



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

Address
City, Date

Our reference: FSCA 4924

IMPORTANT:
URGENT FIELD SAFETY NOTICE
Ref. 30459 – VIDAS® FT4
Batch heterogeneity

Dear bioMérieux Customer,

Our records indicate that your laboratory received the following bioMérieux product :

REF #	Product Name	Lot #	Exp. Date
30459	VIDAS® FT4	1007821050	21-Dec-2020

Description of the issue

VIDAS® FT4 is an automated quantitative enzyme immunoassay for use with the instruments of the VIDAS® family, to determine free thyroxine (FT4) in human serum or plasma (lithium heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay). Measurement of Free Thyroxin is intended for use as an aid in the diagnosis and treatment monitoring of thyroid disorders.

Fortuitously, bioMérieux identified an heterogeneity issue on the batch 1007821050 of VIDAS® FT4 (ref. 30459).

This is due to a punctual issue that occurred during the control of the lot before release. To be noted that no other lot is impacted by this anomaly.

Impact to customer:

The investigation allowed to conclude that this heterogeneity can lead to 3 types of situations :

- Underestimated VIDAS® FT4 results
- Overestimated VIDAS® FT4 results
- Invalid calibration: in this case there is no risk of false result.

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



As indicated in the instructions for use, VIDAS® FT4 assay results should be interpreted as part of a complete clinical evaluation and thyroid function assessment, including at least TSH determination.

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 VIDAS® FT4 (Ref. 30459) lot 1007821050 remaining in your inventory.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.
- Discuss any concerns you may have regarding previously reported patients results obtained with lot 1007821050 of VIDAS® FT4 (Ref. 30459) with your Laboratory Medical Director to determine the appropriate course of action. Results should be reviewed and interpreted in the context of the overall clinical picture and/or in case of inconsistencies noticed by the clinicians.
- Please contact your local customer service if you have any question.

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 4924 - VIDAS® FT4 Ref. 30459 - Batch Heterogeneity

**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 - Ref. 30459 – Batch Heterogeneity ”
- I will implement the required actions, stop using and destroy the affected lot 1007821050 of VIDAS® FT4 (Ref. 30459) 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

REF #	Product Name	Lot #	Quantity received	Quantity discarded
30459	VIDAS® FT4	1007821050		

DATE

SIGNATURE :