

IMPORTANT:

URGENT FIELD SAFETY NOTICE

VIDAS® CK-MB – Ref 30421 – Invalid calibration

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 5801

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	1009900940	25-Jan-2024

Dear bioMérieux Customer,

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

The aim of this communication is to inform you about calibration issues with VIDAS® CK-MB (Ref. 30421) lot 1009900940 due to S1 value out-of-range high.

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



Required actions

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

- Stop using and destroy the impacted lot 1009900940.
- 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 1009900940 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 1009900940.

The preliminary results of this investigation focus on an S1/C1 problem.

To date, the issue was not confirmed on other lots of VIDAS® CK-MB (Ref. 30421) available on the market. The only other lot of VIDAS® CK-MB (Ref. 30421) having an identical composition of S1 and C1 as impacted lot 1009900940 remains within its specifications and will be closely monitored until the root-cause identified.

Impact to Patients

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

The risk of false results was excluded since the calibration would be out of range before the result of the assay is misinterpreted.

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)



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY/CORRECTIVE NOTICE

5801 - FSCA - VIDAS® CK-MB - Ref 30421 – Invalid calibration

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

Table with 2 columns: Field Name (Name and Address of the laboratory, Contact information, Customer Account Number) and empty space for input.

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 with 7 columns: REF #, Product Name, Batch #, Quantity received, Quantity used, Quantity destroyed, Quantity returned* (N/A)

* Quantity returned to bioMérieux or distributor

Have you encountered impact on patients' results, or reports of illness or injury related to the identified 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)