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

Address
City, Date

Our reference: FSCA#5333

IMPORTANT:

URGENT FIELD SAFETY NOTICE

VIDAS® HBC IGM II 30 TESTS (Ref. 30439)

Substrate Error – Potential delayed results

Dear bioMérieux Customer,

Our records indicate that your laboratory received one/several of the lots indicated in Table 1, below.

Description of the issue:

Based on an unusual rate of complaints from the field for "substrate error" leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

In case of substrate error, there is a potential of delayed results. There is no risk of false results

Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 1:**
    - Identify products listed in Table 1,
    - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
    - Continue product use until revised expiry date.

- Contact your local bioMerieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® HBC IGM II 30 TESTS (Ref. 30439) at 2-8°C as described in Product Instructions for Use.

- 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.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.

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

Table 1 : Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30439	1008636760	VIDAS HBC IGM II 30 TESTS	12-Mar-2022	23-Feb-2022
30439	1008888750	VIDAS HBC IGM II 30 TESTS	29-Jun-2022	08-Jun-2022

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333 - VIDAS® HBC IGM II 30 TESTS (Ref. 30439) - Substrate Error

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TO BE RETURNED TO YOUR BIOMERIEUX 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® HBC IGM II 30 TESTS (Ref. 30439) - Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® HBC IGM II 30 TESTS (Ref. 30439)** 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

DATE ..... **SIGNATURE** : .....