INTERNATIONAL STANDARD

ISO 20776-2

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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

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

Reference number
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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 20776-2 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, In vitro *diagnostic medical devices,* in collaboration with Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

ISO 20776 consists of the following parts, under the general title *Clinical laboratory testing and* in vitro *diagnostic test systems — Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices*:

— *Part 1: Reference method for testing the* in vitro *activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases*

— *Part 2: Evaluation of performance of antimicrobial susceptibility test devices*

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

1 Scope

This part of ISO 20776 establishes acceptable performance criteria for antimicrobial susceptibility test (AST) devices that are used to determine minimum inhibitory concentrations (MIC) and/or interpretive category determinations of susceptible, intermediate and resistant (SIR) strains of bacteria to antimicrobial agents in medical laboratories. This part of ISO 20776 specifies requirements for AST devices (including diffusion test systems) and procedures for assessing performance of such devices. It defines how a performance evaluation of an AST device is to be conducted. This part of ISO 20776 has been developed to guide manufacturers in the conduct of performance evaluation studies.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 20776-1, *Clinical laboratory testing and* in vitro *diagnostic test systems — Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 1: Reference method for testing the* in vitro *activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 Agreement of test results

3.1.1
category agreement
CA
agreement of SIR results between a breakpoint test or an MIC test and the reference method (ISO 20776-1)

Another representation of the concept:

$$\frac{N_{CA} \times 100}{N}$$

where

N_{CA} is the number of bacterial isolates with the same SIR category as the reference method category result;

N is the total number of bacterial isolates tested

NOTE The overall CA is expressed as a percentage.

3.1.2
essential agreement
EA
MIC result obtained with the AST device that is within plus or minus one doubling dilution step from the MIC value established with the reference method (ISO 20776-1)

Another representation of the concept:

$$\frac{N_{EA} \times 100}{N}$$

where

N_{EA} is the number of bacterial isolates with an EA;

N is the total number of bacterial isolates tested

NOTE The overall EA is expressed as a percentage.

3.2
antimicrobial susceptibility test device
AST device
device including all specified components used to obtain test results that allow SIR categorization of bacteria with specific antimicrobial agents

NOTE Specific components include inoculators, disposables and reagents, media, disks and readers. Non-specific components, such as swabs, pipettes and tubes, are not part of the device.

3.3
breakpoint
BP
specific values of parameters, such as MICs, on the basis of which bacteria can be assigned to the clinical categories “susceptible”, “intermediate” and “resistant”

NOTE For current interpretive breakpoints, reference can be made to the latest publications of organizations employing this reference method (e.g. CLSI and EUCAST).

3.3.1
susceptible
S
bacterial strain inhibited *in vitro* by a concentration of an antimicrobial agent that is associated with a high likelihood of therapeutic success

NOTE 1 Bacterial strains are categorized as susceptible by applying the appropriate breakpoints in a defined phenotypic test system.

NOTE 2 This breakpoint can be altered due to changes in circumstances (e.g. changes in commonly used drug dosages, emergence of new resistance mechanisms).