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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0688.2-2024

Replacing YY/T 0688.2-2010

**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**

临床实验室检测和体外诊断系统 感染病原体敏感性试验与抗微生物药物敏感性试验设备的性能评价 第2部分：与肉汤微量稀释参考方法比对的抗微生物药物敏感性试验设备性能评价

(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document replaces YY/T 0688.2-2010 "Clinical laboratory testing and in vitro diagnostic systems for infectious pathogens sensitivity testing and antimicrobial resistance" Performance evaluation of antimicrobial susceptibility test equipment Part 2: Performance evaluation of antimicrobial susceptibility test equipment" Compared with 2010, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

---Deleted "Classification compliance", "Sensitive", "Intermediate", "Resistant", "Non-sensitive", "Breakpoint test", "Major deviation", "Minor deviation", "Major deviation" the terms and definitions of "breakpoint test", "fresh isolate", "recent isolate" and "inhibition zone diameter" (see the 2010 edition of 3.1.1, 3.3.1, 3.3.2, 3.3.3, 3.3.4, 3.4, 3.6.1, 3.6.2, 3.6.3, 3.4, 3.9.1, 3.9.2, 3.15);

--- Added "qualitative test", "reproducibility", "bias of the test method", "sensitivity analysis", "sensitivity analysis", "current isolates", "bacteria the term and definition of "microbial biota" (see 3.7, 3.9, 3.10.3, 3.10.4.1, 3.10.4.2, 3.11.1, 3.16);

--- Changed the definitions of the terms "minimum inhibitory concentration test", "breakpoint", "quality control" and "bias" (see 3.4, 3.6, 3.8, 3.10.1, 2010 version 3.12, 3.3, 3.6);

--- Changed the order of the clauses of the test methods in Chapter 4 (see Chapter 4);

--- Changed the general requirements for performance evaluation (see 4.1, Chapter 4 of the 2010 edition);

--- Changed the quality control section and referred to the quality control scope of EUCAST and CLSI documents (see 4.2);

--- Changed the reference method part (see 4.2.1, 5.2.5 of the 2010 edition);

--- Changed the strain selection to include the new definition of current isolates (3.11.1) (see 4.2.2, 5.2.1 of the 2010 edition);

--- Changed the reproducibility test (see 4.2.5, 5.2.4 of the 2010 edition);

--- Changed the deviation discrimination test (see 4.2.8, 5.2.7 of the 2010 edition);

--- Changed the data analysis and acceptance criteria clauses (see Chapter 5, 5.3, 5.4 of the 2010 edition);

--- Changed the accuracy of the equipment under test and deleted the classification compliance (see 5.1, 5.4.1 of the 2010 edition);

- Changed the data analysis of MIC equipment, deleted the classification compliance, and added bias requirements (see 5.1.1, 5.1.2, 2010 edition 5.2.7);
- Deleted the acceptance of breakpoint AST equipment (see 5.2.4 of the 2010 edition);
- Added acceptance criteria for qualitative AST equipment, including sensitivity and specificity requirements (see 5.1.3);
- Changed the quality control of the test equipment and the reproducibility of the test equipment (see 5.2, 5.3, 5.4.2, 5.4.3 of the 2010 edition).

This document is equivalent to ISO 20776-2:2021 "Clinical laboratory test and in vitro diagnostic system for infectious pathogens susceptibility testing and Performance evaluation of equipment for antimicrobial susceptibility testing - Part 2: Antimicrobial agents compared with a broth microdilution reference method Performance Evaluation of Sensitivity Test Equipment.

Introduction

In vitro antimicrobial susceptibility testing is usually performed on microorganisms that may cause disease, especially those that are considered to be resistant to commonly used antibiotics.

In addition, the test is also used in bacterial resistance monitoring, epidemiological studies of sensitivity, and new Aspects such as comparisons between antimicrobial agents and existing antimicrobial agents are also important.

Antimicrobial susceptibility testing is a method for determining the minimum inhibitory concentration (MIC) of antimicrobial drugs using a dilution method.

Monitoring of bacterial resistance, defining and identifying wild-type phenotypes, comparative testing of new antimicrobial agents, and clinical Microbiological tests that require quantitative results are used to determine the sensitivity of microorganisms that give equivocal results in conventional testing.

The test involves testing the microorganisms in a series of dilutions of the antimicrobial agent in broth (broth dilution method) or on agar plates (agar dilution method).

The ability of an organism to grow visibly.

The minimum inhibitory concentration of an antimicrobial drug refers to the concentration that can inhibit the growth of a specific microorganism under specified in vitro conditions and within a specified time.

The lowest concentration of an antimicrobial drug (in mg/L) that produces visible growth is known as the MIC.

The reproducibility of the soup MIC test requires strict quality control and standardized

operation. The MIC distribution range of quality control (QC) strains is generally There is a 3-fold dilution range with a main central value, but there can also be a 4-fold dilution range.

The broth microdilution method is a broth dilution test performed in a microdilution plate.

One of the microbial sensitivity test methods.

This document is equivalent to ISO 20776-2:2021 and is intended to evaluate the efficacy of antibiotics based on the standard broth microdilution reference method (ISO 20776-1).

Microbiological test equipment. Use pure cultures of readily grown aerobic bacteria grown overnight on agar in a solution containing standardized Mueller-Grows well in standardized microdilution plates in Hinton broth (volume $\leq 200 \mu\text{L}$).

Make adjustments.

The quantitative MIC and qualitative assessments detailed in this document are measured using a standard broth microdilution reference method.

The accuracy, reproducibility and quality control of tests performed by equipment testing antimicrobial drugs with MIC values. This document does not cover antimicrobial Agar disc diffusion test.

This document has been revised on the premise that the MIC test is an in vitro test that is subject to intra- and inter-laboratory variability.

In comparing any derived test to a reference method, it is appropriate to use only indicators of analytical performance and not the interpretation of the results.

For this reason, and because the interpretive categories have been removed from ISO 20776-1:2019, the classification is consistent with (CA) and its related terms.

The term is no longer applicable, as described in the Clinical and Laboratory Standards Institute (CLSI) M23 document and other international documents.

Avoiding the need to evaluate the CA when changes (outside of the test itself) occur also helps reduce the need to automatically re-evaluate test performance.

This document is applicable to new performance evaluations initiated after the publication of the standard; studies conducted before the acceptance date of this document should not use these Standard redesign and/or reanalysis. Studies conducted prior to these standards or acceptance of this document were conducted in accordance with standard practice at the time of the study or guide.

For derivatization experiments with more than 3 dilution series, analytical performance was measured using a protocol designed to measure both essential agreement (EA) and bias.

The accuracy of the assay was evaluated using the EA alone as a tool to measure precision.