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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**



AS ISO 20776.2:2024

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- Australian Institute of Medical and Clinical Scientists
- Australian Society for Microbiology
- Human Genetics Society of Australasia
- IVD Australia
- Medical Technology Association of Australia
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- National Pathology Accreditation Advisory Council
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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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## Preface

This Standard was prepared by the Standards Australia Committee HE-029 Clinical Laboratory Testing and *in vitro* Diagnostic Test Systems, to supersede AS ISO 20776.2:2017, *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*.

The objective of this document is to establish acceptable performance criteria for antimicrobial susceptibility test (AST) devices that are used to determine minimum inhibitory concentrations (MIC) of bacteria to antimicrobial agents in medical laboratories.

This document specifies requirements for AST devices and procedures for assessing performance of such devices. It defines how a performance evaluation of an AST device is to be conducted.

This document has been developed to guide manufacturers in the conduct of performance evaluation studies.

This document is identical with, and has been reproduced from, ISO 20776-2:2021, *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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# Contents

<b>Preface</b> .....	<b>ii</b>
<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>vi</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Test methods</b> .....	<b>5</b>
4.1 General .....	5
4.2 Methods .....	5
4.2.1 Reference method .....	5
4.2.2 Strain selection .....	5
4.2.3 Quality control (QC) .....	6
4.2.4 Quality control (QC) of the reference method .....	6
4.2.5 Reproducibility testing of test device .....	6
4.2.6 Isolate testing protocol .....	7
4.2.7 Inoculum preparation .....	7
4.2.8 Discrepancy resolution testing .....	7
4.2.9 System under evaluation .....	7
<b>5 Data analysis and acceptance criteria</b> .....	<b>8</b>
5.1 Accuracy of test device .....	8
5.1.1 General .....	8
5.1.2 MIC devices .....	8
5.1.3 Qualitative AST devices .....	8
5.2 Quality control (QC) of test device .....	8
5.3 Reproducibility of test device .....	8
5.4 Documents related to study .....	8
<b>Annex A</b> (informative) <b>Evaluating the performance of MIC tests</b> .....	<b>9</b>
<b>Annex B</b> (informative) <b>Rationale for bias analysis</b> .....	<b>12</b>
<b>Annex C</b> (informative) <b>Sensitivity and specificity analyses for qualitative tests</b> .....	<b>14</b>
<b>Bibliography</b> .....	<b>16</b>

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