

Supplemental Table 1. Calculation of Method Comparison Agreement and Error Categories and Acceptable Criteria

Agreement or Error Category	Calculation Formula	Calculation Formula Terms	Acceptance Criteria <sup>1</sup>
Category Agreement (CA)	$N_{CA}/NT \times 100$	$N_{CA}$ – number of isolates with an AST Result with the same categorical interpretation as reference method NT – number of isolates tested	$\geq 90\%$ CA
Essential Agreement (EA)	$N_{EA}/NT \times 100$	$N_{EA}$ – number of isolates with the same or within one doubling dilution MIC value as the reference method NT – number of isolates with same or within one doubling dilution MIC value as the reference method	$\geq 90\%$ EA
Minor Error (mE)	$N_{ME}/NT \times 100$	$N_{ME}$ – number of isolates having minor errors NT- number of isolates tested	$\leq 10\%$ mE
Major Error (ME)	$N_{ME}/N_{RefS} \times 100$	$N_{ME}$ – number of isolates that yielded false-resistant results $N_{RefS}$ – number of isolates susceptible by the reference method	$< 3\%$ ME
Very Major Error (VME)	$N_{VME}/N_{RefR} \times 100$	$N_{VME}$ – number of isolates that tested false-susceptible $N_{RefR}$ – number of isolates resistant by the reference method	$< 3\%$ VME <sup>2</sup>

<sup>1</sup> from reference (1, 2)

<sup>2</sup>FDA uses VME rate acceptance criteria of 1.5%

Supplemental Table 2. Acceptance performance rates for cASTs, by the error-rate bound method, for antimicrobials with an intermediate category

Reference (BMD) MIC range for isolates to include in denominator of error calculations		Acceptable Error Rates		
1-dilution intermediate range	2-dilution intermediate range	mE	ME	VME
$\geq I + 2$	$\geq I_{\text{high}} + 2$	< 2%	ND	<5%
I+1 to I-1	$I_{\text{high}} + 1$ to $I_{\text{low}} - 1$	<40%	<10%	<10%
$\leq I - 2$	$\leq I_{\text{low}} - 2$	ND	<2%	<5%

MIC, minimal inhibitory concentration; mE, minor error; ME, major error; VME, very major error; I, intermediate MIC value;  $I_{\text{high}}$ , high end of the MIC range for the intermediate category;  $I_{\text{low}}$ , low end of the MIC range for the intermediate category; ND, not determined

Supplemental Table 3. Acceptance performance rates for ASTs, by the error-rate bound method, when no intermediate category exists.

Reference (BMD) MIC range for isolates to include in denominator of error calculations	Acceptable Error Rates		
	mE	ME	VME
$\geq R + 1$	< 2%	ND	5%
$R + S$	< 40%	<10%	<10%
$\leq S - 1$	ND	<2%	<5%

MIC, minimal inhibitory concentration; mE, minor error; ME, major error; VME, very major error; R, resistant MIC value; S, susceptible MIC value; ND, not determined

Supplemental Table 4. Hypothetical examples of arbitrating discrepancies between cAST and BMD, for an antimicrobial with the following breakpoints:  $\leq 0.25$   $\mu\text{g/mL}$  (S),  $0.5$   $\mu\text{g/mL}$  (I),  $\geq 1$   $\mu\text{g/mL}$  (R)

	MIC ( $\mu\text{g/mL}$ )				Final arbitrated result	Error / rationale
	Original result	Repeat #1	Repeat #2	Repeat #3		
<b>Example #1</b>						
cAST	1 (R)	0.12 (S)	-		0.12 (S)	none
BMD*	0.06 (S)	0.06 (S)	-		0.06 (S)	cAST MIC corrected on repeat test
<b>Example #2</b>						
cAST	1 (R)	0.12 (S)	0.5 (I)		0.5 (I)	mE
BMD*	0.06 (S)	0.06 (S)	0.06 (S)		0.06 (S)	Final cAST MIC within 1 dilution of initial result
<b>Example # 3</b>						
cAST	0.06 (S)	0.06 (S)	0.06 (S)		0.06 (S)	none
BMD*	1 (R)	0.06 (S)	0.5 (I)	1 (R)	0.25 (S)	Final BMD MIC = mode of 3 results
<b>Example #4</b>						
cAST	1 (R)	0.12 (S)	32 (R)		Inconclusive	-
BMD*	0.06 (S)	0.06 (S)	0.06 (S)		0.06	Check isolate further for purity, ID, etc.
<b>Example #5</b>						
cAST	1 (R)	1 (R)	0.5 (I)		1 (R)	ME

BMD*	0.06 (S)	0.06 (S)	0.06 (S)	0.06 (S)	Final cAST MIC = mode of 3 results
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\*DD or AD when one of these methods is the essential reference method for agent evaluated

mE, minor error; ME, major error; cAST, commercial antimicrobial susceptibility test; BMD, broth microdilution; MIC, minimum inhibitory concentration; S, susceptible; I, intermediate; R, resistant

1. **CLSI.** 2016. M23-A4. Development of *in vitro* susceptibility testing criteria and quality control parameters: fourth edition. Clinical and Laboratory Standards Institute, Wayne, PA.
2. **CLSI.** 2016. Verification of Commercial Microbial Identification and Susceptibility Test Systems, M52 Guideline. Clinical and Laboratory Standards Institute, Wayne, PA.