



PLEASE DELIVER UPON RECEIPT to LAB DIRECTOR or LAB MANAGER

Date : 5th April 2022

Urgent Product Correction Notice

Our Ref: FSCA 5615

Dear Valued bioMérieux Customer,

Our records indicate that your laboratory may be using VITEK® 2 Software version 8.01, 8.02, 9.02, 9.03 or 9MR2 on your VITEK® 2 System with the external communication configured to HL7® protocol. External communication is used to send between VITEK® 2 and your LIS (Laboratory Information System).

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).

Description of Issue:

During internal bioMérieux testing, a VITEK® 2 software issue was identified whereby results sent to the LIS via HL7 format for antibiotic screen tests and synergy tests do not include the user-corrected or AES-corrected interpretation. This can potentially lead to incorrect final screen/synergy test results at the LIS. Results at the VITEK 2 PC remain accurate.

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 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 is not to say 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 result.

The resolution for this issue has been implemented in VITEK 2 Systems Software Maintenance Release 9MR3.



To confirm if your laboratory is impacted by this issue, 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.

System Mode

Clinical Industry

Note: Changing mode may impact SRF, AES, 21 CFR 11, demographic configuration settings and other configuration options located on a different tab in this workspace.

Enable 21 CFR 11 Mode

External Communication:
HL7®
MYLA®
HL7®
BCI

If MYLA® or BCI are selected, you are **NOT** impacted by this issue and no further action is required.

If HL7® is selected, you **ARE** impacted by this issue. Please contact your local bioMérieux representative to discuss installation of the 9MR3 software.

Potential workarounds, pending installation of 9MR3, to insure no adverse impact to patients:

1. Use BCILINK instead of HL7 for LIS communication. This change may imply development of a new LIS driver.
OR
2. Verify all screen/synergy test results against the VITEK 2 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 result (at the LIS) associated with this issue. Results at the VITEK 2 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.
- Store this letter with your bioMérieux VITEK® 2 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 (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.

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