

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® - VIDAS® DENGUE NS1 AG 60T - Ref 423077 - Calibration Issue

Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Laboratory Medical Director

August 2023
bioMérieux Nordic countries
Customer Service Department
Direct no.: +46 31 68 58 58

Our reference: FSCA 5784

Impacted products			
Product Name	Reference Number	Lot Number/Serial Number/ Product version	Product Expiration Date
VIDAS® DENGUE NS1 AG 60T	423077	1009977620	04-Sep-2024

Dear bioMérieux Customer,

Our records indicate that your laboratory received products listed in table above.

The aim of this communication is to inform you about calibration issues with VIDAS® DENGUE NS1 AG 60T (Ref. 423077) lot 1009977620 due to S1 value out-of-range high.

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Required actions

In this context, we request you to take the following actions. Please:

- Stop using and destroy the impacted lot 1009977620.
- 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.
- Complete the Acknowledgement Form in Attachment A and return it to bioMérieux to confirm receipt of this notice. It is important that you return the acknowledgement form to bioMérieux even if you determine that this urgent product safety notice does not impact your facility.

Description of the issue

bioMérieux received complaints from the field for invalid calibration with VIDAS® DENGUE NS1 AG 60T (Ref. 423077) lot 1009977620 due to S1 value out-of-range high and confirmed the product issue on this batch in our complaints laboratory.

An investigation is in progress to identify the root cause of invalid calibration on the lot 1009977620.

To date, the issue was not confirmed on other lots of VIDAS® DENGUE NS1 AG 60T (Ref. 423077) available on the market, and the evolution of the calibration of all VIDAS® DENGUE NS1 AG 60T (Ref. 423077) lots available on the field will be closely monitored until the root cause is identified.

Impact to Patients

Invalid calibration due to S1 out of range too high is associated with a risk of delayed patient results.

The risk of false results was excluded, the serologic interpretation is not impacted by the evolution of the calibration. The calibration would be out of range before the result of the assay is misinterpreted.

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

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Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY/CORRECTIVE NOTICE

5784 - FSCA - VIDAS® DENGUE NS1 AG 60T - Ref 423077 - Calibration Issue

TO BE RETURNED TO YOUR BIOMERIEUX CUSTOMER SERVICE BY REPLYING TO THE EMAIL IN WHICH THIS FSCA WAS COMMUNICATED

Name and Address of the laboratory	
Contact information	
Customer Account Number	

I am not impacted by the issue. Please provide rationale:

I have implemented the required actions.

REF #	Product Name	Batch #	Quantity received	Quantity used	Quantity destroyed	Quantity returned*
423077	VIDAS® DENGUE NS1 AG 60T	1009977620				N/A

* Quantity returned to bioMérieux or distributor

Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue?

Yes No

DATE.....SIGNATURE.....

It is important that you complete this Acknowledgement Form and return it to bioMérieux

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