



CLINICAL

PLEASE DELIVER UPON RECEIPT to LAB DIRECTOR or LAB MANAGER

[to be date of distribution]

Urgent Product Correction Notice

Our Ref: 4654 FSCA

Dear Valued bioMérieux Customer,

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

VITEK® 2 Card AST-N371 lot 0210932204.

Our records indicate you have received the potentially affected card lot mentioned above. This letter is intended for all VITEK® 2 AST-N371 lot 0210932204 users.

This notice has been initiated due to a potential for compromised top seal integrity of the test card package which could lead to elevated MICs and possibly false resistant results for some antibiotics on the AST panel.

Description of Issue:

A potential issue was identified relating to the top seal of card pouches for the VITEK® 2 test card lot AST-N371 0210932204. Local distribution of AST-N371 0210932204 was stopped after initial customer complaint inquiries. bioMérieux has determined that there was an intermittent integrity issue for approximately 1 in 94 of the VITEK® 2 test card top seals in this lot.

Based on our investigation, a compromised test card top seal can impact antibiotics on the card due to the entry of moisture.

Impact to customer/patient:

bioMérieux studies have demonstrated that a top seal integrity issue can allow entry of moisture which can impact some antibiotics on the card. Moisture sensitivity can lead to antibiotic degradation (loss of potency). The anticipated consequence would be elevated MIC results, and possibly false resistant results, of some antimicrobials. The antibiotic class most affected by moisture is the beta-lactam class. This includes penicillins, cephalosporins, and carbapenems. Nitrofurantoin is also moisture sensitive, and therefore may also be an indicator of a pouch breach.

The following combination of results can be indicative of a top seal integrity issue:

- A resistant carbapenem 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)
- Any quality control test results with these agents that are outside of the expected ranges



Actions:

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 of your inventory to identify if you have VITEK® 2 Card AST-N371 lot 0210932204.
3. Destroy any inventory of VITEK® 2 Card AST-N371 lot 0210932204 and contact your bioMérieux representative for credit.
4. Please use this letter as input into your local risk management process as needed.
5. Please store this letter with your bioMérieux VITEK® 2 documentation.
6. Complete the attached Acknowledgement Form and return it to your local bioMérieux 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. If you have any questions or concerns, please contact your local bioMérieux representative.

Thank you for your continued use of bioMérieux products,

bioMérieux, Inc.





Attachment A: Acknowledgement Form

URGENT PRODUCT CORRECTION NOTICE

FSCA 4654 : VITEK[®] 2 – Card Pouch Integrity AST N371 lot 0210932204

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
422024	VITEK [®] 2 AST-N371 lot 0210932204

Questions:

	Yes	No
1. Did you read the enclosed Urgent Product Correction Notice regarding VITEK [®] 2 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:

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Signature: _____

Date: _____

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

Please fax this form to: [\[Enter Local Contact\]](#) To the attention of: [\[Enter Local Contact\]](#)