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CLSI M100™

Performance Standards for Antimicrobial Susceptibility Testing

Sample

CLSI M100 includes updated tables for the Clinical and Laboratory Standards Institute antimicrobial susceptibility testing standards CLSI M02, M07, and M11.

A CLSI supplement for global application.

Performance Standards for Antimicrobial Susceptibility Testing

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Abstract

The data in the tables are valid only if the methodologies in CLSI M02,¹ M07,² and M11³ are followed. These standards contain information about disk diffusion (CLSI M02¹) and dilution (CLSI M07² and CLSI M11³) test procedures for aerobic and anaerobic bacteria. Clinicians depend heavily on information from the microbiology laboratory for treating their seriously ill patients. The clinical importance of antimicrobial susceptibility test results demands that these tests be performed under optimal conditions and that laboratories have the capability to provide results for the newest antimicrobial agents. The tables presented in CLSI M100 represent the most current information for drug selection, interpretation, and QC using the procedures standardized in CLSI M02,¹ M07,² and M11.³ Users should replace previously published tables with these new tables. Changes in the tables since the previous edition appear in boldface type.

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Instructions for Use of Tables

These instructions apply to:

- Tables 1A through 1J: suggested tiers of antimicrobial agents that should be considered for testing and reporting by microbiology laboratories. These suggestions include clinical efficacy, current consensus recommendations for first-choice and alternative drugs, and US Food and Drug Administration (FDA) clinical indications for use. In other countries, placement of antimicrobial agents in Tables 1A through 1J should be based on available drugs approved for clinical use by relevant regulatory organizations.
- Tables 2A through 2J: tables for each organism group that contain:
 - Recommended testing conditions
 - QC recommendations (also see CLSI M02¹ and CLSI M07²)
 - General comments for testing the organism group and specific comments for testing particular agent/organism combinations
 - Agents that should be considered for routine testing and reporting by medical microbiology laboratories, as specified in Tables 1A through 1J (test/report tiers 1, 2, 3, and 4), including agents reported only on organisms isolated from the urinary tract (designated by “U”)
 - Agents that are appropriate for the respective organism group but are not listed in Tables 1 and would generally not warrant routine testing by a medical microbiology laboratory in the United States (designated with an asterisk as “other”; designated with “Inv.” for “investigational” [not yet approved **by any regulatory agency**]), including agents reported only on organisms isolated from the urinary tract (designated by “U”)
 - Zone diameter and minimal inhibitory concentration (MIC) breakpoints
- Tables 1J and 2J: tables containing specific recommendations for testing and reporting results on anaerobes and some of the information listed in the bullets above
- Tables 3A through 3L: tables describing tests to detect particular resistance types in specific organisms or organism groups

I. Selecting Antimicrobial Agents for Testing and Reporting

A. Appropriate Agents for Routine Testing

Selecting the most appropriate antimicrobial agents to test and report is a decision best made by each laboratory in consultation with the antimicrobial stewardship team and other relevant institutional stakeholders.

The suggestions for each organism group in Tables 1A through 1J include agents of proven efficacy that show acceptable *in vitro* test performance. Considerations in the assignment of agents to specific tiers include:

- Clinical efficacy
- Prevalence of resistance
- Minimizing emergence of resistance
- FDA clinical indications for use
- Current consensus recommendations for first-choice and alternative drugs
- Cost

Tests on selected agents may be useful for infection-prevention purposes (eg, testing ceftazidime for Enterobacterales to indicate potential extended-spectrum β -lactamase production; see Table 3A).

B. Equivalent Agents

Antimicrobial agents listed together in a single box are agents for which interpretive categories (susceptible, intermediate, susceptible-dose dependent, or resistant) and clinical efficacy are similar. A laboratory will often test only 1 agent from a box routinely, typically the agent that is on its formulary. In some cases, a laboratory may not test any agents from a box, depending on institutional needs.

In some boxes, the agents will be listed with an “or” between them. The “or” identifies agents for which cross-resistance and cross-susceptibility are nearly complete. Results from 1 agent connected by an “or” can be used to predict results for the other agent (ie, equivalent agents). For example, Enterobacterales susceptible to cefotaxime can be considered susceptible to ceftriaxone. The results obtained from testing cefotaxime could be reported along with a comment that the isolate is also susceptible to ceftriaxone. For drugs connected with an “or,” combined major and very major errors are fewer than 3%, and minor errors are fewer than 10%, based on a large population of bacteria tested (see CLSI M23⁴ for description of error types). In addition, to qualify for an “or,” at least 100 strains with resistance to the agents in question must be tested and a result of “resistant” must be obtained with all agents for at least 95% of the strains. “Or” is also used for comparable agents when tested against organisms for which “susceptible-only” breakpoints are provided (eg, cefotaxime or ceftriaxone with *Haemophilus influenzae*). When no “or” connects agents within a box, testing of 1 agent cannot be used to predict results for another, owing either to discrepancies or insufficient data (see Section VIII, which describes equivalent agent tests).

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