

IMPORTANT:

URGENT FIELD SAFETY NOTICE

VIDAS® CK-MB - Reference 30421 - Lot 1010473720 - Calibration Issue (S1 standard high OOR)

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-000017

Impacted products <i>(to be adapted at local level if necessary including for names and ref #, local license #, name and address of manufacturer)</i>			
Product Name	Reference Number	Lot Number/Serial Number/ Product version	Product Expiration Date (if applicable)
VIDAS® CK-MB	30421	1010473720	20-Dec-2024

Dear bioMérieux Customer,

Our records indicate that your laboratory received the product listed in table above.

The aim of this communication is to inform you about calibration issues with VIDAS® CK-MB - Reference 30421 - Lot 1010473720 - Calibration Issue (S1 standard high OOR).

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

Required actions

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

- Please continue using the lot 1010473720 if there is a current valid calibration. Once the VIDAS instrument requires a new calibration, stop using and discard the impacted lot 1010473720.
- 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 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 safety notice does not impact your facility.

Description of the issue

bioMérieux received complaints from the field for invalid calibration with VIDAS® CK-MB (Ref. 30421) lot 1010473720 due to S1 value out-of-range high and confirmed the product issue on this batch in the bioMérieux complaints laboratory.

An investigation is in progress to identify the root cause of invalid calibration on the lot 1010473720.

The scope of the issue has been isolated VIDAS® CK-MB (Ref. 30421) lot 1010473720. No other lots on the market are impacted.

Impact to User/Customer/Patients

Invalid calibration due to S1 standard high out-of-range too is associated with a potential risk of delayed patient results.

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



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

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.

URGENT FIELD SAFETY NOTICE

**FSCA - FIELD SAFETY CORRECTIVE ACTION FA-TWD-000017
VIDAS® CK-MB - Reference 30421 - Lot 1010473720 - Calibration Issue
(S1 standard high OOR)**

**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.

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*
30421	VIDAS® CK-MB	1010473720				

* Quantity returned to bioMérieux or distributor

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



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)