

IMPORTANT:

URGENT FIELD SAFETY NOTICE

VIDAS® DENGUE NS1 Ag (ref. 423077) - Invalid calibration

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 - FIELD SAFETY CORRECTIVE ACTION - FA-TWD-000016

Subsidiary name (if applicable) / Nom de la filiale (si approprié)

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 (if applicable)
VIDAS® DENGUE NS1 Ag	423077	1010311970	26-MAR-2025
VIDAS® DENGUE NS1 Ag	423077	1010360350	23-APR-2025
VIDAS® DENGUE NS1 Ag	423077	1010360380	23-APR-2025
VIDAS® DENGUE NS1 Ag	423077	1010449760	10-JUN-2025
VIDAS® DENGUE NS1 Ag	423077	1010550540	31-JUL-2025
VIDAS® DENGUE NS1 Ag	423077	1010652000	18-AUG-2025
VIDAS® DENGUE NS1 Ag	423077	1010696870	16-OCT-2025
VIDAS® DENGUE NS1 Ag	423077	1010772810	20-NOV-2025

Dear bioMérieux Customer,

Our records indicate that your laboratory may be using or may have used VIDAS® DENGUE NS1 Ag (ref. 423077) products listed in 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 (Ref. 423077) due to S1 value out-of-range high.

Our teams are currently implementing improvements on both manufacturing process and MLE range calculation in order to avoid this issue from occurring again. The first batch including those improvements will be released in October 2024.

Subsidiary name (if applicable) / Nom de la filiale (si approprié)

Required actions

In this context, we request you to take the following actions. 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.
- Keep using impacted lot as long as you don't encounter an invalid calibration.
- If you encounter a calibration issue with impacted lots, contact your local customer service to order a new kit (free of charge).
- We remind you to follow the storage conditions as mentioned in the package insert of VIDAS® DENGUE NS1 Ag (Ref. 423077):
 - Store the kit at +2°C/+8°C.
 - Do not freeze reagents.
 - Store all unused reagents at +2°C/+8°C.
 - After opening the kit, check that the SPR pouches are correctly sealed and undamaged. If not, do not use the SPR devices.
 - After use, carefully reseal the pouch with the desiccant inside to maintain stability of the SPR devices, and return the complete kit to +2°C/+8°C.
 - If stored according to the recommended conditions, all components are stable until the expiration date indicated on the box label.
- 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.

Description of the issue

Following complaints from the field and monitoring of S1 signal of VIDAS® DENGUE NS1 AG 60T (Ref. 423077), bioMérieux identified that eight lots of VIDAS® DENGUE NS1 AG 60T (Ref. 423077) have an S1 signal evolution that is close to the upper limit of the MLE range which could lead to an invalid calibration.

Subsidiary name (if applicable) / Nom de la filiale (si approprié)

While the investigation and the monitoring are still ongoing, the following were identified:

- The eight impacted lots of VIDAS® DENGUE NS1 Ag (ref. 423077, lots: 1010311970, 1010360350, 1010360380, 1010449760, 1010550540, 1010652000, 1010696870, 1010772810) show a similar trend in the evolution of the S1 signal, approaching the upper limit of the MLE ranges, and are therefore included in the scope of this urgent field safety notice.
- For the next lots, improvement of manufacturing process and MLE range calculation are optimized for the release of future lots of VIDAS® DENGUE NS1 Ag (ref. 423077). All future lots will be closely monitored (calibrations and complaints) until the issue is fixed.

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 calibration.

Therefore, there is 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.

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.

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



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

Subsidiary name (if applicable) / Nom de la filiale (si approprié)

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



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

**FSCA - FIELD SAFETY CORRECTIVE ACTION FA-TWD-000016
VIDAS® DENGUE NS1 Ag (ref. 423077) - Invalid calibration**

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

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.

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

Subsidiary name (if applicable) / Nom de la filiale (si approprié)