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Our Ref.: 3388 - FSCA - ETEST OXACILLIN OX 256 Foam packaging Ref. 520558 - 520518 False Resistant results

Gothenburg, 13 APRIL 2017

URGENT PRODUCT CORRECTION NOTICE

ETEST OXACILLIN OX 256 Foam packaging Ref. 520558 - 520518 False Resistant results

Dear customer,

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.
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 should 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.

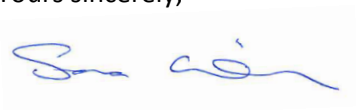
Among tests previously performed, we are asking you to identify any possible false Resistant results, analyze the related risks and determine appropriate actions if relevant.

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 the email to customersupport.nordic@biomerieux.com 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.

Yours sincerely,



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