

16 January 2017

Attachment 4

**URGENT FIELD SAFETY NOTICE  
FSCA3193**

**ETEST® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618) FOAM packaging**

Dear

Our records indicate that your laboratory received the following products. This letter is intended for all ETEST® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618) FOAM packaging US & World Wide users. Product reference and lot numbers are included 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® Ciprofloxacin CI 32 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® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618) FOAM packaging starting after 12 months of shelf-life.

**Impact:**

As a result of the observed performance issue, there is a potential to obtain a 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® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618) FOAM** packaging (lots listed Table 1 below) 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® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618)**, 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® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618) that is *E.coli* ATCC25922 strain (Expected range-MIC: 0,004-0,016 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.
- If replacement product is received, discontinue using and discard **ETEST® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618)**, lots listed in Table 1.

**Product with remaining shelf life:**

- Identify products in **Table 2**. These products may be used within the revised shelf life requirements defined within Table 2.
- Correct the 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® Ciprofloxacin CI32 (Ref. 412310, 412311) SPB** packaging performs within the specifications until the 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 Department



**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
508610	1001026950	CI 32 (F) WW	60	12	7-Jan-2013
508610	1001199360	CI 32 (F) WW	60	12	7-Jan-2013
508610	1001427690	CI 32 (F) WW	60	12	15-May-2013
508610	1001518090	CI 32 (F) WW	60	12	15-May-2013
508610	1001595490	CI 32 (F) WW	60	12	30-Jul-2013
508610	1001740320	CI 32 (F) WW	60	12	30-Jul-2013
508610	1001989260	CI 32 (F) WW	60	12	10-Dec-2013
508618	1001032350	CI 32 (F) WW	60	12	7-Jan-2013
508618	1001242030	CI 32 (F) WW	60	12	7-Jan-2013
508618	1001338050	CI 32 (F) WW	60	12	7-Jan-2013
508618	1001416820	CI 32 (F) WW	60	12	7-Jan-2013
508618	1001471720	CI 32 (F) WW	60	12	15-May-2013
508618	1001595500	CI 32 (F) WW	60	12	15-May-2013
508618	1001627650	CI 32 (F) WW	60	12	15-May-2013
508618	1001720440	CI 32 (F) WW	60	12	15-May-2013
508618	1001728140	CI 32 (F) WW	60	12	30-Jul-2013
508618	1001786480	CI 32 (F) WW	60	12	30-Jul-2013
508618	1001956220	CI 32 (F) WW	60	12	10-Dec-2013
508618	1002109250	CI 32 (F) WW	60	12	28-Jan-2014
508618	1002338880	CI 32 (F) WW	60	12	23-May-2014
508618	1002435190	CI 32 (F) WW	60	12	26-Jun-2014
508618	1002566960	CI 32 (F) WW	60	12	26-Aug-2014
508618	1002718380	CI 32 (F) WW	60	12	30-Oct-2014
508618	1002975330	CI 32 (F) WW	60	12	25-Feb-2015
508618	1003886270	CI 32 (F) WW	60	12	23-Mar-2016
508618	1003894060	CI 32 (F) WW	60	12	25-Mar-2016
508618	1003981160	CI 32 (F) WW	60	12	2-May-2016
508618	1004064990	CI 32 (F) WW	60	12	6-Jun-2016
508618	1004075190	CI 32 (F) WW	60	12	9-Jun-2016
508618	1004168390	CI 32 (F) WW	60	12	18-Jul-2016
508618	1004490810	CI 32 (F) WW	60	12	29-Nov-2016
508650	1001060450	CI 32 (F) US	60	12	7-Jan-2013
508650	1001154650	CI 32 (F) US	60	12	7-Jan-2013
508650	1001212890	CI 32 (F) US	60	12	7-Jan-2013
508650	1001264540	CI 32 (F) US	60	12	7-Jan-2013
508650	1001319180	CI 32 (F) US	60	12	7-Jan-2013
508650	1001390080	CI 32 (F) US	60	12	7-Jan-2013
508650	1001390440	CI 32 (F) US	60	12	15-May-2013



508650	1001409510	CI 32 (F) US	60	12	15-May-2013
508650	1001409520	CI 32 (F) US	60	12	15-May-2013
508650	1001441760	CI 32 (F) US	60	12	15-May-2013
508650	1001540660	CI 32 (F) US	60	12	30-Jul-2013
508650	1001589490	CI 32 (F) US	60	12	30-Jul-2013
508650	1001621240	CI 32 (F) US	60	12	30-Jul-2013
508650	1001656460	CI 32 (F) US	60	12	30-Jul-2013
508658	1001093880	CI 32 (F) US	60	12	7-Jan-2013
508658	1001154820	CI 32 (F) US	60	12	7-Jan-2013
508658	1001265110	CI 32 (F) US	60	12	7-Jan-2013
508658	1001319480	CI 32 (F) US	60	12	7-Jan-2013
508658	1001390570	CI 32 (F) US	60	12	7-Jan-2013
508658	1001441910	CI 32 (F) US	60	12	15-May-2013
508658	1001487610	CI 32 (F) US	60	12	15-May-2013
508658	1001647880	CI 32 (F) US	60	12	15-May-2013
508658	1001708510	CI 32 (F) US	60	12	15-May-2013
508658	1001811360	CI 32 (F) US	60	12	30-Jul-2013
508658	1002041010	CI 32 (F) US	60	12	10-Dec-2013
508658	1002102920	CI 32 (F) US	60	12	10-Dec-2013
508658	1002435570	CI 32 (F) US	60	12	26-Jun-2014
508658	1002567240	CI 32 (F) US	60	12	26-Aug-2014
508658	1002725010	CI 32 (F) US	60	12	3-Nov-2014
508658	1003246020	CI 32 (F) US	60	12	30-Jun-2015
508658	1003889730	CI 32 (F) US	60	12	24-Mar-2016
508658	1004168400	CI 32 (F) US	60	12	18-Jul-2016
508658	1004364330	CI 32 (F) US	60	12	10-Oct-2016
508658	1004491220	CI 32 (F) US	60	12	29-Nov-2016

**Table 2: Product with remaining shelf life**

REF	Lot#	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
508618	1004939640	CI 32 (F) WW	60	12	9-Jun-2017
508658	1004939670	CI 32 (F) US	60	12	9-Jun-2017





**Attachment A: Acknowledgement Form- FSCA 3193**

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**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® Ciprofloxacin CI 32 (Ref. 508650, 508658, 508610, 508618) 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: .....

