



Field Actions UK  
bioMérieux UK Ltd

For the attention of the Laboratory Manager

24 MAR 2021

**IMPORTANT: URGENT FIELD SAFETY NOTICE**

**Ref. 30205 – VIDAS® CMV IgM Calibration issue leading to potential delayed results**

Our ref.: FSCA 5109

Dear bioMérieux Customer,

This is a follow up notification to FSCA 5087 dated 2<sup>nd</sup> March 2021 whereby our records indicate that your laboratory received one or more of the lot numbers of the VIDAS® CMV IgM (Ref. 30205) listed in Table 1 below.

Table 1:

Product Ref. Number	Description	Lot Number	Expiry date
30205	VIDAS® CMV IgM	1008143230	04 MAY 2021
		1008182270*	26 MAY 2021
		1008363970	01 SEP 2021
		1008433580	15 OCT 2021

\*The Field Safety Corrective Action (FSCA#5087) issued on 02 March 2021 informed customers of the identified issue, reminded of good practices, and instructed to stop using and destroy the lot 1008182270 of VIDAS® CMV IGM (Ref. 30205).

**Description of the issue**

VIDAS® CMV IgM is an automated qualitative enzyme immunoassay for use on the VIDAS® family instruments, for the detection of anti-cytomegalovirus IgM (CMVM) in human serum, using the ELFA technique (Enzyme Linked Fluorescent Assay).

bioMérieux received complaints about calibration issue observed on VIDAS® CMV IgM (ref 30205), with the lots mentioned in table 1.

In the case of an invalid calibration, an error message appears and it is not possible to perform further testing. In the case of a valid calibration, there is no impact on patient's results; the kit can be used as normal. There is no need to perform any retrospective analysis of previous results obtained with impacted kits.

To date the calibration issue has still not been reproduced internally and the root cause investigation is ongoing. We are however continuing to monitor very closely the signal evolution of the standard S1 of VIDAS CMV IgM in both newly produced and future batches of this assay.

**bioMérieux UK Ltd**



**Impact to customer:**

In the case of an invalid calibration, there is no risk of getting a false result; however, there is a risk of delayed results if the analysis cannot be done.

**Required actions:**

As of the 11<sup>th</sup> March 2021, we have only shipped a **new lot number, lot 1008556240**.

As we have now released this new lot of CMV IGM kits, we request you to take the following actions at this time:

- 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.
- As the issue has not been reproduced internally, the required action is based on the number of complaints recorded and on the monitoring of the signal evolution regarding the standard S1 of the calibration kits.
- Stop using and destroy any stock of reagent lots VIDAS® CMV IgM (Ref. 30205) mentioned in Table 1 remaining in your inventory and that were not already discarded through the Urgent Field Safety notice FSCA#5087
- Complete the Acknowledgement Form in Attachment A and return it to [fieldactions.uk@biomerieux.com](mailto:fieldactions.uk@biomerieux.com) to confirm receipt of this notice.
- Contact your local customer service if you have any questions, at [uktechnical@biomerieux.com](mailto:uktechnical@biomerieux.com).

**Important information regarding the new batch of VIDAS® CMV IgM (Ref. 30205), lot 1008556240 and future batches:**

We would like to take the opportunity to inform you that, as the investigation confirmed that the calibrator's value increases during the first few days after production, an immediate corrective action has been implemented during the manufacturing process of this and other new manufactured lot numbers. Lots are now stabilized for a few days before their release and they will be continuously monitored by our Quality Department. Following this, lot. #1008556240, is the first release to incorporate this change of process. We expect to see a reduction in the numbers of this calibration issue in the field with this newly implemented action.

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

We sincerely apologise for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux technical support at [uktechnical@biomerieux.com](mailto:uktechnical@biomerieux.com).

Yours faithfully,

Field Actions UK  
[Fieldactions.UK@biomerieux.com](mailto:Fieldactions.UK@biomerieux.com)

On behalf of bioMérieux Global Customer Services



**Attachment A: Acknowledgement Form.**

**IMPORTANT: URGENT FIELD SAFETY NOTICE**

**FSCA 5109 - VIDAS® CMV IgM Ref. 30205– Calibration issue - Potential delayed results**

**TO BE RETURNED TO YOUR BIOMERIEUX CUSTOMER SERVICE:**

EMAIL: FIELDACTIONS.UK@biomerieux.com

BY POST: FIELD ACTIONS, BIOMERIEUX UK LTD, GRAFTON WAY, BASINGSTOKE, HAMPSHIRE,  
RG22 6HY

Name of the laboratory:

City:

**Customer number:**

- I acknowledge receipt of the bioMérieux letter regarding the “VIDAS® CMV IgM - Ref. 30205 – Calibration issue”
- I will implement the required actions, stop using and destroy the affected lots listed in Table 1 as indicated in the Urgent Field Safety Notice.
- Have you encountered impact on patients’ results, or reports of illness or injury related to the identified issue ?
  - Yes    No

REF #	Product Name	Lot #	Quantity received	Quantity discarded
30205	VIDAS® CMV IgM	1008143230		
30205	VIDAS® CMV IgM	1008182270		
30205	VIDAS® CMV IgM	1008363970		
30205	VIDAS® CMV IgM	1008433580		

DATE .....

SIGNATURE : .....