PLEASE DELIVER UPON RECEIPT to LAB DIRECTOR or LAB MANAGER

[to be date of distribution]

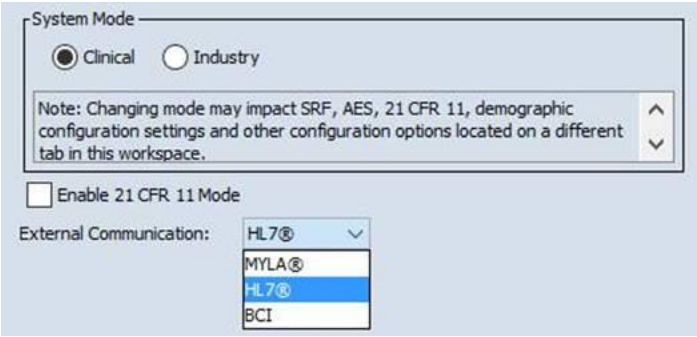
Urgent Product Correction Notice

Our Ref: 5026 FSCA
Dear Valued bioMérieux Customer,

Our records indicate that your laboratory may be using VITEK® 2 Software V8.0x or V9.0x on your VITEK® 2 or VITEK® 2 Compact System with the external communication configured to HL7®.
External communication is used to send data to/from VITEK® 2 to/from your LIS.

Description of Issue:
If your VITEK® 2 system has the external communication configured to HL7®, it has been determined that expertised results with a therapeutic correction are correctly sent the first time but when sent more than once, therapeutic correction will not be transferred to your Laboratory Information System (LIS). This transfer error would apply to all causes of therapeutic corrections including phenotype, forcing rule, and biologic corrections.

The external communication configuration can be verified as follows:
1. Log into the VITEK® 2 Systems Application.
2. On the main view, press the **Configuration** icon and select **General Configuration** from the list.
3. On the **Systems** tab, review the **External Communication** setting.



Note: If MYLA® or BCI are selected, you are **NOT** impacted by this FSCA and there is no need to implement the corrections below.

Please don't hesitate to contact your bioMérieux representative should you need assistance with this external communication verification.

If HL7® is selected, you ARE impacted by this FSCA and you HAVE to implement the following corrections

The following corrections have been identified:

1. Contact your bioMérieux representative for guidance on how to verify expertised results in your VITEK® 2 system and LIS. Manual changes to the antibiotic interpretation impacted by the anomaly in the LIS may be necessary.

2. To correct the issue, it will be necessary to either:
   - Convert your VITEK® 2 System external communication to MYLA® which also uses HL7 connectivity without this anomaly. This change may imply minor LIS driver changes. If MYLA® is not used in your Lab, please contact your local representative for a quotation.

     OR
   - Update your VITEK® 2 System from software version 8.0x to 9.02 or higher.
     Once updated to 9.02 or higher, a software patch 9MR2 can be deployed to correct VITEK® 2 HL7® external communication. The software patch is under development and will be deployed before Dec 2022.

     OR
   - Convert your VITEK® 2 System external communication to BCI. This change may imply development of a new LIS driver.

A bioMérieux representative will be contacting you regarding these activities.

Please note: if you choose not to update to software version 9.02 with 9MR2 applied, not use MYLA® or not use BCI, you will need to continue to verify the expertised results in the LIS before reporting them.

Impact to patient/user:
bioMérieux has identified a potential safety risk worst case of a false susceptible erroneous test result associated with this event.

Actions:
Please take the following actions at this time:

- Confirm this letter has been distributed to, and reviewed by, all appropriate personnel within your organization.

- Please store this letter with your bioMérieux instrument documentation.

- Please apply the proposed corrections as needed.

- Complete the Acknowledgement Form and return it to your local bioMérieux representative.
  It is important that you return the acknowledge form to bioMérieux even if you determine that your external communication was not configured to HL7®. Please indicate your configuration (BCI or MYLA®) on the acknowledgement form.

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.

Attachment A: Acknowledgement Form

URGENT PRODUCT CORRECTION NOTICE

FSCA 5026 : VITEK® 2 – Therapeutic Corrections / LIS / HL7

Customer Information:
Customer Account Number: _____ Organization Name: _____

Street Address: _____

City, State and Postal Code: _____

Contact Name: _____

Contact Title: _____

Phone Number: _____

Product Information: VITEK® 2 Systems Versions 8.0x and 9.0x

Questions:

	Yes	No
1. Did you read the enclosed Urgent Product Correction Notice for VITEK® 2 Versions 8.01 and 9.01 when using a LIS with HL7 format?		
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. Being sure to record your external communication configuration (BCI, MYLA® or HL7).		
3. Have you received reports of any 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: To the attention of: