

IMPORTANT:

URGENT FIELD SAFETY NOTICE

VIDAS® FPSA - Ref. 30440 - Slow Drift leading to potential Overestimated Result

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-000006

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® FPSA	30440	1009453100	23-May-23
VIDAS® FPSA	30440	1009487340	21-Jun-23
VIDAS® FPSA	30440	1009584820	18-Aug-23
VIDAS® FPSA	30440	1009650220	12-Sep-23
VIDAS® FPSA	30440	1009698340	13-Oct-23
VIDAS® FPSA	30440	1009807810	13-Dec-23
VIDAS® FPSA	30440	1009875100	17-Jan-24
VIDAS® FPSA	30440	1009916000	08-Feb-24
VIDAS® FPSA	30440	1009971000	12-Mar-24
VIDAS® FPSA	30440	1010036350	12-Apr-24
VIDAS® FPSA	30440	1010130650	11-Jun-24
VIDAS® FPSA	30440	1010229580	01-Aug-24
VIDAS® FPSA	30440	1010274360	03-Sep-24
VIDAS® FPSA	30440	1010357680	16-Oct-24
VIDAS® FPSA	30440	1010462360	04-Dec-24
VIDAS® FPSA	30440	1010540310	11-Jan-25
VIDAS® FPSA	30440	1010630590	15-Mar-25

Dear bioMérieux Customer,

Our records indicate that your laboratory may be using or may have used VIDAS® FPSA (Ref. 30440) products listed in table above.

An overestimation of FPSA results when using VIDAS® FPSA Ref. 30440 has been identified. The aim of this communication is to inform you of the issue and to provide guidance on the continued use of the product, including the application of a corrected threshold when communicating FPSA results and FPSA/TPSA ratio results to clinicians.

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

Required actions

In this context, please take the following actions.

- Follow the guidance in this letter as follows:
 - **For new testing performed with the impacted lots**, you can continue using the kits by applying a corrected threshold described below.
 - **For patient results obtained between May 2023 to current using the impacted lots**, bioMérieux suggests you discuss any concern you may have with your laboratory director or your clinician to potentially review the result applying the corrected thresholds detailed below. Results should be reviewed and interpreted in the overall clinical context as this test is an aid of diagnosis.

CORRECTED THRESHOLD ADJUSTMENTS

Example of Table Use: If you are using **15%** and above as the decision threshold for the FPSA/TPSA ratio for considering BPH to be more likely, then the corrected threshold percentage to use would be **18%**.

Decision Threshold Used for FPSA/TPSA Ratio for Considering BPH to be More Likely	Corrected Threshold Percentage to be Used
15%	18%
16%	19%
17%	20%
18%	22%
19%	23%
20%	24%
21%	25%
22%	26%
23%	27%
24%	29%
25%	30%

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

- 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 does not impact your facility.

Description of the issue

An overestimation of FPSA results when using VIDAS® FPSA (Ref. 30440) lots listed above was internally detected, now identified as resulting from a slow drift of the adjustment panel used in the Quality Control calibration process.

The IFU currently states that an FPSA/TPSA ratio <18% is more indicative of prostate cancer and a ratio of 18% or greater is more indicative of BPH. Taking the overestimated FPSA into account, a corrected FPSA/TPSA ratio threshold was identified for patient results obtained using the impacted lots of FPSA Ref. 30440 listed above. This will allow you to continue the use of involved products by applying the corrected threshold.

In the meantime, a corrective action at the manufacturing site was already implemented to correct the issue and manufacture new lots within the performance claims. All new manufactured lots to be released will be conform to performance claims. The new conforming lot (Lot 1010713540) will be manufactured in the upcoming weeks and will not require any correction to be applied.

As a reminder, FPSA testing may be performed to differentiate between prostate cancer and BPH following an initial measurement of TPSA indicating 4 – 10 ng/mL range, with close monitoring of concerned patients in this range. Repeating TPSA and FPSA testing may be considered by the urologist and the patient before performing a prostate biopsy and is usually done before 12 months, depending on the patient's history, results of any other tests performed and on the urologist's advice.

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



Impact to User/Customer/Patients

The potential risk associated with the issue is an overestimated FPSA concentration leading to overestimated ratio of FPSA/TPSA.

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-000006
VIDAS® FPSA - Ref. 30440 - Slow Drift leading to potential
Overestimated Result**

**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. 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 ?

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)