

16 January 2017

**Attachment 5**

**URGENT FIELD SAFETY NOTICE  
FSCA3193**

**ETEST® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518) FOAM packaging**

Dear

Our records indicate that your laboratory received the following products. This letter is intended for all ETEST® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518) 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® Vancomycin VA 256 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 have been identified:

- ⇒ QC failure (MICs above the upper QC limit) for some Quality Control strains listed in the Instructions For Use on ETEST® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518) FOAM packaging over the product shelf-life 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. 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® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518) FOAM** packaging (lots listed 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® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518)** 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® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518) that are *E. faecalis* ATCC 29212 (Expected range-MIC: 1-4 µg/ml) and *S.pneumoniae* ATCC 49619 (Expected range-MIC: 0.125-0.5 µg/ml). The MIC result 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® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518)** 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 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, **ETEST® (Vancomycin) SPB packaging (Ref. 412486, 412488) 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
525510	1001051200	VA 256 (F) WW	60	12	28-Jan-2013
525510	1001125840	VA 256 (F) WW	60	12	4-Mar-2013
525510	1001416930	VA 256 (F) WW	60	12	4-Mar-2013
525510	1001455150	VA 256 (F) WW	60	12	4-Mar-2013
525510	1001548250	VA 256 (F) WW	60	12	26-Jun-2013
525510	1001596090	VA 256 (F) WW	60	12	26-Jun-2013
525518	1001192860	VA 256 (F) WW	60	12	28-Jan-2013
525518	1001223460	VA 256 (F) WW	60	12	28-Jan-2013
525518	1001317000	VA 256 (F) WW	60	12	28-Jan-2013
525518	1001338170	VA 256 (F) WW	60	12	4-Mar-2013
525518	1001416940	VA 256 (F) WW	60	12	4-Mar-2013
525518	1001416950	VA 256 (F) WW	60	12	15-Apr-2013
525518	1001492590	VA 256 (F) WW	60	12	29-May-2013
525518	1001566860	VA 256 (F) WW	60	12	29-May-2013
525518	1001634070	VA 256 (F) WW	60	12	26-Jun-2013
525518	1001728340	VA 256 (F) WW	60	12	26-Jun-2013
525518	1001761460	VA 256 (F) WW	60	12	16-Sep-2013
525518	1001887350	VA 256 (F) WW	60	12	18-Nov-2013
525518	1001894800	VA 256 (F) WW	60	12	22-Nov-2013
525518	1002007990	VA 256 (F) WW	60	12	9-Jan-2014
525518	1002045080	VA 256 (F) WW	60	12	23-Jan-2014
525518	1002113290	VA 256 (F) WW	60	12	17-Feb-2014
525518	1002197250	VA 256 (F) WW	60	12	20-Mar-2014
525518	1002287970	VA 256 (F) WW	60	12	29-Apr-2014
525518	1002338070	VA 256 (F) WW	60	12	22-May-2014
525518	1002369060	VA 256 (F) WW	60	12	2-Jun-2014
525518	1002440920	VA 256 (F) WW	60	12	30-Jun-2014
525518	1002463490	VA 256 (F) WW	60	12	8-Jul-2014
525518	1002496690	VA 256 (F) WW	60	12	21-Jul-2014
525518	1002565090	VA 256 (F) WW	60	12	25-Aug-2014
525518	1002583690	VA 256 (F) WW	60	12	2-Sep-2014
525518	1002604690	VA 256 (F) WW	60	12	11-Sep-2014
525518	1002663860	VA 256 (F) WW	60	12	8-Oct-2014
525518	1002809200	VA 256 (F) WW	60	12	8-Dec-2014
525518	1002809880	VA 256 (F) WW	60	12	9-Dec-2014
525518	1002876470	VA 256 (F) WW	60	12	13-Jan-2015
525518	1002922750	VA 256 (F) WW	60	12	3-Feb-2015
525518	1003079740	VA 256 (F) WW	60	12	10-Apr-2015



525518	1003134480	VA 256 (F) WW	60	12	11-May-2015
525518	1003373510	VA 256 (F) WW	60	12	24-Aug-2015
525518	1003621540	VA 256 (F) WW	60	12	3-Dec-2015
525518	1003778630	VA 256 (F) WW	60	12	9-Feb-2016
525518	1003809630	VA 256 (F) WW	60	12	19-Feb-2016
525518	1003910700	VA 256 (F) WW	60	12	1-Apr-2016
525518	1003972790	VA 256 (F) WW	60	12	27-Apr-2016
525518	1004052410	VA 256 (F) WW	60	12	1-Jun-2016
525518	1004121860	VA 256 (F) WW	60	12	28-Jun-2016
525518	1004150380	VA 256 (F) WW	60	12	8-Jul-2016
525518	1004256770	VA 256 (F) WW	60	12	25-Aug-2016
525518	1004371490	VA 256 (F) WW	60	12	12-Oct-2016
525518	1004496990	VA 256 (F) WW	60	12	30-Nov-2016
525518	1004508060	VA 256 (F) WW	60	12	6-Dec-2016
525550	1001094650	VA 256 (F) US	60	12	28-Jan-2013
525550	1001136230	VA 256 (F) US	60	12	4-Mar-2013
525550	1001212920	VA 256 (F) US	60	12	4-Mar-2013
525550	1001293800	VA 256 (F) US	60	12	4-Mar-2013
525550	1001302920	VA 256 (F) US	60	12	4-Mar-2013
525550	1001319720	VA 256 (F) US	60	12	4-Mar-2013
525550	1001334090	VA 256 (F) US	60	12	4-Mar-2013
525550	1001391310	VA 256 (F) US	60	12	4-Mar-2013
525550	1001430030	VA 256 (F) US	60	12	4-Mar-2013
525550	1001518060	VA 256 (F) US	60	12	26-Jun-2013
525550	1001686190	VA 256 (F) US	60	12	26-Jun-2013
525558	1001174720	VA 256 (F) US	60	12	28-Jan-2013
525558	1001251340	VA 256 (F) US	60	12	4-Mar-2013
525558	1001334100	VA 256 (F) US	60	12	15-Apr-2013
525558	1001368020	VA 256 (F) US	60	12	15-Apr-2013
525558	1001442000	VA 256 (F) US	60	12	29-May-2013
525558	1001566840	VA 256 (F) US	60	12	26-Jun-2013
525558	1001647970	VA 256 (F) US	60	12	15-Jul-2013
525558	1001734920	VA 256 (F) US	60	12	15-Jul-2013
525558	1001761450	VA 256 (F) US	60	12	15-Jul-2013
525558	1001761480	VA 256 (F) US	60	12	16-Sep-2013
525558	1001897000	VA 256 (F) US	60	12	18-Nov-2013
525558	1001898600	VA 256 (F) US	60	12	22-Nov-2013
525558	1002008040	VA 256 (F) US	60	12	9-Jan-2014
525558	1002073480	VA 256 (F) US	60	12	23-Jan-2014
525558	1002197270	VA 256 (F) US	60	12	21-Mar-2014
525558	1002282890	VA 256 (F) US	60	12	28-Apr-2014



525558	1002338820	VA 256 (F) US	60	12	22-May-2014
525558	1002365880	VA 256 (F) US	60	12	2-Jun-2014
525558	1002443950	VA 256 (F) US	60	12	30-Jun-2014
525558	1002465840	VA 256 (F) US	60	12	8-Jul-2014
525558	1002558040	VA 256 (F) US	60	12	21-Aug-2014
525558	1002562240	VA 256 (F) US	60	12	25-Aug-2014
525558	1002733640	VA 256 (F) US	60	12	6-Nov-2014
525558	1002751340	VA 256 (F) US	60	12	14-Nov-2014
525558	1003171920	VA 256 (F) US	60	12	26-May-2015
525558	1003449250	VA 256 (F) US	60	12	22-Sep-2015
525558	1003679000	VA 256 (F) US	60	12	29-Dec-2015
525558	1003836080	VA 256 (F) US	60	12	3-Mar-2016
525558	1004040220	VA 256 (F) US	60	12	26-May-2016
525558	1004121870	VA 256 (F) US	60	12	28-Jun-2016
525558	1004151340	VA 256 (F) US	60	12	8-Jul-2016
525558	1004173130	VA 256 (F) US	60	12	19-Jul-2016
525558	1004256780	VA 256 (F) US	60	12	25-Aug-2016
525558	1004264340	VA 256 (F) US	60	12	30-Aug-2016
525558	1004371500	VA 256 (F) US	60	12	12-Oct-2016
525558	1004491190	VA 256 (F) US	60	12	30-Nov-2016
525558	1004509340	VA 256 (F) US	60	12	6-Dec-2016

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

REF	Lot #	Product Name	Current Shelf Life	Corrected Shelf Life	Corrected Expiration Date
525518	1004564470	VA 256 (F) WW	60	12	4-Jan-2017
525518	1004775890	VA 256 (F) WW	60	12	4-Apr-2017
525518	1004913990	VA 256 (F) WW	60	12	1-Jun-2017
525518	1004980270	VA 256 (F) WW	60	12	27-Jun-2017
525518	1005027170	VA 256 (F) WW	60	12	18-Jul-2017
525518	1005132320	VA 256 (F) WW	60	12	4-Sep-2017
525518	1005186480	VA 256 (F) WW	60	12	26-Sep-2017
525558	1004735790	VA 256 (F) US	60	12	16-Mar-2017
525558	1004767430	VA 256 (F) US	60	12	30-Mar-2017
525558	1004775900	VA 256 (F) US	60	12	4-Apr-2017
525558	1004914010	VA 256 (F) US	60	12	1-Jun-2017
525558	1004980280	VA 256 (F) US	60	12	27-Jun-2017
525558	1005027180	VA 256 (F) US	60	12	18-Jul-2017
525558	1005132340	VA 256 (F) US	60	12	4-Sep-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® Vancomycin VA 256 (Ref. 525550, 525558, 525510, 525518) 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: .....

