[to be date of distribution]

URGENT Product Correction Notice

Dear Valued bioMérieux customer,

Our records indicate that your laboratory performs VITEK® 2 Antimicrobial Susceptibility Testing (AST) using one or more of these susceptibility products:

Reference	Description
410028	VITEK® 2 AST-ST01
420915	VITEK® 2 AST-ST02
421040	VITEK® 2 AST-ST03

Description of Issue:
Customers in Europe reported false resistant Ceftriaxone results for *Streptococcus anginosus* and *Streptococcus constellatus* strains when using VITEK® 2 AST-ST01 and AST-ST03 cards and VITEK® 2 Systems Software with EUCAST breakpoints. These false resistant results were reproduced internally by testing customer strains. A Ceftriaxone MIC overestimation was observed compared to the reference result.

An internal study confirmed the performance of *Streptococcus anginosus, Streptococcus constellatus*, and *Streptococcus intermedius* had shifted for Ceftriaxone. With EUCAST Global European-based breakpoints, having no Intermediate MIC, this may constitute a category difference. Many strains demonstrated a result of MIC=1 (R) with EUCAST breakpoints, when an MIC=1 remains susceptible (S) for CLSI, Global CLSI-based and FDA breakpoints.

The VITEK® 2 Ceftriaxone test is included on all AST-ST cards intended for testing streptococci. All lots of AST-ST01, AST-ST02, and AST-ST03 are impacted and are distributed globally.

Limitation	VITEK® 2 AST-ST Limitation
Perform an alternate method of testing prior to reporting resistant results for the following antibiotic/organism combination(s).	• Ceftriaxone (cro01n): *Streptococcus anginosus* *Streptococcus constellatus* *Streptococcus intermedius*

The VITEK® 2 system can be configured via bioART to automatically notify the user of the associated Limitation during testing of an impacted antibiotic/organism combination (reference the VITEK® 2 Software User Manual, 514742-1XX1 where XX is the two-letter language designation).

This letter applies only to customers using EUCAST breakpoints. Existing VITEK® 2 Limitations for EUCAST breakpoints remain in effect and are not impacted by those referenced in this letter.

Impact to customer:
There exists the potential to report false resistant ceftriaxone results for *Streptococcus anginosus*, *Streptococcus constellatus*, and *Streptococcus intermedius.*

Actions:
We request you take the following action at this time:

- Please confirm this letter has been distributed and reviewed by all appropriate personnel within your organization.
- Reference your Laboratory Standard Operating Procedures to identify card types and breakpoints used in your facility to determine if your laboratory is impacted by the issue described in this letter.
- Reference your Laboratory Standard Operating Procedures to identify if retrospective analysis is required for reported results associated with the referenced limitation.
- For systems utilizing EUCAST breakpoints and operating with VITEK® 2 Systems Software, create a bioART Rule for the referenced limitation associated with Ceftriaxone (cro01n).
- Please store this letter with your bioMérieux instrument documentation.

Please complete the attached Acknowledgement Form (Attachment A) and return it to bioMérieux, Inc.

bioMérieux, Inc. is committed to providing our customers with the highest quality products, and we apologize for any inconvenience this has caused your business. If you have any questions or concerns, please contact your local bioMérieux representative.

Thank you for your continued use of bioMérieux products,

bioMérieux, Inc.

[Enter Local Contact]

Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE

FSCA - 4075 – VITEK® 2 AST-ST Ceftriaxone EUCAST Limitation for *Streptococcus anginosus* group

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Customer Information:

Customer Account Number: _____ Organization Name: _____

Street Address: _____

City, State and Postal Code: _____

Contact Name: _____

Contact Title: _____

Phone Number: _____

Product Information:

Catalog Number	Description
410028	VITEK® 2 AST-ST01
420915	VITEK® 2 AST-ST02
421040	VITEK® 2 AST-ST03

Questions:

	Yes	No
1. Have you read the enclosed Product Removal Notice regarding VITEK® 2 AST-ST Ceftriaxone EUCAST Limitation issue?		
2. Have you followed the instructions and 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 VITEK® 2 AST-ST Ceftriaxone EUCAST Limitation issue?		
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]**