



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

Address
City, Date

Our reference: FSCA 4647

IMPORTANT:

URGENT FIELD SAFETY NOTICE

Ref. 30458 – VIDAS® NT-proBNP2 – lots 1007679480 and 1007679500

Error analysis during calibration on VIDAS® PC instrument

Dear bioMérieux Customer,

Our records indicate that your laboratory received VIDAS® NT-proBNP2 (Ref. 30458) – lots 1007679480 and 1007679500 exp. 16-Oct-2020.

Description of the issue

VIDAS® NT-proBNP2 (PBN2) is an automated quantitative test for use on the instruments of the VIDAS® family for the determination of N-terminal fragment of Brain-type natriuretic peptide in human serum or plasma (lithium and sodium heparin) using the ELFA technique (Enzyme-Linked Fluorescent Assay). The VIDAS® NT-proBNP2 (PBN2) test is used as an aid in the diagnosis of suspected heart failure.

Following customers' complaints about error analysis during calibration, bioMérieux investigation has confirmed an issue with the specific lots 1007679480 and 1007679500 of VIDAS® NT-proBNP2 (Ref. 30458) on VIDAS® PC instrument.

The investigation confirmed that the calibration of lots 1007679480 and 1007679500 cannot be performed on VIDAS® PC instrument. At the end of the calibration analysis on the VIDAS® PC instrument, an error message "Error Analysis" is obtained. The tests performed during the investigation showed that the issue occurs only with lots 1007679480 and 1007679500 when using VIDAS® PC instrument. Indeed, this issue does not occur when lots 1007679480 and 1007679500 are used on the VIDAS® 3 or on the MINI VIDAS® instruments and when other lots of VIDAS® NT-proBNP2 are used on any VIDAS® instrument.

The investigation and root cause analysis are still ongoing.

Impact to customer:

As the calibration for these specific lots 1007679480 and 1007679500 cannot be performed on VIDAS® PC instrument, it is not possible to obtain results of patients' samples.

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The main risk caused by this issue is a delayed result for the patient as the patient samples cannot be tested if calibration is invalid and if no other lot is available in the laboratory. There is also a risk of sample loss when calibration is launched concomitantly with sample testing.

There is no risk of false result because the equipment cannot give any result as the calibration failed.

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.
- Stop using and destroy any stock of lots 1007679480 and 1007679500 of VIDAS® NT-proBNP2 (Ref. 30458) you might have in your laboratory.

To avoid confusion in the customers' laboratories, this removal is applicable to all customers having received the affected lots 1007679480 and 1007679500 regardless of the VIDAS® instrument used (VIDAS® PC, VIDAS® 3 or MINI VIDAS®)

- 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.

bioMérieux is committed to provide 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 4647 - VIDAS[®] NT-proBNP2 Ref. 30458 - lots 1007679480 and 1007679500 - Error analysis during calibration on VIDAS[®] PC instrument

**TO BE RETURNED TO YOUR BIO-MERIEUX CUSTOMER SERVICE AT THE FOLLOWING
FAX NUMBER : XXXXXXXX**

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “VIDAS[®] NT-proBNP2 - Ref. 30458 lots 1007679480 and 1007679500 - Error analysis during calibration on VIDAS[®] PC instrument”
- I will implement the required actions, stop using and destroy the affected lots 1007679480 and 1007679500 of VIDAS[®] NT-proBNP2 (Ref. 30458) as indicated in the Urgent Field Safety Notice.
- Have you encountered patient’s delayed results, or reports of illness or injury related to the identified issue ?
 - Yes No

DATE

SIGNATURE :