



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

23.03.2021.

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.



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

TO BE RETURNED TO YOUR BIO-MERIEUX CONTACT – A&B D.O.O.

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 :



Dodatak A: Obrazac potvrde primitka

URGENT FIELD SAFETY NOTICE

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

ISPUNJENI OBRAZAC VRATITI KONTAKTU ZA BIOMERIEUX - A&B D.O.O.

Ime laboratorija:

Grad:

Oznaka (broj) kupca:

- Potvrđujem primitak bioMérieux obavijesti vezane za “VIDAS® CMV IgM - Ref. 30205 ; 30205-01 – Calibration issue”
- Napraviti ću zahtjevane radnje, zaustaviti upotrebu i uništiti LOT brojeve navedene u tablici 1 kako je navedeno u ovoj obavijesti.
- Je li ova situacija imala utjecaj na rezultate pacijenata ili imate saznanja o bolestima ili ozljedama vezanim za ovu situaciju?
 - Da
 - Ne

Kat.br. #	Naziv proizvoda	Lot #	Zaprimljena količina	Količina za uništenje
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		

DATUM.....

POTPIS :