Setting the **Global** Standard for Quality in Laboratory Testing

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To: Recipients of M100, 27th ed.

From: Jennifer K. Adams, MT(ASCP), MSHA

Subject: Corrections

This notification is to inform you of corrections made to CLSI document M100, Performance Standards for Antimicrobial Susceptibility Testing, 27th ed. The corrections are described below and shown as highlighted and/or stricken text, as necessary.

#### General:

"Cefepime-tazobactam (1:1)" has been revised throughout the document to read "cefepime-tazobactam." The "(1:1)" ratio designation has been deleted; the affected pages are: xvii, xviii, 144, 147, 162, 165, 168, 218, 236, 240. Footnotes have been added to Tables 4A and 5A to clarify the change.

### Table 3D, Modified Carbapenem Inactivation Method for Suspected Carbapenemase **Production in** *Enterobacteriaceae:*

The ATCC® number for Escherichia coli in the Test Reagents and Materials section of Table 3D is listed incorrectly as ATCC® 29522. The correct ATCC® number is ATCC® 25922. The Table 3D correction is shown in the table excerpt below.

Table 3D. Modified Carbapenem Inactivation Method for Suspected Carbapenemase Production in Enterobacteriaceae

Test	mCIM						
	For epidemiological or infection control purposes. NOTE: No change in the interpretation carbapenem susceptibility test results is necessary for mCIM positive isolates. mCIM testing						
When to Do This Test:	not currently recommended for routine use.						
Test Method	Meropenem disk inactivation						
Test Reagents and Materials	TSB (2 mL aliquots)						
	• Meropenem disks (10 μg)						
	• 1-μL and 10-μL inoculation loops						
	Nutrient broth (eg, Mueller-Hinton, TSB) or normal saline (3.0-5.0 mL aliquots)						
	MHA plates (100 mm or 150 mm)						
	<ul> <li>Meropenem-susceptible indicator strain - E. coli (ATCC<sup>®</sup> 2952225922)</li> </ul>						

Abbreviations; ATCC®, American Type Culture Collection; mCIM, modified carbapenem inactivation method; MHA, Mueller-Hinton agar; MIC, minimal inhibitory concentration; QC, quality control; TSB, trypticase soy broth.

# Table 4A, Disk Diffusion: Quality Control Ranges for Nonfastidious Organisms (Unsupplemented Mueller-Hinton Medium):

- The column heading for *Klebsiella pneumoniae* ATCC® 700603 on the first page of Table 4A has two footnotes (b and d) associated with it; however, the footnote designations are missing on subsequent Table 4A pages (ie, Table 4A [Continued]). The footnote designations have been added to the column headings on the subsequent pages. Similar edits were made to the *Escherichia coli* ATCC® 25922 and *Escherichia coli* ATCC® 35218 column headings (ie, edits to ensure all footnotes that appear in the headings on the first page of Table 4A also appear in the headings on subsequent pages).
- Footnote designations are missing from the QC ranges in the *Klebsiella pneumoniae* ATCC® 700603 column for cefepime-tazobactam and ceftolozane-tazobactam. Footnote "d" has been added to the QC range for each agent.
- To clarify the disk diffusion QC ranges for reporting cefepime-tazobactam, a new footnote (r) was added that reads: "Cefepime-tazobactam (30/20-µg) disk diffusion QC ranges are for use with the cefepime-tazobactam high proportion (1:1 ratio) dosing regimen."

The Table 4A corrections are shown in the table excerpt below.

Table 4A. Disk Diffusion: Quality Control Ranges for Nonfastidious Organisms (Unsupplemented Mueller-Hinton Medium)

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		Disk Diffusion QC Ranges (mm)					
		Escherichia			Escherichia	Klebsiella	
Antimicrobial Agent	Disk Content	coli ATCC®a 25922	Staphylococcus aureus ATCC® 25923	Pseudomonas aeruginosa ATCC® 27853	<i>coli</i> ATCC® 35218 <sup>b,c,d</sup>	pneumoniae ATCC® 700603 <sup>b,d</sup>	
Cefepime-							
tazobactam <sup>d,e,</sup> r	30/20 μg	32-37	24-30	27-31	-	25-30 <mark>d</mark>	
Ceftolozane- tazobactam	30/10 μg	24-32	10-18	25-31	25-31	17-25 <mark>d</mark>	

Abbreviations: ATCC®, American Type Culture Collection; QC, quality control.

#### **Footnotes**

- d. *K. pneumoniae* ATCC® 700603 must be used for routine QC of **cefepime-tazobactam**—(1:1), ceftazidime-avibactam, and aztreonam-avibactam. Either *K. pneumoniae* ATCC® 700603 or *E. coli* ATCC® 35218 can be used for routine QC of ceftolozane-tazobactam.
- r. Cefepime-tazobactam (30/20-µg) disk diffusion QC ranges are for use with the cefepime-tazobactam high proportion (1:1 ratio) dosing regimen.

## Table 5A, MIC: Quality Control Ranges (µg/mL) for Nonfastidious Organisms (Unsupplemented Mueller-Hinton Medium [Cation-Adjusted if Broth]):

• The column heading for *Klebsiella pneumoniae* ATCC® 700603 on the first page of Table 5A has two footnotes (b and g) associated with it; however, the footnote designations are missing on subsequent Table 5A pages (ie, Table 5A [Continued]). The footnote designations have been added to the column headings on the subsequent pages.

#### Table 5A (Continued):

- In the cefepime-tazobactam row, footnotes "e" and "g" are attached to the agent name; however, only footnote "e" should be associated with the agent name. Footnote "g" should only be attached to the QC range for cefepime-tazobactam and *Klebsiella pneumoniae* ATCC® 700603. Footnote "g" has been moved to the QC range for *Klebsiella pneumoniae* ATCC® 700603.
- In the meropenem-vaborbactam row, the QC ranges are listed incorrectly. QC ranges for each organism have been corrected as follows:
  - Staphylococcus aureus ATCC® 29213: Range changed from 0.03-0.12 to 0.03/8-0.12/8.
  - *Escherichia coli* ATCC® 25922: Range changed from 0.008-0.06 to 0.008/8-0.06/8.
  - Pseudomonas aeruginosa ATCC® 27853: Range changed from 0.12-1 to 0.12/8-1/8.
  - Escherichia coli ATCC® 35218: Range changed from 0.008-0.06 to 0.008/8-0.06/8.
  - Klebsiella pneumoniae ATCC® 700603: Range changed from 0.015-0.06 to 0.015/8-0.06/8.
- In the Table 5A footnote list, there are two footnotes designated as "t" and two footnotes designated as "u."
  - The footnote stating "QC range for S. aureus ATCC" 25923 with tedizolid is 0.12-0.5 μg/mL; this strain exhibits less trailing and MIC end points are easier to interpret. S. aureus ATCC" 25923 is considered a supplemental QC strain and not required for routine QC of tedizolid MIC tests" has been redesignated as footnote "v" and reordered alphabetically.
  - The footnote stating "For QC organisms for vancomycin screen test for enterococci, see Table 3G" has been redesignated as footnote "w" and reordered alphabetically.
  - As a result of the redesignation of the above footnotes as "v" and "w," the footnote associated with tedizolid has been changed to "v" and the footnote associated with vancomycin has been changed to "w."
- For consistency with the edits made to the QC ranges in the meropenem-vaborbactam row, footnote "t" has been revised to read, "QC range for K. pneumoniae ATCC® BAA-1705™ with meropenem-vaborbactam is 0.015/8-0.06/8 µg/mL."
- To clarify the broth dilution QC ranges for reporting cefepime-tazobactam, a new footnote (x) was added that reads: "Cefepime-tazobactam (fixed 8 µg/mL) MIC QC ranges are for use with the cefepime-tazobactam high proportion (1:1 ratio) dosing regimen."

#### Table 5A (Continued):

The Table 5A changes are shown in the table excerpt below.

Table 5A. MIC: Quality Control Ranges (µg/mL) for Nonfastidious Organisms (Unsupplemented Mueller-Hinton Medium [Cation-Adjusted if Broth])

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Antimicrobial Agent	Staphylococcus aureus ATCC®a 29213	Enterococcus faecalis ATCC® 29212	Escherichia coli ATCC® 25922	Pseudomonas aeruginosa ATCC® 27853	Escherichia coli ATCC® 35218 <sup>b,c,g</sup>	Klebsiella pneumoniae ATCC® 700603 <sup>b,g</sup>	
Cefepime- tazobactam (1:1) <sup>e</sup> , <sup>ex</sup>	1/8-4/8	-	0.03/8- 0.12/8	0.5/8-4/8	-	0.12/8-0.5/8 <mark>8</mark>	
Meropenem- vaborbactam <sup>t,u</sup>	0.03 <mark>/8</mark> -0.12 <mark>/8</mark>	-	0.008 <mark>/8</mark> - 0.06 <mark>/8</mark>	0.12 <mark>/8</mark> -1 <mark>/8</mark>	0.008 <mark>/8</mark> - 0.06 <mark>/8</mark>	0.015 <mark>/8</mark> - 0.06 <mark>/8</mark>	
Tedizolid <mark><sup>ŧv</sup></mark>	0.12-1	0.25-1	_	-	-	-	
Vancomycin <sup>uw</sup>	0.5-2	1-4	-	-	-	-	

Abbreviations: ATCC®, American Type Culture Collection; MIC, minimal inhibitory concentration.

#### Footnotes

- t. QC range for K. pneumoniae ATCC® BAA-1705™ with meropenem-vaborbactam is 0.015<mark>/8</mark>-0.06<mark>/8</mark> µg/mL.
- u. Test S. aureus ATCC® 29213 routinely when testing gram-positive organisms. Test P. aeruginosa ATCC® 27853 routinely when testing gram-negative organisms. Ranges are provided for other QC organisms as supplemental QC.
- Lev. QC range for S. aureus ATCC® 25923 with tedizolid is 0.12-0.5 μg/mL; this strain exhibits less trailing and MIC end points are easier to interpret. S. aureus ATCC® 25923 is considered a supplemental QC strain and not required for routine QC of tedizolid MIC tests.
- www. For QC organisms for vancomycin screen test for enterococci, see Table 3G.
- x. Cefepime-tazobactam (fixed 8 µg/mL) MIC QC ranges are for use with the cefepime-tazobactam high proportion (1:1 ratio) dosing regimen.

### Table 5D, MIC: Quality Control Ranges for Anaerobes (Agar Dilution Method):

• In Table 5D, the ertapenem QC range for *Bacteroides thetaiotaomicron* ATCC® 29741 was incomplete. The range has been corrected from "0.25-" to "0.25-1." The Table 5D correction is shown in the table excerpt below.

Table 5D. MIC: Quality Control Ranges for Anaerobes (Agar Dilution Method)

	MIC QC Ranges (μg/mL)					
Antimicrobial Agent	Bacteroides fragilis ATCC® 25285	Bacteroides thetaiotaomicron ATCC® 29741	Clostridium difficile ATCC® 700057	Eggerthella lenta (formerly Eubacterium lentum) ATCC® 43055 <sup>b</sup>		
Ertapenem	0.06-0.25	0.25- <mark>1</mark>	-	0.5-2		

Abbreviations: ATCC\*, American Type Culture Collection; MIC, minimal inhibitory concentration, QC, quality control.

# Glossary II, Abbreviations/Routes of Administration/Drug Class for Antimicrobial Agents Listed in M100, 27th ed.:

- The title has been corrected to reflect the current edition of M100: "M100, 27th ed."
- The three-letter designation for cefepime-tazobactam has been changed from "FPZ" to "FPT."

The Glossary II corrections are shown in the glossary excerpt below.

### Glossary II. Abbreviations/Routes of Administration/Drug Class for Antimicrobial Agents Listed in M100\$, 2627th ed.

Antimicrobial Agent	Agent Abbreviation <sup>a</sup>	Rout	tes of	Admi	nistration <sup>b</sup>	Drug Class or Subclass
		PO	IM	IV	Topical	
Cefepime-tazobactam (1:1)	<del>FPZ</del> FPT			Х		β-lactam/β-lactamase inhibitor

Abbreviations: PO, per OS (oral); IM, intramuscular; IV, intravenous.

If you require any additional clarification regarding these corrections, please contact CLSI Customer Service (customerservice@clsi.org).

We appreciate your commitment to CLSI and regret any inconvenience.