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**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**

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*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

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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);