



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® D DIMER EXCLUSION II 60T (Ref. 30455,
30455-02), VIDAS® D DIMER EXCLUSION II 60T
US (Ref. 30455-01) and VIDAS® D DIMER
EXCLUSION II 30T (Ref. 30455-30)
Substrate Error - Potential delayed results

Dear bioMérieux Customer,

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

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



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 bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® D DIMER EXCLUSION II 60T (Ref. 30455, 30455-02), VIDAS® D DIMER EXCLUSION II 60T US (Ref. 30455-01) and VIDAS® D DIMER EXCLUSION II 30T (Ref. 30455-30) 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 remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30455	1008589450	VIDAS D DIMER EXCLUSION II 60T	17-Feb-2022	25-Jan-2022
30455	1008815230	VIDAS D DIMER EXCLUSION II 60T	13-Jun-2022	17-May-2022
30455	1008761040	VIDAS D DIMER EXCLUSION II 60T	22-May-2022	28-Apr-2022
30455	1008770900	VIDAS D DIMER EXCLUSION II 60T	31-May-2022	04-May-2022
30455	1008778210	VIDAS D DIMER EXCLUSION II 60T	30-May-2022	28-Apr-2022
30455	1008800130	VIDAS D DIMER EXCLUSION II 60T	03-Jun-2022	08-May-2022
30455	1008815200	VIDAS D DIMER EXCLUSION II 60T	14-Jun-2022	27-May-2022
30455-01	1008696660	VIDAS D DIMER EXCLUSION II 60T US	13-Apr-2022	22-Mar-2022
30455-01	1008761020	VIDAS D DIMER EXCLUSION II 60T US	22-May-2022	28-Apr-2022
30455-01	1008864290	VIDAS D DIMER EXCLUSION II 60T US	15-Jul-2022	16-Jun-2022
30455-01	1008891690	VIDAS D DIMER EXCLUSION II 60T US	27-Jul-2022	29-Jun-2022
30455-02	1008656010	VIDAS D-DIMER EXCLUSION II 60T	23-Mar-2022	03-Mar-2022
30455-02	1008696080	VIDAS D-DIMER EXCLUSION II 60T	13-Apr-2022	22-Mar-2022
30455-02	1008705690	VIDAS D-DIMER EXCLUSION II 60T	18-Apr-2022	07-Apr-2022
30455-02	1008589420	VIDAS D-DIMER EXCLUSION II 60T	16-Feb-2022	26-Jan-2022
30455-02	1008592150	VIDAS D-DIMER EXCLUSION II 60T	23-Feb-2022	03-Feb-2022
30455-02	1008609020	VIDAS D-DIMER EXCLUSION II 60T	26-Feb-2022	03-Feb-2022
30455-02	1008720080	VIDAS D-DIMER EXCLUSION II 60T	18-Apr-2022	07-Apr-2022
30455-02	1008732940	VIDAS D-DIMER EXCLUSION II 60T	04-May-2022	19-Apr-2022
30455-02	1008744900	VIDAS D-DIMER EXCLUSION II 60T	07-May-2022	19-Apr-2022
30455-02	1008756000	VIDAS D-DIMER EXCLUSION II 60T	17-May-2022	04-May-2022
30455-02	1008761030	VIDAS D-DIMER EXCLUSION II 60T	22-May-2022	28-Apr-2022
30455-02	1008762030	VIDAS D-DIMER EXCLUSION II 60T	25-May-2022	28-Apr-2022
30455-02	1008763980	VIDAS D-DIMER EXCLUSION II 60T	24-May-2022	04-May-2022
30455-02	1008771100	VIDAS D-DIMER EXCLUSION II 60T	31-May-2022	04-May-2022



30455-02	1008778230	VIDAS D-DIMER EXCLUSION II 60T	30-May-2022	28-Apr-2022
30455-02	1008781240	VIDAS D-DIMER EXCLUSION II 60T	03-Jun-2022	08-May-2022
30455-02	1008815220	VIDAS D-DIMER EXCLUSION II 60T	14-Jun-2022	27-May-2022
30455-02	1008815240	VIDAS D-DIMER EXCLUSION II 60T	13-Jun-2022	17-May-2022
30455-02	1008864310	VIDAS D-DIMER EXCLUSION II 60T	15-Jul-2022	16-Jun-2022
30455-02	1008891770	VIDAS D-DIMER EXCLUSION II 60T	27/07/2022	29-Jun-2022
30455-02	1008917580	VIDAS D-DIMER EXCLUSION II 60T	17-Aug-2022	27-Jul-2022
30455-02	1008918050	VIDAS D-DIMER EXCLUSION II 60T	31-May-2022	04-May-2022
30455-02	1008918060	VIDAS D-DIMER EXCLUSION II 60T	03-Jun-2022	08-May-2022
30455-30	1008589440	VIDAS D-DIMER EXCLUSION II 30T	16-Feb-2022	26-Jan-2022
30455-30	1008660630	VIDAS D-DIMER EXCLUSION II 30T	23-Mar-2022	03-Mar-2022
30455-30	1008705360	VIDAS D-DIMER EXCLUSION II 30T	13-Apr-2022	22-Mar-2022
30455-30	1008732910	VIDAS D-DIMER EXCLUSION II 30T	04-May-2022	19-Apr-2022
30455-30	1008763990	VIDAS D-DIMER EXCLUSION II 30T	24-May-2022	04-May-2022
30455-30	1008891780	VIDAS D-DIMER EXCLUSION II 30T	27-Jul-2022	29-Jun-2022
30455-30	1008864300	VIDAS D-DIMER EXCLUSION II 30T	15-Jul-2022	16-Jun-2022



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333 - VIDAS® D DIMER EXCLUSION II 60T (Ref. 30455, 30455-02), VIDAS® D DIMER EXCLUSION II 60T US (Ref. 30455-01) and VIDAS® D DIMER EXCLUSION II 30T (Ref. 30455-30) - 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® D DIMER EXCLUSION II 60T (Ref. 30455, 30455-02), VIDAS® D DIMER EXCLUSION II 60T US (Ref. 30455-01) and VIDAS® D DIMER EXCLUSION II 30T (Ref. 30455-30) - Substrate Error”

- I will implement the required actions regarding impacted lots of VIDAS® D DIMER EXCLUSION II 60T (Ref. 30455, 30455-02), VIDAS® D DIMER EXCLUSION II 60T US (Ref. 30455-01) and VIDAS® D DIMER EXCLUSION II 30T (Ref. 30455-30) 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 :