

<b>STN</b>	<b>Skúšanie citlivosti infekčných činiteľov a hodnotenie výkonnosti zariadení na skúšanie antimikrobiálnej citlivosti</b> <b>Časť 1: Referenčná metóda mikroriedenia bujónu na skúšanie in vitro aktivity antimikrobiálnych látok na rýchlorastúce aeróbne baktérie spôsobujúce infekčné ochorenia (ISO 20776-1: 2019, opravená verzia 2019-12)</b>	<b>STN EN ISO 20776-1</b>  85 1021
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Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 1: Broth micro-dilution reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases (ISO 20776-1:2019, including Corrected version 2019-12)

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 09/20

Obsahuje: EN ISO 20776-1:2020, ISO 20776-1:2019

Oznámením tejto normy sa od 31.07.2023 ruší  
STN EN ISO 20776-1 (85 1021) z augusta 2007

**131673**

EUROPEAN STANDARD

EN ISO 20776-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2020

ICS 11.100.20

Supersedes EN ISO 20776-1:2006

English Version

Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 1: Broth micro-dilution reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases (ISO 20776-1:2019, including Corrected version 2019-12)

Sensibilité in vitro des agents infectieux et évaluation des performances des dispositifs pour antibiogrammes - Partie 1: Méthode de référence de microdilution en bouillon pour la détermination de la sensibilité in vitro aux agents antimicrobiens des bactéries aérobies à croissance rapide impliquées dans les maladies infectieuses (ISO 20776-1:2019, y compris version corrigée 2019-12)

Labormedizinische Untersuchungen und In-vitro-Diagnostika-Systeme - Empfindlichkeitsprüfung von Infektionserregern und Evaluation von Geräten zur antimikrobiellen Empfindlichkeitsprüfung - Teil 1: Referenzmethode zur Testung der In-vitro-Aktivität von antimikrobiellen Substanzen gegen schnell wachsende aerobe Bakterien, die Infektionskrankheiten verursachen (ISO 20776-1:2019, einschließlich der korrigierten Fassung von 2019-12)

This European Standard was approved by CEN on 22 April 2020.

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## **European foreword**

This document (EN ISO 20776-1:2020) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 "In vitro diagnostic medical devices" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2021, and conflicting national standards shall be withdrawn at the latest by July 2023.

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

This document supersedes EN ISO 20776-1:2006.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## **Endorsement notice**

The text of ISO 20776-1:2019, including Corrected version 2019-12 has been approved by CEN as EN ISO 20776-1:2020 without any modification.

**INTERNATIONAL  
STANDARD****ISO  
20776-1**Second edition  
2019-06Corrected version  
2019-12

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**Susceptibility testing of infectious  
agents and evaluation of performance  
of antimicrobial susceptibility test  
devices —**

Part 1:

**Broth micro-dilution reference  
method for testing the in vitro activity  
of antimicrobial agents against rapidly  
growing aerobic bacteria involved in  
infectious diseases***Sensibilité in vitro des agents infectieux et évaluation des  
performances des dispositifs pour antibiogrammes —**Partie 1: Méthode de référence de microdilution en bouillon pour la  
détermination de la sensibilité in vitro aux agents antimicrobiens des  
bactéries aérobies à croissance rapide impliquées dans les maladies  
infectieuses*Reference number  
ISO 20776-1:2019(E)

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Published in Switzerland

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# ISO 20776-1:2019(E)

## 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)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*.

This second edition cancels and replaces the first edition (ISO 20776-1:2006), which has been technically revised.

The main changes compared to the previous edition are as follows:

- revised to a broth micro-dilution only performance document;
- removal of S, I, R breakpoint definitions and information;
- moved embedded tables to annexes;
- removed quality control range table;
- updated table (now [Annex B](#)) on solvents and diluents for antimicrobial agents used globally;
- updated information on special culture media and method performance for specific currently used antimicrobial agents.

A list of all parts in the ISO 20776 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

This corrected version of ISO 20776-1:2019 incorporates the following correction:

- Correction of the diluent pH value for ampicillin from 8,0 to 6,0 in [Annex B](#).



## Introduction

In vitro antimicrobial susceptibility tests are performed on micro-organisms 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 for antimicrobial susceptibility testing. MIC methods are used in resistance surveillance, defining identifying wild type phenotypes, 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, micro-organisms are tested for their ability to produce visible growth in broth (broth dilution) containing serial dilutions of the antimicrobial agent or on a series of agar plates (agar dilution).

The lowest concentration of an antimicrobial agent (in mg/l) that, under defined in vitro conditions, prevents the appearance of visible growth of a micro-organism 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 standardization is required for intra- and inter-laboratory reproducibility of broth MIC tests. The MICs generally span two to three doubling dilutions with a dominant central value.

**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 micro-organisms.

**Broth micro-dilution** denotes the performance of the broth dilution test in micro-dilution trays.

The method described in this document is intended for the testing of pure cultures of aerobic bacteria that are easily grown by overnight incubation on agar and grow well in standardized micro-dilution trays containing standardized Mueller-Hinton broth (volume of  $\leq 200 \mu\text{l}$ ), which may need to be modified depending on the antimicrobial agent being tested.

The broth micro-dilution method described in this document is essentially the same as those used in many countries, and as the methods published by the Clinical and Laboratory Standards Institute (CLSI) [1] and the European Committee on Antimicrobial Susceptibility Testing (EUCAST) [2]. These methods are based on those described by Ericsson and Sherris [3].

# Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices —

## Part 1:

# Broth micro-dilution reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases

**WARNING —** The use of this document may involve hazardous materials, operations and equipment. This document does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this document to establish appropriate safety and health practices and to determine the applicability of any other restrictions prior to use.

## 1 Scope

This document describes one reference method, broth micro-dilution, for determination of MICs. The MIC can be a guide for the clinician, and reflects the activity of the drug under the described test conditions, by taking into account other factors, such as drug pharmacology, pharmacokinetics, or bacterial resistance mechanisms. This allows categorisation 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 document, modifications of the basic method are required for certain antimicrobial agent - bacteria combinations to facilitate clinical interpretation. These modifications are included in a separate annex of this document. It is necessary to compare other susceptibility testing methods (e.g. disc diffusion or diagnostic test devices) with this reference method for validation, in order to ensure comparable and reliable results.

## 2 Normative references

There are no normative references in this document.

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**