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CLINICAL AND LABORATORY STANDARDS INSTITUTE°

19 June 2017

To: Recipients of M45, 3rd ed.

From: Jennifer K. Adams, MT(ASCP), MSHA Vice President, Standards and Quality

Subject: Combined Corrections

This notice is intended to inform users of corrections made to CLSI document M45, *Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria*, 3rd ed. The corrections are described below and shown as highlighted and/or stricken text in the excerpts.

Correction: 19 June 2017

In several locations, the ATTC[®] number for quality control (QC) with *Pseudomonas aeruginosa* is listed incorrectly as ATTC[®] 27583. The correct ATTC[®] number throughout the guideline is ATTC[®] 27853. The corrections are shown as highlighted and/or stricken text in the items listed below.

• Corrections were made in the Overview of Changes, in which the ATTC[®] number for *P*. *aeruginosa* was listed incorrectly in four instances. The text was revised as follows.

Table 3. Aeromonas spp. (Includes Members of Aeromonas caviae Complex, Aeromonas hydrophila Complex, and Aeromonas veronii Complex)

Added *Pseudomonas aeruginosa* ATCC[®] 2758327853 as recommended QC strain for carbapenems.

Table 22. Summary of Testing Conditions and Quality Control Recommendations for Infrequently Isolated or Fastidious Bacteria

Added *P. aeruginosa* ATCC[®] 2758327853 as a recommended QC strain for carbapenems when testing *Aeromonas hydrophila* complex and *Vibrio* spp. (including *V. cholerae*).

Table 23A. MIC: Quality Control Ranges for Nonfastidious Organisms (Unsupplemented Cation-Adjusted Mueller-Hinton Broth)

Revised QC ranges for *P. aeruginosa* ATCC[®] 2758327853 with:

- Ceftazidime
- Doripenem
- Ertapenem
- Imipenem
- Meropenem
- Tetracycline

Table 24A. Disk Diffusion: Quality Control Ranges for Nonfastidious Organisms (Unsupplemented Mueller-Hinton Medium)

Revised QC ranges for *P. aeruginosa* ATCC[®] 2758327853 with:

- Doripenem
- Ertapenem
- Imipenem
- Meropenem
- Corrections were made in Table 22, Summary of Testing Conditions and Quality Control Recommendations for Infrequently Isolated or Fastidious Bacteria, in which the ATTC[®] number for *P. aeruginosa* was listed incorrectly in two instances. The text was revised as follows in the table excerpt.

Table 22. Summary of Testing Conditions and Quality Control Recommendations for Infrequently Isolated or Fastidious Bacteria

Table No.	Organism/Organism Group	Broth Microdilution MIC Test Method	Broth Microdilution MIC Incubation Conditions	Disk Diffusion Test Medium/Incubation Conditions	QC Strain(s) (see Tables for QC Ranges)
20	<i>Vibrio</i> spp. (including <i>V. cholerae</i>)	CAMHBd	35°C; ambient air; 16-20 h	MHA (unsupplemented/35°C; ambient air; 16-18 h) ^d	E. coli ATCC® 25922 E. coli ATCC® 35218 ^b P. aeruginosa ATCC® 27583 27853°

Abbreviations: ATCC[®], American Type Culture Collection; CAMHB, cation-adjusted Mueller-Hinton broth; CAMHB-LHB, cationadjusted Mueller-Hinton broth supplemented with lysed horse blood; QC, quality control; MHA, Mueller-Hinton agar; MIC, minimal inhibitory concentration; N/A, not applicable; No., number.

Footnotes

- a. ATCC[®] is a registered trademark of the American Type Culture Collection.
- b. *E. coli* ATCC[®] 35218 is used for QC when testing β -lactam/ β -lactamase inhibitor combination drugs.
- c. *P. aeruginosa* ATCC[®] 2758327853 is used for QC when testing carbapenems.
- d. Prepare inoculum in 0.85% NaCl (normal saline).

NOTE: Information in boldface type is new or modified since the previous edition.

Correction: 12 August 2016

There are two footnote errors in Table 22.

In Table 22, the MIC Test Medium column (column 3) for *Vibrio* spp. originally cited footnote "d," which referred to quality control (QC) for carbapenams. The footnote that should have been cited refers to inoculum preparation. Due to footnote reordering while resolving this error, the footnote is still "d" but the footnote text now refers to inoculum preparation.

In the QC Strains column (column 6), the *B. pseudomallei* row originally cited footnote "c" for *E. coli* ATCC[®] 35218, which referred to inoculum preparation. The text has been corrected to cite footnote "b," which refers to using *E. coli* ATCC[®] 35218 for QC when testing B-lactam/B-

lactamase inhibitor combination drugs.

The footnote citations have been corrected and the footnotes have been reordered per CLSI style. The affected rows are shown in the Table 22 excerpt below, with the changed footnotes highlighted:

Table No.	Organism/Organism Group	Broth Microdilution MIC Test Method	Broth Microdilution MIC Incubation Conditions	Disk Diffusion Test Medium/Incubation Conditions	QC Strain(s) (see Tables for QC Ranges)		
20	Vibrio spp. (including V. cholerae)	CAMHB ^₄	35°C; ambient air; 16-20 h	MHA (unsupplemented/35°C; ambient air; 16-18 h) ^d	E. coli ATCC® 25922 E. coli ATCC® 35218 ^b P. aeruginosa ATCC® 27583 ^c		
Potential Bacterial Agents of Bioterrorism							
21	B. pseudomallei	САМНВ	35°C; ambient air; 16-20 h	N/A	E. coli ATCC® 25922 E. coli ATCC® 35218 ^b P. aeruginosa		

 Table 22. Summary of Testing Conditions and Quality Control Recommendations for Infrequently

 Isolated or Fastidious Bacteria

Abbreviations: ATCC[®], American Type Culture Collection; CAMHB, cation-adjusted Mueller-Hinton broth; CAMHB-LHB, cationadjusted Mueller-Hinton broth supplemented with lysed horse blood; QC, quality control; MHA, Mueller-Hinton agar; MIC, minimal inhibitory concentration; N/A, not applicable; No., number.

Footnotes

ATCC[®] 27853

- a. ATCC[®] is a registered trademark of the American Type Culture Collection.
- b. *E. coli* ATCC[®] 35218 is used for QC when testing β -lactam/ β -lactamase inhibitor combination drugs.
- c. *P. aeruginosa* ATCC[®] 27583 is used for QC when testing carbapenems.
- d. Prepare inoculum in 0.85% NaCl (normal saline).

NOTE: Information in boldface type is new or modified since the previous edition.

There is a reference error in footnote "b" in Table 24A.

In Table 24A, footnote "b" currently cites CLSI document M07 as a reference; however, CLSI document M02 is the correct reference. Footnote "b" has been corrected to read "refer to CLSI document M02" and the reference citation has been corrected. This change is highlighted below.

Table 24A. Disk Diffusion: Quality Control Ranges for Nonfastidious Organisms (Unsupplemented Mueller-Hinton Medium)

		Disk Diffusion QC Ranges (mm)			
Antimicrobial Agent	Disk Content	<i>E. coli</i> ATCC®ª 25922	S. <i>aureus</i> ATCC® 25923	E. coli ATCC® 35218 ^b	P. aeruginosa ATCC® 27853
Amikacin	30 µg	19-26	20-26	-	-
Amoxicillin-clavulanate	20/10 µg	18-24	28-36	17-22	-
Ampicillin	10 µg	16-22	27-35	6	-
Ampicillin-sulbactam	10/10 μg	19-24	29-37	13-19	-
Azithromycin	15 µg	-	21-26	-	-
Aztreonam	30 µg	28-36	-	-	-
Cefazolin	30 µg	21-27	29-35	-	-
Cefepime	30 µg	31-37	23-29	-	-
Cefotaxime	30 µg	29-35	25-31	-	-

Cefoxitin	30 µg	23-29	23-29	-	-
Ceftazidime	30 µg	25-32	16-20	-	-
Ceftriaxone	30 µg	29-35	22-28	-	-
Cefuroxime	30 µg	20-26	27-35	-	-
Cephalothin	30 µg	15-21	29-37	-	-
Chloramphenicol	30 µg	21-27	19-26	-	-
Ciprofloxacin	5 µg	30-40	22-30	-	-
Clarithromycin	15 μg	-	26-32	-	-
Doripenem	10 µg	-	-	-	28-35
Doxycycline	30 µg	18-24	23-29	-	-
Ertapenem	10 µg	29-36	24-31	-	13-21
Erythromycin	15 μg	-	22-30	-	-
Gentamicin	10 µg	19-26	19-27	-	-
Imipenem	10 µg	26-32	-	-	20-28
Levofloxacin	5 µg	29-37	25-30	-	-
Meropenem	10 µg	28-34	29-37	-	27-33
Ofloxacin	5 µg	29-33	24-28	-	-
Piperacillin	100 µg	24-30	-	12-18	-
Piperacillin-tazobactam	100/10 μg	24-30	27-36	24-30	-
Tetracycline	30 µg	18-25	24-30	-	-
Trimethoprim- sulfamethoxazole	1.25/23.75 μg	23-29	24-32	-	-

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

Footnotes

- a. ATCC[®] is a registered trademark of the American Type Culture Collection.
- b. Because *E. coli* ATCC[®] 35218 may lose its plasmid, careful organism maintenance is required; refer to CLSI document M07M02.¹²

NOTE: Information in boldface type is new or modified since the previous edition.

As a result of a comment submitted during the Proposed Draft vote, the breakpoints for cephems were deleted from Table 4, *Bacillus* spp. (Not *Bacillus anthracis*) and Related Genera. However, this deletion was not noted in the Overview of Changes in the published document. Therefore, the following text has been added for Table 4 in the Overview of Changes: "Deleted the cephalosporin breakpoints due to ability of *Bacillus* spp. to produce potent cephalosporinases."

Correction: 9 March 2016

In Tables 23C, 23D, and 23F, a footnote ("a") was attached to "ATCC[®]" in the column header for *C. jejuni* (23C), *H. pylori* (23D), and *E. coli* (23F), respectively. There are no corresponding footnotes below these tables. The footnote letters have been deleted.

In Table 23E, a footnote ("b") was attached to "ATCC[®]" in the column header for S. *aureus*. There is no corresponding footnote "b" below this table. The footnote letter "b" has been deleted.

In Table 17, a footnote ("a") was attached to four dashes in the MIC "R" column. There are no corresponding footnotes below this table. The locations where the footnote letters have been

deleted are highlighted in Table 17, below.

Antimicrobial	Antimicrobial	Disk	Zone Interr	Diameter pretive Cr	(mm) riteria	MIC Interpre	(µg/ml tive Cr	.) iteria	Comments
Class	Agent	Content	S		R	S	I	R	
PENICILLINS AND β-LACTAM/β-LACTAMASE INHIBITOR COMBINATIONS									
	Amoxicillin	-	-	-		≤0.5	-	- <mark>a</mark>	See comment (2).
	Amoxicillin-	20/10 μg	≥27	-	-	≤	-	- <mark>a</mark>	See comment (2).
	clavulanate			1 1 1		0.5/0.25			
	Ampicillin	10 µg	≥27	-	-	≤0.5	-	- <mark>a</mark>	See comment (2).
	Penicillin	10 units	≥25	-	-	≤0.5	-	- <mark>a</mark>	See comment (2).

Table 17. Pasteurella spp.

Abbreviations: I, intermediate; MIC, minimal inhibitory concentration; R, resistant; S, susceptible.

With the exception of footnote "b" in the Ciprofloxacin row, the footnote labeling in Table 23B is incorrect. The locations where the footnotes have been corrected (deleted or changed) are highlighted in Table 23B, below.

Table 23B. MIC: Quality Control Ranges for Broth Microdilution Methods (Cation-Adjusted Mueller-Hinton Broth With Lysed Horse Blood [2.5% to 5% v/v])

	MIC QC Ranges (µg/mL)				
Antimicrobial Agent	S. pneumoniae ATCC® <mark>*</mark> 49619	E. coli ATCC® 25922	E. coli ATCC® 35218ª		
Amoxicillin	0.03-0.12	-	≥256		
Amoxicillin-clavulanate	0.03/0.015-0.12/0.06	-	4/2-16/8 <mark>^b</mark>		
Ampicillin	0.06-0.25	-	-		
Ampicillin-sulbactam	-	-	8/4-32/16 ^b		
Azithromycin	0.06-0.25	-	-		
Cefepime	0.03-0.25	-	-		
Cefotaxime	0.03-0.12	-	-		
Ceftriaxone	0.03-0.12	-	-		
Chloramphenicol	2-8	-	-		
Ciprofloxacin	0.25-1 ^b	-	-		
Clarithromycin	0.03-0.12	-	-		
Clindamycin	0.03-0.12	-	-		
Daptomycin ^c	0.06-0.5	-	-		
Doxycycline	0.015-0.12	-	-		
Erythromycin	0.03-0.12	-	-		

	MIC QC Ranges (µg/mL)				
Antimicrobial Agent	S. pneumoniae	E. coli ATCC® 25922	E. coli ATCC® 35218ª		
Gatifloxacin	0.12-0.5	-	-		
Gentamicin	-	0.25-1 <mark>b</mark>	-		
Imipenem	0.03-0.12	-	-		
Levofloxacin	0.5-2	-	-		
Linezolid	0.25-2	-	-		
Meropenem	0.06-0.25	-	-		
Minocycline	-	0.25-1 <mark>b</mark>	-		
Moxifloxacin	0.06-0.25	-	-		
Penicillin	0.25-1	-	-		
Quinupristin-dalfopristin	0.25-1	-	-		
Rifampin	0.015-0.06	-	-		
Tetracycline	0.06-0.5	-	-		
Trimethoprim-sulfamethoxazole	0.12/2.4-1/19	-	-		
Vancomycin	0.12-0.5	-	-		

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

Footnotes

- a. Because *E. coli* ATCC[®] 35218 may lose its plasmid, careful organism maintenance is required; refer to CLSI document M07.²
- b. These QC ranges were validated for tests performed in cation-adjusted Mueller-Hinton broth with lysed horse blood (2.5% to 5% v/v) and were not established by the studies outlined in CLSI document M23.⁶ The validation studies were conducted in at least three laboratories using multiple lots of media.
- c. QC ranges reflect MICs obtained when Mueller-Hinton broth is supplemented with calcium to a final concentration of 50 μ g/mL. Agar dilution has not been validated for daptomycin.

NOTE: Information in boldface type is new or modified since the previous edition.

In Table 24B, the footnote labeling is incorrect. The locations where the footnotes have been corrected (deleted or changed) are highlighted in Table 24B, below.

Table 24B. Disk Diffusion: Quality Control Ranges for Fastidious Organisms (Mueller-Hinton Medium With 5% Sheep Blood)

Antimicrobial		S. pneumoniae ATCC® * 49619
Agent	Disk Content	Disk Diffusion QC Ranges (mm)
Amoxicillin-clavulanate ^a	20/10	-
Ampicillin	10 µg	30-36
Azithromycin	15 μg	19-25
Ceftriaxone	30 µg	30-35
Chloramphenicol	30 µg	23-27
Doxycycline	30 µg	25-34

Erythromycin	15 μg	25-30
Levofloxacin	5 µg	20-25
Moxifloxacin	5 µg	25-31
Penicillin	10 units	24-30
Tetracycline	30 µg	27-31
Trimethoprim-Sulfamethoxazole	1.25/23.75 μg	20-28

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

Footnote

a. Testing of S. *aureus* ATCC[®] 25923 using Mueller-Hinton agar (MHA) supplemented with 5% sheep blood has been shown to produce zones within the acceptable range (28 to 36 mm) noted in CLSI document M100³ for unsupplemented MHA.

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.