



PLEASE DELIVER UPON RECEIPT to LAB DIRECTOR or LAB MANAGER

[to be date of distribution]

Urgent Product Correction Notice

Dear Valued bioMérieux Customer,

Our records indicate that your laboratory has received one or more of the VITEK® 2 Antimicrobial Susceptibility Testing (AST) test kits indicated in Table 1.

TABLE 1: VITEK® 2 AST Test Kits

REF #	Product Name	Lot #	Expiry Date
418579	VITEK® 2 AST-P640	7400081103*	15-FEB-2018
		7400236403*	20-JUL-2018
		7400410103	10-JAN-2019
		7400697403	24-OCT-2019
421913	VITEK® 2 AST-P655	8050348103	09-NOV-2018
		8050452403	21-FEB-2019
		8050655403	12-SEP-2019
		8050690403	17-OCT-2019

*The lot has expired.

Description of Issue:

Internal review of manufacturing records at bioMérieux has identified eight (8) VITEK® 2 AST card lots were manufactured with less antibiotic (gentamicin) than required for the Gentamicin High-Level Resistance Screen Test (ghlr01n).

Investigation determined a configuration error occurred when manufacturing the gentamicin high-level resistance solution resulting in a lower antibiotic amount to be applied. The identified discrepancy resulted in gentamicin concentrations of 100mcg/ml or 75mcg/ml of gentamicin, instead of the required 150mcg/ml.

The root cause of this issue has been identified and resolved. In addition, review of the antibiotic concentration parameters for all other AST card types has been assessed with no similar issue found.



Impact to patient/customer:

The High Level Gentamicin Screen Test (ghlr01n) contained on the VITEK® 2 AST cards is indicated for use only for Enterococci and *Streptococcus agalactiae* (Group B Streptococcus) to predict synergy between a cell-wall-active agent such as penicillin, ampicillin or vancomycin in combination with an aminoglycoside such as gentamicin. This synergy is best predicted by screening isolates for high level resistance with an aminoglycoside. The VITEK® 2 card utilizes a Gentamicin High-Level Resistance (GHLR) well that contains 150mcg/ml of gentamicin.

The risk of the identified discrepancy is that strains with gentamicin MICs listed in Table 2 would call false positive. The positive result would indicate that combination therapy would not work for that strain and an alternate course of treatment would be required. True high-level resistant organisms will be correctly reported as GHLR-positive.

TABLE 2: VITEK® 2 AST MIC Ranges

REF #	Product Name	Lot #	MIC Range
418579	AST-P640 MASTER FORMULARY	7400081103	≥75mcg/ml to ≤150 mcg/ml
418579	AST-P640 MASTER FORMULARY	7400236403	
418579	AST-P640 MASTER FORMULARY	7400410103	
421913	AST-P655 MASTER FORMULARY	8050452403	
421913	AST-P655 MASTER FORMULARY	8050348103	≥100mcg/ml to ≤150 mcg/ml
421913	AST-P655 MASTER FORMULARY	8050655403	
421913	AST-P655 MASTER FORMULARY	8050690403	
418579	AST-P640 MASTER FORMULARY	7400697403	

Any negative (susceptible) GHLR result would be correct and gentamicin could be utilized for expected synergic effect against the organism.

As only testing for Enterococcus and Group B Streptococcus strains may be impacted by this discrepancy, testing of other organisms (e.g. Staphylococcus species) is not affected.

Actions:

Please implement the following actions at this time:

- Confirm this letter has been distributed to, and reviewed by, all appropriate personnel within your organization.
- There are three options available to address this issue:
 1. Perform an alternative method of testing for strains producing GHLR-positive results.
 2. In routine, perform alternative method testing in combination with the VITEK® 2 AST-P640 and AST-P655 test kit lots indicated in Table 1.
 3. Discard impacted card lots from your inventory, and contact your local bioMérieux representative for credit.
- Please store this letter with your bioMérieux instrument documentation.
- Complete the Acknowledgement Form and return it to your local bioMérieux representative.



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

Thank you for your continued use of bioMérieux products,

bioMérieux, Inc.

[\[Enter Local Contact\]](#)



Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE

FSCA - 4005 – VITEK® 2 – High Level Gentamicin

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
418579	VITEK® 2 AST-P640 Test Kit
421913	VITEK® 2 AST-P655 Test Kit

Questions:

	Yes	No
1. Did you read the enclosed Urgent Product Correction Notice regarding VITEK® 2 High Level Gentamicin discrepancy?		
2. Have you 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 described issue?		

Comments:

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: [\[Enter Local Contact\]](#)