



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

Address
City, Date

Our reference: FSCA#5333-1

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® ESTRADIOL II 60 TESTS (Ref. 30431 & 30431-01)
Substrate Error – Potential delayed results with no medical impact

Dear bioMérieux Customer,

This FSCA #5333-1 is a follow-up of FSCA #5333 (released on 22-Sep-2021). FSCA #5333-1 concerns all lots of clinical VIDAS® immuno-assay product references for which a delayed result **has no medical impact but can lead to a major inconvenience for you.**

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, corrective actions involving a revised expiration date for all lots of clinical VIDAS® Immuno-assay products are required to ensure that the specified products will continue to perform per their labelled performance specifications.

Indeed, even if there is no medical impact of a delayed result when using the impacted lots of clinical VIDAS® Immuno-assay products listed in Table 1, as a conservative approach and to avoid a major inconvenience at your level, bioMérieux has decided to implement a Field Safety Corrective Action (FSCA #5333-1).

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



Impact to Customer/Patient:

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

For impacted VIDAS® immuno-assay products listed in Tables 1, there is no medical impact of a delayed result but the issue can lead to a major inconvenience.

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 bioMérieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® ESTRADIOL II 60 TESTS (Ref. 30431 & 30431-01) 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 |
|------------|--------------|------------------------------|----------------------------|----------------------------|
| 30431 | 1008671380 | VIDAS® ESTRADIOL II 60 TESTS | 29-Mar-22 | 3-Mar-22 |
| 30431 | 1008757870 | VIDAS® ESTRADIOL II 60 TESTS | 18-May-22 | 19-Apr-22 |
| 30431 | 1008856950 | VIDAS® ESTRADIOL II 60 TESTS | 22-Jun-22 | 27-May-22 |
| 30431 | 1008872270 | VIDAS® ESTRADIOL II 60 TESTS | 19-Jul-22 | 14-Jun-22 |
| 30431-01 | 1008757880 | VIDAS® ESTRADIOL II 60 TESTS | 18-May-22 | 19-Apr-22 |



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

**FSCA 5333-1 - VIDAS® ESTRADIOL II 60 TESTS (Ref. 30431 & 30431-01)
- 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® ESTRADIOL II 60 TESTS (Ref. 30431 & 30431-01) – Substrate Error**”
- I will implement the required actions regarding impacted lots of **VIDAS® ESTRADIOL II 60 TESTS (Ref. 30431 & 30431-01)** 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 :