



PLEASE DELIVER UPON RECEIPT to LAB DIRECTOR or LAB MANAGER

Urgent Product Removal Notice

Our Ref: FSCA 5688

Dear Valued bioMérieux Customer,

Our records indicate that your laboratory performs ID/AST testing with a VITEK® 2 System which may be interfaced with a LIS (Laboratory Information System) **configured to the HL7® Communication Protocol**.

IMPORTANT NOTE: If your VITEK 2 system is **not** configured to an LIS using HL7 Protocol, you only need to complete and return the Acknowledgement Form attached at the end of this letter.

Intended Use:

VITEK® 2 is an automated system consisting of instruments, software and reagent test kits designed for the identification and antimicrobial susceptibility testing of bacteria and yeast. The VITEK® 2 utilizes growth-based biochemical patterns to determine identification. The VITEK® 2 provides minimal inhibitory concentration (MIC) results for most organism/drug combinations as well as a category interpretation (S, I, or R).

HL7® is a connection used to establish communications between bioMérieux Analysis Instruments and Laboratory Information System (LIS) host computers.

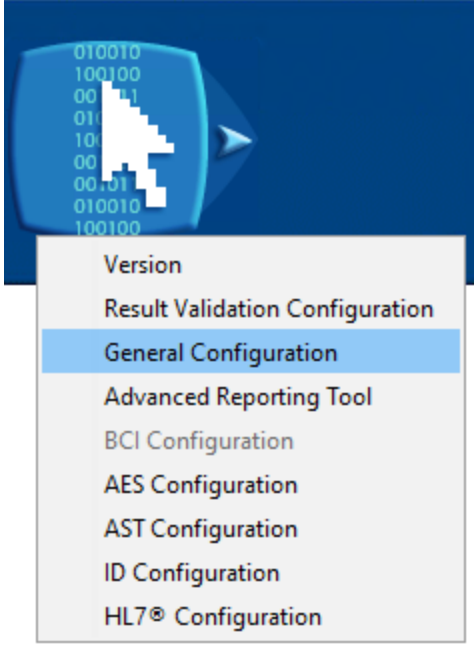
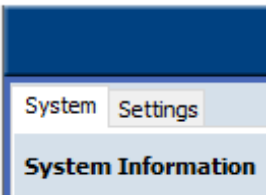
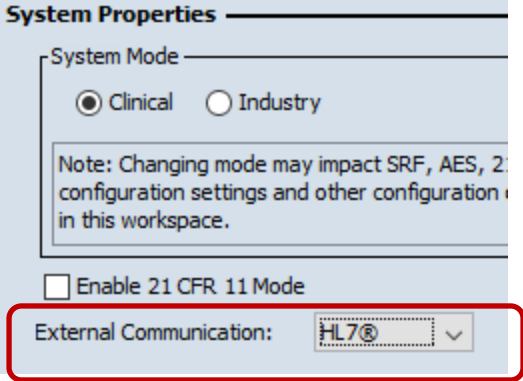

Description of Issue:

This **Removal Notice** only applies to VITEK 2 systems connected to an LIS (Laboratory Information System) using the **HL7 Communication Protocol selected within VITEK 2 or within the bioMérieux MYLA® product**.

Please follow the instructions below to determine if your VITEK 2 system is using HL7 Protocol as a direct LIS connection.

Step Number	Description	Screen grab
1	Press this Desktop icon to launch the VITEK® 2 Systems application.	
2	Login as a member of the Supervisors group following the lab's Standard Operating Procedure.	



Step Number	Description	Screen grab
3	<p>From the main menu, press the Configuration button and select General Configuration.</p>	
4	<p>If necessary, select the “System” tab.</p>	
5	<p>Near the center of the view in the “System Properties” section there is an option for External Communication.</p> <p>If this option is set to HL7, then the lab is using the HL7 protocol to communicate with the LIS.</p> <p>If set to any other value (BCI or MYLA) then the lab is not using HL7.</p>	
6	<p>Close the VITEK® 2 Systems application by pressing the “X” in the upper right corner.</p>	



If your VITEK 2 is connected to MYLA, the connection configuration is defined in the MYLA BCI Connect interface.

For these HL7 LIS connections, bioMérieux has identified multiple potential issues whereby VITEK 2 ID/AST test results may be negatively impacted. The HL7 Communication Protocol option is included in the following VITEK 2 software versions:

- VITEK 2 8.01
- VITEK 2 8.02 (veterinary only)
- VITEK 2 9.01
- VITEK 2 9.02 (with or without 9MR2 and/or 9MR3)
- VITEK 2 9.03 (with or without 9MR2 and/or 9MR3)
- MYLA V4.8
- MYLA V4.9

Potential adverse behavior includes:

1. Organism ID and/or AST results can be linked to an incorrect patient.
2. Erroneous ID/AST results at the LIS.

These anomalies only impact VITEK 2 systems receiving/sending results from/to an LIS **via HL7 Protocol** (either directly, or via MYLA®). VITEK 2 connections using a non-HL7 BCI connection are not impacted.

Impact to patient/user:

bioMérieux has determined there is a potential safety risk of incorrect ID/AST results and/or results linked to incorrect patients.

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. **Confirm if your VITEK 2 system is connected via LIS interface using HL7 Protocol.**
 - **If no, please complete and return the Acknowledgement Form attached at the end of this letter.**
 - **If yes, please continue to step 3.**
3. Contact your local bioMérieux representative to determine the next steps for your specific situation. In case of HL7 connection through MYLA, a software correction patch will be proposed in order to correct these issues.
4. **Contact your facility IT/IS administrator to immediately disconnect/disable the VITEK 2 from any HL7 interface (“VITEK® 2 direct” or “VITEK 2 via MYLA”). Please note that VITEK 2 is capable of providing ID/AST results in “stand-alone” mode.**
5. Contact your LIS vendor and/or local bioMérieux representative for assistance with implementation of a non-HL7 BCI connection, if desired.
6. **Complete the attached 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 LIS interface is not configured to HL7®. Please indicate your configuration (VITEK® 2 BCI, or via MYLA®) in Question 2 on the acknowledgement form.**
7. Store this letter with your bioMérieux VITEK® 2 documentation.

bioMérieux is committed to providing our customers with the highest quality products, and we sincerely apologize for the inconvenience this has 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



Attachment A: Acknowledgement Form

URGENT PRODUCT REMOVAL NOTICE

FSCA 5688 : VITEK® 2 – HL7 Protocol – Safety Anomalies

Customer Information:

Customer Account Number: _____ Organization Name: _____

Street Address: _____

City, State and Postal Code: _____

Contact Name & Title: _____

Phone Number: _____

Product Information: VITEK® 2 Systems Versions 8.01, 8.02, 9.01, 9.02, 9.03, 9MR2, and 9MR3

Questions:

	Yes	No
1. Did you read the enclosed Urgent Product Removal Notice?		
2. What type of LIS connection do you currently have (circle one)? <ul style="list-style-type: none">• VITEK 2 direct via non-HL7 BCI connection• VITEK 2 direct via HL7• VITEK 2 via MYLA to LIS (non-HL7)• VITEK 2 via MYLA to LIS (HL7)• None		
3. Have you followed the instructions as indicated in this Urgent Product Removal Notice? If no, please indicate the reason in the Comments section below.		
4. Have you received reports of any illness or injury related to the described issue? If yes, please provide details in the Comments section below.		

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