

Dec. 11, 2023

Subject: FDA Breakpoint Update

Dear Customer,

Effective January 2024, clinical laboratories performing antimicrobial susceptibility testing (AST) will be required to use breakpoints currently recognized by Clinical and Laboratory Standards Institute (CLSI) and/or US Food and Drug Administration (FDA) as required by both the College of American Pathologists (CAP) and the Clinical Laboratory Improvement Amendments (CLIA).

The business has reviewed our AST portfolio and have modified panels, as required, to comply with both the FDA susceptibility test interpretive criteria (STIC) or 'breakpoint' ranges and those breakpoints which are currently cleared by Thermo Fisher Scientific. If necessary, updated panel formats have been re-designed to comply with the breakpoint ranges, as well as include new, antimicrobials to provide more testing options to your laboratory.

Appendix I will provide a list of affected standard panels and required actions, if any. For more information on actions required, refer to the 2023 Breakpoint Implementation Toolkit (2023 BIT). For guidance on the validation of new panels, please refer to the guidelines in the CLSI M52 document.

Appendix II will provide a current list of cleared antimicrobials under the new FDA STIC guidance, as of Dec. 11, 2023.

We will continue to provide updates as more antimicrobials are cleared. If you have further questions, please contact your local account manager, or the Technical Support Team at uscletechsupport@thermofisher.com

Sincerely,

Amanda Kulwicki

Amanda Kulwicki
Sr. Product Manager
Microbiology
Thermo Fisher Scientific

Appendix I:

SKU	FDA STIC Compliant	Customer Action to comply with STIC	New Panel Availability
Gram Negative			
GN7F	Yes	Refer to 2023 BIT	N/A
GN6F	No	Move to GN7F for most current breakpoints available	N/A
GN4F	No	Move to GN7F for most current breakpoints available	N/A
GN3F	No	Move to GN7F for most current breakpoints available	N/A
GN2F	No	Move to GN7F for most current breakpoints available	N/A
NF	No	Move to GN7F for most current breakpoints available	N/A
ESB1F	No	Format to be updated to ESB2F ; Move to ESB2F for updated breakpoints	N/A
ESB2F	Yes	New panel, refer to M52 CLSI guideline and 2023 BIT	Feb. 2024
GNUR3F	No	Format to be updated to GNUR6F ; Move to GNUR6F for updated breakpoints	N/A
GNUR5F	No		N/A
GNUR6F	Yes	New panel, refer to M52 CLSI guideline and 2023 BIT	Feb. 2024
MDRGN3F	Yes	Refer to 2023 BIT	N/A
MDRGNXXF	Yes	Refer to 2023 BIT	N/A
Haemophilus influenzae			
HPB1	Yes	Can be used for <i>Haemophilus influenzae as-is</i> ; Format to be updated to HPB2 for <i>Haemophilus influenzae only</i>	N/A
HPB2	Yes	New panel, refer to M52 CLSI guideline	Feb. 2024
Gram Positive			
GPALL1F	Yes	Refer to 2023 BIT	N/A
GPALL3F	Yes	Refer to 2023 BIT	N/A
FDANDSF	Yes	Refer to 2023 BIT	N/A
FDANDPF	Yes	Refer to 2023 BIT	N/A
Fastidious Strep			
STP6F	No	Format to be updated to STP8F* ; Move to STP8F for updated breakpoints	N/A
STP7F	No		N/A
STP8F*	Yes	New panel, refer to M52 CLSI guideline	Jan. 2024
Yeast			
YO9	No	Format to be updated to YO11* ; Move to YO11 for updated breakpoints	N/A
YO11*	Yes	New panel, refer to M52 CLSI guideline – includes new antifungal rezafungin	Jan. 2024
YO2IVD	No	Format to be updated to YO4IVD* ; Move to YO4IVD for updated breakpoints	N/A
YO3IVD	No		N/A
YO4IVD*	Yes	New panel, refer to M52 CLSI guideline - includes new antifungal rezafungin	Jan. 2024

There may be a need for customers to perform testing prior to the adoption of new, or continued usage of our panels to allow for the use of off-label breakpoints as a stopgap prior to regulatory approval. For this reason, existing panels were evaluated for their clinical usability for both historic and current breakpoints. All current panels will remain available during this transition to allow for validation of new panels. New panels, as indicated by bold text and an asterisk (*), are active SKUs and orders can be placed now for these new formats. The expected availability date of the panels is noted in the table above. Note: New panels without an asterisk, are not yet available to order. An updated communication will be provided when these are available.

Appendix II:

Antimicrobial	Status	
	Cleared	Not cleared
YEAST		
Caspofungin	X	
Voriconazole	X	
Fluconazole	X	
Rezafungin	X	
FASTIDIOUS STREP		
Dalbavancin	X	
Delafoxacin	X	
Meropenem		X
Penicillin		X
Ertapenem		X
Cefepime		X
Tetracycline		X
Imipenem		X
FASTIDIOUS-Haemophilus influenzae		
Cefotaxime		X
Cefotetan		X
Ceftolozane-tazobactam	X	
Imipenem-relebactam	X	
Delafoxacin	X	
GRAM-NEGATIVE NON-FASTIDIOUS		
Sulbactam-durlobactam	X	
Amikacin		X
Ampicillin/Sulbactam 2:1		X
Aztreonam		X
Cefazolin		X
Cefoxitin		X
Ciprofloxacin		X
Tetracycline		X
Cefepime		X
Cefotaxime		X
Cefuroxime		X
Gentamicin		X
Imipenem		X
Imipenem-relebactam		X
Ceftazidime		X
Levofloxacin		X
Meropenem		X
Pip/tazo		X
Tobramycin		X
GRAM-POSITIVE NON-FASTIDIOUS		
Dalbavancin		X
Amikacin		X

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Antimicrobial	Status	
	Cleared	Not cleared
GRAM-POSITIVE NON-FASTIDIOUS		
Eravacycline		X
Lefamulin		X
Linezolid		X
Moxifloxacin		X
Oxacillin		X
Tobramycin		X
Vancomycin		X
Daptomycin		X
Delafloxacin		X