9 May 2017

Urgent Product Correction Notice

Dear

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

VITEK® 2 Identification / Antimicrobial Susceptibility Test Cards referenced in Appendix A (**one additional batch highlighted in yellow**)

Our records indicate your laboratory received one or more of the affected products referenced in Appendix A. (**one additional batch highlighted in yellow**). 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. (**one additional batch highlighted in yellow**) 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.

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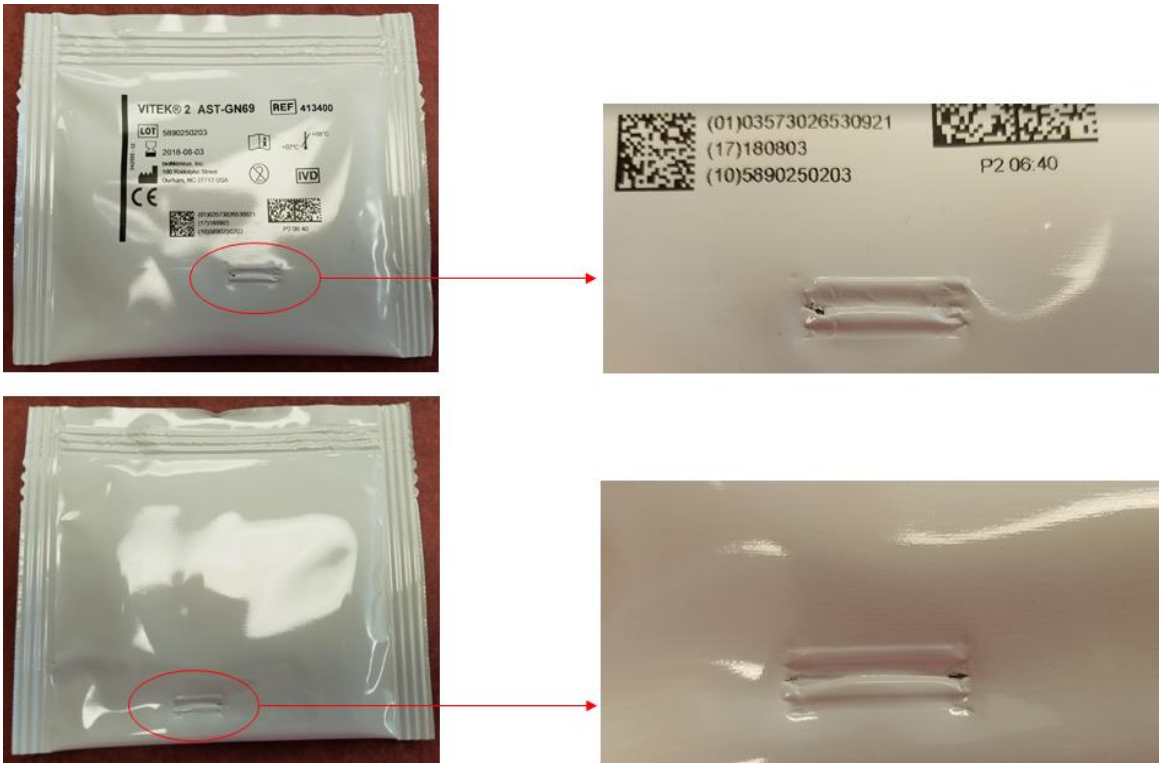
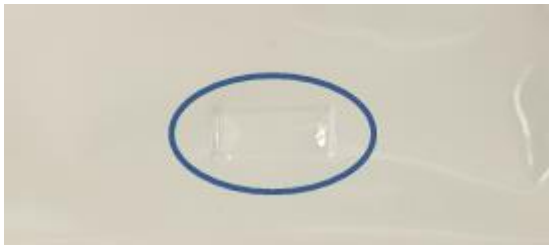
Figure A - Example of Pouch Defect



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. Card lots manufactured after March 16, 2017 include a new stitch seal (see Figure B below) and are not affected by the described issue.

Figure B - New Stitch Seal



Impact:
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. Examination via human eye is sufficient; no magnifying tools are necessary.***

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 our Technical Service Department on 0044 (0) 1256 480711 or email uktechnical@biomerieux.com for credit. Until such time as card lots with the new stitch seal become prevalent, there is the potential that replacement cards will include a product lot listed in Attachment A. In this event, please continue to follow these instructions.**

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 organisation.**
- **Please store this letter with your bioMérieux VITEK® 2 documentation.**
- **Complete the attached Acknowledgement Form and return it for the attention of UKVigilance to fax number 0044 (0) 1256 816863 or scan and email to UKVIGILANCE@biomerieux.com**

bioMérieux, is committed to providing our customers with the highest quality products, and we apologise for any inconvenience this has caused your institution. If you have any questions or concerns, please contact our Technical Service Department on 0044 (0) 1256 480711 or email UKtechnical@biomerieux.com.

Thank you for your continued use of bioMérieux products.

Yours sincerely
UKVIGILANCE

Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE -
FSCA - 3445 – VITEK® 2 - Card Pouch Integrity

It is a requirement of the Competent Authority that this form be completed and returned Please return for the attention of UKVIGILANCE to fax number 0044 (0) 1256 816863 or scan and email to UKVIGILANCE@biomerieux.com

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Product Information:

Catalog Number	Description
Multiple	See Appendix A (**one additional batch highlighted in yellow)**

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: _____

PSS 3443 Batch List

APPENDIX A	
21341 - VITEK 2 GN ID	Batch Expiry
241398120	7-Nov-2017
241398720	13-Nov-2017
2410037103	2-Jan-2018
2410047203	12-Jan-2018
2410071103	5-Feb-2018
2410072103	6-Feb-2018
2410091203	25-Feb-2018
21342 - VITEK 2 GP ID	
2420157103	2-May-2018
2420185103	30-May-2018
2420200103	14-Jun-2018
2420253203	6-Aug-2018
21343 - VITEK 2 YST ID	
2430199103	13-Jun-2018
21346 - VITEK 2 NH ID	
2450162203	7-May-2018
2450204203	18-Jun-2018
2450221203	5-Jul-2018
21347 - VITEK 2 ANC ID	
2440168103	13-May-2018
2440202103	16-Jun-2018
22335 - VITEK 2 AST P607	
4870131203	6-Apr-2018
410028 - VITEK 2 AST ST01	
5400122223	28-Mar-2018
5400136203	11-Apr-2018
5400136223	11-Apr-2018
5400136243	11-Apr-2018
5400192203	6-Jun-2018
5400192243	6-Jun-2018
5400199203	13-Jun-2018
5400216203	30-Jun-2018
5400221203	5-Jul-2018
5400238223	22-Jul-2018
5400238243	22-Jul-2018
5400269203	22-Aug-2018
412608 - VITEK 2 AST GN65	
5850166103	11-May-2018
5850217403	1-Jul-2018
5850248103	1-Aug-2018
413410 - VITEK 2 AST GN84	
6740247103	31-Jul-2018
413722 - VITEK 2 AST N253	
6530208203	22-Jun-2018
413723 - VITEK 2 AST N254	
6540146203	21-Apr-2018
6540252103	5-Aug-2018

PSS 3443 Batch List

6540290203	12-Sep-2018
414967 - VITEK 2 AST YS07	
2870143203	18-Apr-2018
2870209403	23-Jun-2018
2870235203	19-Jul-2018
2870248403	1-Aug-2018
415671 - VITEK 2 AST P634	
7340290103	12-Sep-2018
415672 - VITEK 2 AST N297	
7170138203	13-Apr-2018
7170145203	20-Apr-2018
416911 - VITEK 2 AST P635	
7350166103	11-May-2018
7350291103	13-Sep-2018
418424 - VITEK 2 AST GP76	
2760186403	31-May-2018
2760241203	25-Jul-2018
420739 - VITEK 2 AST YS08	
2880150203	25-Apr-2018
421037 - VITEK 2 AST N350	
7900118203	24-Mar-2018
7900139203	14-Apr-2018
7900259103	12-Aug-2018
421040 - VITEK 2 AST ST03	
5420269203	22-Aug-2018
421257 - VITEK 2 AST N351	
791383620	16-Mar-2018
7910163203	8-May-2018
7910246203	30-Jul-2018
421258 - VITEK 2 AST N352	
7920118203	24-Mar-2018
7920164103	9-May-2018
7920272103	25-Aug-2018