

16 January 2017

Attachment 9

**URGENT FIELD SAFETY NOTICE
FSCA3193**

ETEST® Imipenem IP32 (Ref. 513610, 513618, 513658, 513650) Foam packaging

Dear

Our records indicate that your laboratory received the referenced products. This letter is intended for all ETEST® Imipenem IP32 (Ref. 513610, 513618, 513658, 513650) Foam packaging US & World Wide users. Product reference and lot numbers are included in 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® Imipenem IP32 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 thirty-six (36) months.

When used within the revised shelf-life, the product will continue to perform per its labeled performance specifications, the following have been identified:

- ⇒ QC failure (MICs above the upper QC limit) for some Quality Control strains listed in the Instructions For Use on ETEST® IP32 (Ref. 513610, 513618, 513658, 513650) Foam packaging after T36 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 36 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® IP32 (Ref. 513610, 513618, 513658, 513650) FOAM** packaging (lots listed in Table 1 below) which are now expired.
- Immediately order the replacement products appropriate for your institution.



- Laboratories should continue to follow their current QC procedures for **ETEST® IP32 (Ref. 513610, 513618, 513658, 513650)** 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 organisms defined as the stability indicators for ETEST® IP32 (Ref. 513610, 513618, 513658, 513650) that are the following strains:
 - *E coli* ATCC 25922 (Expected range-MIC: 0.064-0.25 µg/mL)
 - *P. aeruginosa* ATCC 27853 (Expected range-MIC: 1-4 µg/mL)
 - *S.pneumoniae* ATCC 49619 (Expected range-MIC: 0.032-0.125 µg/mL)
 - *B.tethaiotaomicron* ATCC 29741 (Expected range-MIC: 0.064-0.25 µg/mL)
- The MIC results for those specific strains 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 impacted **ETEST® IP32 (Ref. 513610, 513618, 513658, 513650)** lots listed in Table 1.

Product with remaining shelf life:

- Identify products listed in Table 2. These products may be used within the revised shelf life requirements as defined in 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.
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- Please work with your institution's risk management team to determine if retrospective analysis of results is required for your patients.
 - Please note that **ETEST® IP32 Imipenem (Ref. 412373, 412374) SPB** packaging performs within the specifications until 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
513610	1001125240	IP 32 (F) WW	60	36	22-Feb-2015
513610	1001610770	IP 32 (F) WW	60	36	26-Aug-2015
513618	1001193130	IP 32 (F) WW	60	36	22-Feb-2015
513618	1001223300	IP 32 (F) WW	60	36	22-Feb-2015
513618	1001316710	IP 32 (F) WW	60	36	22-Feb-2015
513618	1001377740	IP 32 (F) WW	60	36	22-Feb-2015
513618	1001454060	IP 32 (F) WW	60	36	19-Apr-2015
513618	1001454090	IP 32 (F) WW	60	36	10-Jun-2015
513618	1001527340	IP 32 (F) WW	60	36	10-Jun-2015
513618	1001633670	IP 32 (F) WW	60	36	10-Jun-2015
513618	1001721100	IP 32 (F) WW	60	36	10-Jun-2015
513618	1001801280	IP 32 (F) WW	60	36	10-Jun-2015
513618	1001804930	IP 32 (F) WW	60	36	30-Sep-2015
513618	1002029820	IP 32 (F) WW	60	36	13-Jan-2016
513618	1002234950	IP 32 (F) WW	60	36	11-Apr-2016
513618	1002238110	IP 32 (F) WW	60	36	14-Apr-2016
513618	1002269280	IP 32 (F) WW	60	36	22-Apr-2016
513618	1002476170	IP 32 (F) WW	60	36	14-Jul-2016
513618	1002593870	IP 32 (F) WW	60	36	8-Sep-2016
513618	1002699130	IP 32 (F) WW	60	36	21-Oct-2016
513618	1002702380	IP 32 (F) WW	60	36	22-Oct-2016
513650	1001135740	IP 32 (F) US	60	36	22-Feb-2015
513650	1001154700	IP 32 (F) US	60	36	22-Feb-2015
513650	1001251110	IP 32 (F) US	60	36	22-Feb-2015
513650	1001319240	IP 32 (F) US	60	36	22-Feb-2015
513650	1001333960	IP 32 (F) US	60	36	22-Feb-2015
513650	1001409550	IP 32 (F) US	60	36	10-Jun-2015
513650	1001557360	IP 32 (F) US	60	36	10-Jun-2015
513650	1001574370	IP 32 (F) US	60	36	26-Aug-2015
513658	1001154880	IP 32 (F) US	60	36	22-Feb-2015
513658	1001265150	IP 32 (F) US	60	36	22-Feb-2015
513658	1001368000	IP 32 (F) US	60	36	19-Apr-2015
513658	1001390590	IP 32 (F) US	60	36	19-Apr-2015
513658	1001487630	IP 32 (F) US	60	36	10-Jun-2015
513658	1001609830	IP 32 (F) US	60	36	10-Jun-2015
513658	1001676400	IP 32 (F) US	60	36	10-Jun-2015
513658	1001735190	IP 32 (F) US	60	36	10-Jun-2015



513658	1001811380	IP 32 (F) US	60	36	30-Sep-2015
513658	1002056670	IP 32 (F) US	60	36	13-Jan-2016
513658	1002230910	IP 32 (F) US	60	36	11-Apr-2016
513658	1002478800	IP 32 (F) US	60	36	14-Jul-2016
513658	1002596830	IP 32 (F) US	60	36	8-Sep-2016

Table 2: Product with remaining shelf life.

REF	Lot #	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
513618	1003066070	IP 32 (F) WW	60	36	6-Apr-2017
513658	1003066090	IP 32 (F) US	60	36	6-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 Department to fax number 0044 (0) 1256 816863

I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the ETEST® IP32 (Ref. 513610, 513618, 513658, 513650) 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:

