



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® BRAHMS PROCALCITONIN 60T (Ref. 30450, 30450-01 & 30450-86) and VIDAS® BRAHMS PROCALCITONIN 30T (Ref. 30450-30)**  
**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® BRAHMS PROCALCITONIN 60T (Ref. 30450, 30450-01 & 30450-86) and VIDAS® BRAHMS PROCALCITONIN 30T (Ref. 30450-30) 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
30450	1008591130**	VIDAS BRAHMS PROCALCITONIN 60T	15-Aug-2022	20-Sep-2021
30450	1008633310**	VIDAS BRAHMS PROCALCITONIN 60T	08-Sep-2022	28-Sep-2021
30450	1008641870**	VIDAS BRAHMS PROCALCITONIN 60T	08-Sep-2022	28-Sep-2021
30450-01	1008584190**	VIDAS BRAHMS PROCALCITONIN 60T	10-Aug-2022	19-Sep-2021
30450-01	1008603580**	VIDAS BRAHMS PROCALCITONIN 60T	22-Aug-2022	20-Sep-2021
30450-86	1008562400**	VIDAS BRAHMS PROCALCITONIN 60T	13-Jul-2022	06-Sep-2021
30450-86	1008594750**	VIDAS BRAHMS PROCALCITONIN 60T	21-Aug-2022	20-Sep-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
30450	1008661450	VIDAS BRAHMS PROCALCITONIN 60T	21-Sep-2022	26-Oct-2021
30450	1008722440	VIDAS BRAHMS PROCALCITONIN 60T	27-Oct-2022	30-Nov-2021
30450	1008741790	VIDAS BRAHMS PROCALCITONIN 60T	07-Nov-2022	30-Nov-2021
30450	1008769030	VIDAS BRAHMS PROCALCITONIN 60T	24-Nov-2022	31-Dec-2021
30450	1008796890	VIDAS BRAHMS PROCALCITONIN 60T	11-Dec-2022	31-Dec-2021
30450	1008784200	VIDAS BRAHMS PROCALCITONIN 60T	30-Nov-2022	09-Jan-2022
30450	1008817120	VIDAS BRAHMS PROCALCITONIN 60T	15-Dec-2022	24-Jan-2022
30450	1008886330	VIDAS BRAHMS PROCALCITONIN 60T	18-Jan-2023	08-Feb-2022
30450	1008926040	VIDAS BRAHMS PROCALCITONIN 60T	08-Feb-2023	21-Mar-2022
30450-01	1008647850	VIDAS BRAHMS PROCALCITONIN 60T	14-Sep-2022	18-Oct-2021
30450-01	1008748010	VIDAS BRAHMS PROCALCITONIN 60T	14-Nov-2022	30-Nov-2021
30450-01	1008888030	VIDAS BRAHMS PROCALCITONIN 60T	19-Jan-2023	12-Feb-2022
30450-01	1008903210	VIDAS BRAHMS PROCALCITONIN 60T	31-Jan-2023	21-Feb-2022



30450-01	1008926050	VIDAS BRAHMS PROCALCITONIN 60T	08-Feb-2023	21-Mar-2022
30450-30	1008741800	VIDAS BRAHMS PROCALCITONIN 30T	07-Nov-2022	30-Nov-2021
30450-30	1008926060	VIDAS BRAHMS PROCALCITONIN 30T	08-Feb-2023	21-Mar-2022
30450-86	1008784190	VIDAS BRAHMS PROCALCITONIN 60T	30-Nov-2022	09-Jan-2022
30450-86	1008817140	VIDAS BRAHMS PROCALCITONIN 60T	15-Dec-2022	24-Jan-2022
30450-86	1008671350	VIDAS BRAHMS PROCALCITONIN 60T	29-Sep-2022	26-Oct-2021
30450-86	1008714950	VIDAS BRAHMS PROCALCITONIN 60T	24-Oct-2022	30-Nov-2021
30450-86	1008741810	VIDAS BRAHMS PROCALCITONIN 60T	07-Nov-2022	30-Nov-2021
30450-86	1008769290	VIDAS BRAHMS PROCALCITONIN 60T	24-Nov-2022	31-Dec-2021
30450-86	1008868260	VIDAS BRAHMS PROCALCITONIN 60T	12-Jan-2023	12-Feb-2022
30450-86	1008888040	VIDAS BRAHMS PROCALCITONIN 60T	19-Jan-2023	12-Feb-2022
30450-86	1008892830	VIDAS BRAHMS PROCALCITONIN 60T	19-Jan-2023	12-Feb-2022
30450-86	1008903360	VIDAS BRAHMS PROCALCITONIN 60T	31-Jan-2023	21-Feb-2022



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333 - VIDAS® BRAHMS PROCALCITONIN 60T (Ref. 30450, 30450-01 & 30450-86) and VIDAS® BRAHMS PROCALCITONIN 30T (Ref. 30450-30) - 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® BRAHMS PROCALCITONIN 60T (Ref. 30450, 30450-01 & 30450-86) and VIDAS® BRAHMS PROCALCITONIN 30T (Ref. 30450-30) – Substrate Error"
I will implement the required actions regarding impacted lots of VIDAS® BRAHMS PROCALCITONIN 60T (Ref. 30450, 30450-01 & 30450-86) and VIDAS® BRAHMS PROCALCITONIN 30T (Ref. 30450-30) 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 : .....