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

STANDARDS Australia

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- 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 describe one reference method, broth microdilution, for determination of minimum inhibitory concentrations (MICs). The MIC reflects the activity of the drug under the described test conditions, and can be interpreted for clinical management purposes by taking into account other factors, such as drug pharmacology or bacterial resistance mechanisms. This allows categorization of bacteria as susceptible (S), intermediate (I), or resistant (R).

This Standard is identical with, and has been reproduced from ISO 20776-1:2006, *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*.

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.

CONTENTS

INTRODUCTION

In vitro susceptibility tests are performed on microorganisms suspected of causing disease, particularly if the organism is thought to belong to a species that may exhibit resistance to frequently used antimicrobial agents. The tests are also important in resistance surveillance, epidemiological studies of susceptibility and in comparisons of new and existing agents.

Dilution procedures are used to determine the minimum inhibitory concentrations (MICs) of antimicrobial agents and are the reference method for antimicrobial susceptibility testing. MIC methods are used in resistance surveillance, comparative testing of new agents, to establish the susceptibility of organisms that give equivocal results in routine tests, for tests on organisms where routine tests may be unreliable and when a quantitative result is required for clinical management. In dilution tests, microorganisms are tested for their ability to produce visible growth on a series of agar plates (agar dilution) or in broth (broth dilution) containing serial dilutions of the antimicrobial agent.

The lowest concentration of an antimicrobial agent (in mg/l) that, under defined *in vitro* conditions, prevents the appearance of visible growth of a microorganism within a defined period of time is known as the MIC. The MIC is a guide for the clinician to the susceptibility of the organism to the antimicrobial agent and aids treatment decisions. Careful control and standardisation is required for intra- and inter-laboratory reproducibility, as results may be significantly influenced by the method used. It is generally accepted that broth MIC tests are reproducible to within one doubling dilution of the real end point (i.e. ± one well or tube in a doubling dilution series).

Broth dilution is a technique in which containers holding identical volumes of broth with antimicrobial agent solutions in incrementally (usually geometrically) increasing concentrations are inoculated with a known number of microorganisms.

Broth microdilution denotes the performance of the broth dilution test in microdilution trays.

The method described in this part of ISO 20776 is intended for the testing of pure cultures of aerobic bacteria that are easily grown by overnight incubation on agar and grow well in Mueller-Hinton broth, which may be supplemented. The broth microdilution method described in this part of ISO 20776 is essentially the same as those used in many countries, including France[1], Germany[2], Sweden[3], the United Kingdom[4], and the United States[5]. The method is also essentially the same as the broth microdilution method published by the European Committee on Antimicrobial Susceptibility Testing (EUCAST)[6]. All these methods are based on those described by Ericsson and Sherris[7].

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WARNING — The use of this part of ISO 20776 may involve hazardous materials, operations and equipment. This part of ISO 20776 does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this part of ISO 20776 to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

1 Scope

This part of ISO 20776 describes one reference method, broth microdilution, for determination of MICs. The MIC reflects the activity of the drug under the described test conditions, and can be interpreted for clinical management purposes by taking into account other factors, such as drug pharmacology or bacterial resistance mechanisms. This allows categorization of bacteria as “susceptible” (S), “intermediate” (I), or “resistant” (R). In addition, MIC distributions can be used to define wild type or non-wild type bacterial populations. Although clinical interpretation of the MIC value is beyond the scope of this part of ISO 20776, modifications of the basic method are required for certain antimicrobial agent - bacteria combinations to facilitate clinical interpretation. These modifications are included in a separate table. It is advisable to compare other susceptibility testing methods (e.g. routine methods or diagnostic test devices) with this reference method for validation, in order to ensure comparable and reliable results.

2 Terms and definitions

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

2.1
antimicrobial agent
substance of biological, semi-synthetic or synthetic origin that inhibits the growth of or kills bacteria, and is thus of potential use in the treatment of infections

NOTE Disinfectants, antiseptics and preservatives are not included in this definition.

2.2 Antimicrobial agents — properties

2.2.1
potency
antimicrobially active fraction of a test substance, determined in a bioassay against a reference powder of the same substance

