New CLSI Antimicrobial Susceptibility Testing (AST) Recommendations
M100-S16 Checklist

NA, not applicable

New CLSI Documents for AST			
Have	**Will Obtain**	**NA**	**Document**
			M2-A9. 2006. Performance standards for antimicrobial disk susceptibility tests. Ninth edition. Approved Standard.
			M7-A7. 2006. Methods for dilution antimicrobial susceptibility tests for bacteria that grow aerobically. Seventh edition. Approved Standard.
			M100-S16. 2006. Performance standards for antimicrobial susceptibility testing. Sixteenth informational supplement.
			M39-A2. 2005. Analysis and presentation of cumulative antimicrobial susceptibility test data. Second edition. Approved Guideline.
			M45-P. 2005. Methods for antimicrobial dilution and disk susceptibility testing of infrequently isolated or fastidious bacteria. Proposed Guideline.

Will Implement	**Previously Implemented**	**NA**	**Action**
General			
			Review **current product insert** from commercial antimicrobial susceptibility testing products used in my laboratory and ensure all recommendations for testing/reporting are followed. The procedures in the manufacturer's product insert take precedent over those found in CLSI standards.
			Obtain **written documentation** from medical staff for testing/reporting of organisms/antimicrobial agents beyond those suggested in CLSI standards.
			Add modified definition of **"Susceptible"** to our laboratory procedures. This definition is: "Susceptible implies that isolates are inhibited by the usually achievable concentrations of antimicrobial agent when the recommended dosage is used for the site of infection."
			Add modified definition of **"Resistant"** to our laboratory procedures. This definition is: "Resistant implies that isolates are not inhibited by the usually achievable concentrations of the agent with normal dosage schedules and/or that demonstrate MICs that fall in the range where specific microbial resistance mechanisms are likely (e.g., β-lactamases), and clinical efficacy of that agent against the isolate has not been reliably shown in treatment studies."
			Review those drug/bug combinations for which there **are only "S" breakpoints** and note those for which resistance has never been reported and those for which resistance has been reported on rare occasions. (see chart below)
			Review recommended **temperature ranges** for CLSI disk diffusion and MIC reference procedures: 35°C +/- 2°C for all organisms except *Neisseria gonorrhoeae* (range is 36°C +/- 1°C). Make sure tests for MRS are not incubated above 35°C. If using a commercial AST, follow manufacturer's recommendations for incubation temperatures.

Will Implement	Previously Implemented	NA	Action
Gram Negatives			
			Perform **ESBL testing on *Proteus mirabilis*** when isolated from significant sources (e.g., blood culture). Note that cefpodoxime, ceftazidime, and cefotaxime are appropriate drugs to screen for ESBL production in *P. mirabilis* and screening breakpoints for cefpodoxime differ from those for *E. coli* and *Klebsiella* spp. For disk diffusion, cefpodoxime screening breakpoint for *P. mirabilis* is ≤22 mm and for MIC testing breakpoint is >1 µg/ml. Phenotypic confirmatory testing and reporting for *P. mirabilis* is identical to that for *E. coli* and *Klebsiella* spp.
			Make certain aminoglycosides, first and second generation cephalosporins and cephamycins are not reported for ***Salmonella* spp**. and ***Shigella* spp.**
			Review procedure for deciding when to perform AST on fecal isolates of ***Salmonella* spp**. with medical staff. Testing may not be necessary for all isolates since mild cases of intestinal salmonellosis are often self limiting.
			Review agents tested/reported on ***Pseudomonas aeruginosa, Acinetobacter* spp., *Burkholderia cepacia,* and *Stenotrophomonas maltophilia*** and make certain appropriate disk diffusion and/or MIC breakpoints are used (see new breakpoint Tables 2B-1 thru 2B-4).
			Eliminate or modify report ***(Rx)*** comment related to combination therapy for serious ***Pseudomonas aeruginosa*** infections. Previous ***Rx*** comment (now eliminated from M100): "*P. aeruginosa* infections in granulocytopenic patients and serious infections in other patients should be treated with maximum doses of the selected antipseudomonal penicillin (carboxypenicillin or ureidopenicillin) or ceftazidime in combination with an aminoglycoside."
			Identify a strategy for testing supplemental agents when an isolate is encountered that is resistant to all drugs on routine test panel. This may include MIC testing of **colistin** or **polymyxin B** for highly resistant *Acinetobacter* spp. Standard CLSI methods for testing colistin and polymyxin on other organisms are not yet available. Reference laboratory assistance may be appropriate.
			Follow CLSI M2, M7, and M100 recommendations for AST of ***Haemophilus* spp**. when testing *H. influenzae* and *H. parainfluenzae*. Use CLSI M45 when testing other *Haemophilus* spp.
			Identify a strategy for AST of ***Neisseria meningitidis*,** when requested. Include a safety protocol for handling this species. Disk diffusion or MIC testing can be done and reference laboratory assistance may be appropriate. Note: ampicillin and penicillin can only be tested by an MIC method.

Will Implement	Previously Implemented	NA	Action
Gram Positives			
			Discontinue disk diffusion testing of **daptomycin**.
			Use **cefoxitin** disk in lieu of oxacillin disk for disk diffusion testing of staphylococci. Report oxacillin (not cefoxitin) as cefoxitin is a surrogate for oxacillin in detection of *mec*A-mediated resistance in staphylococci.
			Use CLSI or FDA disk diffusion and MIC breakpoints when testing **gatifloxacin, levofloxacin and moxifloxacin** with **staphylococci**.
			Use CLSI or FDA MIC breakpoints when testing **vancomycin** with ***S. aureus***. Investigate any isolate with an MIC of 4µg/ml or greater.
			If using an AST that is unreliable in detecting VISA or VRSA, perform **BHI-vancomycin (6 µg/ml) screen.**
			Add CDC's **"Algorithm for Testing *S. aureus* with Vancomycin"** to AST procedure for *S. aureus.*
			Eliminate report ***(Rx)*** comment related to combination therapy with vancomycin for serious enterococcal infections. Previous ***Rx*** comment (now eliminated from M100): "If vancomycin is used for serious enterococcal infections, such as endocarditis, combined therapy with an aminoglycoside is usually indicated."
			Review definitions of results for **enterococci and high-level aminoglycoside resistance (HLAR) tests** performed by **disk diffusion** (definitions are similar to those that have been in place for MIC testing). Ensure any isolate with a result that falls in the "inconclusive" category is tested by a dilution method. HLAR testing only pertains to isolates from sources where combination therapy is needed (e.g., sterile body site isolates)
			Review **drugs tested on CSF isolates of *Streptococcus pneumoniae*** to ensure at least one of the following is reported: cefotaxime, ceftriaxone, or meropenem. Testing must be done by an MIC method as disk diffusion is unreliable for these drugs.
QA/QC			
			Add **Disk Diffusion** and/or **MIC QC Troubleshooting Guide** to procedure manual.
Other			
			Incorporate new broth microdilution QC ranges for testing ***Campylobacter* spp**. into procedure manual.
M2-A9 and M7-A7 **Note: changes in M2-A9 and M2-A7 are consistent with those published in M100-S14, M100-S15, and M100-S16. For many issues, more details are provided in M2-A9 and M7-A7 and these should be used as references for AST procedures performed in clinical laboratories.**			
			Review new **M2-A9 Standard "Summary of Major Changes"** on page vii. Read those sections applicable to practices in our laboratory and make certain we comply with the recommendations stated.
			Review new **M7-A7 Standard "Summary of Major Changes"** on page vii. Read those sections applicable to practices in our laboratory and make certain we comply with the recommendations stated.
			Review **"Summary of Comments and Subcommittee Responses"** at end of M2-A9.
			Review **"Summary of Comments and Subcommittee Responses"** at end of M7-A7.

Drug / Organism Combinations with Only "S" Breakpoints

Organism	Drug	In vitro resistance (e.g., result other than "S") has not been reported to date	In vitro resistance (e.g., result other than "S") has been reported on rare occasions
Gram Negatives			
Haemophilus influenzae	aztreonam		X
	carbapenem		X
	3rd-generation cephalosporin	X	
	fluoroquinolone		X
Neisseria gonorrhoeae	3rd-generation cephalosporin		X
Gram Positives			
Enterococcus spp.	daptomycin		X
Staphylococcus aureus	daptomycin		X
	linezolid		X
Staphylococcus, coagulase-negative	daptomycin		X
	linezolid		X
Streptococcus pneumoniae	linezolid	X	
	vancomycin	X	
Streptococcus, beta group	ampicillin or penicillin	X	
	3rd-generation cephalosporin		X
	daptomycin		X
	linezolid		X
	vancomycin	X	
Streptococcus, viridans group	daptomycin		X
	linezolid		X
	vancomycin		X