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

Address
City, Date

Our reference: FSCA 5537

**IMPORTANT:**
**URGENT FIELD SAFETY NOTICE**

**Ref. 30205, 30205-01 – VIDAS® CMV IgM – Invalid Calibration leading to potential delayed results**

**Part I: Lot 1008873250 and Lot 1008873260**
**Part II: Lot 1008988860 and Lot 1009095380**

Dear Valued bioMérieux Customer,

Our records indicate that your laboratory has received one of the following lots of VIDAS® CMV IgM (Ref. 30205, 30205-01) in Table 1.

**Table 1: List of Affected Products**

| Reference Number | Lot Number | Unique Device Identifier | Manufacturing Date | Product Expiration Date |
|---|---|---|---|---|
| 30205 | 1008873250 | 03573026064396 | 20AUG2021 | 01JUN2022 |
| 30205-01 | 1008873260 | 03573026156848 | 20AUG2021 | 01JUN2022 |
| 30205 | 1008988860 | 03573026064396 | 08OCT2021 | 27JUL2022 |
| 30205 | 1009095380 | 03573026064396 | 08DEC2021 | 27SEP2022 |

**Description of 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), Lot 1008873250 and Lot 1008873260.

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.



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 find the root cause

By comparing results and raw material history, a likely root cause of invalid calibration over time could be the conjugate used to manufacture the strips. The investigation analysis of the raw materials showed that the profile of this lot of conjugate solution is similar to others, and there was no change in the process in connection with the issue

The four lots listed in Table 1 were manufactured with this same batch of conjugate solution; however, by comparing the change in S1 signal to other lots at the same time of their shelf life, only Lot 1008873250 and Lot 1008873260 are showing a different evolution. The signal of the S1 for those two lots has a significant increase while it is stable for the two others: Lots 1008988860 and 1009095380.

In conclusion, though the current probable root cause is linked to the same conjugate solution lot used for four impacted lots in the scope of this issue, the evolution difference and increased signal is noted only on Lot 1008873250 and Lot 1008873260. These two lots are associated with the noted increase in customer complaints. The investigation has not confirmed any defect in the similar raw material used in all four of these lots, and bioMérieux continues to monitor closely the signal evolution regarding the standard S1 of all the lots on the market.

**Impact to User:**

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.

**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 on each lot and on the monitoring of the signal evolution regarding the standard S1 of the calibration kits.

- *** Part I: Required actions regarding Lot 1008873250 and Lot 1008873260**

    - Stop using and destroy any stock of Lot 1008873250 and Lot 1008873260 of VIDAS® CMV IgM (Ref. 30205, 30205-01).
    - 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 Lot 1008988860 and Lot 1009095380**

- 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.

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 5537 - VIDAS® CMV IgM Ref. 30205, 30205-01 – Calibration issue

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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 lot of VIDAS® CMV IgM (Ref. 30205, 30205-01) Lot 1008873250 and Lot 1008873260 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 | 1008873250 | | |
| 30205-01 | VIDAS® CMV IgM | 1008873260 | | |

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