

15 June 2015

Our reference: FSCA 2544

Dear Sir / Madam

IMPORTANT :

URGENT FIELD SAFETY NOTICE

Etest® CEFOTAXIME CT 256

Our records indicate that your laboratory has received one or more of the following products.

Table 1:

| Product Ref. Number | Description | Lot Number | Expiry date |
|---------------------|---------------------------|------------|-------------|
| 505518 | CEFOTAXIME CT 256 WW F100 | 1002774320 | 25NOV2015 |
| | | 1002377890 | 06JUN2015 |
| | | 1002590470 | 06SEP2015 |

Description of the issue

During a recent internal investigation of retained lots, it was observed that retained batches of the Etest CEFOTAXIME CT 256 showed failed internal QC testing. The batches were originally released with conform QC results. However, current investigations of the lots listed above show that the strips deviated from acceptable QC parameters which may result in clinical strains that are expected to be Susceptibly potentially may appear as Resistant.

Impact

The identified non-conformity could lead to erroneous results (Susceptible strains potentially could appear as Resistant). If QC was performed and acceptable when the strips in question were tested, then the results can be assumed to be accurate.

Cont..

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.
- Discontinue using and discard any remaining inventory of Etest® CEFOTAXIME CT 256 lots reported in table1.
- Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.
- **Complete and return the Acknowledgement Form in Attachment A for the attention of Customer Services to fax number 0044 (0) 1256 816863 to confirm receipt of this notice and for product compensation.**

bioMérieux can confirm that the Competent Authorities have been advised of this issue.

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 your local bioMérieux Customer Service representative.

Yours sincerely

Customer Services Department

Attachment A: Acknowledgement Form – 2544

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

I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the Etest® CEFOTAXIME CT 256 product issue.

| Product : Etest® CEFOTAXIME CT 256 | | | | |
|------------------------------------|---------------------------|------------|--------------------------|--|
| 505518 | CEFOTAXIME CT 256 F100 | 1002774320 | Number of kits received | |
| | | | Number of kits destroyed | |
| | | 1002377890 | Number of kits received | |
| | | | Number of kits destroyed | |
| | | 1002590470 | Number of kits received | |
| | | | Number of kits destroyed | |

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

In order to comply with Competent Authority Regulations it is important that you complete the acknowledgement form and return it to bioMérieux UK Ltd

**Please return for the attention of Sheila Marsh to fax number : 0044 (0) 1256 816863
or scan and email to sheila.marsh@biomerieux.com**

Upon receipt of this completed form a credit will be provided on any destroyed stock

NAME : **SIGNATURE:** **DATE:**