



Please distribute the attached customer letter

To the Laboratory Manager

To the attention of the Healthcare center Chairman

To the attention of the Reactovigilance correspondent

Address
City, Date

Our reference: FSCA 3763

IMPORTANT:

Urgent Field Safety notice

ETEST® Polymyxin B (PO1024)
Blister packaging (Ref. 533400 & 533408)

Dear valued bioMérieux Customer,

This letter is intended for all customers using ETEST Polymyxin B (PO1024) blister packaging (Ref: 533400 & 533408); and our records indicate that your laboratory has received one or more of the batches listed in the attached appendix.

Description of the issue

Following a study conducted on ETEST Polymyxin B with 180 clinical strains (*Pseudomonas aeruginosa*, *Acinetobacter* and *Enterobacteriaceae*), an underestimation of MICs has been observed for *Pseudomonas aeruginosa* and *Acinetobacter* species, compared to those obtained using the Broth Micro-Dilution (BMD) reference method. This has led to false susceptible results when the ETEST Polymyxin B results are interpreted using CLSI breakpoints; there are no breakpoints for this drug in the EUCAST guidelines.

As a consequence of our findings, ETEST Polymyxin B (Ref. 533400 & 533408) Blister packaging can no longer be recommended for use with *Pseudomonas aeruginosa* or *Acinetobacter* strains.

Impact to patient/customer:

There is a potential performance issue for strains identified as *Pseudomonas aeruginosa* or *Acinetobacter*, which could lead to False Susceptible Polymyxin B results, if CLSI breakpoints are applied.

Required actions:

We request that you take the following actions at this time:

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy for your files, and forward this information to all parties that may use this product, including others to whom you may have transferred this product.

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- **Do NOT use ETEST Polymyxin B strips to determine the MICs for *Pseudomonas aeruginosa* or Acinetobacter species.**
- **Laboratories can continue to use ETEST Polymyxin B for Enterobacteriaceae species.**
- For tests previously performed using ETEST Polymyxin B, we are asking you to identify any possible False Susceptible results that may have occurred on *Pseudomonas aeruginosa* and Acinetobacter, to analyze the related risks and to determine appropriate actions, if relevant.
- Complete the attached Acknowledgement Form in Attachment A and return it to your local bioMérieux representative.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Thank you for your continued use of bioMérieux products,

bioMérieux, Inc.

[\[Enter Local Contact\]](#)

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Attachment A: Acknowledgement Form.

FIELD SAFETY NOTIFICATION NOTICE

FSCA 3763 – ETEST® PO1024 (Polymyxin B) (Ref. 533400-533408) Blister packaging – False Susceptible results

TO BE RETURNED TO YOUR BIO-MERIEUX CUSTOMER SERVICE AT THE FOLLOWING

FAX NUMBER : XXXXXXXX

Name of the laboratory:

City:

Customer number:

I acknowledge receipt of this bioMérieux Urgent Field Safety Notice regarding regarding **ETEST® PO1024 (Polymyxin B) (Ref. 533400-533408) Blister packaging** product issue.

I have followed the instructions and implemented the actions as indicated in the Urgent Field Safety Notice.

Have you received reports of illness or injury related to the identified issue?

Yes or No

DATE

SIGNATURE :

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Table 1- List of impacted products:

Product Name	Reference	Batch	Expiry date DD/MM/YYYY
POLYMYXIN B PO 1024 WW B30	533400	1005851000	05/07/2022
POLYMYXIN B PO 1024 WW B30	533400	1005807890	14/06/2022
POLYMYXIN B PO 1024 WW B30	533400	1005753830	03/05/2022
POLYMYXIN B PO 1024 WW B30	533400	1005558710	27/02/2022
POLYMYXIN B PO 1024 WW B30	533400	1005497750	17/01/2022
POLYMYXIN B PO 1024 WW B30	533400	1005329410	09/11/2021
POLYMYXIN B PO 1024 WW B30	533400	1005325780	09/11/2021
POLYMYXIN B PO 1024 WW B30	533400	1005161530	23/08/2021
POLYMYXIN B PO 1024 WW B30	533400	1005020680	28/06/2021
POLYMYXIN B PO 1024 WW B30	533400	1004951670	09/06/2021
POLYMYXIN B PO 1024 WW B30	533400	1004773920	08/03/2021
POLYMYXIN B PO 1024 WW B30	533400	1004414690	13/10/2020
POLYMYXIN B PO 1024 WW B30	533400	1004348480	09/09/2020
POLYMYXIN B PO 1024 WW B30	533400	1004296350	25/08/2020
POLYMYXIN B PO 1024 WW B30	533400	1004193060	15/07/2020
POLYMYXIN B PO 1024 WW B30	533400	1004164300	29/06/2020
POLYMYXIN B PO 1024 WW B30	533400	1003957060	31/03/2020
POLYMYXIN B PO 1024 WW B30	533400	1003655420	03/12/2019
POLYMYXIN B PO 1024 WW B30	533400	1003538020	01/10/2019
POLYMYXIN B PO 1024 WW B30	533400	1003288010	01/07/2019
POLYMYXIN B PO 1024 WW B30	533400	1003230410	02/06/2019
POLYMYXIN B PO 1024 WW B30	533400	1003187220	21/05/2019
POLYMYXIN B PO 1024 WW B30	533400	1002797130	20/10/2018
POLYMYXIN B PO 1024 WW B30	533400	1002735070	20/10/2018
POLYMYXIN B PO 1024 WW B30	533400	1002639240	29/08/2018
POLYMYXIN B PO 1024 WW B30	533400	1002559300	06/06/2018
POLYMYXIN B PO 1024 WW B30	533400	1002446640	06/06/2018
POLYMYXIN B PO 1024 WW B100	533408	1005851010	05/07/2022
POLYMYXIN B PO 1024 WW B100	533408	1005716410	03/05/2022
POLYMYXIN B PO 1024 WW B100	533408	1005659460	11/04/2022
POLYMYXIN B PO 1024 WW B100	533408	1005536040	17/01/2022
POLYMYXIN B PO 1024 WW B100	533408	1005329420	09/11/2021
POLYMYXIN B PO 1024 WW B100	533408	1005020690	28/06/2021
POLYMYXIN B PO 1024 WW B100	533408	1004955950	09/06/2021
POLYMYXIN B PO 1024 WW B100	533408	1004838770	20/04/2021
POLYMYXIN B PO 1024 WW B100	533408	1004767110	08/03/2021
POLYMYXIN B PO 1024 WW B100	533408	1004530070	30/11/2020
POLYMYXIN B PO 1024 WW B100	533408	1004370570	21/09/2020
POLYMYXIN B PO 1024 WW B100	533408	1004347610	09/09/2020
POLYMYXIN B PO 1024 WW B100	533408	1004164310	29/06/2020
POLYMYXIN B PO 1024 WW B100	533408	1003719640	05/01/2020
POLYMYXIN B PO 1024 WW B100	533408	1003655460	03/12/2019
POLYMYXIN B PO 1024 WW B100	533408	1003553910	01/10/2019

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POLYMYXIN B PO 1024 WW B100	533408	1003322180	01/07/2019
POLYMYXIN B PO 1024 WW B100	533408	1003230380	12/06/2019
POLYMYXIN B PO 1024 WW B100	533408	1003006080	24/02/2019
POLYMYXIN B PO 1024 WW B100	533408	1002797270	20/10/2018
POLYMYXIN B PO 1024 WW B100	533408	1002762220	20/10/2018
POLYMYXIN B PO 1024 WW B100	533408	1002605340	29/08/2018
POLYMYXIN B PO 1024 WW B100	533408	1002431510	06/06/2018
POLYMYXIN B PO 1024 WW B100	533408	1002280140	11/03/2018

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