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Our Ref.: 3815 - FSCA - VITEK 2 Compact
15_30 - Isolates Remain at Preliminary

Gothenburg, March 2018

IMPORTANT : URGENT FIELD SAFETY NOTICE
FSCA 3815 - VITEK 2 Compact 15_30 - Isolates Remain at Preliminary

Dear Valued bioMérieux Customer,

Our records indicate that your laboratory performs Identification (ID) and Antimicrobial Susceptibility Testing (AST) using the VITEK® 2 Compact 15 or VITEK® 2 Compact 30 system. A software anomaly has been identified following update to VITEK® 2 Systems software version 8.01.

Description of Issue:
Customers have reported that some VITEK® 2 isolate records are remaining in preliminary status, and not finalizing after ejection of the associated card from the instrument. The issue was reported to occur on VITEK® 2 Compact 15 and Compact 30 systems following VITEK® 2 System Software update to version 8.01.

Internal investigation has demonstrated that in specific cases when a card is processed in, and ejected from, a slot number greater than 15 or 30 (all VITEK® 2 Compact reader carousels contain 60 physical slots), respectively, the final data packet for the card fails to be accepted by the computer, and the isolate status remains at "preliminary".

When the anomaly occurs, subsequent data for current and future cards will not be transferred to the computer until the offending data packet is removed. Since the card has completed processing, as evidenced by the card ejection from the VITEK® 2 Compact reader, the results indicated in the lab report are the final results. As the card data for the ejected card will be lost after record removal, it is recommended the user print the lab report prior to removal of the record.

Impact to patient/customer:
Evaluation of the identified issue indicates the potential for delayed patient results. The duration of the delay is dependent upon the timeframe in which the offending data packet is deleted and the method by which any repeat testing is performed.

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.
- Please refrain from performing the VITEK® 2 Systems Software 8.01 update. A solution has been identified, and your local bioMérieux representative will contact you with further instruction.
- If you recently updated your VITEK® 2 Systems Software to version 8.01 [within the last seven (7) days], please contact your local bioMérieux representative. Established updates (>7 days) that have not exhibited the described anomaly do not need further attention.
- 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 NORDICS
Customer Service Department
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Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA - 3815 – VITEK® 2 Compact 15/30 - Isolates Remain at Preliminary

It is important that you complete this Acknowledgement Form and email it back to:
fieldactions.nordic@biomerieux.com

Customer Information:
Organization Name:

City, State and Postal Code:

Contact Name:

Product Information:

Catalog Number	Description
27415	VITEK® 2 Compact 15
27415R	VITEK® 2 Compact 15 (Refurbished)
27530	VITEK® 2 Compact 30 (Clinical)
27530R	VITEK® 2 Compact 30 (Clinical Refurbished)
27630	VITEK® 2 Compact 30 (Industry)
27630R	VITEK® 2 Compact 30 (Industry Refurbished)

Questions:

	Yes	No
1. Did you read the enclosed Urgent Product Correction Notice regarding VITEK® 2 Compact 15/30 Isolate Anomaly?		
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: _____
