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:

GLOBAL FIELD SAFETY NOTICE - Correction

VIDAS® Immuno-Assays Multiple references

Substrate error - Potential delayed results without medical impact

Dear bioMérieux Customer,

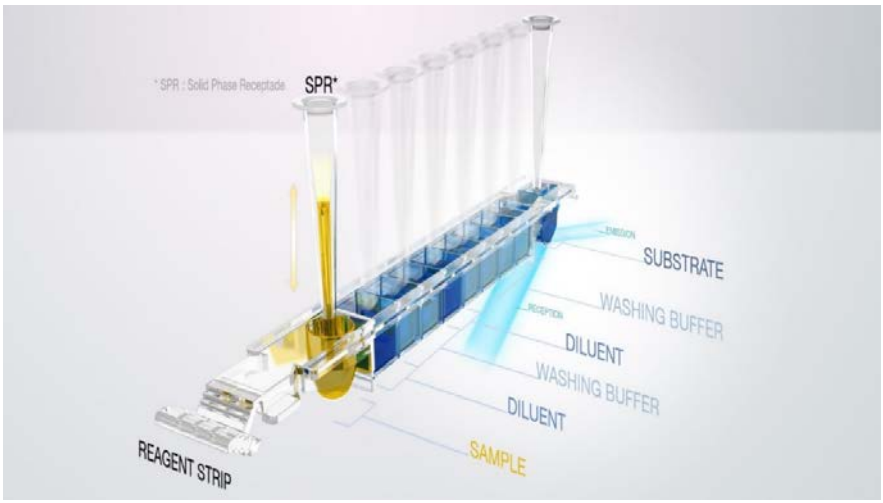
This FSCA #5333-1 is a follow-up of FSCA #5333 (released on 22-Sep-2021). FSCA #5333-1 concerns all lots of clinical VIDAS® immuno-assay product references for which a delayed result **has no medical impact but can lead to a major inconvenience for you.**

The intent of this letter is to share with you important information regarding clinical VIDAS® Immuno-Assays references products listed below in Table 1. Your laboratory received one/several of the listed clinical VIDAS® Immuno-Assays references products and lots.

Description of the issue

Since July 2021, bioMérieux has been receiving an increasing number of complaints linked to a VIDAS® "substrate error". It prevents the test from being run, therefore leads to a potential delayed results as you need to run another test.

A measurement of the background noise signal (RFU) is made by the VIDAS® system prior to launching the reaction. An acceptable limit is defined during product design for each reference of finished goods. Three values exist as acceptable limits depending on the assay: 300, 350 and 500 RFU. The substrate is present in the last well of the strip of all VIDAS® immuno-assays and allows fluorescence when degraded by the enzyme (PAL).



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

The level of fluorescence is then correlated with the results of all tests.

When you are performing a test, if the RFU is higher than the acceptable limit defined during the product development, there is an error message displayed by the system: ”Substrate Error”. The test is stopped and this alarm prevents the system to provide any result .

This alarm being present on all the systems of the VIDAS® family, it guarantees that no false results can be given in case of a substrate degradation. This means that there is only a potential risk of delayed results.

Investigations were immediately initiated to identify the root-cause, the following were identified:

- All lots impacted of VIDAS® Immuno-assays were conform to the specifications at release.
- The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using a common lot of raw material (4-MUP) that was identified as the most probable common root-cause.
- The scope of the issue was identified on all lots of VIDAS® Immuno-Assays manufactured using substrate batches containing this concerned lot of raw material. Most of the lots of VIDAS® Immuno-Assays since February 2021 were manufactured using this impacted raw material but not all of them.
- The problem is due to an accelerated degradation of the substrate. It follows a linear model over time leading to RFU acceptable limits being reached before the end of the registered shelf life of the product. This reinforced the reason why the VIDAS® Immuno-Assays with the lowest RFU limit (set at 300), were the first assays impacted : VIDAS® HIV DUO QUICK (Ref. 30447).
- Kinetic evolution analyzes were performed by measuring substrate RFU of a statistically representative number of VIDAS® immuno- assays retained batches (manufactured with the substrate containing the concerned raw material) at different shelf-lives. The model was validated on numerous data (~ 450 000) collected from the field (customers) .
- The analysis of the kinetic model allows us to predict the degradation trend of the substrate using the concerned batch of 4MUP and therefore to revise the expiry dates for each lot of impacted 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-assays products are required to ensure that the specified products will continue to perform per labelled performance specifications.
- Indeed, even if there is no medical impact in case of delayed result when using the impacted lots of clinical VIDAS® Immuno-assays listed in Table 1 below, 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).

We understand this complex matter requires an extra time commitment from you and your team. We thank you for your cooperation which is essential to ensure the successful implementation of this corrective action, in order to protect the safety of our patients.

To clarify the actions you are required to take, we have provided an attachment for each VIDAS® Immuno-assays product (Table 1) below. The attachments will clearly explain the following information:

- A list of all impacted lot numbers for each clinical VIDAS® Immuno-assay and associated product reference number,
- The revised expiration date for each impacted lot,
- Identification of lots that should be discarded due to revised expiry date,
- Additional actions required to be implemented within your institution.

Please determine which product references you currently have in stock that are referenced in Table 1, and implement the actions defined in the applicable attachments.

We are currently reworking some lots of VIDAS® Immuno-Assays in stock applying a sticker with the revised expiry date on top of the kits. However, to ensure service continuity you may receive, for a short period of time, impacted lots of clinical VIDAS® Immuno-Assays without sticker. All those lots are in the scope of this Urgent Field Safety Notice, and detailed in the different attachments of the table 1.

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, your local bioMérieux Customer Service representative will be here to assist you.

Yours faithfully,

Customer Service

Table 1: List of impacted clinical VIDAS® Immuno-Assay references (for which a delayed result has no medical impact)

Product Ref.	Product name	Attachments
30115	VIDAS® PROTEIN C 30 TESTS	See attachment 1
30218	VIDAS® MUMPS IGG 60 TESTS	See attachment 2
30219	VIDAS® MEASLES IGG 60 TESTS	See attachment 3
30221	VIDAS® RUB IGG II 60 TESTS	See attachment 4
30222	VIDAS® TOXO IGG AVIDITY 30TESTS	See attachment 5
30222-01		
30226	VIDAS® RUB IGG 60 TESTS	See attachment 6
30235	VIDAS® EBNA IGG 30 TESTS	See attachment 7
30236	VIDAS® EBV VCA.EA IGG 30 TESTS	See attachment 8
30237	VIDAS® EBV VCA IGM 30 TESTS	See attachment 9
30305	VIDAS® HBE.ANTI-HBE 30 TESTS	See attachment 10
30312	VIDAS® ANTI-HAV TOTAL 30 TESTS	See attachment 11
30319	VIDAS® LYME IGM 60 TESTS	See attachment 12
30320	VIDAS® LYME IGG 60 TESTS	See attachment 13
30400	VIDAS® TSH 60 TESTS	See attachment 14
30402	VIDAS® FT3 60 TESTS	See attachment 15
30403	VIDAS® T3 60 TESTS	See attachment 16
30404	VIDAS® T4 60 TESTS	See attachment 17
30406	VIDAS® LH 60 TESTS	See attachment 18
30406-01		
30407	VIDAS® FSH 60 TESTS	See attachment 19
30407-01		
30410	VIDAS® PROLACTINE 60 TESTS	See attachment 20
30411	VIDAS® FERRITINE 60 TESTS	See attachment 21
30413	VIDAS® AFP 60 TESTS	See attachment 22
30419	VIDAS® IGE 60 TESTS	See attachment 23
30420	VIDAS® B2 MICROGLOBULI 30 TESTS	See attachment 24
30426	VIDAS® CA 125II 30 TESTS	See attachment 25
30427	VIDAS® CA 19-9 30 TESTS	See attachment 26
30428	VIDAS® TPSA 60 TESTS	See attachment 27
30429	VIDAS® CA 15-3 30 TESTS	See attachment 28
30431	VIDAS® ESTRADIOL II 60 TESTS	See attachment 29
30431-01		
30436	VIDAS® VWF 30 TESTS	See attachment 30
30440	VIDAS® FPSA 30 TESTS	See attachment 31
30441	VIDAS® TSH3 60 TESTS	See attachment 32
30453	VIDAS® CEA (S) 60 TESTS	See attachment 33
30459	VIDAS® FT4N 60 TESTS	See attachment 34
30461	VIDAS® ANTI-TPO 30 T	See attachment 35
30462	VIDAS® ANTI-TG 30 T	See attachment 36
30463	VIDAS® 25-OH VITAMINE D TOTAL 60T	See attachment 37

414320	VIDAS® TESTOSTERONE II 30 TESTS	See attachment 38
416436	VIDAS® LYME IGM II 60 TESTS	See attachment 39
417011	VIDAS® AMH 30 TESTS	See attachment 40
417401	VIDAS® LYME IGG II 60 TESTS	See attachment 41
418116	VIDAS® HEV IGG 30T	See attachment 42
422010	VIDAS® PTH (1-84) 30T	See attachment 43
423079	VIDAS® ANTI-DENGUE IGG 60 TESTS	See attachment 44
423111	VIDAS® TB-IGRA 60 TESTS	See attachment 45
423833	VIDAS® SARS-COV-2 IgM (9COM) 60T	See attachment 46
423833-01		
423834	VIDAS® SARS-COV-2 IgG (9COG) 60T	See attachment 47
423834-01		
424114	VIDAS® SARS-COV-2 IgG II	See attachment 48

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® MEASLES IGG 60 TESTS (Ref. 30219)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® MEASLES IGG 60 TESTS (Ref. 30219) 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
30219	1008890110	VIDAS® MEASLES IGG 60 TESTS	16-Jun-22	14-Jun-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® MEASLES IGG 60 TESTS (Ref. 30219) - 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® MEASLES IGG 60 TESTS (Ref. 30219) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® MEASLES IGG 60 TESTS (Ref. 30219)** 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** : .....

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® RUB IGG II 60 TESTS (Ref. 30221)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® RUB IGG II 60 TESTS (Ref. 30221) 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
30221	1008566150	VIDAS® RUB IGG II 60 TESTS	2-Feb-22	12-Jan-22
30221	1008566660	VIDAS® RUB IGG II 60 TESTS	2-Feb-22	12-Jan-22
30221	1008611770	VIDAS® RUB IGG II 60 TESTS	1-Mar-22	9-Feb-22
30221	1008701600	VIDAS® RUB IGG II 60 TESTS	22-Apr-22	25-Mar-22
30221	1008809720	VIDAS® RUB IGG II 60 TESTS	15-Jun-22	17-May-22
30221	1008851780	VIDAS® RUB IGG II 60 TESTS	8-Jul-22	8-Jun-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® RUB IGG II 60 TESTS (Ref. 30221) - 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® RUB IGG II 60 TESTS (Ref. 30221)– Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® RUB IGG II 60 TESTS (Ref. 30221)** 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** : .....

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® EBNA IGG 30 TESTS(Ref. 30235)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® EBNA IGG 30 TESTS (Ref. 30235) 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
30235	1008760410	VIDAS® EBNA IGG 30 TESTS	20-May-22	28-Apr-22
30235	1008908880	VIDAS® EBNA IGG 30 TESTS	2-Aug-22	13-Jul-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® EBNA IGG 30 TESTS (Ref. 30235)- 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® EBNA IGG 30 TESTS (Ref. 30235) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® EBNA IGG 30 TESTS (Ref. 30235)**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** : .....

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® ANTI-HAV TOTAL 30 TESTS (Ref. 30312)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® ANTI-HAV TOTAL 30 TESTS (Ref. 30312) 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
30312	1008589520	VIDAS® ANTI-HAV TOTAL 30 TESTS	16-Feb-22	25-Jan-22
30312	1008762100	VIDAS® ANTI-HAV TOTAL 30 TESTS	21-May-22	19-Apr-22
30312	1008920480	VIDAS® ANTI-HAV TOTAL 30 TESTS	17-Aug-22	24-Jul-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® ANTI-HAV TOTAL 30 TESTS (Ref. 30312) - 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® ANTI-HAV TOTAL 30 TESTS (Ref. 30312) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® ANTI-HAV TOTAL 30 TESTS (Ref. 30312)** 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** : .....

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® LYME IGG 60 TESTS (Ref. 30320)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® LYME IGG 60 TESTS (Ref. 30320) 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
30320	1008800180	VIDAS® LYME IGG 60 TESTS	14-Jun-22	9-Jan-22
30320	1008900310	VIDAS® LYME IGG 60 TESTS	30-Jul-22	15-Feb-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® LYME IGG 60 TESTS (Ref. 30320) - 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® LYME IGG 60 TESTS (Ref. 30320) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® LYME IGG 60 TESTS (Ref. 30320)** 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** : .....

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® T3 60 TESTS (Ref. 30403)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® T3 60 TESTS (Ref. 30403) 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
30403	1008612240	VIDAS® T3 60 TESTS	2-Mar-22	25-Jan-22
30403	1008589770	VIDAS® T3 60 TESTS	18-Feb-22	25-Jan-22
30403	1008637510	VIDAS® T3 60 TESTS	17-Mar-22	23-Feb-22
30403	1008666330	VIDAS® T3 60 TESTS	25-Mar-22	3-Mar-22
30403	1008671650	VIDAS® T3 60 TESTS	2-Apr-22	3-Mar-22
30403	1008687730	VIDAS® T3 60 TESTS	9-Apr-22	22-Mar-22
30403	1008706040	VIDAS® T3 60 TESTS	22-Apr-22	25-Mar-22
30403	1008720580	VIDAS® T3 60 TESTS	4-May-22	7-Apr-22
30403	1008739140	VIDAS® T3 60 TESTS	10-May-22	19-Apr-22
30403	1008770970	VIDAS® T3 60 TESTS	3-Jun-22	28-Apr-22
30403	1008838990	VIDAS® T3 60 TESTS	2-Jul-22	8-Jun-22
30403	1008856820	VIDAS® T3 60 TESTS	9-Jul-22	14-Jun-22
30403	1008882160	VIDAS® T3 60 TESTS	21-Jul-22	20-Jun-22
30403	1008897120	VIDAS® T3 60 TESTS	5-Aug-22	30-Jun-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® T3 60 TESTS (Ref. 30403) - 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® T3 60 TESTS (Ref. 30403) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® T3 60 TESTS (Ref. 30403)** 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** : .....

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® LH 60 TESTS (Ref. 30406 & 30406-01)

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).

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 Table 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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® LH 60 TESTS (Ref. 30406 & 30406-01) 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
30406	1008699160	VIDAS® LH 60 TESTS	19-Apr-22	17-Nov-21
30406	1008813780	VIDAS® LH 60 TESTS	14-Jun-22	9-Jan-22
30406	1008848620	VIDAS® LH 60 TESTS	1-Jul-22	5-Feb-22
30406-01	1008848600	VIDAS® LH 60 TESTS	1-Jul-22	5-Feb-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® LH 60 TESTS (Ref. 30406 & 30406-01) - Substrate Error

---

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® LH 60 TESTS (Ref. 30406 & 30406-01) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® LH 60 TESTS (Ref. 30406 & 30406-01)** 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** : .....

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® FSH 60 TESTS (Ref. 30407 & 30407-01)

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 Tables 1 and 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, 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 Tables 1 and 2, 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).

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com
Legal notice / Mentions légales de la société émettrice

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 and 2, 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

Tables 1 or 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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® FSH 60 TESTS (Ref. 30407 & 30407-01) 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 NO remaining shelf life (taking into account the revised expiry date).

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30407	1008580750**	VIDAS® FSH 60 TESTS	8-Feb-22	19-Sep-21
30407	1008660520**	VIDAS® FSH 60 TESTS	22-Mar-22	18-Oct-21

** 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
30407	1008730980	VIDAS® FSH 60 TESTS	4-May-22	30-Nov-21
30407	1008781450	VIDAS® FSH 60 TESTS	3-Jun-22	21-Dec-21
30407	1008794330	VIDAS® FSH 60 TESTS	3-Jun-22	21-Dec-21
30407	1008860760	VIDAS® FSH 60 TESTS	8-Jul-22	31-Jan-22
30407-01	1008781470	VIDAS® FSH 60 TESTS	3-Jun-22	21-Dec-21

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® FSH 60 TESTS (Ref. 30407 & 30407-01) - 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® FSH 60 TESTS (Ref. 30407 & 30407-01) – Substrate Error**"
- ❑ I will implement the required actions regarding impacted lots of **VIDAS® FSH 60 TESTS (Ref. 30407 & 30407-01)** 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** : .....

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® AMH 30 TESTS (Ref. 417011)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® AMH 30 TESTS (Ref. 417011) 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
417011	1008605020	VIDAS® AMH 30 TESTS	28-Aug-22	9-Feb-22
417011	1008667580	VIDAS® AMH 30 TESTS	26-Sep-22	3-Mar-22
417011	1008730610	VIDAS® AMH 30 TESTS	31-Oct-22	7-Apr-22
417011	1008854280	VIDAS® AMH 30 TESTS	3-Jan-23	13-Jun-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® AMH 30 TESTS (Ref. 417011) - 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® AMH 30 TESTS (Ref. 417011) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® AMH 30 TESTS (Ref. 417011)** 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** : .....

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® LYME IGG II 60 TESTS (Ref. 417401)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® LYME IGG II 60 TESTS (Ref. 417401) 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
417401	1008714880	VIDAS® LYME IGG II 60 TESTS	25-Jul-22	30-Nov-21
417401	1008824220	VIDAS® LYME IGG II 60 TESTS	12-Sep-22	9-Jan-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® LYME IGG II 60 TESTS (Ref. 417401) - Substrate Error

---

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® LYME IGG II 60 TESTS (Ref. 417401) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® LYME IGG II 60 TESTS (Ref. 417401)** 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** : .....

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® SARS-COV-2 IgG II (Ref. 424114)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® SARS-COV-2 IgG II (Ref. 424114) 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
424114	1008693260	VIDAS® SARS-COV-2 IgG II	19-Apr-22	25-Mar-22
424114	1008737650	VIDAS® SARS-COV-2 IgG II	3-May-22	19-Apr-22
424114	1008766600	VIDAS® SARS-COV-2 IgG II	25-May-22	19-Apr-22
424114	1008768870	VIDAS® SARS-COV-2 IgG II	31-May-22	19-Apr-22
424114	1008793180	VIDAS® SARS-COV-2 IgG II	8-Jun-22	8-May-22
424114	1008799340	VIDAS® SARS-COV-2 IgG II	7-Jun-22	26-May-22
424114	1008806170	VIDAS® SARS-COV-2 IgG II	11-Jun-22	26-May-22
424114	1008812180	VIDAS® SARS-COV-2 IgG II	10-Jun-22	26-May-22
424114	1008821130	VIDAS® SARS-COV-2 IgG II	21-Jun-22	26-May-22
424114	1008826440	VIDAS® SARS-COV-2 IgG II	20-Jun-22	26-May-22
424114	1008840470	VIDAS® SARS-COV-2 IgG II	1-Jul-22	8-Jun-22
424114	1008845260	VIDAS® SARS-COV-2 IgG II	5-Jul-22	1-Jun-22
424114	1008850980	VIDAS® SARS-COV-2 IgG II	6-Jul-22	1-Jun-22
424114	1008859210	VIDAS® SARS-COV-2 IgG II	12-Jul-22	14-Jun-22
424114	1008881730	VIDAS® SARS-COV-2 IgG II	19-Jul-22	23-Jun-22
424114	1008915730	VIDAS® SARS-COV-2 IgG II	9-Aug-22	5-Jul-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® SARS-COV-2 IgG II (Ref. 424114) - 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® SARS-COV-2 IgG II (Ref. 424114) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® SARS-COV-2 IgG II (Ref. 424114)** 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** : .....

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® PROLACTINE 60 TESTS (Ref. 30410)
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 Tables 1 and 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, 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 Tables 1 and 2, 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).

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com
Legal notice / Mentions légales de la société émettrice

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 and 2, 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

Tables 1 or 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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® PROLACTINE 60 TESTS (Ref. 30410) 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
30410	1008661910**	VIDAS® PROLACTINE 60 TESTS	22-Mar-22	26-Oct-21

** 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
30410	1008753000	VIDAS® PROLACTINE 60 TESTS	18-May-22	19-Dec-21
30410	1008757170	VIDAS® PROLACTINE 60 TESTS	18-May-22	19-Dec-21
30410	1008829010	VIDAS® PROLACTINE 60 TESTS	28-Jun-22	25-Jan-22
30410	1008900440	VIDAS® PROLACTINE 60 TESTS	29-Jul-22	27-Feb-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® PROLACTINE 60 TESTS (Ref. 30410) - 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® PROLACTINE 60 TESTS (Ref. 30410) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® PROLACTINE 60 TESTS (Ref. 30410)** 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** : .....

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® TSH 60 TESTS (Ref. 30400)

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 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, 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 and 2, 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).

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com
Legal notice / Mentions légales de la société émettrice

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 and 2, 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 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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® TSH 60 TESTS (Ref. 30400) 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
30400	1008581260**	VIDAS® TSH 60 TESTS	17-Feb-22	6-Sep-21
30400	1008572270**	VIDAS® TSH 60 TESTS	8-Feb-22	6-Sep-21

** 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
30400	1008794370	VIDAS® TSH 60 TESTS	10-Jun-22	9-Jan-22
30400	1008784130	VIDAS® TSH 60 TESTS	29-May-22	9-Jan-22
30400	1008693180	VIDAS® TSH 60 TESTS	19-Apr-22	14-Nov-21
30400	1008708180	VIDAS® TSH 60 TESTS	21-Apr-22	27-Nov-21
30400	1008727020	VIDAS® TSH 60 TESTS	29-Apr-22	27-Nov-21
30400	1008800070	VIDAS® TSH 60 TESTS	14-Jun-22	9-Jan-22
30400	1008825270	VIDAS® TSH 60 TESTS	28-Jun-22	19-Jan-22
30400	1008840210	VIDAS® TSH 60 TESTS	2-Jul-22	24-Jan-22
30400	1008864740	VIDAS® TSH 60 TESTS	16-Jul-22	12-Feb-22
30400	1008886320	VIDAS® TSH 60 TESTS	26-Jul-22	22-Feb-22
30400	1008903990	VIDAS® TSH 60 TESTS	9-Aug-22	18-Mar-22
30400	1008923240	VIDAS® TSH 60 TESTS	17-Aug-22	7-Mar-22
30400	1008926570	VIDAS® TSH 60 TESTS	20-Aug-22	21-Mar-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® TSH 60 TESTS (Ref. 30400) - 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® TSH 60 TESTS (Ref. 30400) – Substrate Error**"
- ❑ I will implement the required actions regarding impacted lots of **VIDAS® TSH 60 TESTS (Ref. 30400)** 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** : .....

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).

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 bioMerieux 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 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® 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** : .....

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® AFP 60 TESTS (Ref. 30413)

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).

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 Table 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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® AFP 60 TESTS (Ref. 30413) 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
30413	1008805600	VIDAS® AFP 60 TESTS	8-Jun-22	9-Jan-22
30413	1008921510	VIDAS® AFP 60 TESTS	11-Aug-22	7-Mar-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® AFP 60 TESTS (Ref. 30413) - Substrate Error

---

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® AFP 60 TESTS (Ref. 30413) – Substrate Error**"
- ❑ I will implement the required actions regarding impacted lots of **VIDAS® AFP 60 TESTS (Ref. 30413)** 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** : .....

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® HEV IGG 30T (Ref. 418116)
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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® HEV IGG 30T (Ref. 418116) 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
418116	1008684310	VIDAS® HEV IGG 30T	3-Oct-22	10-Mar-22
418116	1008831640	VIDAS® HEV IGG 30T	25-Dec-22	26-May-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® HEV IGG 30T (Ref. 418116) - 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® HEV IGG 30T (Ref. 418116) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® HEV IGG 30T (Ref. 418116)** 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** : .....

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® 25-OH VITAMINE D TOTAL 60T (Ref. 30463)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® 25-OH VITAMINE D TOTAL 60T (Ref. 30463) 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
30463	1008764090	VIDAS® 25-OH VITAMINE D TOTAL 60T	25-Aug-22	19-Apr-22
30463	1008609060	VIDAS® 25-OH VITAMINE D TOTAL 60T	25-May-22	9-Feb-22
30463	1008676430	VIDAS® 25-OH VITAMINE D TOTAL 60T	30-Jun-22	3-Mar-22
30463	1008693940	VIDAS® 25-OH VITAMINE D TOTAL 60T	18-Jul-22	10-Mar-22
30463	1008717350	VIDAS® 25-OH VITAMINE D TOTAL 60T	28-Jul-22	7-Apr-22
30463	1008747560	VIDAS® 25-OH VITAMINE D TOTAL 60T	9-Aug-22	19-Apr-22
30463	1008772230	VIDAS® 25-OH VITAMINE D TOTAL 60T	31-Aug-22	28-Apr-22
30463	1008776690	VIDAS® 25-OH VITAMINE D TOTAL 60T	25-Aug-22	19-Apr-22
30463	1008796740	VIDAS® 25-OH VITAMINE D TOTAL 60T	5-Sep-22	17-May-22
30463	1008841360	VIDAS® 25-OH VITAMINE D TOTAL 60T	29-Sep-22	8-Jun-22
30463	1008869580	VIDAS® 25-OH VITAMINE D TOTAL 60T	18-Oct-22	20-Jun-22
30463	1008892600	VIDAS® 25-OH VITAMINE D TOTAL 60T	25-Oct-22	30-Jun-22
30463	1008914140	VIDAS® 25-OH VITAMINE D TOTAL 60T	15-Nov-22	24-Jul-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® 25-OH VITAMINE D TOTAL 60T (Ref. 30463) - 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® 25-OH VITAMINE D TOTAL 60T (Ref. 30463) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® 25-OH VITAMINE D TOTAL 60T (Ref. 30463)** 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** : .....

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® EBV VCA IGM 30 TESTS (Ref. 30237)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® EBV VCA IGM 30 TESTS (Ref. 30237) 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
30237	1008733860	VIDAS® EBV VCA IGM 30 TESTS	15-Apr-22	25-Mar-22
30237	1008854070	VIDAS® EBV VCA IGM 30 TESTS	19-Jun-22	27-May-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® EBV VCA IGM 30 TESTS (Ref. 30237) - 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® EBV VCA IGM 30 TESTS (Ref. 30237) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® EBV VCA IGM 30 TESTS (Ref. 30237)** 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** : .....

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® ANTI-DENGUE IGG 60 TESTS (Ref. 423079)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® ANTI-DENGUE IGG 60 TESTS (Ref. 423079) 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
423079	1008693240	VIDAS® ANTI-DENGUE IGG 60 TESTS	16-Oct-22	10-Mar-22
423079	1008832050	VIDAS® ANTI-DENGUE IGG 60 TESTS	25-Dec-22	26-May-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® ANTI-DENGUE IGG 60 TESTS (Ref. 423079) - 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® ANTI-DENGUE IGG 60 TESTS (Ref. 423079) – Substrate Error**"
- ❑ I will implement the required actions regarding impacted lots of **VIDAS® ANTI-DENGUE IGG 60 TESTS (Ref. 423079)** 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** : .....

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® CEA (S) 60 TESTS (Ref. 30453)

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 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, 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 and 2, 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).

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com
Legal notice / Mentions légales de la société émettrice

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 and 2, 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 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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® CEA (S) 60 TESTS (Ref. 30453) 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
30453	1008626550**	VIDAS® CEA (S) 60 TESTS	8-Mar-22	4-Oct-21

** 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
30453	1008705700	VIDAS® CEA (S) 60 TESTS	20-Apr-22	17-Nov-21
30453	1008827310	VIDAS® CEA (S) 60 TESTS	21-Jun-22	19-Jan-22
30453	1008888060	VIDAS® CEA (S) 60 TESTS	26-Jul-22	22-Feb-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® CEA (S) 60 TESTS (Ref. 30453) - 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® CEA (S) 60 TESTS (Ref. 30453) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® CEA (S) 60 TESTS (Ref. 30453)** 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** : .....

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® LYME IGM II 60 TESTS (Ref. 416436)

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 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, 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 and 2, 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).

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com

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 and 2, 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 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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® LYME IGM II 60 TESTS (Ref. 416436) 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
416436	1008636750**	VIDAS® LYME IGM II 60 TESTS	9-Jun-22	20-Sep-21

** 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
416436	1008768920	VIDAS® LYME IGM II 60 TESTS	15-Aug-22	12-Dec-21
416436	1008857410	VIDAS® LYME IGM II 60 TESTS	3-Oct-22	24-Jan-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® LYME IGM II 60 TESTS (Ref. 416436) - 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® LYME IGM II 60 TESTS (Ref. 416436) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® LYME IGM II 60 TESTS (Ref. 416436)** 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** : .....

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® TPSA 60 TESTS (Ref. 30428)

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 Tables 1 and 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, 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 Tables 1 and 2, 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).

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com
Legal notice / Mentions légales de la société émettrice

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 and 2, 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

Tables 1 or 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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® TPSA 60 TESTS (Ref. 30428) 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
30428	1008678810**	VIDAS® TPSA 60 TESTS	26-Mar-22	2-Nov-21
30428	1008616040**	VIDAS® TPSA 60 TESTS	22-Feb-22	28-Sep-21

** 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
30428	1008757280	VIDAS® TPSA 60 TESTS	4-May-22	12-Dec-21
30428	1008705160	VIDAS® TPSA 60 TESTS	14-Apr-22	17-Nov-21
30428	1008830760	VIDAS® TPSA 60 TESTS	22-Jun-22	24-Jan-22
30428	1008842800	VIDAS® TPSA 60 TESTS	23-Jun-22	31-Jan-22
30428	1008930910	VIDAS® TPSA 60 TESTS	6-Aug-22	18-Mar-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® TPSA 60 TESTS (Ref. 30428) - 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® TPSA 60 TESTS (Ref. 30428) – Substrate Error**"
- ❑ I will implement the required actions regarding impacted lots of **VIDAS® TPSA 60 TESTS (Ref. 30428)** 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** : .....

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® EBV VCA.EA IGG 30 TESTS (Ref. 30236)
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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® EBV VCA.EA IGG 30 TESTS (Ref. 30236) 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
30236	1008731540	VIDAS® EBV VCA.EA IGG 30 TESTS	4-May-22	7-Apr-22
30236	1008908700	VIDAS® EBV VCA.EA IGG 30 TESTS	2-Aug-22	13-Jul-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® EBV VCA.EA IGG 30 TESTS (Ref. 30236) - 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® EBV VCA.EA IGG 30 TESTS (Ref. 30236) – Substrate Error**"
- ❑ I will implement the required actions regarding impacted lots of **VIDAS® EBV VCA.EA IGG 30 TESTS (Ref. 30236)** 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** : .....

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® VIDAS PTH (1-84) 30T (Ref. 422010)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® VIDAS PTH (1-84) 30T (Ref. 422010) 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
422010	1008572010	VIDAS® VIDAS PTH (1-84) 30T	8-Feb-22	12-Jan-22
422010	1008690000	VIDAS® VIDAS PTH (1-84) 30T	1-Apr-22	10-Mar-22
422010	1008842830	VIDAS® VIDAS PTH (1-84) 30T	24-Jun-22	26-May-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® VIDAS PTH (1-84) 30T (Ref. 422010) - 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® VIDAS PTH (1-84) 30T (Ref. 422010) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® VIDAS PTH (1-84) 30T (Ref. 422010)** 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** : .....

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® TB-IGRA 60 TESTS (Ref. 423111)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® TB-IGRA 60 TESTS (Ref. 423111) 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
423111	1008779880	VIDAS® TB-IGRA 60 TESTS	28-Nov-22	28-Apr-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® TB-IGRA 60 TESTS (Ref. 423111) - Substrate Error

---

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® TB-IGRA 60 TESTS (Ref. 423111) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® TB-IGRA 60 TESTS (Ref. 423111)** 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** : .....

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® HBE/ANTI-HBE 30 TESTS (Ref. 30305)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® HBE/ANTI-HBE 30 TESTS (Ref. 30305) 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
30305	1008789580	VIDAS® HBE.ANTI-HBE 30 TESTS	19-May-22	19-Apr-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® HBE/ANTI-HBE 30 TESTS (Ref. 30305) - Substrate Error

---

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® HBE/ANTI-HBE 30 TESTS (Ref. 30305) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® HBE/ANTI-HBE 30 TESTS (Ref. 30305)** 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** : .....

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® LYME IGM 60 TESTS (Ref. 30319)

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 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, 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 and 2, 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).

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com

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 and 2, 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 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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® LYME IGM 60 TESTS (Ref. 30319) 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
30319	1008694220**	VIDAS® LYME IGM 60 TESTS	13-Apr-22	2-Nov-21

** 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
30319	1008855250	VIDAS® LYME IGM 60 TESTS	6-Jul-22	18-Jan-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® LYME IGM 60 TESTS (Ref. 30319) - 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® LYME IGM 60 TESTS (Ref. 30319) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® LYME IGM 60 TESTS (Ref. 30319)** 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** : .....

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® SARS-COV-2 IgM (9COM) 60T (Ref. 423833 & 423833-01)

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).

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® SARS-COV-2 IgM (9COM) 60T (Ref. 423833 & 423833-01) 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
423833	1008710940	VIDAS® SARS-COV-2 IgM (9COM) 60T	4-Mar-22	30-Nov-21
423833	1008771420	VIDAS® SARS-COV-2 IgM (9COM) 60T	18-May-22	31-Dec-21
423833	1008781210	VIDAS® SARS-COV-2 IgM (9COM) 60T	31-May-22	31-Dec-21
423833	1008787590	VIDAS® SARS-COV-2 IgM (9COM) 60T	7-Jun-22	31-Dec-21
423833	1008812250	VIDAS® SARS-COV-2 IgM (9COM) 60T	16-Jun-22	18-Jan-22
423833	1008843370	VIDAS® SARS-COV-2 IgM (9COM) 60T	28-Jun-22	31-Jan-22
423833	1008851220	VIDAS® SARS-COV-2 IgM (9COM) 60T	5-Jul-22	24-Jan-22
423833	1008886980	VIDAS® SARS-COV-2 IgM (9COM) 60T	22-Jul-22	22-Feb-22
423833	1008918390	VIDAS® SARS-COV-2 IgM (9COM) 60T	16-Aug-22	18-Mar-22
423833-01	1008710950	VIDAS® SARS-COV-2 IgM (9COM) 60T	4-Mar-22	30-Nov-21

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® SARS-COV-2 IgM (9COM) 60T (Ref. 423833 & 423833-01) - 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® SARS-COV-2 IgM (9COM) 60T (Ref. 423833 & 423833-01) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® SARS-COV-2 IgM (9COM) 60T (Ref. 423833 & 423833-01)** 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** : ……

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® TOXO IGG AVIDITY 30 TESTS (Ref. 30222 & 30222-01)

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).

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com
Legal notice / Mentions légales de la société émettrice

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® TOXO IGG AVIDITY 30 TESTS (Ref. 30222 & 30222-01) 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
30222	1008721750	VIDAS® TOXO IGG AVIDITY 30 TESTS	23-Mar-22	10-Mar-22
30222	1008861600	VIDAS® TOXO IGG AVIDITY 30 TESTS	22-Jun-22	8-Jun-22
30222-01	1008861590	VIDAS® TOXO IGG AVIDITY 30 TESTS	22-Jun-22	8-Jun-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® TOXO IGG AVIDITY 30 TESTS (Ref. 30222 & 30222-01)- 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® TOXO IGG AVIDITY 30 TESTS (Ref. 30222 & 30222-01) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® TOXO IGG AVIDITY 30 TESTS (Ref. 30222 & 30222-01)** 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** : .....

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® FERRITINE 60 TESTS (Ref. 30411)

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).

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 Table 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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® FERRITINE 60 TESTS (Ref. 30411) 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
30411	1008747640	VIDAS® FERRITINE 60 TESTS	11-May-22	27-Nov-21
30411	1008748190	VIDAS® FERRITINE 60 TESTS	10-May-22	19-Dec-21
30411	1008755660	VIDAS® FERRITINE 60 TESTS	21-May-22	19-Dec-21
30411	1008757920	VIDAS® FERRITINE 60 TESTS	27-May-22	12-Dec-21
30411	1008793210	VIDAS® FERRITINE 60 TESTS	2-Jun-22	9-Jan-22
30411	1008809670	VIDAS® FERRITINE 60 TESTS	14-Jun-22	9-Jan-22
30411	1008812930	VIDAS® FERRITINE 60 TESTS	3-Jun-22	9-Jan-22
30411	1008815210	VIDAS® FERRITINE 60 TESTS	13-Jun-22	9-Jan-22
30411	1008816700	VIDAS® FERRITINE 60 TESTS	17-Jun-22	9-Jan-22
30411	1008821300	VIDAS® FERRITINE 60 TESTS	16-Jun-22	9-Jan-22
30411	1008828840	VIDAS® FERRITINE 60 TESTS	28-Jun-22	25-Jan-22
30411	1008838350	VIDAS® FERRITINE 60 TESTS	27-Jun-22	25-Jan-22
30411	1008845330	VIDAS® FERRITINE 60 TESTS	1-Jul-22	5-Feb-22
30411	1008854100	VIDAS® FERRITINE 60 TESTS	8-Jul-22	8-Feb-22
30411	1008903380	VIDAS® FERRITINE 60 TESTS	2-Aug-22	22-Feb-22
30411	1008903160	VIDAS® FERRITINE 60 TESTS	1-Aug-22	7-Mar-22
30411	1008928580	VIDAS® FERRITINE 60 TESTS	20-Aug-22	21-Mar-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® FERRITINE 60 TESTS (Ref. 30411) - 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® FERRITINE 60 TESTS (Ref. 30411) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® FERRITINE 60 TESTS (Ref. 30411)** 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** : .....

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® FT4N 60 TESTS (Ref. 30459)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® FT4N 60 TESTS (Ref. 30459) 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
30459	1008576580	VIDAS® FT4N 60 TESTS	10-Feb-22	25-Jan-22
30459	1008622440	VIDAS® FT4N 60 TESTS	5-Mar-22	9-Feb-22
30459	1008652140	VIDAS® FT4N 60 TESTS	22-Mar-22	23-Feb-22
30459	1008589800	VIDAS® FT4N 60 TESTS	10-Feb-22	25-Jan-22
30459	1008695620	VIDAS® FT4N 60 TESTS	13-Apr-22	25-Mar-22
30459	1008714720	VIDAS® FT4N 60 TESTS	23-Apr-22	4-Apr-22
30459	1008791570	VIDAS® FT4N 60 TESTS	7-Jun-22	17-May-22
30459	1008817980	VIDAS® FT4N 60 TESTS	14-Jun-22	17-May-22
30459	1008827280	VIDAS® FT4N 60 TESTS	22-Jun-22	1-Jun-22
30459	1008852180	VIDAS® FT4N 60 TESTS	8-Jul-22	14-Jun-22
30459	1008888200	VIDAS® FT4N 60 TESTS	27-Jul-22	30-Jun-22
30459	1008918000	VIDAS® FT4N 60 TESTS	12-Aug-22	27-Jul-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® FT4N 60 TESTS (Ref. 30459) - 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® FT4N 60 TESTS (Ref. 30459) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® FT4N 60 TESTS (Ref. 30459)** 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** : .....

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® ANTI-TPO 30 T (Ref. 30461)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® ANTI-TPO 30 T (Ref. 30461) 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
30461	1008772240	VIDAS® ANTI-TPO 30 T	21-May-23	26-Apr-22
30461	1008845910	VIDAS® ANTI-TPO 30 T	24-Jun-23	2-Jun-22
30461	1008857460	VIDAS® ANTI-TPO 30 T	5-Jul-23	13-Jun-22
30461	1008926950	VIDAS® ANTI-TPO 30 T	5-Aug-23	28-Jul-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® ANTI-TPO 30 T (Ref. 30461) - Substrate Error

---

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® ANTI-TPO 30 T (Ref. 30461) – Substrate Error**"
- ❑ I will implement the required actions regarding impacted lots of **VIDAS® ANTI-TPO 30 T (Ref. 30461)** 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** : .....

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® TESTOSTERONE II 30 TESTS (Ref. 414320)

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).

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® TESTOSTERONE II 30 TESTS (Ref. 414320) 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
414320	1008755640	VIDAS® TESTOSTERONE II 30 TESTS	15-Aug-22	26-Apr-22
414320	1008815760	VIDAS® TESTOSTERONE II 30 TESTS	9-Sep-22	2-Jun-22
414320	1008862630	VIDAS® TESTOSTERONE II 30 TESTS	3-Oct-22	13-Jun-22
414320	1008892260	VIDAS® TESTOSTERONE II 30 TESTS	21-Oct-22	23-Jun-22
414320	1008905890	VIDAS® TESTOSTERONE II 30 TESTS	26-Oct-22	5-Jul-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® TESTOSTERONE II 30 TESTS (Ref. 414320) - 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® TESTOSTERONE II 30 TESTS (Ref. 414320) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® TESTOSTERONE II 30 TESTS (Ref. 414320)** 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** : .....

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® ANTI-TG 30 T (Ref. 30462)

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).

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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® ANTI-TG 30 T (Ref. 30462) 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
30462	1008748270	VIDAS® ANTI-TG 30 T	2-Aug-22	4-Apr-22
30462	1008770010	VIDAS® ANTI-TG 30 T	15-Aug-22	9-May-22
30462	1008777840	VIDAS® ANTI-TG 30 T	31-Aug-22	26-Apr-22
30462	1008862600	VIDAS® ANTI-TG 30 T	22-Sep-22	13-Jun-22
30462	1008866080	VIDAS® ANTI-TG 30 T	3-Oct-22	23-Jun-22
30462	1008904010	VIDAS® ANTI-TG 30 T	20-Oct-22	5-Jul-22
30462	1008924530	VIDAS® ANTI-TG 30 T	3-Nov-22	5-Jul-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® ANTI-TG 30 T (Ref. 30462) - 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® ANTI-TG 30 T (Ref. 30462) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® ANTI-TG 30 T (Ref. 30462)** 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** : .....

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® T4 60 TESTS (Ref. 30404)

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).

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 Table 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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® T4 60 TESTS (Ref. 30404) 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
30404	1008679630	VIDAS® T4 60 TESTS	6-Apr-22	10-Mar-22
30404	1008598120	VIDAS® T4 60 TESTS	19-Feb-22	25-Jan-22
30404	1008735990	VIDAS® T4 60 TESTS	5-May-22	19-Apr-22
30404	1008815190	VIDAS® T4 60 TESTS	16-Jun-22	27-May-22
30404	1008843810	VIDAS® T4 60 TESTS	2-Jul-22	14-Jun-22
30404	1008905920	VIDAS® T4 60 TESTS	10-Aug-22	29-Jun-22

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® T4 60 TESTS (Ref. 30404) - 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® T4 60 TESTS (Ref. 30404) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® T4 60 TESTS (Ref. 30404)** 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** : .....

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® SARS-COV-2 IgG (9COG) 60T (Ref. 423834 & 423834-01)

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 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, 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 and 2, 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).

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 and 2, 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 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 bioMerieux representative to order the replacement products when appropriate,
- As a reminder, please store the VIDAS® SARS-COV-2 IgG (9COG) 60T (Ref. 423834 & 423834-01) 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 NO remaining shelf life (taking into account the revised expiry date).

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
423834	1008630790**	VIDAS® SARS-COV-2 IgG (9COG) 60T	23-Feb-22	4-Oct-21
423834	1008671420**	VIDAS® SARS-COV-2 IgG (9COG) 60T	29-Mar-22	26-Oct-21
423834	1008674550**	VIDAS® SARS-COV-2 IgG (9COG) 60T	6-Apr-22	26-Oct-21
423834	1008685700**	VIDAS® SARS-COV-2 IgG (9COG) 60T	14-Apr-22	2-Nov-21
423834-01	1008671430**	VIDAS® SARS-COV-2 IgG (9COG) 60T	29-Mar-22	26-Oct-21

** 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
423834	1008714650	VIDAS® SARS-COV-2 IgG (9COG) 60T	28-Apr-22	17-Nov-21
423834	1008730600	VIDAS® SARS-COV-2 IgG (9COG) 60T	30-Apr-22	30-Nov-21
423834	1008747950	VIDAS® SARS-COV-2 IgG (9COG) 60T	11-May-22	12-Dec-21
423834	1008750690	VIDAS® SARS-COV-2 IgG (9COG) 60T	17-May-22	12-Dec-21
423834-01	1008763910	VIDAS® SARS-COV-2 IgG (9COG) 60T	11-May-22	12-Dec-21

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333-1 - VIDAS® SARS-COV-2 IgG (9COG) 60T (Ref. 423834 & 423834-01) - 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® SARS-COV-2 IgG (9COG) 60T (Ref. 423834 & 423834-01) – Substrate Error**"

❑ I will implement the required actions regarding impacted lots of **VIDAS® SARS-COV-2 IgG (9COG) 60T (Ref. 423834 & 423834-01)** 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** : .....