Brussels, 20th April2017

Urgent Product Correction Notice

Dear Valued bioMérieux Customer,

This is to inform you of an Urgent Product Correction Notice involving:

VITEK® 2 Identification / Antimicrobial Susceptibility Test Cards referenced in Appendix A

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

This notice has been initiated due to potential for compromised test card pouch 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

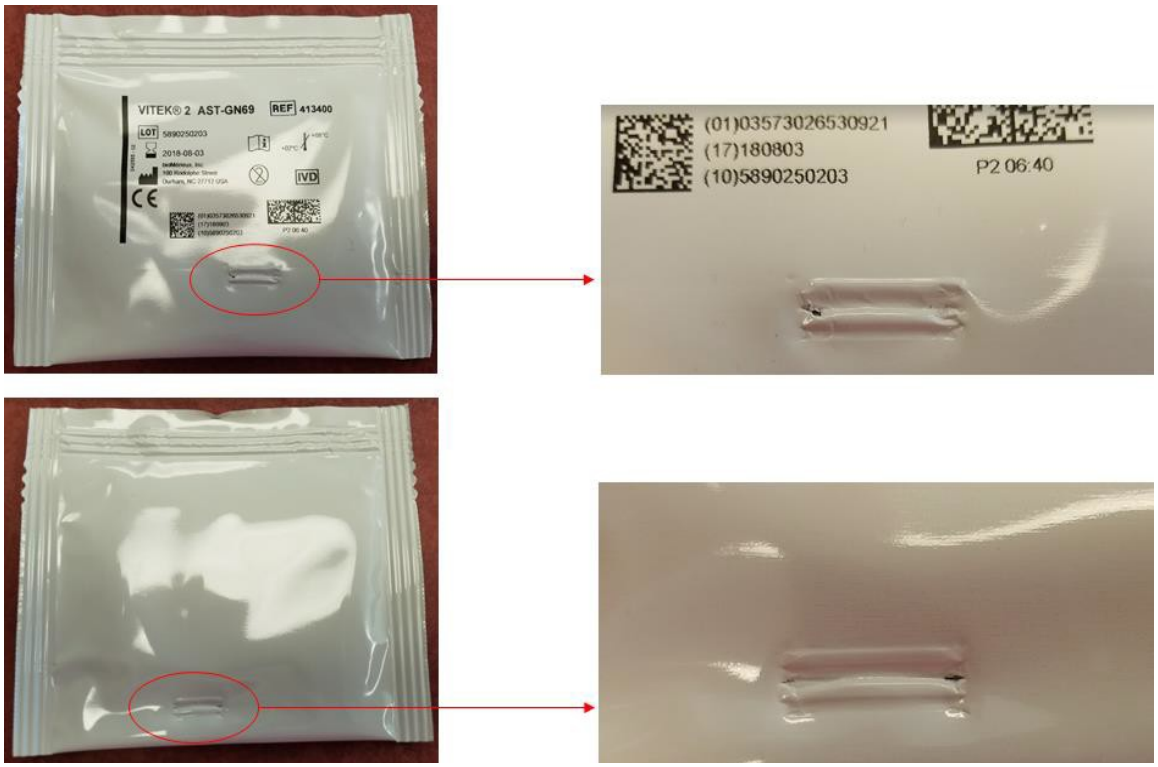
Description of Issue:
A potential issue was identified related to the white pouch which contains VITEK® 2 test cards for the product lots specified in Appendix A. bioMérieux has determined that the integrity of some of the VITEK® 2 test card pouches may be compromised. Based on our investigation, a compromised test card pouch can impact card reagents due to the entry of moisture.

The white pouch is composed of five (5) layers of material, four (4) of which are clear. All five layers must be compromised for a pouch to potentially allow moisture to enter the pouch. Upon visual inspection of the pouch, you may notice a small puncture or tear in the packaging at the "stitch seal" (**see Figure A immediately below**). Per product labeling, do not use the card if the pouch (the white protective package cover) is damaged. Based on internal testing, approximately 20% of card pouches exhibited a visual defect; the majority of card pouches with this visual defect maintained pouch integrity, i.e. at least one of the five material layers remained intact. However, 1 in 200 (0.5%) card pouches that passed careful visual inspection failed further integrity tests, indicating the potential for entry of moisture.

bioMérieux Benelux s.a./n.v.

MEDIA SQUARE - Karabiniersplein 18, B-1030 Brussel
Tel.+32 (0)2 743 01 70 Fax +32 (0)2 743 01 87 - www.biomerieux.com
RPM Bruxelles- RPR Brussel – T.V.A. – B.T.W. BE 0419.144.027

Figure A - Example of Pouch Defect



The root cause of this issue has been identified and corrective measures have been taken to ensure issues of this type do not affect future Manufacturing lots.

Impact to customer/patient:

bioMérieux studies have demonstrated that a test card pouch defect 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 of some antimicrobials (leading to false-resistant results). 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. Therefore, it is the best indicator of a pouch defect. Two other moisture-sensitive antimicrobials are erythromycin and nitrofurantoin.

One exception to the expected elevation in MICs (or false resistance) that can occur due to the pouch defect is the ESBL (Extended-Spectrum β-Lactamase) test, which utilizes clavulanic acid in combination with three cephalosporins. Clavulanic acid is also moisture sensitive, and if degraded, the ESBL test could be falsely negative. The Advanced Expert System™ will determine presence of an ESBL phenotype based on results of all beta lactams, including the ESBL test. Therefore, the impact of a false negative ESBL test should be minimal.

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.

Required Actions:

- *It is not necessary to discard all cards from an impacted lot.*

- *We are recommending a careful visual examination of each test card pouch in the affected lots prior to use.*

1. Check the lot numbers in your inventory against the lot numbers listed in Appendix A.
2. For impacted lots, visually inspect the test card pouches on both sides for the defect.
    a. If the defect is observed, destroy the associated test card(s) and contact your bioMérieux representative for a credit note.
    b. If the defect is not observed, continue testing as per normal procedure, but increase monitoring for potential testing errors, as visual inspection may not identify all affected ID/AST cards. Repeat testing if you observe results potentially indicative of a pouch defect such as:
        i. A resistant imipenem result, particularly if unexpected and/or inconsistent with other results
        ii. A resistant or intermediate nitrofurantoin result which is unusual or inconsistent with other results
        iii. A resistant oxacillin or erythromycin result which is unusual or inconsistent with other results
        iv. Any quality control test result with these agents that is outside of the expected range
3. If imipenem is not tested, review other beta-lactams such as the penicillins, other carbapenems and/or cephalosporins for inconsistent resistance or unusual results, which may also indicate a potential pouch defect.
4. If concerns exist after repeat testing, alternative methods of establishing drug susceptibility should be used. If an unrelated performance issue is suspected, please follow your normal complaint escalation process.

Other Actions Related To This Notice:

- Please confirm this letter has been distributed and reviewed by all appropriate personnel within your organization.

- Please store this letter with your bioMérieux VITEK® 2 documentation.

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

bioMérieux, is committed to providing our customers with the highest quality products, and we apologize for any inconvenience this has caused your institution. If you have any questions or concerns, please contact your local bioMérieux representative.

Thank you for your continued use of bioMérieux products,

…….
bioMérieux Benelux
customer.service.benelux@biomerieux.com

Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE

FSCA - 3445 – 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:

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

Signature: _____ Date: _____

It is important that you complete this Acknowledgement Form and return it to bioMérieux.

Per email to: customer.service.benelux@biomerieux.com **or** Fax: + 32 (0) 2 743 01 87

bioMérieux Benelux s.a./n.v.

MEDIA SQUARE - Karabiniersplein 18, B-1030 Brussel
Tel.+32 (0)2 743 01 70 Fax +32 (0)2 743 01 87 - www.biomerieux.com
RPM Bruxelles- RPR Brussel – T.V.A. – B.T.W. BE 0419.144.027

APPENDIX A

REF #	Product Name	Lot #	Expiry Date
21341	VITEK® 2 GN ID	241398120	07/Nov/17
		241398420	10/Nov/17
		241399520	21/Nov/17
		2410000203	26/Nov/17
		2410031103	27/Dec/17
		2410033103	29/Dec/17
		2410038103	03/Jan/18
		2410044203	09/Jan/18
		2410058103	23/Jan/18
		2410083103	17/Feb/18
		2410085203	19/Feb/18
21342	VITEK® 2 GP ID	2420164103	09/May/18
		2420169103	14/May/18
		2420174203	19/May/18
		2420198203	12/Jun/18
		2420200103	14/Jun/18
		2420204103	18/Jun/18
		2420220203	04/Jul/18
		2420229203	13/Jul/18
		2420253203	06/Aug/18
		2420267103	20/Aug/18
21343	VITEK® 2 YST ID	2430199103	13/Jun/18
		2430199123	13/Jun/18
21346	VITEK® 2 NH ID	2450129203	04/Apr/18
		2450162203	07/May/18
		2450204203	18/Jun/18
		2450221203	05/Jul/18
21347	VITEK® 2 ANC ID	2440168103	13/May/18
		2440202103	16/Jun/18
		2440293203	15/Sep/18
		3570242203	26/Jul/18
22276	VITEK® 2 AST P586	3660165203	10/May/18
		3660256103	09/Aug/18
22287	VITEK® 2 AST P592	3720250103	03/Aug/18
22304	VITEK® 2 AST GP69	1340263203	16/Aug/18
410028	VITEK® 2 AST ST01	5400115203	21/Mar/18
		5400122223	28/Mar/18
		5400136203	11/Apr/18
		5400136223	11/Apr/18
		5400136243	11/Apr/18
		5400143203	18/Apr/18
		5400192203	06/Jun/18
		5400192223	06/Jun/18
		5400216203	30/Jun/18
		5400221203	05/Jul/18
		5400238203	22/Jul/18
		5400238243	22/Jul/18
		5400262223	15/Aug/18
		5400269203	22/Aug/18

APPENDIX A

REF #	Product Name	Lot #	Expiry Date
410223	VITEK® 2 AST P616	4960178203	23/May/18
412608	VITEK® 2 AST GN65	5850217403	01/Jul/18
413171	VITEK® 2 AST N236	6360174203	19/May/18
413172	VITEK® 2 AST N237	637384320	23/Mar/18
413864	VITEK® 2 AST N264	664385120	31/Mar/18
		6640203103	17/Jun/18
413865	VITEK® 2 AST N265	6650188203	02/Jun/18
		6650194203	08/Jun/18
414967	VITEK® 2 AST YS07	2870115203	21/Mar/18
		2870125203	31/Mar/18
		2870129203	04/Apr/18
		2870129223	04/Apr/18
		2870143203	18/Apr/18
		2870150203	25/Apr/18
		2870157203	02/May/18
		2870209403	23/Jun/18
		2870235203	19/Jul/18
		2870248403	01/Aug/18
		2870276203	29/Aug/18
414971	VITEK® 2 AST GP74	2740242403	26/Jul/18
414994	VITEK® 2 AST P633	7330166203	11/May/18
420440	VITEK® 2 AST N344	7840209103	23/Jun/18
		7840245203	29/Jul/18
421296	VITEK® 2 AST P650	8000103203	09/Mar/18
421297	VITEK® 2 AST N353	7930118203	24/Mar/18