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

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To: Recipients of M100, 29th ed.

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

Vice President, Standards and Quality

Daptomycin Breakpoint Revision Subject:

This notice is intended to inform users of a clinically important revision made to daptomycin breakpoints for Enterococcus spp. published in CLSI document M100, Performance Standards for Antimicrobial Susceptibility Testing, 29th ed.

During the 27-29 January 2019 meeting of the CLSI Subcommittee on Antimicrobial Susceptibility Testing, data were presented that warranted the approval of separate daptomycin breakpoints for Enterococcus faecium only and Enterococcus spp. (other than E. faecium). These revisions have been made in all electronic versions of M100, 29th ed. In addition, this memo has been provided to customers who have already received print copies and will be included with all print versions going forward. These revisions will be published in CLSI document M100, 30th ed.

Excerpts from Table 2D are included below. The first excerpt shows the daptomycin breakpoints as they were originally published in the 29th edition. The second excerpt shows the revised daptomycin breakpoints as they will be published in the upcoming 30th edition.

Updates to reflect these revisions were also made in the following locations:

- Overview of Changes
- CLSI Breakpoint Additions/Revisions Since 2010
- Appendix E

Table 2D. Zone Diameter and MIC Breakpoints for Enterococcus spp. (as originally published in 29th ed.)

The daptomycin breakpoints and associated comments for *Enterococcus* spp. as originally published in the 29th edition are shown in the Table 2D excerpt below.

Test/Report	Antimicrobial	Disk	Interpretive Categories and Zone Diameter Breakpoints, nearest whole mm			N		ries ar akpoin mL	nd its,	
Group	Agent	Content	S :		; R	S	SDD	<u>: L</u>	: R	Comments
LIPOPEPTIDES										
В	Daptomycin	-	-	-	-	≤1	2-4	-	≥8	<ul> <li>(11) Daptomycin should not be reported for isolates from the respiratory tract.</li> <li>(12) The breakpoint for susceptible is based on a dosage regimen of 6 mg/kg per day in adults.</li> </ul>
			:							(13) The breakpoint for SDD is based on a dosage regimen of 8- 12 mg/kg per day in adults and is
			:		:					intended for serious infections
			:		:			:		due to Enterococcus spp.
			:		:			:		Consultation with an infectious
			:		:					diseases specialist is
					:			:		recommended.

Table 2D. Zone Diameter and MIC Breakpoints for *Enterococcus* spp. (revised, to be published in upcoming 30th ed.)

The revised daptomycin breakpoints and associated comments are shown in the revised Table 2D excerpt below. All revisions are highlighted.

Test/Report	Antimicrobial	Disk	Interpretive Categories and Zone Diameter Breakpoints, nearest whole mm			Interpretive Categories and MIC Breakpoints, µg/mL				
Group	Agent	Content	S		R	S	SDD	1	R	Comments
LIPOPEPTIDES	5		•							
В	Daptomycin  E. faecium  only	-	-	-		-	<u>≤</u> 4	-	≥8	<ul> <li>(11) Daptomycin should not be reported for isolates from the respiratory tract.</li> <li>(12) The breakpoint for SDD is based on a dosage regimen of 8-12 mg/kg administered every 24 h in adults and is intended for serious infections due to <i>E. faecium</i>.</li> <li>Consultation with an infectious diseases specialist is recommended.</li> </ul>
В	Daptomycin Enterococcus spp. (other than E. faecium)	-	-	-	-	<u>≤ 2</u>	- -	4	≥8	(13) The breakpoint for susceptible is based on a dosage regimen of 6 mg/kg administered every 24 h in adults.  See comment (11).

If you require any additional clarification regarding these revisions, please contact CLSI Customer Service (<a href="mailto:customerservice@clsi.org">customerservice@clsi.org</a>).

We appreciate your commitment to CLSI and regret any inconvenience.