



Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Healthcare center Chairman

Address
City, Date

Our reference: FSCA 5087

IMPORTANT:
URGENT FIELD SAFETY NOTICE
Ref. 30205 – VIDAS® CMV IgM
Calibration issue leading to potential delayed results
Part I: lot 1008182270
Part II: lots 1008143230 ; 1008363970 ; 1008433580

Dear bioMérieux Customer,

Our records indicate that your laboratory received VIDAS® CMV IgM (Ref. 30205) – lot 1008182270 and/or lots 1008143230 ; 1008363970 ; 1008433580.

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), lots 1008182270, 1008143230 ; 1008363970 ; 1008433580.

In case of invalid calibration an error message appears and it will not be possible to perform further testing. In case of valid calibration, there is no impact on patient's results, the kit can be used as usual.

To date the calibration issue has not been reproduced internally and the investigation is ongoing to find the root cause. We monitor closely the signal evolution regarding the standard S1 of the different lots and we identify that the S1 signal of the lot 1008182270 has a significant increase.

Impact to customer:

In case of 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.

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



Required actions:

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.

*** Part I: required actions regarding lot 1008182270:**

- As the issue has not been reproduced internally, the required action is based on the number of complaints recorded on each lot and on the monitoring of the signal evolution regarding the standard S1 of the calibration kits.
- Stop using and destroy any stock of lot 1008182270 of VIDAS® CMV IgM (Ref. 30205).
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.
- Contact your local customer service if you have any question.

*** Part II: required actions regarding lots 1008143230 ; 1008363970 ; 1008433580**

- You can continue to use the kits if the calibration is valid and we thank you to inform bioMérieux in case of invalid calibration.
- Discuss any concerns you may have regarding delayed patients results obtained with your Laboratory Medical Director to determine the appropriate course of action.
- Contact your local customer service if you have any question.

Good practices reminder:

We would like to take the opportunity of this new communication to highlight some important points and remind some best practices regarding the workflow to apply on our VIDAS® instruments.

As mentioned in VIDAS® CMV IgM package insert, in the section PROCEDURE, you should respect the following workflow:

- "Mix the standard, controls and samples using a vortex-type mixer" in order to have an optimized calibration.

- "Initiate the assay as described in the User Manual of VIDAS® instruments, the routine workflow is split into 2 parts with different steps:

1. Outside the instrument

- a. Prepare the samples
- b. Dispense each sample in the sample well of the strip (not necessary using VIDAS 3)



2. On the instrument

- a. Plan the analysis
- b. Load the reagents (strips and SPRs)
- c. Start the run immediately
- d. Unload the reagent when the results are released.

- Perform the required maintenances (user maintenance and preventive maintenance) are also important to maintain instrument performances.

INSTRUMENT MAINTENANCE REMINDER

It is necessary to perform regular instrument maintenance in order to ensure the mini VIDAS®, VIDAS® and VIDAS 3® are functioning correctly and ensure the quality of your daily results. These procedures are described in the mini VIDAS®, VIDAS® or VIDAS 3® User Manuals.

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.

Yours faithfully,

Customer Service



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5087 - VIDAS® CMV IgM Ref. 30205 – Calibration issue - Potential delayed results

**TO BE RETURNED TO YOUR BIO-MERIEUX CUSTOMER SERVICE AT THE FOLLOWING
FAX NUMBER : XXXXXXXX**

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 lot of VIDAS® CMV IgM (Ref. 30205) lot 1008182270 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	1008182270		

DATE

SIGNATURE :