

16 January 2017

Attachment 10

**URGENT FIELD SAFETY NOTICE
FSCA3193**

ETEST® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518) FOAM packaging

Dear

Our records indicate that your laboratory received the referenced products. This letter is intended for all ETEST® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518) 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® Gentamicin GM256 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 forty-eight (48) 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® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518) FOAM packaging after T48 months of shelf-life.

Impact to Patient/User:

As a result of the observed performance issue, there is a potential to obtain a MIC result that is higher than expected after 48 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® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518) 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® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518)** lots listed 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® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518) that are *E.coli* ATCC25922 (Expected range-MIC: 0,25-1 µg/mL) and *P. aeruginosa* ATCC27853 (Expected range-MIC: 0,5-2 µg/mL) strains. 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® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518)** lots listed Table 1.

Product with remaining shelf life:

- Identify products 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.
- 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® GM256 Gentamycin (Ref. 412367, 412368) 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
512510	1001970170	GM256 (F) WW	60	48	2-Dec-2016
512510	1002154750	GM256 (F) WW	60	48	2-Dec-2016
512518	1001595660	GM256 (F) WW	60	48	3-Jul-2016
512518	1001707960	GM256 (F) WW	60	48	3-Jul-2016
512518	1001803880	GM256 (F) WW	60	48	25-Oct-2016
512550	1002001100	GM256 (F) US	60	48	2-Dec-2016
512550	1002048740	GM256 (F) US	60	48	2-Dec-2016
512558	1001564260	GM256 (F) US	60	48	3-Jul-2016
512558	1001676270	GM256 (F) US	60	48	3-Jul-2016
512558	1001733240	GM256 (F) US	60	48	3-Jul-2016
512558	1001793760	GM256 (F) US	60	48	3-Jul-2016
512558	1001873760	GM256 (F) US	60	48	25-Oct-2016

TABLE 2: Product with remaining shelf life.

REF	Lot #	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
512518	1002094250	GM256 (F) WW	60	48	10-Feb-2017
512518	1002229210	GM256 (F) WW	60	48	10-Apr-2017
512518	1002233690	GM256 (F) WW	60	48	11-Apr-2017
512518	1002559790	GM256 (F) WW	60	48	22-Aug-2017
512518	1002684500	GM256 (F) WW	60	48	14-Oct-2017
512518	1002823910	GM256 (F) WW	60	48	15-Dec-2017
512518	1003164040	GM256 (F) WW	60	48	22-May-2018
512518	1003191670	GM256 (F) WW	60	48	5-Jun-2018
512518	1003279330	GM256 (F) WW	60	48	10-Jul-2018
512518	1003604650	GM256 (F) WW	60	48	26-Nov-2018
512518	1004047450	GM256 (F) WW	60	48	30-May-2019
512518	1004157400	GM256 (F) WW	60	48	13-Jul-2019
512518	1004247950	GM256 (F) WW	60	48	22-Aug-2019
512518	1004252220	GM256 (F) WW	60	48	24-Aug-2019
512518	1004528390	GM256 (F) WW	60	48	14-Dec-2019
512518	1004567000	GM256 (F) WW	60	48	5-Jan-2020
512558	1002113320	GM256 (F) US	60	48	10-Feb-2017
512558	1002230930	GM256 (F) US	60	48	11-Apr-2017
512558	1002559800	GM256 (F) US	60	48	22-Aug-2017



512558	1002823250	GM256 (F) US	60	48	15-Dec-2017
512558	1003495040	GM256 (F) US	60	48	9-Oct-2018
512558	1003883840	GM256 (F) US	60	48	22-Mar-2019
512558	1004248160	GM256 (F) US	60	48	22-Aug-2019
512558	1004252230	GM256 (F) US	60	48	24-Aug-2019
512558	1004277880	GM256 (F) US	60	48	5-Sep-2019
512558	1004567040	GM256 (F) US	60	48	5-Jan-2020
512558	1004946070	GM256 (F) US	60	48	12-Jun-2020
512558	1004980260	GM256 (F) US	60	48	23-Jun-2020
512558	1005146190	GM256 (F) US	60	48	8-Sep-2020



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 of 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® Gentamicin GM256 (Ref. 512550, 512510, 512558, 512518) 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:

