SLOVENSKI STANDARD
SIST EN ISO 20776-2:2022

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Nadomešča:
SIST EN ISO 20776-2:2008

Klinični laboratorijski preskusi ter diagnostični preskusni sistemi in-vitro - Preskus občutljivosti povzročiteljev infekcij in vrednotenje delovanja antimikrobno občutljivih preskusnih naprav - 2. del: Vrednotenje delovanja antimikrobno občutljivih naprav (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 (ISO 20776-2:2021)

Labormedizinische Untersuchungen und In-vitro-Diagnostika-Systeme - Empfindlichkeitsprüfung von Infektionserregern und Evaluation von Geräten zur antimikrobiellen Empfindlichkeitsprüfung - Teil 2: Evaluation der Leistung einer Vorrichtung zur antimikrobiellen Empfindlichkeitsprüfung (ISO 20776-2:2021)

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 par rapport à une méthode de référence de microdilution en bouillon (ISO 20776-2:2021)

Ta slovenski standard je istoveten z: **EN ISO 20776-2:2022**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN ISO 20776-2:2022 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 20776-2

January 2022

ICS 11.100.20

Supersedes EN ISO 20776-2:2007

English Version

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 (ISO 20776-2:2021)

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 par rapport à une méthode de référence de microdilution en bouillon (ISO 20776-2:2021)

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This European Standard was approved by CEN on 16 December 2021.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 20776-2:2022) 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 July 2022, and conflicting national standards shall be withdrawn at the latest by January 2025.

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.

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Endorsement notice

The text of ISO 20776-2:2021 has been approved by CEN as EN ISO 20776-2:2022 without any modification.

INTERNATIONAL STANDARD

ISO 20776-2

Second edition
2021-12

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 microdilution

Systèmes d'essais en laboratoire et de diagnostic in vitro — Sensibilité in vitro des agents infectieux et évaluation des performances des dispositifs pour antibiogrammes —

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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).

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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.

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

This second edition cancels and replaces the first edition (ISO 20776-2:2007), which has been technically revised.

The main changes are as follows:

— Revision in the title of this document to better align with the intended information.

— Addition of an Introduction (not present in the first edition).

— Revised Clause 3 as follows:

  — Removed definitions for category agreement, susceptible, intermediate, resistant, non-susceptible, major discrepancy, minor discrepancy, very major discrepancy, breakpoint test and zone diameter;

  — Added definition for contemporary isolate (3.11.1), and removed definitions for fresh isolate, recent isolate;

  — Added definitions for reproducibility (3.9), bias of the test method (3.10.3), sensitivity analysis (3.10.4.1), specificity analysis (3.10.4.2), bacterial organism group (3.16);

  — Added definition for qualitative test (3.7) and removed definition for breakpoint test;

  — Revised definitions for minimum inhibitory concentration test (3.4), breakpoint (3.6), quality control (3.8), discrepancy (3.10.1).

— Reordered Clause 4 (Test methods);

— Moved general requirements for a performance evaluation as a separate section, to the overview (now renamed general section, subclause 4.1) under test methods);

— Revised quality control section, subclause 4.2, and referenced EUCAST and CLSI documents for quality control ranges;

— Revised subclause 4.2.1 (Reference method) to add variability;

— Revised subclause 4.2.2 (Strain selection) and incorporated new definition of contemporary isolates (3.11.1);

— Revised subclause 4.2.5 (Reproducibility testing);

— Updated subclause 4.2.8 (Discrepancy resolution testing);

— Combined data analysis and acceptance criteria subclauses (Clause 5);

— Revised subclause 5.1 (Accuracy of test device) to remove category agreement;

— Revised data analysis for MIC devices to remove category agreement. Added bias requirement;

— Removed acceptance for breakpoint AST devices;

— Added provisions on acceptance criteria for qualitative AST devices (5.1.3) and included sensitivity and specificity requirements;

— Revised subclauses on quality control of test device and reproducibility of test device (5.2 and 5.3);

— Revised Bibliography;

— Added Annex A — Evaluation the Performance of MIC Tests, Annex B — Rationale for Bias Analysis, and Annex C — Sensitivity and Specificity Analyses for Qualitative Tests.

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.