



Symposium 4.1

Updates and Controversial Issues in Susceptibility Testing from the CLSI Perspective

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The Subcommittee on Antimicrobial Susceptibility Testing (AST SC) of the Clinical and Laboratory Standards Institute (CLSI) uses a voluntary consensus process to develop standards that promote accurate antimicrobial susceptibility testing and appropriate reporting. Among the many missions of the AST SC are 1) to establish interpretive criteria (i.e., breakpoints) for the results of standard antimicrobial susceptibility tests and 2) to continually refine standards and optimize the detection of emerging resistance mechanisms through the development of new or revised methods, interpretative criteria, and quality control parameters. During the past two years the CLSI AST has published new and/or changes in breakpoints for *Staphylococcus aureus* and vancomycin as well as several fluoroquinolone agents. In addition, breakpoints for colistin and polymyxin B have been published for *Pseudomonas aeruginosa* and *Acinetobacter* spp. Moreover, the AST SC recently published a new guideline (M45-A) entitled *Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria*. This new M45-A document includes suggested breakpoints to interpret standardized susceptibility tests for a group of organisms that is not currently addressed in the disk (M2) or dilution (M7) AST SC standard documents. In the course of carrying out its mission to develop new breakpoints, or to revise existing breakpoints, it is possible that different breakpoints might exist for the same microorganism/antimicrobial agent combination (e.g. a CLSI breakpoint or a EUCAST breakpoint and an U.S. Food and Drug Administration [FDA] breakpoint); or that a CLSI breakpoint might exist for which there is no breakpoint in a regulatory product label (e.g. FDA or EMEA). In recent years this has resulted in discussions in the United States among the U.S. FDA, the CLSI AST SC, and representatives for both the pharmaceutical and antimicrobial susceptibility testing devices industries. The status of these discussions among the various stakeholders to find a path forward that will allow laboratories to use the most relevant breakpoints for their clinical situation will be discussed. In addition, specific information regarding the organisms listed in M45-A, (e.g., *Aeromonas*, *Bacillus*, *Corynebacterium*, *Campylobacter*, *Erysipelothrix*, HACEK group, *Lactobacillus*, *Leuconostoc*, *Listeria*, *Moraxella*, *Pasteurella*, *Pediococcus*, *Vibrio*) the specific methods, and the reasoning behind breakpoint choices will be presented. Lastly, the status of ongoing discussions regarding possible CLSI breakpoint changes to detect clinically relevant gram-negative bacilli with beta-lactamase resistance mechanisms including ESBLs and other enzymes will be discussed.