16 January 2017

Attachment 12

URGENT FIELD SAFETY REMOVAL
FSCA3193

ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018) FOAM packaging

Dear

This letter is intended for all **ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018) FOAM** packaging US & World Wide users. Our records indicate that your laboratory received the following products (reference and lot numbers are included in Table 1 and Table 2).

As a part of our ongoing thorough analysis of the ETEST® product range, we have observed internally two issues with ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018) FOAM that may affect the test performance.

Issue 1: Description: shelf life claims
We have observed internally that the current shelf-life claims of the ETEST® Ceftriaxone TXL32 products listed in Table 2 are not supported by internal testing. As a result there is a potential for an overestimation of the MIC values for specifically *Neisseria gonorrhoeae*. No increase of the complaint trend was observed for these products, but we are taking the precaution of revising the shelf-life claims.

The following has been identified

- ⇨ QC failure (MICs above the upper QC limit) for some Quality Control strains listed in the Instructions For Use on ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018) FOAM packaging.

Impact:
As a result of the observed performance issue, there is a potential to obtain a MIC result that is higher than expected. This type of error would be detectable during quality control testing as an out of range MIC result would be obtained. Patient results may also be elevated resulting in a false Non-Susceptible or a false Resistant result.

Required actions:
The following recommendations require your immediate attention to ensure the product will continue to perform per its labeled performance specifications, within its revised shelf-life of twelve (12) months.

- Identify impacted lots of **ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018) FOAM** packaging (lots listed in Table 1 below) which are now expired after shelf-life reduction.

- Immediately order the replacement products appropriate for your institution.

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Registered Office: Grafton Way, Basingstoke, Hampshire, RG22 6HY – Registered in England No. 1061914

- Until replacement product is available Laboratories may continue to use their now expired strips with the following recommendations:
    - Laboratories should continue to follow their current QC procedures for **ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018)** for the lots listed in Table 1 in accordance with CLIA and local regulatory requirements, with a modification to increase the frequency of QC testing to weekly or every day of use if previous QC testing exceeds one week.
    - Laboratories should include in the QC testing the strain (*N. gonorrhoeae* ATCC 49226) defined as the stability indicator for ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018). The MIC result for this specific strain must fall in the acceptable range to confirm the validity of the QC test and performance of the ETEST with the clinical isolate.
    - Only report results if all QC is in the acceptable ranges.

- If replacement product is received, discontinue using and discard impacted **ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018)** (listed in Table 1) whatever the product shelf-life.

- Please note that the **FOAM** packaging manufacturing has been already discontinued and all customers will be transitioned to **Single Pack Blister (SPB) packaging.**

Issue 2: Description: A potential performance issue on strain categorization

The following was identified:

- For *Streptococcus pneumoniae* meningitis strains: based on 2016 **CLSI** guidelines a reduced MIC value might be obtained with ETEST® TXL32 (SPB and FOAM packaging) that could lead to a susceptible categorization instead of intermediate categorization (Minor Error) or resistant categorization (Very Major Error) for clinical strains as compared to broth microdulution (BMD) reference method.

- For *Streptococcus pneumoniae* strains (meningitis and non-meningitis): based on 2016 **EUCAST** guidelines a reduced MIC value could be obtained with ETEST® TXL32 SBP and FOAM packaging) leading to a susceptible categorization instead of intermediate categorization for clinical strains as compared to BMD reference method: Minor error.

Impact:

There is a potential to obtain:

- A susceptible result instead of an intermediate result (Minor Error) or resistant result (Very Major Error) for *Streptococcus pneumoniae* meningitis strains with ETEST® TXL32 SPB and FOAM packaging compared to the BMD reference method using 2016 **CLSI** guidelines.
- A susceptible result instead of an intermediate result (Minor Error) for *Streptococcus pneumoniae* strains with ETEST® TXL32 SPB and FOAM packaging compared to the BMD reference method and based on 2016 **EUCAST** guidelines.

Recommendations for users under EUCAST guidelines: to inform the customer that there is a potential to obtain a false susceptible result instead of intermediate result for *Streptococcus pneumoniae* strains compared to the BMD reference method based on 2016 **EUCAST** guidelines for ETEST® TXL32 (FOAM and SPB packaging). Laboratories can continue to use ETEST® TXL32 for *Streptococcus pneumoniae* when applying the following the recommendations:

- Laboratories should verify the result by an alternative method for each *Streptococcus pneumoniae* isolate (meningitis and non-meningitis) with an **ETEST® TXL32** MIC ≥0.5 □g/ml). This verification **is not needed** for isolates that are known to be fully susceptible to benzylpenicillin (MIC ≤0.06 □g/ml) or that have an oxacillin zone diameter >8 mm.

Recommendations for users under CLSI guidelines: To inform customer that there is a potential to obtain a false susceptible result instead of intermediate or resistant result compared to the BMD reference method for *Streptococcus pneumoniae* meningitis based on 2016 CLSI breakpoints with ETEST® TXL32 (FOAM and SPB packaging). Laboratories can continue to use ETEST® TXL32 for *Streptococcus pneumoniae* meningitis when applying the following recommendations:

- **Under the following conditions ETEST® TXL32 results can be directly reported for *Streptococcus pneumoniae* (CLSI meningitis):**
  - Isolate tests penicillin susceptible (MIC ≤0.06 □g/ml) and ceftriaxone susceptible (**ETEST® TXL32** MIC ≤0.5 □g/ml)
  - Isolate tests penicillin resistant (MIC ≥0.12 □g/ml) and ceftriaxone resistant (**ETEST® TXL32** ≥ 2 □g/ml)

- **For isolates testing penicillin resistant (MIC ≥0.12 □g/ml) and ceftriaxone susceptible (ETEST® TXL32 MIC ≤0.5 □g/ml) or intermediate (ETEST® TXL32 MIC=1 □g/ml), the ceftriaxone MIC should be confirmed using an alternative MIC test method.**

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.

- Please work with your institution's risk management team to determine if retrospective analysis of results is required for your patients.

- Alternative methods of testing for Ceftriaxone and Streptococcus pneumonia are available, please contact bioMérieux for automated alternate methods.

- Complete and return the Acknowledgement Form in Attachment A for the attention of Customer Service Department to fax number 0044 (0) 1256 816863 to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologise for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact our Technical Service Department on 0044 (0) 1256 461881.

Yours sincerely

Customer Service Department

Table 1: Product with NO remaining shelf life (after reduction). QC testing required.

REF	Product Name	Lot#
507018	TXL 32 (F) WW	1002940880
507018	TXL 32 (F) WW	1003182290
507018	TXL 32 (F) WW	1003813700
507018	TXL 32 (F) WW	1003851130
507018	TXL 32 (F) WW	1003953490
507018	TXL 32 (F) WW	1004239880
507018	TXL 32 (F) WW	1004316460
507018	TXL 32 (F) WW	1004527210
507018	TXL 32 (F) WW	1004755930
507018	TXL 32 (F) WW	1004828450
507018	TXL 32 (F) WW	1004876850
507018	TXL 32 (F) WW	1004919010
507058	TXL 32 (F) US	1002940890
507058	TXL 32 (F) US	1003128150
507058	TXL 32 (F) US	1003361950
507058	TXL 32 (F) US	1003849820
507058	TXL 32 (F) US	1004041790
507058	TXL 32 (F) US	1004239890
507058	TXL 32 (F) US	1004395510
507058	TXL 32 (F) US	1004525370
507058	TXL 32 (F) US	1004756050
507058	TXL 32 (F) US	1004828430
507058	TXL 32 (F) US	1004876860
507058	TXL 32 (F) US	1004919030

Attachment A: Acknowledgement Form- FSCA 3193

In order to comply with Competent Authority Regulations it is important that you complete and return this acknowledgement form

Please return for the attention of Customer Service Department to fax number 0044 (0) 1256 816863

❑ I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the ETEST® Ceftriaxone TXL32 (Ref. 507058, 507018) 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

Name: ……..

Date: ……

Signature: ……