



Urgent Product Correction Notice

Our Ref: FSCA 5615-1

Dear Valued bioMérieux Customer,

Our records indicate that your laboratory performs AST testing with a VITEK® 2 System connected to an LIS (Laboratory Information System) using the HL7® Communication Protocol. This connection may be “direct” from VITEK 2, or via the bioMérieux MYLA® product.

Intended Use:

VITEK® 2 is an automated system consisting of instruments, software and reagent cards 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).

MYLA® -as middleware- manages the microbiology laboratory workflow from the reception of requests to the transmission of results by transferring, storing and displaying medical device data. The product is used with a downstream application.

Description of Issue:

For HL7 protocol LIS connections, bioMérieux has identified an issue whereby VITEK 2 test results, sent via direct connection or via MYLA connection, do not include a user-corrected or AES-corrected (Advanced Expert System™) result interpretation(s) for <antibiotic Screen tests> and <Synergy tests>. This can potentially lead to incorrect final Screen/Synergy test results at the LIS. Results at the VITEK 2 and MYLA PC remain accurate.

The HL7 Communication Protocol option is included in the following VITEK 2 and MYLA software versions:

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

Internal investigation confirmed that when tests are Final, the results transmitted to the LIS should reflect the expertized and/or user-defined interpretations. This occurs successfully for tests reporting S/I/R interpretations with MIC (Minimum Inhibitory Concentration). However, due to the identified HL7 issue,



Screen tests indicating a positive/negative (+/-) result and Synergy tests providing only S/R results (no MIC) do not take into account the expertized or user-defined interpretations. The impacted tests are:

- Cefoxitin Screen (OXSF)
- Beta-Lactamase (manually entered test)
- Extended Spectrum Beta-Lactamase (ESBL)
- Inducible Clindamycin Resistance (ICR)
- Gentamicin High-Level Resistance (GHLR)
- Streptomycin High-Level Resistance (SHLR)
- Vancomycin Resistant *Staphylococcus aureus* Screen Test (VAS) (retired as of 29-Apr-2019)
- Gentamicin High-Level (synergy) (HLG)
- Kanamycin High-Level (synergy) (HLK)
- Streptomycin High-Level (synergy) (HLS)

This does not mean that all final Screen/Synergy test results at the LIS are incorrect; only that there is potential for an incorrect result if the expertized or user-defined interpretations would have changed the initial VITEK® 2 result.

Please contact your local bioMérieux representative to discuss VITEK 2 and/or MYLA solution implementation.

- For VITEK 2 without MYLA®, the resolution for this issue has been implemented in VITEK 2 Systems Software Maintenance Release 9MR3.
- For VITEK 2 with MYLA, a new MYLA library version is available for installation by your local bioMérieux representative.

Workarounds, pending installation of VITEK 2 9MR3 or MYLA library, to insure no adverse impact to patients:

1. Use BCILINK (VITEK 2 only) instead of HL7 for LIS communication. This change may require development of a new LIS driver.
OR
2. Verify all screen/synergy test results against the VITEK 2 or MYLA prior to providing final results to the physician.

Impact to patient/user:

bioMérieux has determined there is a potential safety risk of “false susceptible” or “false resistant” Screen test or Synergy test results (at the LIS) associated with this issue. Results at the VITEK 2 PC and MYLA PC remain accurate.

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.
- Apply one or more of the proposed workarounds as appropriate.
- Contact your local bioMérieux representative to schedule resolution to the identified issue.
- Store this letter with your bioMérieux VITEK® 2 / MYLA® documentation.
- 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 external communication was not configured to HL7®. Please indicate your configuration (VITEK® 2 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 5615-1 : VITEK® 2 / MYLA® – HL7 Protocol – Screen & Synergy Tests

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 8.01, 8.02, 9.01, 9.02, 9.03 and 9MR2
MYLA Software Versions V4.8 and V4.9

Questions:

	Yes	No
1. Did you read the enclosed Urgent Product Correction Notice for HL7 LIS protocol and Screen/Synergy tests?		
2. Have you implemented actions appropriate to your laboratory as indicated in this Urgent Product Correction Notice? If no, indicate the reason in the Comments section below. Please record your external communication configuration (BCI, MYLA® and/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: