AS ISO 20776.2:2017
ISO 20776-2:2007

AS ISO 20776.2:2017

Australian STANDARD

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

STANDARDS Australia

This Australian Standard® was prepared by Committee HE-029, Clinical Laboratory Testing and In Vitro Diagnostic Test Systems. It was approved on behalf of the Council of Standards Australia on 10 January 2017.
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The following are represented on Committee HE-029:

- Australasian Association of Clinical Biochemists
- Australasian College of Medical Sciences and Research
- Australian Institute of Medical Scientists
- Australian Society for Microbiology
- Human Genetics Society of Australasia
- IVD Australia
- National Association of Testing Authorities Australia
- National Pathology Accreditation Advisory Council
- Pathology Australia
- Royal College of Pathologists of Australasia
- Therapeutic Goods Administration

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PREFACE

This Standard was prepared by the Standards Australia Committee HE-029, Clinical Laboratory Testing and In Vitro Diagnostic Test Systems.

The objective of this Standard is to establish acceptable performance criteria for antimicrobial susceptibility test (AST) devices that are used to determine minimum inhibitory concentrations (MICs) and/or interpretive category determinations of susceptible, intermediate and resistant (SIR) strains of bacteria to antimicrobial agents in medical laboratories.

This Standard is identical with, and has been reproduced from ISO 20776-2:2007, *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.*

As this Standard is reproduced from an International Standard, the following applies:

(a) In the source text 'this part of ISO 20776' should read 'this Australian Standard'.

(b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
20776	Clinical laboratory testing and in vitro diagnostic test systems−Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices	20776	Clinical laboratory testing and in vitro diagnostic test systems−Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices
20776-1	Part 1: Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases	20776.1	Part 1: Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases

Only normative references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

AUSTRALIAN STANDARD

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:

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