



[to be date of distribution]

Urgent Product Correction Notice

Dear Valued bioMérieux Customer,

Our records indicate you have received one or more of the following VITEK® 2 Software version 6.01 products:

Part Number	Product Description
413861	KIT, V2S 6.01 RP5800-WES7 MEDIA
414537	KIT UPDT V2S 6.01 ML1
414538	KIT UPDT V2S 6.01 ML2
414539	KIT UPDT V2S 6.01 DE
414560	KIT UPDT V2S 6.01 EN
414561	KIT UPDT V2S 6.01 ES
414562	KIT UPDT V2S 6.01 FR
414563	KIT UPDT V2S 6.01 IT
414564	KIT UPDT V2S 6.01 JA
414565	KIT UPDT V2S 6.01 NO
414566	KIT UPDT V2S 6.01 PT
414567	KIT UPDT V2S 6.01 DA, SV
414568	KIT UPDT V2S 6.01 EL, TR
414569	KIT UPDT V2S 6.01 ZH
415700	VITEK 2 KIT MISE A JOUR 6.01 FR
6201773	KIT V2S RP5800XPE to 6.01 WES7
6201842	DVD, VITEK 2 DC7100 IMAGE 6.01
6201843	DVD, VITEK 2 DC7700 IMAGE 6.01
6201844	DVD, VITEK 2 DC7800 IMAGE 6.01
6201845	DVD, VITEK 2 RP5800 IMAGE 6.01

This letter is intended for customers performing update of software from version 5.xx to 6.01 Software with their VITEK® 2 system. A product issue has been identified for customers using software version 6.01 and are interfaced with a Laboratory Information System (LIS). New VITEK 2 Systems and new PC 6.01 installs are not impacted by this issue. However, we recommend that you confirm the issue described below is not encountered.

Description of the Issue:

During the update of software from version 5.xx to 6.01, the Bi-directional Computer Interface (BCI) antibiotic codes are not updated properly for Cefovecin (CFO), Prulifloxacin (PRU) and Ceftaroline (CTL). For the referenced antibiotics, the bioMérieux code in the reference table does not match the default host code in version 6.01 software.

<u>Antibiotic name</u>	<u>bioMérieux code</u>	<u>Default host code</u>
Cefovecin (veterinary only antibiotic)	CFO	ctl
Prulifloxacin (deduced antibiotic)	PRU	cfo
Ceftaroline (not released for use, but could be deduced)	CTR	pru

The discrepancy in the BCI antibiotic translation table impacts the results that are uploaded to the LIS through the BCI interface.

- Cefovecin results on the VITEK® 2 would be uploaded to the LIS through BCI interface as Ceftaroline.

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- Prulifloxacin results on the VITEK® 2 would be uploaded to the LIS through BCI interface as Cefovecin.
- Ceftaroline results on the VITEK® 2 would be uploaded to the LIS through BCI interface as Prulifloxacin

The identified anomaly only affects customers with software version 6.01 that are interfaced with a LIS and are not interfaced with OBSERVA. New VITEK 2 System or new PC6.01 installs are not impacted by this anomaly; the discrepancy is in the update process for 5.xx to 6.01 and not in the install process.

Impact to customer:

The impact and subsequent consequence of the antibiotic code discrepancy for Cefovecin, Prulifloxacin and Ceftaroline is that the incorrect AST test result could be sent to the LIS. If the incorrect code for the referenced antibiotics is sent, then there is a potential for misinterpretation of antibiotic codes.

The following summarizes the impact of each discrepancy:

- Cefovecin → Ceftaroline : The results in VITEK® 2 remain correct for Cefovecin. There is no impact to clinical results. This discrepancy only impacts veterinary patients.
- Prulifloxacin → Cefovecin : Prulifloxacin is an antibiotic that can only be deduced. If the antibiotic is chosen for deduction, the results in VITEK® 2 would remain correct and the incorrect antibiotic name would be sent to the LIS. It is likely that the result would be questioned since it is a veterinary antibiotic. The impact is considered negligible because Cefovecin sent to the LIS is an antibiotic that is not used to treat humans.
- Ceftaroline → Prulifloxacin: Ceftaroline is not currently available for testing on VITEK® 2 cards, but is available for deduction. The deduced result for Ceftaroline would be sent to the LIS as Prulifloxacin. In this case, there is a risk of mis-interpretation of antibiotic codes, which could lead to reporting incorrect antibiotic results from the LIS.

Required Actions:

We request you take the following actions at this time:

1. Ensure this Urgent Product Correction Notice and the **Instructions for modifying BCI Translation Codes** (Attachment) are distributed to all appropriate personnel in your organization.
2. Follow the instructions in the attached file (**Instructions for modifying BCI Translation Codes**) to resolve the discrepancy associated with Cefovecin, Prulifloxacin and Ceftaroline in the translation table
3. Complete and return the Acknowledgement Form in Attachment A by Fax to confirm receipt of this notice.

bioMérieux will incorporate a software solution to prevent this issue from occurring, in the next software update, version 7.01 targeted for launch at the end of 2013. bioMérieux is committed to providing our customers with the highest quality product. We apologize for any inconvenience this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Thank you for your continued use of bioMérieux products,

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Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE

FSCA - 1782 – VITEK® 2 (6.01 Software) Mis-interpretation of antibiotic codes sent to LIS

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

Questions:

	Yes	No
1. Did you read the enclosed Urgent Product Correction Notice regarding VITEK® 2 systems?		
2. Have you followed the instructions and implemented the actions as indicated in this Urgent Product Correction Notice?		
3. Have you received reports of injury to patient, unnecessary medical procedure or delay in a necessary medical procedure related to the VITEK 2 BCI antibiotic code discrepancy?		

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

[\[Enter Local Contact Address and telephone\]](#)

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