PLEASE DELIVER UPON RECEIPT
to LAB DIRECTOR
or LAB MANAGER

Brussels, 22 March 2019

Urgent Product Correction Notice

Our Ref: 4215 FSCA VITEK® 2 – Integrity of the Card Pouch

Dear Valued bioMérieux Customer,

This is to inform you of a Product Correction Notice involving:

Our records indicate your laboratory received one or more of the potentially affected products referenced in Appendix A. This letter is intended for all VITEK® 2 ID/AST users.

This notice has been initiated due to potential for compromised test card Top Seal Integrity which could:

- yield false resistance for antibiotics on the AST panel
- cause a false negative ESBL Test
- result in a false positive urea (URE) reaction on ID cards with low risk to identification result

Description of Issue:
A potential issue was identified related to the top seal of card pouches containing the VITEK® 2 test cards for the product lots specified in Appendix A. bioMérieux has determined that the integrity of some of the VITEK® 2 test card top seal may be compromised (see Figure 1). Based on our investigation, a compromised test card top seal can impact card reagents due to the entry of moisture.

bioMérieux investigation concluded that the pouch top seal of the card lots manufactured on a specific card poucher (Poucher 1) between 10Aug2018 and 29Aug2018 is potentially compromised. A small section of the top seal may be improperly sealed for the card lots indicated in Appendix A.

Figure 1: Top Seal and Poucher ID

Top Seal

Poucher ID

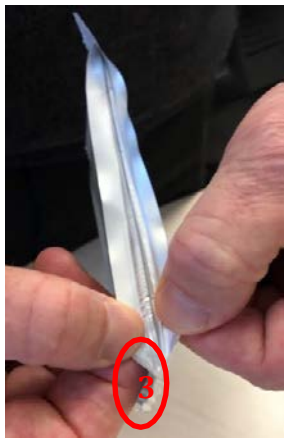
Description of Issue (cont'd):

A "tug test" can be performed to determine if a card pouch is intact, and the card can therefore be used.

1. As VITEK® 2 ID/AST cards may be pouched on different pouching equipment in manufacturing, confirm the card was pouched on Poucher P1 and determine if a P1 indication is present (Figure 1). Cards that have other identifiers, such as P2, P3, etc. are not impacted.

2. Grasp the card pouch so the top seam is facing you.

3. Apply a modest pulling force to each side of the top edge of the pouch, at three (3) separate points as shown in the images below.



4. If the top seam does not pull open, the seal is intact and the card can be used for testing.

5. If the top seam pulls apart at any point along the top seam, discard the pouch and the corresponding card.

Impact to customer/patient:
bioMérieux studies have demonstrated that a Top Seal Integrity issue can allow entry of moisture which can impact the test card reagents. Moisture sensitivity can lead to antibiotic degradation (loss of potency). The anticipated consequence would be elevated MIC results, or false resistant results, of some antimicrobials. The antimicrobial class most affected by moisture is the beta-lactam class. This includes penicillins, cephalosporins, and carbapenems. The most moisture-sensitive of the beta-lactams is imipenem and therefore the best indicator of a Top Seal Integrity issue. Erythromycin and nitrofurantoin are also moisture sensitive, and therefore may also be indicators of a pouch breach..

The following combination of results can be indicative of the Top Seal Integrity issue:

- A resistant imipenem result, particularly if unexpected and/or inconsistent with other results such as susceptibility to third generation cephalosporins and other carbapenems
- A resistant oxacillin result which is unusual or inconsistent with other results (such as a negative Cefoxitin Screen Test)
- A resistant erythromycin result which is unusual or inconsistent with other results
- Any quality control test results with these agents that are outside of the expected ranges
- A negative ESBL Test for *E. coli, Klebsiella oxytoca* or *Klebsiella pneumonia*e with a resistant/intermediate third generation cephalosporin and/ or aztreonam

For VITEK® 2 Identification cards, URE may be sensitive to moisture and a false positive reaction may occur. However, there is low risk of impact to identification result as the identification (ID) algorithm generally allows two atypical reactions and will still provide a correct identification with a high degree of confidence. The knowledge bases are designed to account for both typical and atypical strains so an aberrant reaction should have low impact on identification results.

Actions:
Please note that it is not necessary to discard all cards from an impacted lot. We recommend performing the "tug test", described on page 2 of this letter, for each test card pouch in the impacted card lots prior to use.

Please take the following actions at this time:

1. Confirm this letter has been distributed to, and reviewed by, all appropriate personnel within your organization.

2. Check the lot numbers in your inventory against the lot numbers listed in Appendix A.

3. For the impacted lots, visually inspect the test card pouch to confirm it's impacted and if so, perform the "tug test".
   a. If the defect is observed, destroy the associated test card(s) and contact your bioMérieux customer service representative for credit.
   b. If the defect is not observed, continue testing as per normal procedure.

4. For impacted lots where cards have been used, reference is made to page 3 of this letter as input into your local risk management process.

5. Please store this letter with your bioMérieux VITEK 2 documentation.

6. Complete the attached Acknowledgement Form and return it to your local bioMérieux customer service representative as soon as possible.

bioMérieux, Inc. is committed to providing our customers with the highest quality products, and we apologize for any inconvenience this has caused your institution For any additional information you may require, please contact your local bioMerieux customer service representative.

Tel: +31 (0) 885 06 47 00 or mail: fieldactions.benelux@biomerieux.com

Thank you for your continued use of bioMérieux products,

Yours faithfully,
BioMérieux Customer Support

Customer Service
bioMérieux Benelux

Attachment A: Acknowledgement Form FSCA 4215

URGENT PRODUCT CORRECTION NOTICE

FSCA 4215 : VITEK® 2 – Card Pouch Integrity

Customer Information:

Customer Account Number	
Organization Name	
Street Address	
City, State and Postal Code	
Contact Name	
Contact Title	
Phone Number	

Product Information:

Catalog Number	Description
Multiple	See Appendix A

Questions:

		No	Yes
1.	Did you read the enclosed Urgent Product Correction Notice regarding VITEK® card pouch integrity?		
2.	Have you implemented the actions as indicated in this Urgent Product Correction Notice, if necessary? If no, please indicate the reason in the Comments section below.		
3.	Have you received reports of illness or injury related to the described issue?		
Comments:			

Signature: _____ Date: _____

It is important that you complete this Acknowledgement Form and return it to bioMérieux.
Fax : +32 (0) 2 793 01 44
Email : fieldactions.benelux@biomerieux.com

Appendix A – VITEK® 2 ID / AST Card Types possibly impacted

Reference Number	Lot Number	Description	Manufacture	Expiry
21341	2410602403	GN ID	21-Jul-18	21-Jul-19
21341	2410624103	GN ID	12-Aug-18	12-Aug-19
21341	*2410632203	GN ID	20-Aug-18	20-Aug-19
21341	2410635203	GN ID	23-Aug-18	23-Aug-19
21341	2410636203	GN ID	24-Aug-18	24-Aug-19
21341	2410637203	GN ID	25-Aug-18	24-Aug-19
21342	*2420806103	GP ID	11-Aug-18	10-Feb-20
21342	2420818403	GP ID	23-Aug-18	22-Feb-20
21342	2420822203	GP ID	26-Aug-18	25-Feb-20
21347	*2440811203	ANC ID	16-Aug-18	15-Feb-20
22226	1320808103	AST-GP67	13-Aug-18	12-Feb-20
22226	1320816203	AST-GP67	21-Aug-18	20-Feb-20
22226	1320820403	AST-GP67	25-Aug-18	24-Feb-20
413400	5890806203	AST-GN69	11-Aug-18	10-Feb-20
413399	*5870818203	AST-GN67	23-Aug-18	22-Feb-20
413400	*5890803203	AST-GN69	8-Aug-18	7-Feb-20
413400	*5890820203	AST-GN69	25-Aug-18	24-Feb-20
413404	5930821203	AST-GN73	26-Aug-18	25-Feb-20
413436	*5990817203	AST-GN79	22-Aug-18	21-Feb-20
413439	6720813203	AST-GN82	18-Aug-18	17-Feb-20
415670	2750809103	AST-GP75	14-Aug-18	13-Feb-20
415670	2750823203	AST-GP75	28-Aug-18	27-Feb-20
420739	2880809203	AST-YS08	15-Aug-18	14-Feb-20
420739	2880812203	AST-YS08	17-Aug-18	16-Feb-20
421040	5420809203	AST-ST03	14-Aug-18	13-Feb-20
421040	5420812203	AST-ST03	17-Aug-18	16-Feb-20

*Confirmed via investigation to contain compromised pouch top seals