



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® HIGH SENSITIVE TROPONIN I 60 TESTS**  
**(Ref. 415386) and VIDAS® HS TROPONIN I 30**  
**TESTS (Ref. 415386-30)**  
**Substrate Error – Potential delayed results**

Dear bioMérieux Customer,

Our records indicate that your laboratory received one/several of the lots indicated in Table 1 and Table 2, 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

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



**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 or Table 2.

- **For products with No remaining shelf life (taking into account the revised expiry date) in Table 1:**
  - Identify impacted lots in Table 1,
  - Stop using the listed impacted lots
  - Destroy the remaining lots in your inventory.
  
- **For products with remaining shelf life (taking into account the revised expiry date) in Table 2:**
  - Identify products listed in Table 2,
  - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 2.
  - Continue product use until revised expiry date.
  
- Contact your local bioMérieux representative to order the replacement products when appropriate,
  
- As a reminder, please store the VIDAS® HIGH SENSITIVE TROPONIN I 60 TESTS (Ref. 415386) and VIDAS® HS TROPONIN I 30 TESTS (Ref. 415386-30) 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 NO remaining shelf life (taking into account the revised expiry date).**

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
415386	1008694760**	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	06-Jul-2022	13-Sep-2021
415386	1008727610**	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	29-Jul-2022	29-Sep-2021
415386	1008666230**	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	19-Jun-2022	25-Aug-2021
415386	1008576310**	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	08-May-2022	06-Jul-2021
415386	1008677520**	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	01-Jul-2022	25-Aug-2021

**\*\* Lots under PSS (Product Stop Shipment)**

**Table 2 : Product with remaining shelf life (taking into account the revised expiry date)**

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
415386	1008752990	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	11-Aug-2022	11-Oct-2021
415386	1008768930	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	24-Aug-2022	26-Oct-2021
415386	1008768940	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	21-Aug-2022	30-Oct-2021
415386	1008801930	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	02-Sep-2022	08-Nov-2021
415386	1008809020	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	10-Sep-2022	08-Nov-2021
415386	1008827440	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	17-Sep-2022	18-Nov-2021
415386	1008829290	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	16-Sep-2022	08-Nov-2021
415386	1008843450	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	23-Sep-2022	18-Nov-2021
415386	1008848240	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	30-Sep-2022	30-Nov-2021
415386	1008848270	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	30-Sep-2022	30-Nov-2021
415386	1008867160	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	09-Oct-2022	12-Dec-2021
415386	1008867170	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	09-Oct-2022	12-Dec-2021
415386	1008872350	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	08-Oct-2022	08-Dec-2021
415386	1008882110	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	15-Oct-2022	06-Dec-2021
415386	1008886390	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	19-Oct-2022	06-Dec-2021
415386	1008890790	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	18-Oct-2022	08-Dec-2021
415386	1008893760	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	26-Oct-2022	22-Dec-2021



415386	1008901930	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	28-Oct-2022	22-Dec-2021
415386	1008903780	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	29-Oct-2022	04-Jan-2022
415386	1008912850	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	04-Nov-2022	04-Jan-2022
415386-30	1008912800	VIDAS HS TROPONIN I 30 TESTS	04-Nov-2022	04-Jan-2022



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333 - VIDAS® HIGH SENSITIVE TROPONIN I 60 TESTS (Ref. 415386) and VIDAS® HS TROPONIN I 30 TESTS (Ref. 415386-30) - Substrate Error

TO BE RETURNED TO YOUR BIO-MERIEUX CUSTOMER SERVICE AT THE FOLLOWING FAX NUMBER : XXXXXXXXX

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the "VIDAS® HIGH SENSITIVE TROPONIN I 60 TESTS (Ref. 415386) and VIDAS® HS TROPONIN I 30 TESTS (Ref. 415386-30) – Substrate Error"
I will implement the required actions regarding impacted lots of VIDAS® HIGH SENSITIVE TROPONIN I 60 TESTS (Ref. 415386) and VIDAS® HS TROPONIN I 30 TESTS (Ref. 415386-30) 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 : .....