FSCA
FIELD SAFETY CORRECTIVE ACTION

BIOMÉRIEUX

IMPORTANT:

URGENT FIELD SAFETY NOTICE

VIDAS® CK-MB - Reference 30421 - Lots 1010844200, 1010959330, 1010987820 - 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-000027

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® CK-MB	30421	1010844200	08-JUL-2025
VIDAS® CK-MB	30421	1010959330	28-AUG-2025
VIDAS® CK-MB	30421	1010987820	27-SEP-2025

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 Lots 1010844200, 1010959330, 1010987820.

Required actions

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

- You can continue using the lots 1010844200, 1010959330 and 1010987820 if there is a current valid calibration. Once the VIDAS instrument requires a new calibration, stop using and discard the impacted lots. There is no risk of false results.

The VIDAS® CK-MB assay is an aid in the diagnosis of acute coronary syndromes (ACS), but international guidelines and consensus groups have clearly stated that this test is no longer recommended for use in the diagnosis of ACS. Therefore, substituting troponin (VIDAS® High sensitive Troponin I Reference 415386) for CKMB in the diagnosis of ACS is in line with international recommendations.

For any needs, do not hesitate to proactively contact your local customer service.

- 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 identified, during internal monitoring, a drift of the S1 Relative Fluorescence Value (RFV) on VIDAS® CK-MB Reference 30421 lots 1010844200, 1010959330, and 1010987820. This can lead to an invalid calibration (out-of-range high S1 values).

The only risk associated to the referenced issue is a potential delay in reporting result, there is no risk of false results.

Based on the results of investigation that is still ongoing, bioMérieux suspects a stability issue linked to the manufacturing process of a raw material used in the strip. Consequently, the MLE range for the

S1 may not be sufficient for the impacted lots to absorb the instability and the variability of the reagent through expiration.

The manufacturing of a new raw material has been launched to be able to release conforming lots. Please refer to your local bioMérieux contact for follow up information.

Impact to User/Customer/Patients

Invalid calibration due to S1 standard high out-of-range is associated with a potential risk of delayed patient 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-000027 VIDAS® CK-MB - Reference 30421 - Lots 1010844200, 1010959330, 1010987820 - 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: 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*
30421	VIDAS® CK-MB	1010844200				
30421	VIDAS® CK-MB	1010959330				
30421	VIDAS® CK-MB	1010987820				

** Quantity returned to bioMérieux or distributor*

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

☐ Yes ☐ No

DATE…….....SIGNATURE……

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