Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Healthcare center Chairman

Address
City, Date

Our reference: FSCA 5230

IMPORTANT:

URGENT FIELD SAFETY NOTICE

Ref. 420925 ; 420927 – ETEST® IPR

MIC overestimation with *Pseudomonas aeruginosa* strains

Dear valued bioMérieux Customer,

This letter is intended for all ETEST® Imipenem/Relebactam (IPR) (Ref: 420925 & 420927) users; and our records indicate that your laboratory has received one or more of the batches listed below:

Product Name	Reference	Batch	Expiry date DD/MM/YYYY
ETEST® IMIPENEM RELEBACTAM	420925	1007888860	09-NOV-2021
ETEST® IMIPENEM RELEBACTAM	420925	1008598340	04-DEC-2022
ETEST® IMIPENEM RELEBACTAM	420925	1008701580	29-JAN-2023
ETEST® IMIPENEM RELEBACTAM	420927	1007607290	24-JUN-2021
ETEST® IMIPENEM RELEBACTAM	420927	1007888870	09-NOV-2021
ETEST® IMIPENEM RELEBACTAM	420927	1008390030	06-AUG-2022
ETEST® IMIPENEM RELEBACTAM	420927	1008598350	04-DEC-2022
ETEST® IMIPENEM RELEBACTAM	420927	1008701590	29-JAN-2023

Description of the issue

ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation.

Following customer complaints, a MIC overestimation issue with some *Pseudomonas aeruginosa* strains compared to Broth Microdilution Method (BMD) has been confirmed. The issue was observed

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by different users during methodology validation on CDC panel strains and it was observed on different lot numbers of ETEST® Imipenem/Relebactam (IPR).

Following the customer results, major errors (Resistant result instead of Susceptible result) were observed with *Pseudomonas aeruginosa* strains. No issue was observed with the other species tested.

The customers issue has been reproduced internally during Research & Development (R&D) tests with *Pseudomonas aeruginosa* strains from CDC Panel and internal bioMérieux collection.

No issue has been observed with *Enterobacteriaceae* tested. This group of species can be tested with ETEST® IPR as mentioned in the package insert.

Impact to customer:

There is a potential performance issue for strains identified as *Pseudomonas aeruginosa*, which could lead to False Resistant or False Intermediate Imipenem/Relebactam results, if CLSI or EUCAST breakpoints are applied.

Required actions:

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

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- **You can continue to use ETEST® IPR but a resistant or intermediate result obtained with ETEST® IPR and *Pseudomonas aeruginosa* strains must be confirmed using an alternative method.**
- For tests previously performed using ETEST® IPR, we are asking you to identify any possible False Resistant/ Intermediate results that may have occurred on *Pseudomonas aeruginosa*, to analyze the related risks and to determine appropriate actions, if relevant.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.

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]

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5230 - ETEST® IPR Ref. 420925 ; 420927 – MIC overestimation with *Pseudomonas aeruginosa* strains

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TO BE RETURNED TO YOUR BIOMERIEUX CUSTOMER SERVICE AT THE FOLLOWING FAX NUMBER : XXXXXXXX

Name of the laboratory:

City:

Customer number:

❑ I acknowledge receipt of the bioMérieux letter regarding the "ETEST® IPR Ref. 420925 ; 420927 – MIC overestimation with *Pseudomonas aeruginosa* strains"

❑ I will implement the required actions indicated in the Urgent Field Safety Notice.

❑ Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue ?

❑ Yes ❑ No

DATE ..... **SIGNATURE** : .....

Subsidiary name (if applicable) / **Nom de la filiale** (si approprié)

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