[to be date of distribution]

Urgent Product Correction Notice

Dear Valued bioMérieux Customer,

This is a follow-up to the previously issued Urgent Product Correction Notice regarding compromised VITEK® 2 card pouches. In regards to the VITEK® 2 Identification / Antimicrobial Susceptibility Test Cards referenced in the previous Urgent Product Correction Notice, three (3) additional card lots have been identified.

Reference	Description	Batch / Lot	Expiration
21341	GN ID Test Kit 20 Cards	2410047203	12-JAN-2018
413062	AST-N208 Test Kit 20 Cards	5780255103	08-AUG-18
414967	AST-YS07 Test Kit 20 Cards	2870221203	05-JUL-18

Our records indicate your laboratory received one or more of the referenced products.

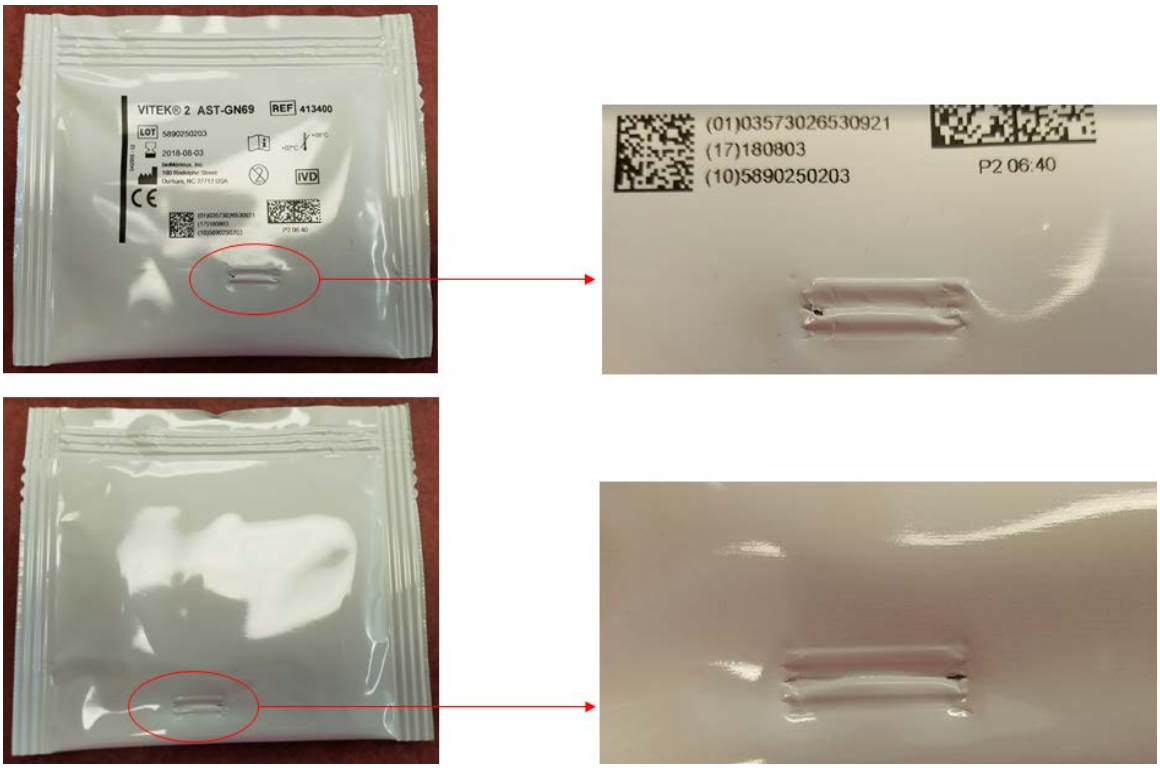
This notice has been initiated due to potential for compromised test card pouch integrity which could:

- 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 referenced product lots. 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.

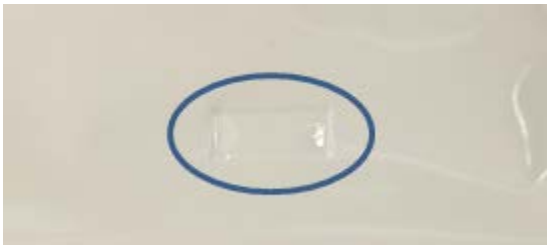
The white pouch is composed of five (5) layers of material, four (4) of which are clear. All five layers must be compromised for a pouch to potentially allow moisture to enter the pouch. Upon visual inspection of the pouch, you may notice a small puncture or tear in the packaging at the "stitch seal" (**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.

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

1. **Check the lot numbers in your inventory against the referenced lot numbers.**
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 credit or replacement. Until such time as card lots with the new stitch seal become prevalent, there is the potential that replacement cards will include a referenced product lot. 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.**

<u>Other Actions Related To This Notice:</u>

- **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.**

bioMérieux, Inc. 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, Inc.
[Enter Local Contact]