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

Address
City, Date

Our reference: FSCA 5109

**IMPORTANT:**

**URGENT FIELD SAFETY NOTICE**

**Ref. 30205 ; 30205-01 – VIDAS® CMV IgM**

**Calibration issue leading to potential delayed results**

Dear bioMérieux Customer,

Our records indicate that your laboratory received lots of VIDAS® CMV IgM (Ref. 30205 ; 30205-01) listed in Table 1 below.

Table 1:

| Product Ref. Number | Description | Lot Number | Expiry date |
|---|---|---|---|
| 30205 ; 30205-01 | VIDAS® CMV IgM | 1008143230 | 04 MAY 2021 |
| | | 1008143260 (US) | 04 MAY 2021 |
| | | 1008182270* | 26 MAY 2021 |
| | | 1008363970 | 01 SEP 2021 |
| | | 1008363980 (US) | 01 SEP 2021 |
| | | 1008433580 | 15 OCT 2021 |

**The Field Safety Corrective Action (FSCA#5087) issued on the 23rd of February 2021 informed customers of the identified issue, remind good practices along with instructions 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 ; 30205-01), lots mentioned in table 1.

In case of invalid calibration an error message appears and it will not be possible to perform further testing. As in case of valid calibration the kits can be used as usual, there is no need to perform any retrospective analysis of previous results obtained with impacted kits.



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

To date the calibration issue has not been reproduced internally and the investigation is ongoing to identify the root cause. We monitor closely the signal evolution regarding the standard S1 of VIDAS CMV IgM upcoming batches.

**Impact to customer:**

In case of invalid calibration, there is a risk of delayed results as further analysis cannot be done on patient samples. In case of valid calibration, the results obtained will be correct.

**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.
- 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 lots VIDAS® CMV IgM (Ref. 30205 and 30205-01) lots mentioned in Table 1 remaining in your inventory and not already discarded through the Urgent Field Safety notice related to FSCA#5087
- 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.

**Important information regarding next batch of VIDAS® CMV IgM (Ref. 30205), lot 1008556240:**

We would like to take the opportunity of this new communication to inform you that as the investigation confirmed that the calibrator's value increases during the first few days after, an immediate corrective action has been implemented during manufacturing process of the new manufactured lots, the new lots are now stabilized a few days before the release and they will be continuously monitored. Then, with the lot. #1008556240, that is the first one including this immediate action we expect an improvement of the calibration problem in the field.

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 5109 - VIDAS® CMV IgM Ref. 30205 ; 30205-01 – Calibration issue - Potential delayed results

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**TO BE RETURNED TO YOUR BIOMERIEUX 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 ; 30205-01 – 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 | | |
| 30205-01 | VIDAS® CMV IgM | 1008143260 | | |
| 30205 | VIDAS® CMV IgM | 1008182270 | | |
| 30205 | VIDAS® CMV IgM | 1008363970 | | |
| 30205-01 | VIDAS® CMV IgM | 1008363980 | | |
| 30205 | VIDAS® CMV IgM | 1008433580 | | |

**DATE** ..... **SIGNATURE** : .....