



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

Address
City, Date

Our reference: FSCA #5708

IMPORTANT:
URGENT FIELD SAFETY NOTICE
Ref. 423111- VIDAS® TB IGRA 60 TESTS
False positive results

Dear bioMérieux Customer,

Our records indicate that your laboratory received at least one of the lots of VIDAS® TB IGRA 60 TESTS (Ref. 423111) indicated in table 1 below.

Table 1: List of impacted lots:

Reference	Product	Lot #	Expiry
423111	VIDAS® TB IGRA 60 TESTS	1008446570	22-Feb-2022
423111	VIDAS® TB IGRA 60 TESTS	1008800300	22-Feb-2022
423111	VIDAS® TB IGRA 60 TESTS	1008800310	02-Mar-2022
423111	VIDAS® TB IGRA 60 TESTS	1008454760	02-Mar-2022
423111	VIDAS® TB IGRA 60 TESTS	1008779880	28-Apr-2022
423111	VIDAS® TB IGRA 60 TESTS	1008949330	26-Feb-2023
423111	VIDAS® TB IGRA 60 TESTS	1009196920	14-Jan-2024
423111	VIDAS® TB IGRA 60 TESTS	1009233340	01-Feb-2024
423111	VIDAS® TB IGRA 60 TESTS	1009376590	04-Apr-2024
423111	VIDAS® TB IGRA 60 TESTS	1009376580	05-Apr-2024
423111	VIDAS® TB IGRA 60 TESTS	1009371190	19-Apr-2024

Description of the issue:

In July 2022, two proficiency studies coordinated by bioMérieux using 3 lots of VIDAS® TB IGRA 60 TESTS (Ref. 423111), showed an unexpected positivity rate on one of the lots for a population at low risk of latent tuberculosis (blood donors). For those two studies, preanalytical steps were reviewed and were found to be correctly executed. Therefore, they could not explain the observed high positivity rate. In parallel, some complaints for potential false positive results were received from the field.

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



Thus, bioMérieux initiated an investigation to confirm the product issue and identify the root cause:

- all lots available on the market and not already expired were tested or are currently under testing by R&D department on samples coming from population at low risk of latent tuberculosis (mainly blood donor samples from Rhones Alpes region in France). To date, we observed unexpected positivity rates varying from one lot to another.
- interchanging kit components between a lot with low positivity and a lot with high positivity demonstrated that unexpected high positivity rates are not carried by stimulation vials as previously thought, but by the strip.
- the unexpected high positivity rate seems to be triggered by an unidentified component of a specific well of the strip where the stimulation occurs.
- investigations are ongoing to identify the responsible components of the strip with two main focus: non biological raw material used in strip manufacturing and/or a contamination of the strip.

As a conclusion, to date, the unexpected high positivity rate was confirmed on several lots of VIDAS® TB IGRA 60 TESTS. Even if R&D analysis did not highlight unexpected high positivity rates on all lots listed in table 1, we cannot exclude that all these lots could be impacted by the issue since the root cause is not yet identified.

Impact to customers:

Due to the referenced issue, there is a risk of potential false positive results when using the lots of VIDAS® TB IGRA 60 TESTS listed in table 1.

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.
- Please stop the use and discard lots of VIDAS® TB IGRA 60 TESTS (Ref. 423111) listed in table 1 remaining in your inventory.
- Discuss any concerns you may have regarding previously reported patient results obtained with lots 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 5708 - VIDAS® TB IGRA 60 TESTS Ref. 423111 – False positive results

**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® TB IGRA 60 TESTS Ref. 423111 – False positive results ”
- I will implement the required actions, stop using and destroy the affected lot of **VIDAS® TB IGRA 60 TESTS Ref. 423111 – False positive results** 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® TB IGRA 60 TESTS	423111	1008949330		
VIDAS® TB IGRA 60 TESTS	423111	1009196920		
VIDAS® TB IGRA 60 TESTS	423111	1009233340		
VIDAS® TB IGRA 60 TESTS	423111	1009376590		
VIDAS® TB IGRA 60 TESTS	423111	1009376580		
VIDAS® TB IGRA 60 TESTS	423111	1009371190		

DATE

SIGNATURE :