



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

Address
City, Date

Our reference: FSCA #5698

IMPORTANT:
URGENT FIELD SAFETY NOTICE
Ref. 30459 - VIDAS® FT4 60 TEST
Underestimated results with patient samples

Dear bioMérieux Customer,

Our records indicate that your laboratory received at least one of the lots of VIDAS® FT4 60 TEST (Ref. 30459) indicated in table 1 below.

Table 1: List of impacted lots:

Reference	Product	Lot #	Expiry
30459	VIDAS® FT4 60 TEST	1009142040	02-Dec-2022
30459	VIDAS® FT4 60 TEST	1009140070	10-Dec-2022
30459	VIDAS® FT4 60 TEST	1009168620	28-Dec-2022
30459	VIDAS® FT4 60 TEST	1009384040	28-Apr-2023
30459	VIDAS® FT4 60 TEST	1009434270	01-Jun-2023

Description of the issue:

Following complaints from the field for underestimated results on patient samples using VIDAS® FT4 60 TEST (Ref. 30459) lots #1009142040 and #1009140070. bioMérieux initiated investigation to confirm product issue and identify the root cause.

According to the first investigation results, the underestimated results are more important on the euthyroid zone, switching interpretation of results from euthyroidism to hypothyroidism. According to the Product Instructions for Use of VIDAS® FT4 60 TEST (Ref. 30459), assay results should be interpreted as a part of a complete clinical evaluation and thyroid function assessment, including at least TSH level measurement.

While the investigation is ongoing, the followings were identified:

- Investigation showed that batches. #1009142040, #1009140070 and a third batch #1009168620 listed in table 1 contain the same lot of standard S1 (lot 2055910). The signal of this lot of S1 shows a more important decrease over time compared to other lots of S1 contained in other batches of VIDAS® FT4 60 TEST (Ref. 30459).
- Investigation was done on the raw materials used for standard S1 (lot 2055910) compared to other lots of S1 that don't show an important decrease of signal over the product's shelf life. The S1 (lot

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



2055910) contains a same raw material (human serum) reference while the other S1 lots contain another raw material (human serum) reference..

- Two other lots of S1 containing the same raw material (human serum) reference used in S1 (lot 2055910), were used in the manufacturing of two other batches of VIDAS® FT4 60 TEST: 1009384040 and 1009434270 listed in Table 1. A stability study was conducted to see if the suspected raw material (serum) has an impact on those 2 other S1 lots. The study's results seem to show a similar behavior between lots 2089010, 2100360 and lot 2055910 of S1 which contain the suspected raw material reference. This reinforces the most probable root cause is related to this specific raw material reference.

Therefore, we cannot exclude that those 2 batches of VIDAS® FT4 60 TEST (Ref. 30459) manufactured with those 2 lots of S1 could have the same issue over time

- The characterization of the suspected serum has been launched and a research on potential factors related to the process is ongoing

As a conclusion, to date, the investigation shows that there is a more important decrease of the signal for lot 2055910 of S1 and potentially lots 2089010 and 2100360 of S1 manufactured with a same raw material reference and used to produce 5 batches of VIDAS® FT4 60 TEST (Ref. 30459) listed in table 1.

This more important decrease of the stability of the S1 could lead to potential underestimated results.

Impact to customer:

The more important decrease of the stability of the S1 could lead to potential underestimated results.

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 lots of VIDAS® FT4 60 TEST (Ref. 30459) listed in Table 1 and destroy the kits of those lots remaining in your inventory.
- Discuss any concerns you may have regarding previously reported patient results obtained with lots of VIDAS® FT4 60 TEST (Ref. 30459) listed in Table 1 with your Laboratory Medical Director to determine the appropriate course of action.

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.

Yours faithfully,

Customer Service



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5698 - VIDAS® FT4 60 TEST Ref. 30459 – Underestimated results with patient samples

**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® FT4 60 TEST Ref. 30459 – Underestimated results with patient samples**”
- I will implement the required actions, stop using and destroy the affected lot of **VIDAS® FT4 60 TEST Ref. 30459 – Underestimated results with patient samples** as indicated in the Urgent Field Safety Notice.
- Have you encountered impact on patients’ results, or reports of illness or injury related to the identified issue ?
 - Yes No

Product	Reference	Lot #	Quantity Received	Quantity Destroyed
VIDAS® FT4 60 TEST	30459	1009142040		
VIDAS® FT4 60 TEST	30459	1009140070		
VIDAS® FT4 60 TEST	30459	1009168620		
VIDAS® FT4 60 TEST	30459	1009384040		
VIDAS® FT4 60 TEST	30459	1009434270		

DATE

SIGNATURE :