IMPORTANT:

URGENT FIELD SAFETY NOTICE

VIDAS® HIV DUO AG/AB Ref. 424480 - Corrupted MLE while using VIDAS® KUBE

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: FSCA - FIELD SAFETY CORRECTIVE ACTION - FA-TWD-000041

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**	**Product Expiration Date (if applicable)**
VIDAS® HIV DUO AG/AB (HIV)	424480	All lot on the field and the new lots until the new knowledge base is released.	

Dear bioMérieux Customer,

Our records indicate that your laboratory is using VIDAS® HIV DUO AG/AB (Ref. 424480) product listed in the table above.

The aim of this communication is to inform you that you may encounter an error message if you are using VIDAS® HIV DUO AG/AB (424480) on a VIDAS® KUBE only during the calibration phase while you used VIDAS® HIV DUO Ultra before.

Required actions

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

- 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.

- If you did not encounter the issue yet, please,
  - Reboot the VIDAS® KUBE instrument
  - Disable the VIDAS® HIV Duo Ultra parameter until the new Knowledge base is available.

- If you face the issue, please:
  - Disable VIDAS® HIV Duo Ultra
  - Reboot the system
  - Scan a new MLE of VIDAS® HIV DUO AB/AG (Ref. 424480). **Important**: lot number must be different than the one for which the calibration failed previously. If you don't have another lot in stock, reach your local bioMérieux contact to obtain kits from a different lot)
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative (to be adapted at local level) 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 received customers' complaints who reported that after launching a calibration of the assay VIDAS® HIV DUO AG/AB (Ref. 424480) on VIDAS® KUBE (Ref. 423912), the instrument did not calculate the result and showed an error 3502 “Impossible to compute result”. After this error occurs, the customer could not use the assay VIDAS® HIV DUO AG/AB and there is no available workaround for the customer.

While the investigations are still ongoing, the following were identified:

- The issue could occur **only when VIDAS® HIV DUO AG/AB (Ref. 424480) assays are used in conjunction with VIDAS® KUBE (Ref. 423912) instrument**.

- The issue is confirmed as a corruption of the Master Lot Entry (MLE) of the assay VIDAS® HIV DUO AG/AB when used on the same VIDAS® KUBE instrument where VIDAS® HIV DUO Ultra was previously used.
- The problem occurs when a result for an assay VIDAS® HIV DUO Ultra is computed on the instrument before scanning the MLE of VIDAS® HIV DUO AG/AB
- The issue does not occur when the system is rebooted between the last VIDAS® HIV DUO Ultra result computation and the scan of the MLE of VIDAS® HIV DUO AG/AB (Ref. 424480).
- Workarounds are already available to prevent the issue at your level or fix it if it already occure until the new Knowledge Base that solves the issue will be at your disposal by the end of August 2025.

Note: you will not be able to use both assays VIDAS® HIV DUO Ultra and VIDAS® HIV DUO AG/AB in parallel until the new Knowledge Base is available.

Impact to User/Customer/Patients

The potential risk associated to the VIDAS® HIV DUO AG/AB corrupted MLE in conjunction with VIDAS® KUBE is a delay in rendering the patients' results.

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)*.

Yours faithfully,

Customer Service

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA - FIELD SAFETY CORRECTIVE ACTION FA-TWD-000041 VIDAS® HIV DUO AG/AB Ref. 424480 - Corrupted MLE while using VIDAS® KUBE

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

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.

Table to be added and adapted if necessary to monitor quantities received/discarded (products names and ref.# to be adapted at local level if necessary) depending on the required actions.

REF #	Product Name	Batch #	Quantity received	Quantity used	Quantity destroyed	Quantity returned*
424480	VIDAS® HIV DUO AG/AB (HIV)	All lot on the field and the new lots until the new knowledge base is released.	N/A	N/A	N/A	N/A

** Quantity returned to bioMérieux or distributor*

REF #	Product Name	Serial number # / Version number	Quantity received	Quantity updated**	Quantity returned*
423912	VIDAS® KUBE				N/A

*** Update: reboot of the instrument and disable the VIDAS® HIV DUO Ultra parameter until the new Knowledge Base is available.*

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