16 January 2017

Attachment 1

URGENT FIELD SAFETY NOTICE
FSCA3193

ETEST® Ceftazidime TZ256 (Ref. 506758, 506718) Foam packaging

Dear

Our records indicate that your laboratory received the following products. This letter is intended for all ETEST® Ceftazidime TZ256 (Ref. 506758, 506718) Foam packaging US & World Wide users. Product reference and lot numbers are indicated on Table 1 and Table 2.

Description of the issue:

As a part of our ongoing thorough analysis of the ETEST® product range, we have observed internally that current shelf-life claims of the ETEST® Ceftazidime TZ256 product listed in Table 1 and Table 2 are not supported by internal testing. No increase of the complaint trend was observed for these products, but we are taking the precaution of revising the shelf-life claims, that requires your immediate attention to ensure proper use of the product within its revised shelf-life of twelve (12) months.
When used within the revised shelf-life, the product will continue to perform per its labeled performance specifications. The following issue has been identified:

⇨ QC failure (MICs above the upper QC limit) for some Quality Control strains listed in the Instructions For Use on ETEST® Ceftazidime TZ256 (Ref. 506758, 506718) Foam packaging after 12 months of shelf-life.

Impact:

As a result of the observed performance issue, there is a potential to obtain an MIC result that is higher than expected after 12 months of shelf-life. 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 resistant result.

Required actions:

Product with NO remaining shelf life (after reduction):

- Identify impacted lots of **ETEST® Ceftazidime TZ256 (Ref. 506758, 506718), Foam packaging** (lots listed in Table 1) which are now designated as expired.
- Immediately order the replacement products appropriate for your institution.
- Laboratories should continue to follow their current QC procedures for **ETEST® Ceftazidime TZ256 (Ref. 506758, 506718)** 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 and only report results if the QC is in the acceptable range. Also, we recommend to include in the QC testing, the organism defined as the stability indicator for ETEST® Ceftazidime TZ256 (Ref. 506758, 506718) that is *E.coli* ATCC25922 strain (Expected range- MIC: 0,064-0.5 µg/mL). 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 strip.

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- If replacement product is received, discontinue using and discard impacted **ETEST® Ceftazidime TZ256 (Ref. 506758, 506718)** lots listed in Table 1.

Product with remaining shelf life:

- The remaining products in Table 2, may be used within the revised shelf life requirements as defined in Table 2 below.
- Correct expiration date of the remaining usable product to meet the new shelf life specified in Table 2.

Additional 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.

    - Please note, **ETEST® Ceftazidime TZ256 (Ref. 412293, 412292) SPB** packaging performs within the specifications until its labeled expiration date.

- **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 Manager

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

REF	Lot #	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
506718	1003788640	**TZ256 (F)** WW	24	12	11-Feb-2016
506718	1003823960	**TZ256 (F)** WW	24	12	19-Mar-2016
506718	1003945320	**TZ256 (F)** WW	24	12	16-Apr-2016
506718	1004427210	**TZ256 (F)** WW	24	12	3-Nov-2016
506718	1004510360	**TZ256 (F)** WW	24	12	8-Dec-2016
506758	1003693010	**TZ256 (F)** US	24	12	7-Jan-2016
506758	1003922720	**TZ256 (F)** US	24	12	7-Apr-2016
506758	1003945330	**TZ256 (F)** US	24	12	16-Apr-2016
506758	1004193850	**TZ256 (F)** US	24	12	29-Jul-2016
506758	1004325620	**TZ256 (F)** US	24	12	24-Sep-2016
506758	1004427220	**TZ256 (F)** US	24	12	3-Nov-2016
506758	1004510540	**TZ256 (F)** US	24	12	8-Dec-2016

Table 2: Product with remaining shelf life.

REF	Lot #	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
506718	1004719300	**TZ256 (F)** WW	24	12	10-Mar-2017
506718	1004830170	**TZ256 (F)** WW	24	12	27-Apr-2017
506758	1004720640	**TZ256 (F)** US	24	12	10-Mar-2017
506758	1004830190	**TZ256 (F)** US	24	12	27-Apr-2017

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 Departemnt to fax number 0044 (0) 1256 816863

❑ I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the ETEST® Ceftazidime TZ256 (Ref. 506758, 506718) 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: ……