

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® MYOGLOBINE 30 TESTS - 30446 - Lot 1010749670 - SPR Encoding Problem

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-000026

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® MYOGLOBINE 30 TESTS	30446	1010749670	27-MAY-2025

Dear bioMérieux Customer,

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

The aim of this communication is to inform you about SPR Encoding Problem **with VIDAS® MYOGLOBINE 30 TESTS – Ref. 30446 lot #1010749670 when used in conjunction with VIDAS 3 and / or VIDAS KUBE instruments only. There is no issue with this lot when used with VIDAS PC and Mini VIDAS instruments.**

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

Required actions

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

- Upon receipt of this letter, in case you are using VIDAS® MYOGLOBINE 30 TESTS – Ref. 30446 in conjunction with VIDAS 3 and/or VIDAS KUBE instruments, please order a new kit of VIDAS® MYOGLOBINE 30 TESTS Reference 30446 or replace kit of lot 1010749670 by another one in your inventory. Discard the kits of lot 1010749670 remaining in your inventory.

If you are using VIDAS® MYOGLOBINE 30 TESTS – Ref. 30446 with other types of VIDAS instruments (i.e. MiniVIDAS, VIDAS PC), you are not impacted by the issue and you can still use the lot 1010749670.

- 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.

Description of the issue

bioMérieux has received several complaints from customers about an impossibility to run tests with VIDAS® MYOGLOBINE 30 TESTS - 30446, lot 1010749670 because they got the error message "The SPR does not match the MYO analysis planned. Solution: load a MYO SPR and restart the section" on their VIDAS 3 instrument or "No MLE data linked to SPR" on VIDAS® their KUBE instrument. **Only VIDAS 3 and VIDAS® KUBE customers could face the issue.**

The only risk associated to the referenced issue is a potential delay in reporting result, there is no risk of false result.

An investigation has identified the cause of the issue that is linked to a defect on one equipment during the Solid Phase Receptacle (SPR) sealing step. The defect has been fixed immediately

No other lot of VIDAS® MYOGLOBINE 30 TESTS or other VIDAS® parameters for clinical use were impacted by the issue.

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



Impact to User/Customer/Patients

The SPR Encoding Problem is associated with a potential risk of delayed patient results.

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

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



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

**FSCA - FIELD SAFETY CORRECTIVE ACTION FA-TWD-000026
VIDAS® MYOGLOBINE 30 TESTS - 30446 - Lot 1010749670 - SPR
Encoding Problem**

**TO BE RETURNED TO YOUR *BIOMERIEUX* 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 as I am using other instruments (VIDAS PC, Mini VIDAS).
- I am using VIDAS 3 and/or VIDAS KUBE instruments only and 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.

REF #	Product Name	Batch #	Quantity received	Quantity used	Quantity destroyed	Quantity returned*
30446	VIDAS® MYOGLOBINE 30 TESTS	1010749670				

* Quantity returned to bioMérieux or distributor

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



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)