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

Address
City, Date

Our reference: FSCA #5286

IMPORTANT:

URGENT FIELD SAFETY NOTICE

Ref. 30237 - VIDAS® EBV VCA IgM

Calibration issue with a potential risk of delayed results and false negative results

Dear bioMérieux Customer,

Our records indicate that your laboratory received the lot indicated in table 1 below.

Table 1: List of impacted lots:

Product	Reference	Lot #	Expiry date
VIDAS® EBV VCA IgM	30237	1008591990	27-Jan-2022

Description of the issue:

Based on complaints reported from the field for invalid calibration with VIDAS® EBV VCA IGM (Ref. 30237) lot. #1008591990 due to S1 value out-of-range too low, bioMérieux has initiated an investigation to confirm product issue and identify the root cause.

To date, the investigation confirmed the calibration issue on the impacted lot.#1008591990.

Also, the investigation showed that all internal samples used for the control of this lot were within their specifications. There were no false negative results.

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

Other lots of the product reference VIDAS® EBV VCA IGM (Ref. 30237) are conform to the specifications and will be monitored closely until the root cause is identified.

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. Also, as the root-cause has not been identified yet, bioMérieux still doesn't know if the issue is related to a decrease of the S1 value or related to the strip. Therefore, there is a potential risk of false negative result between the last

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valid calibration and the first invalid calibration, 28 days later (as per recommendation for recalibration of the kit). In this case, between both calibrations, there is a potential risk of false negative result if you have not tested a control in parallel of the sera.

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.
- Stop using and destroy any kits of lot. #1008591990 in Table 1 remaining in your inventory.
- Discuss any concerns you may have regarding previously reported patient results obtained since the last valid calibration with your Laboratory Medical Director to determine the appropriate course of action. Results should be reviewed and interpreted in the context of the overall clinical picture.

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 5286 - VIDAS® EBV VCA IGM Ref. 30237 – 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® EBV VCA IGM Ref. 30237 – Calibration issue"**

❑ I will implement the required actions, stop using and destroy the affected lot of **VIDAS® EBV VCA IGM Ref. 30237** 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

Product	Reference	Lot #	Quantity Received	Quantity Destroyed
VIDAS® EBV VCA IGM	30237	1008591990		

DATE …… **SIGNATURE** : ……