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 3388

IMPORTANT:

URGENT FIELD SAFETY NOTICE

ETEST® OX 256 (OXACILLIN) Foam packaging (Ref. 520558, 520518)

Our records indicate that your laboratory has received the following products. This letter is intended for all ETEST® OX 256 (OXACILLIN) Foam packaging (Ref. 520558, 520518) users (product reference and lot numbers included below).

Table 1- Product References impacted:

Reference	Description	Lot Number	Expiry date
520518	ETEST®OXACILLIN OX 256 WW F100 520518	1003055340	01-Apr-2017
		1003315740	28-Jul-2017
		1004070580	08-Jun-2018
		1004319590	22-Sep-2018
		1004818850	21-Apr-2019
		1004890270	24-May-2019
		1005366110	12-Dec-2019
520558	ETEST®OXACILLIN OX 256 US F100	1003059010	01-Apr-2017
		1003315830	28-Jul-2017
		1004071250	08-Jun-2018
		1004818860	21-Apr-2019
		1004890400	24-May-2019

Description of the issue

Based on QC failures (MIC out of range high) for *S.aureus* ATCC 29213 strain on ETEST® OX 256 (OXACILLIN) Foam packaging (Ref. 520558, 520518) reported from the field, bioMérieux initiated a complaint investigation to confirm product issue and determine root cause.
The following have been identified:

⇨ The investigation confirmed a potential performance issue **for *S. aureus* ATCC 29213 QC strain and clinical *Staphylococcus* strains** on ETEST® OX 256 (OXACILLIN) Foam packaging (Ref. 520558, 520518) **whatever the media used, when compared to the Agar Dilution reference method, that could lead to False Resistant results.**

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Tél. / Phone : + 33 (0) 820 22 9090 - Fax : + 33 (0) 04 78 87 73 07 - www.biomerieux.com
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⇨ **The investigation states that ETEST® OX 256 (OXACILLIN) SPB configuration (Ref. 412431, 412432) performs within the expected specifications.**

Impact to Patient/User:

As a result of the referenced issue, there is a potential **performance issue on strain categorization for *Staphylococcus* strains that could lead to Major errors when compared to the AD (Agar Dilution) reference method** (Resistant result instead of Susceptible result) **when using 2017 CLSI or 2017 EUCAST** standards**.**

Required actions:

- 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.

- **Recommendations for the users of 2017 CLSI and 2017 EUCAST clinical guidelines,:**

  Laboratories can continue to use ETEST® OX256 FOAM (Ref. 520558, 520518) listed in table 1 **and can directly report the results for *Staphylococcus* spp. only when applying the following recommendations:**

  1 – Perform systematically the Quality Control with *S. aureus* ATCC 29213 to detect performance issues. The expected range is 0.125 – 0.5 µg/mL. An out of range QC result for the strain S. aureus ATCC 29213 would **invalidate the analysis** and **the patient result should not be reported**.

  2 – Oxacillin result **can be directly reported when the following cases occur**:
  - ETEST® OX256 is Susceptible i.e ≤2 µg/mL for *S. aureus*, *S. lugdunensis* or ≤0.25 µg/mL for all other species of Staphylococci –in accordance with CLSI 2017 breakpoints
  - ETEST® OX256 is Susceptible i.e ≤2 mg/L for *S. aureus*, *S. lugdunensis, S. saprophyticus* or ≤0.25 mg/L for coagulase-negative staphylococci except *S. lugdunensis* and *S. saprophyticus* in accordance to EUCAST 2017 breakpoints

  3 - Oxacillin result s**hould be confirmed by an alternative method when the following cases occur**:
  - ETEST® OX256 is Resistant i.e ≥4 µg/mL for *S. aureus*, *S. lugdunensis* or ≥0.5 µg/mL for all others Staphylococci according to CLSI 2017 breakpoints
  - ETEST® OX256 is Resistant i.e >2 mg/L for *S. aureus*, *S. lugdunensis* and *S. saprophyticus* or >0.25 mg/L for the coagulase-negative staphylococci except *S. lugdunensis* and *S. saprophyticus* according to EUCAST 2017 breakpoints.

- Among tests previously performed, we are asking you to identify any possible false Resistant results, analyze the related risks and determine appropriate actions if relevant.

- Contact your local bioMérieux representative for product compensation, if needed, until impacted products will be replaced by ETEST® OX 256 (OXACILLIN) SPB configuration.

- Complete and return the Acknowledgement Form in Attachment A by Fax to confirm receipt of this notice.

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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.

Yours sincerely,
Medical Customer Service

Attachment A: Acknowledgement Form.

PLEASE RETURN TO YOUR CUSTOMER SERVICE

Fax : …….
Name of the laboratory:

City:

Customer number:

❑ I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the **ETEST® OX256 FOAM packaging** (Ref. 520558, 520518) 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 : …….**