FSCA
FIELD SAFETY CORRECTIVE ACTION

BIOMÉRIEUX

IMPORTANT:

URGENT FIELD SAFETY/CORRECTIVE NOTICE

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

Date

bMx local contact information

(to be adapted at local level)

Our reference: FSCA 5803

Impacted products ***(to be adapted at local level if necessary including for names and ref #, local license #, name and address of manufacturer)***			
Product Name	**Reference Number**	**Lot Number/Serial Number/ Product version**	**Product Expiration Date**
VIDAS® DENGUE NS1 AG 60T	423077	1010033400	10-Oct-2024
VIDAS® DENGUE NS1 AG 60T	423077	1010098270	05-Nov-2024
VIDAS® DENGUE NS1 AG 60T	423077	1010150640	19-Dec-2024
VIDAS® DENGUE NS1 AG 60T	423077	1010208490	27-Jan-2025

Dear bioMérieux Customer,

Our records indicate that your laboratory received at least one of the lots of VIDAS® DENGUE NS1 AG 60T (Ref. 423077) listed in the table above.

The aim of this communication is to inform you that you may encounter an invalid calibration with one of the above-listed lots of VIDAS® DENGUE NS1 AG 60T (Ref. 423077) due to S1 value out-of-range high.

Required actions

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

- Keep using impacted lot as long as you don't encounter an invalid calibration
- You will receive in the coming days at least one kit of another lot. Upon receipt of this kit, calibrate it and keep it in your stock as a back-up in case you encounter invalid calibration with impacted lots.
- If you encounter a calibration issue with impacted lots, use the back-up kit already provided. In parallel, immediately contact your local customer service to order a new kit (free of charge) of non-impacted lots.
- 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 *your local bioMérieux representative (to be adapted at local level)* 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 correction notice/information/recommendation *(to be adapted based on issue)* does not impact your facility.

[in the event of different actions depending on lots/products/serial numbers, please ensure that actions are clearly distinguished in order to ease the adaptation at local level based on lots/batches/serial numbers available]

Description of the issue

BioMérieux identified that four lots: 1010033400, 1010098270, 1010150640, 1010208490 of VIDAS® DENGUE NS1 AG 60T (Ref. 423077) have an S1 signal evolution that is already close to the upper limit of the MLE range which could lead to an invalid calibration.

According to the product's Instructions For Use, "Calibration, using the standard provided in the kit, must be performed each time a new lot of reagents is opened, after the MLE data have been entered, and then every 56 days. The standard, identified by S1, must be tested in duplicate . The standard value must be within the set RFV (Relative Fluorescence Value) range. If this is not the case: recalibrate using S1."

Therefore, an invalid calibration is not considered as a product malfunction. To be noted that, when the calibration is invalid, a message is displayed on the VIDAS® report showing that the calibration is invalid and the customer should not release patient results if they are preceded by an invalid

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Legal notice / Mentions légales de la société émettrice

calibration. **Therefore, there is no impact on patient sample results and no risk of false results. The only risk related to an invalid calibration is a potential delayed result as the rest of the kit would not be usable.**

While the investigation is ongoing, the following were identified:

- The four impacted lots were all produced on a similar manufacturing set-up (process and raw materials), and are therefore included in the scope of this urgent field safety notice.
- For the next lots, changes were made to the raw materials and their S1 signal evolution is still low. Therefore, they are not included in the scope of this urgent field safety notice. **Those lots are already available in the field to ensure continuation of your activities.** These lots and all future lots will be closely monitored (calibrations and complaints) until the issue is fixed.

Impact to User/Customer/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.

Local legal mentions to be added if necessary at local level (e.g. in case of recall, reporting to NCA, recall methods)

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 (to be adapted at local level)*.

Yours faithfully,

Customer Service

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY/CORRECTIVE NOTICE

FSCA 5803 – VIDAS® DENGUE NS1 AG 60T - Ref 423077 - Calibration Issue

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TO BE RETURNED TO *YOUR BIOMERIEUX CUSTOMER SERVICE (TO BE ADAPTED AT LOCAL LEVEL)*
AT THE FOLLOWING
FAX NUMBER: XXXXXXXX OR EMAIL ADDRESS: XXXXXXX

Name and Address of the laboratory	
Contact information	
Customer Account Number	

Local legal mentions to be added if necessary at local level)

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

☐ I have implemented the required actions.

Table to be added and adapted if necessary to monitor quantities received/discarded (products names and ref.# to be adapted at local level if necessary) depending on the required actions.

If reagent, please use the following table:

REF #	Product Name	Batch #	Quantity used
423077	VIDAS® DENGUE NS1 AG 60T	1010033400	
423077	VIDAS® DENGUE NS1 AG 60T	1010098270	
423077	VIDAS® DENGUE NS1 AG 60T	1010150640	
423077	VIDAS® DENGUE NS1 AG 60T	1010208490	

Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue ? *(to be completed based on FCA/FSCA issue)*

☐ Yes ☐ No

DATE……SIGNATURE……

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