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

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 20776-2:2008 sisaldab Euroopa standardi EN ISO 20776-2:2007 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 20776-2:2008 consists of the English text of the European standard EN ISO 20776-2:2007.
Standard on kinnitatud Eesti Standardikeskuse 28.01.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 28.01.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on .	Date of Availability of the European standard text .
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.100.20

Võtmesõnad:

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 20776-2

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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 (ISO 20776-2:2007)

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 (ISO 20776-2:2007)

Labormedizinische Untersuchungen und In-vitro-Diagnostika-Systeme - Empfindlickeitsprüfung von Infektionserregern und Evalution von Geräten zur antimikrobiellen Empfindlichkeitsprüfung - Teil 2: Evalution der Leistung einer Vorrichtung zur antimikrobiellen Empfindlichkeitsprüfung (ISO 20776-2:2007)

This European Standard was approved by CEN on 24 June 2007.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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Ref. No. EN ISO 20776-2:2007: E

Foreword

This document (EN ISO 20776-2:2007) has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems".

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 2008, and conflicting national standards shall be withdrawn at the latest by January 2008.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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:

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