

IMPORTANT:

URGENT FIELD CORRECTIVE NOTICE

VITEK® 2 Software 9.01-9.04 Anomaly in Firefox Web Browser - Navigation Arrow Key Implementation
During Batch Edit of Accession IDs in Firefox Web Browser

Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Laboratory Medical Director

Date
bMx local contact information
(to be adapted at local level)

Our reference: FCA - FIELD CORRECTIVE ACTION - FA-TWD-000008

Impacted products (to be adapted at local level if necessary including for names and ref #, local license #, name and address of manufacturer)		
Product Name	Reference Number	Lot Number/Serial Number/ Product version
KIT, UPDT VTK2 9.01/9.02 IND	423585	9.01/9.02 – Industry
KIT, VITEK® 2 UPDATE 09.03 ML	423887	9.03
KIT, VITEK® 2 UPDATE 09.04 ML	424327	9.04
KIT, UPDT VTK2 09.01/ 09.02	423487	9.01/9.02

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



Dear bioMérieux Customer,

Our records indicate that your laboratory may be using a VITEK® 2 Software version listed in the table above.

The aim of this communication is to inform our customers of a software anomaly that may occur while using a specific workflow (non-recommended) to edit Accession IDs (Lab IDs) of on an isolate, or a batch of isolates, while using the Firefox web browser. This letter is to provide you with recommendations and/or advice on how to avoid the anomaly.

Required actions

In this context, we request you to take the following actions. Please:

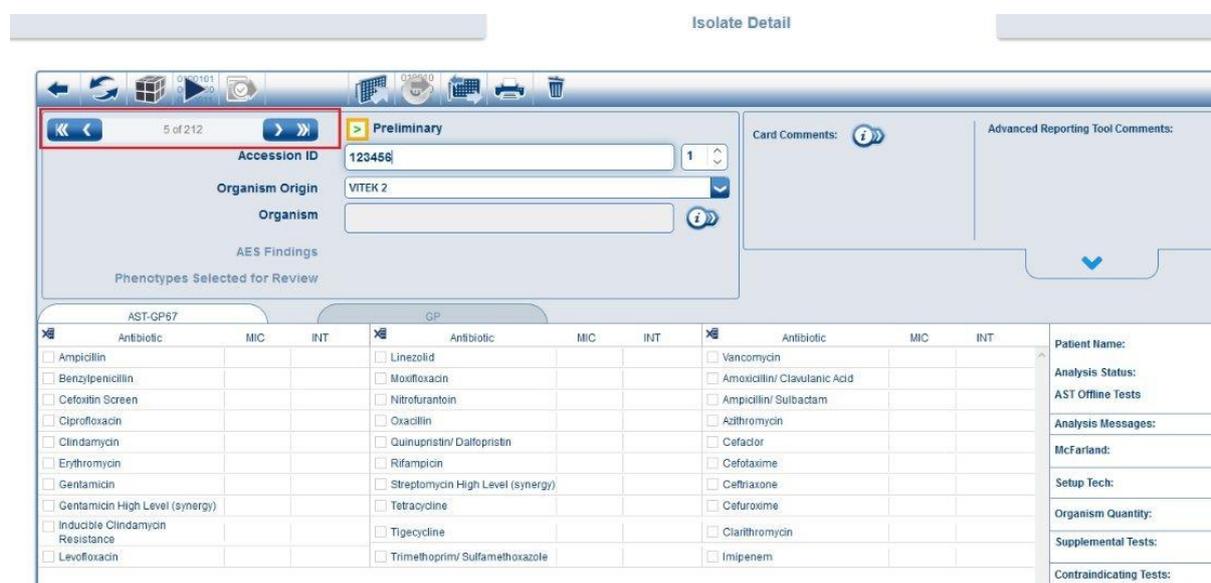
- Distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice. It is important that you return the acknowledgement form to bioMérieux even if you determine that this urgent product correction notice does not impact your facility.

Description of the issue

bioMérieux has become aware that when using the Firefox web browser to access the VITEK® 2 Software versions 9.01-9.04 and editing the Accession ID on an isolate, or a batch of isolates, an anomaly can occur. The described combination above will lead to mismatched results if the arrow navigation keys (in Isolate Detail View) are used to move to the next isolate in the list after a change to the Accession ID field. Currently, in the Firefox web browser ONLY, the use of the navigation arrow keys  (located immediately above the "Accession ID" field name) pushes the edited field (e.g. Accession ID) to the next Isolate in the work list rather than the intended isolate.

Subsidiary name (if applicable) / Nom de la filiale (si approprié)

Figure 1: Example of Isolate Detail View



The anomaly occurs only when editing the Accession ID on an isolate, or a batch of isolates, using the Firefox web browser. The arrow navigation keys in Isolate Detail View do not exhibit the same behavior in other web browsers, such as Microsoft Edge or Google Chrome.

When performing an edit to an Accession ID, in the Isolate Detail View, the user is reminded to use good practice and perform the change on one isolate at a time. The recommended workflow when editing the Accession ID, is to click outside the edit box or to press the tab key on the keyboard to save the change, after the edit is complete. The 'Enter' key will not apply the change.

Impact to User/Customer/Patients

Potential impact to customers is mismatched results in the customer's LIS (laboratory information system), and VITEK 2 Software worklist, where the Accession ID may not match the intended isolate.

Local legal mentions to be added if necessary at local level (e.g. in case of recall, reporting to NCA, recall methods)

bioMérieux is committed to providing our customers with the highest quality product possible.

We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact *your local bioMérieux Customer Service representative (to be adapted at local level)*.

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



Yours faithfully,
Customer Service

Subsidiary name (if applicable) / Nom de la filiale (si approprié)

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com
Legal notice / Mentions légales de la société émettrice



Attachment A: Acknowledgement Form.

FCA

**FCA - FIELD CORRECTIVE ACTION FA-TWD-000008
VITEK® 2 Software 9.01-9.04 Anomaly in Firefox Web Browser -
Navigation Arrow Key Implementation During Batch Edit of Accession
IDs in Firefox Web Browser**

**TO BE RETURNED TO YOUR BIOMERIEUX CUSTOMER SERVICE (TO BE ADAPTED AT LOCAL LEVEL)
AT THE FOLLOWING
FAX NUMBER: XXXXXXXX OR EMAIL ADDRESS: XXXXXXXX**

Name and Address of the laboratory	
Contact information	
Customer Account Number	

Local legal mentions to be added if necessary at local level)

I am not impacted by the issue. Please provide rationale:

I have implemented the required actions.

Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue ? *(to be completed based on FCA/FSCA issue)*

Yes No

DATE.....SIGNATURE.....

It is important that you complete this Acknowledgement Form and return it to bioMérieux

Subsidiary name (if applicable) / Nom de la filiale (si approprié)