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

WS/T 639-2018

Replacing WS/T 125-1999; WS/T 248-2005

**Technical specification on antimicrobial susceptibility tests
(English Translation)**

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard replaces WS/T 125-1999 "Standard Test Standard for Antibacterial Drugs by Paper Method" and WS/T 248-2005 "Anti-microbial Resistance to Anaerobic Bacteria" Drug sensitivity test method. This standard integrates the contents of WS/T 125-1999 and WS/T 248-2005 with the following changes.

- Increased the principles and reporting formats for routine susceptibility testing reports;
- Added other susceptibility test methods such as dilution method, gradient diffusion method and automated instrument method;
- Increased performance verification of rare drug susceptibility criteria and commercial drug susceptibility testing systems;
- Revised the detection and quality control requirements for common resistance phenotypes of common bacteria.

This standard was drafted. Peking University People's Hospital, Anhui Provincial Hospital, Beijing Friendship Hospital affiliated to Capital Medical University, Beijing Hospital.

1 Scope

This standard specifies the technical requirements for clinical antibiotic susceptibility testing, including drug selection and reporting for routine susceptibility testing, and drug susceptibility testing.

Test methods, various bacterial susceptibility tests, special resistance phenotype detection of common bacteria, quality control of drug susceptibility test, commercial drug susceptibility test System performance verification.

This standard applies to clinical laboratories at all levels for clinical microbiological testing.

2 Terms and definitions

The following terms and definitions apply to this document.

Antimicrobial susceptibility testing Detecting the in vitro sensitivity of microbes (this document specifically refers to bacteria) against microbial drugs (specifically referred to as antibacterial drugs) to guide the bed is rationally selected for the microbiological test of the drug, referred to as the drug sensitivity test.

Minimum inhibitory concentration Minimal inhibitory concentration; MIC the minimum antibacterial concentration that inhibits macroscopic growth of microorganisms in agar or broth dilution drug sensitivity test.

Breakpoint Breakpoint can predict clinical treatment effects to determine sensitive, intermediate, dose-dependent, resistant, non-sensitive minimum inhibitory concentrations (MIC) or the value of the diameter of the inhibition zone (mm).

2.3.1

Sensitive Susceptible;S when the antibacterial drug is in the sensitive range of the MIC value or the inhibition zone diameter of the isolate, the recommended dose is used for treatment, and the drug is infected.

The concentration usually reached at the site can inhibit the growth of the tested bacteria, and clinical treatment may be effective.

2.3.2

Intermediary Intermediate; I when the MIC value of the strain or the diameter of the zone of inhibition is intermediate, the value is close to the concentration reached by the drug in the blood and tissue, thereby treating the response rate is lower than the sensitive flora. This classification means that the treatment may be higher than the conventional dose or at the site where the drug is physiologically concentrated.

effective. This classification can also be used as a "buffer domain" to prevent significant deviations caused by minor, uncontrollable technical factors, especially toxicity.

A narrower range of drugs.

2.3.3

Dose-dependent sensitive Susceptible-dose dependent;SDD the sensitivity of bacterial strains to antimicrobial agents depends on the dose of antimicrobial agents. When a drug

has a MIC or inhibition zone diameter for the strain in SDD in the scope, the clinical efficacy can be achieved by modifying the dosage regimen by increasing the dose and/or increasing the frequency of administration.

2.3.4

Resistant Resistant; R when the MIC value or the inhibition zone diameter of the antibacterial agent is in the classification range, the conventional treatment plan is used, and the drug is in the infection department.

The concentration of the drug achieved does not inhibit bacterial growth, and/or the test strain acquires a special resistance mechanism, and therapeutic studies have shown that the clinical efficacy of the drug is not clear.

2.3.5

Non-sensitive Nonsusceptible; NS for those antibacterial drugs that have only sensitive refracts due to unrepresented or rare resistance, when the MIC value of the drug is higher or lower than that of an isolate this classification is non-sensitive when the diameter of the circle is below the sensitive point.

Epidemiological cutoff value; ECV Differentiating the microbial population into MIC values or zone of inhibition with or without acquired resistance is the upper limit of population sensitivity. According to ECV, the strains were divided into wild type and non-wild type.

2.4.1

Wild type Wild-type; WT According to the ECV value, a strain that has not obtained a resistance mechanism or a decrease in sensitivity in the evaluation of antibiotics (including antifungal drugs) is defined as Wild type.

2.4.2

Non-wild type Non-wild-type; NWT According to the ECV value, the antibiotics (including antifungal drugs) are evaluated in a drug resistance mechanism or a strain with reduced sensitivity.

It is non-wild type.

Potency Potency

The antibacterial activity of the antibacterial component is determined by the same standard substance. The unit is mg/g, IU/g or expressed as a percentage.

Basic agreement; EA

The MIC value of the MIC system to be tested differs from the reference method by no more than one dilution factor. When the method to be evaluated is the disk diffusion method, the EA is not calculated.

Classification consistency Categorical agreement; CA the drug sensitivity method and the reference method were evaluated to judge the test results as consistency of sensitivity, mediation and drug resistance.

Very significant error; Very major error; VME Misjudgment of resistance is sensitive, that is, false sensitivity.

Major error, major error, ME Sensitive mistakes are judged as drug resistance, that is, false drug resistance.

2.10

Minor error

The agent is judged to be sensitive or resistant, or to be resistant or sensitive.

2.11

Routine test

A paper diffusion method, broth or agar dilution method for routine clinical testing.

2.12

Supplementary (unconventional) drug sensitivity test (Supplemental (not routing) test Sensitivity or drug resistance of a certain type of drug is detected by methods other than conventional disk diffusion method, broth or agar dilution method, and the method does not require additional testing to confirm the sensitivity or drug resistance of the drug.

2.13

Screening test

Provide a test of the assumed results. When the screening result is positive, additional tests are required to confirm.

2.14

Alternative drug test Surrogate agent test when the drug sensitivity of the target antibacterial drug cannot be detected or the drug sensitivity detection performance of the substitute drug is superior to the target drug, the drug can replace the target drug the drug was tested for drug susceptibility.

2.15

Equivalent agent test A drug can predict the drug susceptibility results of similar drugs that are closely related to it, and the drug susceptibility test for the drug can reduce the detection of other related drugs.

Quantity to improve detection efficiency.