint test and zone diameter;

  — Added definition for contemporary isolate (3.11.1), and removed definitions for fresh isolate, recent isolate;

  — Added definitions for reproducibility (3.9), bias of the test method (3.10.3), sensitivity analysis (3.10.4.1), specificity analysis (3.10.4.2), bacterial organism group (3.16);

  — Added definition for qualitative test (3.7) and removed definition for breakpoint test;

  — Revised definitions for minimum inhibitory concentration test (3.4), breakpoint (3.6), quality control (3.8), discrepancy (3.10.1).

— Reordered Clause 4 (Test methods);

