Thermo Fisher Scientific
Microbiology
Units 17-19
Birches Industrial Estate
East Grinstead
West Sussex
RH19 1XZ
United Kingdom

Phone: +44 (0) 1342 318777
Fax: +44 (0) 1342 318666
www.thermofisher.com

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Subject: FDA Breakpoint Update

Dear Customer,

As communicated in December 2023 and 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 now concluded a thorough review of our AST portfolio and has modified panels, as required, to comply with the FDA susceptibility test interpretive criteria (STIC) or 'breakpoint' ranges for which Thermo Fisher Scientific has gained FDA clearance. 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 final list of affected standard panels and associated information, including availability dates and timeline for discontinuation of impacted formats.

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 June 25, 2024.

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

Sincerely,

MB

Mark Brightwell
Product Manager

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Appendix I:

Product / SKU	Product Action	Alternative SKU	Final Order Date	Maximum Order Quantity	Alternative SKU Availability
Gram Negative					
GN6F	Discontinuation	GN7F	November 21, 2024	50 Boxes	Immediate
GN4F	Discontinuation	GN7F	November 21, 2024	20 Boxes	Immediate
GN3F	Discontinuation	GN7F	November 21, 2024	20 Boxes	Immediate
GN2F	Discontinuation	GN7F	November 21, 2024	20 Boxes	Immediate
NF	Discontinuation	GN7F	November 21, 2024	20 Boxes	Immediate
GNUR5F	Discontinuation	GN7F*	November 21, 2024	N/A	Immediate
GNUR3F	Discontinuation	GN7F*	November 21, 2024	40 Boxes	Immediate
GNURXF	Discontinuation	GN7F*	November 21, 2024	N/A	Immediate
ESB1F	Discontinuation	GN7F / MDRGN4F**	November 21, 2024	20 Boxes	Immediate / July 1, 2024
MDRGN3F	Discontinuation	MDRGN4F**	November 21, 2024	20 Boxes	July 1, 2024
MDRGNXXF	Discontinuation	MDRGNX4F**	November 21, 2024	30 Boxes	July 1, 2024
Gram Positive					
GPALL1F	Discontinuation	GPALL3F	November 21, 2024	20 Boxes	Immediate
FDANDPF	Moved to MTO***	GPALL3F	N/A	N/A	Immediate
Fastidious - *Streptococcus species*					
STP6F	Discontinuation	STP8F	November 21, 2024	40 Boxes	Immediate
STP7F	Discontinuation	STP8F	November 21, 2024	20 Boxes	Immediate
FDANDSF	Moved to MTO***	STP8F	N/A	N/A	Immediate
Fastidious - *Haemophilus influenzae*					
HPB1	Discontinuation	HPB2****	November 21, 2024	30 Boxes	July 14, 2024

* Potential update to GNUR6F is currently under review, as a solution for Gram negative testing utilize GN7F.
** Newly launched MDRGN4F & MDRGNX4F for Gram negative MDROs, now with Sulbactam / Durlobactam.
*** FDANDPF & FDANDSF have, with immediate effect, been moved to 'Made-To-Order' only.
**** Newly launched panel HPB2 for *H. influenzae*, now with Lefamulin & Ceftolozane / Tazobactam.

All products slated for discontinuation remain available for order until Friday **November 21, 2024**, with fulfillment by **December 26, 2024**. Orders will be processed through normal mechanisms but may experience order fulfillment delays, with the added caveat that product specific maximum order quantities will apply per customer. Requests above and outside of these quantities will be reviewed on a case-by-case basis. To avoid workflow disruption, please transition to new or already available products which meet the latest FDA STIC requirements as soon as it is feasible.

There may be a need to perform testing prior to the adoption of new, or continued usage of our existing 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. Current panels remain available during this transition to allow for validation of new products. New panels are active SKUs and orders can be placed, with availability dates as per the table above.

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Appendix II:

Antimicrobic	Status	
Yeast	**Cleared**	**Not Cleared**
Caspofungin	x	
Voriconazole	x	
Fluconazole		x
Rezafungin	x	
Fastidious - *Streptococcus species*		
Dalbavancin	x	
Delafloxacin	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	
Delafloxacin	x	
Non-fastidious - Gram Negative		
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
Piperacillin-Tazobactam		x
Tobramycin		x
Non-fastidious - Gram Positive		
Dalbavancin		x
Amikacin		x
Eravacycline		x
Lefamulin		x
Linezolid		x
Moxifloxacin		x
Oxacillin		x
Tobramycin		x
Vancomycin		x
Daptomycin		x
Delafloxacin		x