



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

Address
City, Date

Our reference: FSCA#5333

IMPORTANT:
GLOBAL FIELD SAFETY NOTICE - Correction
VIDAS® Immuno-Assays Multiple references
Substrate error - Potential delayed results

Dear bioMérieux Customer,

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 following 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)



- This 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, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products (listed in Table 1 below) is required to ensure that the specified products will continue to perform per labelled performance specifications.

We understand this complex matter creates a significant inconvenience. 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-assays 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-Assays references products:

| Product Reference | Product name | Attachements |
|-------------------|----------------------------------|-----------------------------------|
| 30118 | VIDAS® C. difficile Toxin A & B | See attachment 1 |
| 30118-01 | | |
| 30125 | VIDAS® C. difficile GDH | See attachment 2 |
| 30125-01 | | |
| 30211 | VIDAS® TOXO Compétition | See attachment 3 |
| 30308 | VIDAS® Anti-HCV | See attachment 4 |
| 30314 | VIDAS® Anti-HBc Total II | See attachment 5 |
| 30315 | VIDAS® HBs Ag Ultra | See attachment 6 |
| 30318 | VIDAS® Anti-HBs Total II | See attachment 7 |
| 30405 | VIDAS® HCG | See attachment 8 |
| 30409 | VIDAS® Progesterone | See attachment 9 |
| 30409-01 | | |
| 30421 | VIDAS® CK-MB | See attachment 10 |
| 30439 | VIDAS® HBc IgM II | See attachment 11 |
| 30443 | VIDAS® HIV DUO Ultra | See attachment 12 |
| 30446 | VIDAS® Myoglobin | See attachment 13 |
| 30447 | VIDAS® HIV DUO Quick | See attachment 14 |
| 30450 | VIDAS® B•R•A•H•M•S PCT™ | See attachment 15 |
| 30450-01 | | |
| 30450-30 | | |
| 30450-86 | | |
| 30455 | VIDAS® D-Dimer Exclusion II™ | See attachment 16 |
| 30455-01 | | |
| 30455-02 | | |
| 30455-30 | | |
| 30458 | VIDAS® NT-proBNP2 | See attachment 17 |
| 30458-30 | | |
| 30603 | VIDAS® Digoxin | See attachment 18 |
| 415386 | VIDAS® High sensitive Troponin I | See attachment 19 |
| 415386-30 | | |
| 418115 | VIDAS® Anti-HEV IgM | See attachment 20 |
| 421172-03 | VIDAS® NEPHROCHECK® | See attachment 21 |
| 423077 | VIDAS® DENGUE NS1 Ag | See attachment 22 |
| 423078 | VIDAS® Anti-DENGUE IgM | See attachment 23 |



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

Address
City, Date

Our reference: FSCA#5333

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® CD A.B 60 TESTS (Ref. 30118) & VIDAS®
C.DIFFICILE TOXIN A&B (Ref. 30118-01)
Substrate Error - Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify products listed in Table 1,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® CD A.B 60 TESTS (Ref. 30118) & VIDAS® C.DIFFICILE TOXIN A&B (Ref. 30118-01) 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 |
|------------|--------------|-----------------------------|----------------------------|----------------------------|
| 30118 | 1008731010 | VIDAS CD A.B 60 TESTS | 09-Apr-2022 | 10-Mar-2022 |
| 30118 | 1008926680 | VIDAS CD A.B 60 TESTS | 08-Jul-2022 | 01-Jun-2022 |
| 30118-01 | 1008730880 | VIDAS C.DIFFICILE TOXIN A&B | 09-Apr-2022 | 10-Mar-2022 |



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333 - VIDAS® CD A.B 60 TESTS (Ref. 30118) & VIDAS® C.DIFFICILE TOXIN A&B (Ref. 30118-01) - Substrate Error

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “**VIDAS® CD A.B 60 TESTS (Ref. 30118) & VIDAS® C.DIFFICILE TOXIN A&B (Ref. 30118-01) - Substrate Error**”

- I will implement the required actions regarding impacted lots of **VIDAS® CD A.B 60 TESTS (Ref. 30118) & VIDAS® C.DIFFICILE TOXIN A&B (Ref. 30118-01)** 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

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® GDH 60 TESTS (Ref. 30125)
& VIDAS® C DIFFICILE GDH 60 TESTS
(Ref.30125-01)
Substrate Error – Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify products listed in Table 1,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® GDH 60 TESTS (Ref. 30125) & VIDAS® C DIFFICILE GDH 60 TESTS (Ref.30125-01) 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.

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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 |
|------------|--------------|--------------------------------|----------------------------|----------------------------|
| 30125 | 1008597480 | VIDAS GDH 60 TESTS | 18-Apr-2022 | 25-Jan-2022 |
| 30125 | 1008686700 | VIDAS GDH 60 TESTS | 06-Jun-2022 | 03-Mar-2022 |
| 30125 | 1008859220 | VIDAS GDH 60 TESTS | 03-Sep-2022 | 13-Jun-2022 |
| 30125-01 | 1008686690 | VIDAS C DIFFICILE GDH 60 TESTS | 06-Jun-2022 | 03-Mar-2022 |



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

**FSCA 5333 - VIDAS® GDH 60 TESTS (Ref. 30125)
& VIDAS® C DIFFICILE GDH 60 TESTS
(Ref.30125-01) - Substrate Error**

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “VIDAS® GDH 60 TESTS (Ref. 30125) & VIDAS® C DIFFICILE GDH 60 TESTS (Ref.30125-01) - Substrate Error”

- I will implement the required actions regarding impacted lots of VIDAS® GDH 60 TESTS (Ref. 30125) & VIDAS® C DIFFICILE GDH 60 TESTS (Ref.30125-01) 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

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® ANTI-HCV 60 TESTS (Ref. 30308)
Substrate Error – Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify products listed in Table 1,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® ANTI-HCV 60 TESTS (Ref. 30308) 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.

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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 |
|------------|--------------|-------------------------|----------------------------|----------------------------|
| 30308 | 1008624280 | VIDAS ANTI-HCV 60 TESTS | 30-May-2022 | 26-Jan-2022 |
| 30308 | 1008837640 | VIDAS ANTI-HCV 60 TESTS | 14-Sep-2022 | 26-May-2022 |
| 30308 | 1008722870 | VIDAS ANTI-HCV 60 TESTS | 20-Jul-2022 | 25-Mar-2022 |
| 30308 | 1008808970 | VIDAS ANTI-HCV 60 TESTS | 09-Sep-2022 | 17-May-2022 |
| 30308 | 1008857200 | VIDAS ANTI-HCV 60 TESTS | 01-Oct-2022 | 16-Jun-2022 |
| 30308 | 1008860610 | VIDAS ANTI-HCV 60 TESTS | 01-Oct-2022 | 16-Jun-2022 |



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

**FSCA 5333 - VIDAS® ANTI-HCV 60 TESTS (Ref. 30308)
- Substrate Error**

**TO BE RETURNED TO YOUR BIO-MERIEUX 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-HCV 60 TESTS (Ref. 30308) - Substrate Error**

- I will implement the required actions regarding impacted lots of **VIDAS® ANTI-HCV 60 TESTS (Ref. 30308)** 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

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® ANTI-HBC TOTAL II 60 TEST (Ref. 30314)
Substrate Error – Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify products listed in Table 1,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® ANTI-HBC TOTAL II 60 TEST (Ref. 30314) 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 |
|------------|--------------|------------------------------------|----------------------------|----------------------------|
| 30314 | 1008654830 | VIDAS ANTI-HBC TOTAL II 60 TEST | 11-Mar-2022 | 23-Feb-2022 |



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

**FSCA 5333 - VIDAS® ANTI-HBC TOTAL II 60 TEST (Ref. 30314)
- Substrate Error**

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “**VIDAS® ANTI-HBC TOTAL II 60 TEST (Ref. 30314) - Substrate Error**”
- I will implement the required actions regarding impacted lots of **VIDAS® ANTI-HBC TOTAL II 60 TEST (Ref. 30314)** 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

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® HBS AG ULTRA 60 TESTS (Ref. 30315)
Substrate Error – Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify products listed in Table 1,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® HBS AG ULTRA 60 TESTS (Ref. 30315) 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 |
|------------|--------------|-----------------------------|----------------------------|----------------------------|
| 30315 | 1008612250 | VIDAS HBS AG ULTRA 60 TESTS | 26-Mar-2022 | 25-Jan-2022 |
| 30315 | 1008614380 | VIDAS HBS AG ULTRA 60 TESTS | 26-Mar-2022 | 25-Jan-2022 |
| 30315 | 1008642570 | VIDAS HBS AG ULTRA 60 TESTS | 22-Apr-2022 | 23-Feb-2022 |
| 30315 | 1008735620 | VIDAS HBS AG ULTRA 60 TESTS | 26-May-2022 | 07-Apr-2022 |
| 30315 | 1008790310 | VIDAS HBS AG ULTRA 60 TESTS | 05-Jul-2022 | 17-May-2022 |
| 30315 | 1008790410 | VIDAS HBS AG ULTRA 60 TESTS | 05-Jul-2022 | 17-May-2022 |
| 30315 | 1008861610 | VIDAS HBS AG ULTRA 60 TESTS | 06-Aug-2022 | 16-Jun-2022 |



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

**FSCA 5333 - VIDAS® HBS AG ULTRA 60 TESTS (Ref. 30315)
- Substrate Error**

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “**VIDAS® HBS AG ULTRA 60 TESTS (Ref. 30315) - Substrate Error**”
- I will implement the required actions regarding impacted lots of **VIDAS® HBS AG ULTRA 60 TESTS (Ref. 30315)** 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

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® ANTI HBS TOTAL II 60T (Ref. 30318)
Substrate Error – Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify products listed in Table 1,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® ANTI HBS TOTAL II 60T (Ref. 30318) 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 |
|------------|--------------|-----------------------------|----------------------------|----------------------------|
| 30318 | 1008719940 | VIDAS ANTI HBS TOTAL II 60T | 29-Jul-2022 | 30-Nov-2021 |
| 30318 | 1008830740 | VIDAS ANTI HBS TOTAL II 60T | 07-Oct-2022 | 18-Jan-2022 |
| 30318 | 1008865350 | VIDAS ANTI HBS TOTAL II 60T | 03-Nov-2022 | 06-Feb-2022 |



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

**FSCA 5333 - VIDAS® ANTI HBS TOTAL II 60T (Ref. 30318)
- Substrate Error**

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “**VIDAS® ANTI HBS TOTAL II 60T (Ref. 30318) - Substrate Error**”
- I will implement the required actions regarding impacted lots of **VIDAS® ANTI HBS TOTAL II 60T (Ref. 30318)** 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

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® Progesterone 60 TESTS (Ref. 30409 &
30409-01)
Substrate Error – Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify products listed in Table 1,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® Progesterone 60 TESTS (Ref. 30409 & 30409-01) 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 |
|----------|------------|-----------------------------|---------------------|---------------------|
| 30409 | 1008615920 | VIDAS PROGESTERONE 60 TESTS | 02-Mar-2022 | 03-Feb-2022 |
| 30409 | 1008685480 | VIDAS PROGESTERONE 60 TESTS | 20-May-2022 | 07-Apr-2022 |
| 30409 | 1008686900 | VIDAS PROGESTERONE 60 TESTS | 13-Apr-2022 | 22-Mar-2022 |
| 30409 | 1008730710 | VIDAS PROGESTERONE 60 TESTS | 29-Apr-2022 | 04-Apr-2022 |
| 30409 | 1008775650 | VIDAS PROGESTERONE 60 TESTS | 28-May-2022 | 09-May-2022 |
| 30409 | 1008816010 | VIDAS PROGESTERONE 60 TESTS | 10-Jun-2022 | 09-May-2022 |
| 30409 | 1008816030 | VIDAS PROGESTERONE 60 TESTS | 10-Jun-2022 | 09-May-2022 |
| 30409 | 1008873190 | VIDAS PROGESTERONE 60 TESTS | 08-Jul-2022 | 23-Jun-2022 |
| 30409 | 1008911230 | VIDAS PROGESTERONE 60 TESTS | 06-Aug-2022 | 05-Jul-2022 |
| 30409-01 | 1008685490 | VIDAS PROGESTERONE 60 TESTS | 13-Apr-2022 | 22-Mar-2022 |
| 30409-01 | 1008766980 | VIDAS PROGESTERONE 60 TESTS | 29-Apr-2022 | 04-Apr-2022 |
| 30409-01 | 1008775630 | VIDAS PROGESTERONE 60 TESTS | 28-May-2022 | 09-May-2022 |
| 30409-01 | 1008873180 | VIDAS PROGESTERONE 60 TESTS | 08-Jul-2022 | 23-Jun-2022 |
| 30409-01 | 1008911240 | VIDAS PROGESTERONE 60 TESTS | 06-Aug-2022 | 05-Jul-2022 |



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333 - VIDAS® Progesterone 60 TESTS (Ref. 30409 & 30409-01) - Substrate Error

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “**VIDAS® Progesterone 60 TESTS (Ref. 30409 & 30409-01) - Substrate Error**”
- I will implement the required actions regarding impacted lots of **VIDAS® Progesterone 60 TESTS (Ref. 30409 & 30409-01)** 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

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® HBC IGM II 30 TESTS (Ref. 30439)
Substrate Error – Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify products listed in Table 1,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® HBC IGM II 30 TESTS (Ref. 30439) 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 |
|------------|--------------|---------------------------|----------------------------|----------------------------|
| 30439 | 1008636760 | VIDAS HBC IGM II 30 TESTS | 12-Mar-2022 | 23-Feb-2022 |
| 30439 | 1008888750 | VIDAS HBC IGM II 30 TESTS | 29-Jun-2022 | 08-Jun-2022 |



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333 - VIDAS® HBC IGM II 30 TESTS (Ref. 30439) - Substrate Error

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “**VIDAS® HBC IGM II 30 TESTS (Ref. 30439) - Substrate Error**”
- I will implement the required actions regarding impacted lots of **VIDAS® HBC IGM II 30 TESTS (Ref. 30439)** 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

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® HIV DUO ULTRA 60 TESTS (Ref. 30443)
Substrate Error – Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

Required actions:

We request you to take the following actions at this time:

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



Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1 or Table 2.

- **For products with No remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify impacted lots in Table 1,
 - Stop using the listed impacted lots
 - Destroy the remaining lots in your inventory.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 2:**
 - Identify products listed in Table 2,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 2.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® HIV DUO ULTRA 60 TESTS (Ref. 30443) 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 |
|-------|--------------|------------------------------|---------------------|---------------------|
| 30443 | 1008675340** | VIDAS HIV DUO ULTRA 60 TESTS | 30-Mar-2022 | 13-Sep-2021 |

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

| REF | Lot # | Product Name | Current Expiry date | Revised Expiry date |
|-------|------------|------------------------------|---------------------|---------------------|
| 30443 | 1008745740 | VIDAS HIV DUO ULTRA 60 TESTS | 27-Apr-2022 | 18-Oct-2021 |
| 30443 | 1008829020 | VIDAS HIV DUO ULTRA 60 TESTS | 29-Jun-2022 | 19-Dec-2021 |
| 30443 | 1008834410 | VIDAS HIV DUO ULTRA 60 TESTS | 21-Jun-2022 | 06-Dec-2021 |

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



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333 - VIDAS® HIV DUO ULTRA 60 TESTS (Ref. 30443) - Substrate Error

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “**VIDAS® HIV DUO ULTRA 60 TESTS (Ref. 30443) – Substrate Error**”
- I will implement the required actions regarding impacted lots of **VIDAS® HIV DUO ULTRA 60 TESTS (Ref. 30443)** 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

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® MYOGLOBIN 30 TESTS (Ref. 30446)
Substrate Error - Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 2:**
 - Identify products listed in Table 1,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® MYOGLOBIN 30 TESTS (Ref. 30446) 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 |
|------------|--------------|--------------------------|----------------------------|----------------------------|
| 30446 | 1008658660 | VIDAS MYOGLOBIN 30 TESTS | 23-Mar-2022 | 26-Oct-2021 |
| 30446 | 1008708120 | VIDAS MYOGLOBIN 30 TESTS | 22-Apr-2022 | 14-Nov-2021 |
| 30446 | 1008802100 | VIDAS MYOGLOBIN 30 TESTS | 08-Jun-2022 | 01-Jan-2022 |
| 30446 | 1008813810 | VIDAS MYOGLOBIN 30 TESTS | 08-Jun-2022 | 01-Jan-2022 |



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333 - VIDAS® MYOGLOBIN 30 TESTS (Ref. 30446) - Substrate Error

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “**VIDAS® MYOGLOBIN 30 TESTS (Ref. 30446) - Substrate Error**”
- I will implement the required actions regarding impacted lots of **VIDAS® MYOGLOBIN 30 TESTS (Ref. 30446)** 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

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® HIV DUO QUICK 60 TESTS (Ref. 30447)
Substrate Error - Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications.

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1 or Table 2.

- **For products with No remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify impacted lots in Table 1,
 - Stop using the listed impacted lots
 - Destroy the remaining lots in your inventory.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 2:**
 - Identify products listed in Table 2,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 2.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® HIV DUO QUICK 60 TESTS (Ref. 30447) 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 |
|-------|--------------|------------------------------|---------------------|---------------------|
| 30447 | 1008592410** | VIDAS HIV DUO QUICK 60 TESTS | 31-Jan-2022 | 07-Aug-2021 |

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

| REF | Lot # | Product Name | Current Expiry date | Revised Expiry date |
|-------|--------------|------------------------------|---------------------|---------------------|
| 30447 | 1008680850** | VIDAS HIV DUO QUICK 60 TESTS | 11-Apr-2022 | 02-Oct-2021 |
| 30447 | 1008802860 | VIDAS HIV DUO QUICK 60 TESTS | 13-Jun-2022 | 27-Nov-2021 |

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



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333 - VIDAS® HIV DUO QUICK 60 TESTS (Ref. 30447) - Substrate Error

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “**VIDAS® HIV DUO QUICK 60 TESTS (Ref. 30447) – Substrate Error**”
- I will implement the required actions regarding impacted lots of **VIDAS® HIV DUO QUICK 60 TESTS (Ref. 30447)** 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

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® BRAHMS PROCALCITONIN 60T (Ref. 30450, 30450-01 & 30450-86) and VIDAS® BRAHMS PROCALCITONIN 30T (Ref. 30450-30)
Substrate Error - Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of ^{complaints} from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1 or Table 2.

- **For products with No remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify impacted lots in Table 1,
 - Stop using the listed impacted lots
 - Destroy the remaining lots in your inventory.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 2:**
 - Identify products listed in Table 2,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 2.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® BRAHMS PROCALCITONIN 60T (Ref. 30450, 30450-01 & 30450-86) and VIDAS® BRAHMS PROCALCITONIN 30T (Ref. 30450-30) at 2-8°C as described in Product Instructions for Use.

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.

- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible.

We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Yours faithfully,
Customer Service



Table 1: Product with NO remaining shelf life (taking into account the revised expiry date).

| REF | Lot # | Product Name | Current Expiry date | Revised Expiry date |
|----------|--------------|-----------------------------------|---------------------|---------------------|
| 30450 | 1008591130** | VIDAS BRAHMS PROCALCITONIN 60T | 15-Aug-2022 | 20-Sep-2021 |
| 30450 | 1008633310** | VIDAS BRAHMS PROCALCITONIN 60T | 08-Sep-2022 | 28-Sep-2021 |
| 30450 | 1008641870** | VIDAS BRAHMS PROCALCITONIN 60T | 08-Sep-2022 | 28-Sep-2021 |
| 30450-01 | 1008584190** | VIDAS BRAHMS PROCALCITONIN 60T | 10-Aug-2022 | 19-Sep-2021 |
| 30450-01 | 1008603580** | VIDAS BRAHMS PROCALCITONIN 60T | 22-Aug-2022 | 20-Sep-2021 |
| 30450-86 | 1008562400** | VIDAS BRAHMS PROCALCITONIN 60T | 13-Jul-2022 | 06-Sep-2021 |
| 30450-86 | 1008594750** | VIDAS BRAHMS PROCALCITONIN 60T | 21-Aug-2022 | 20-Sep-2021 |

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

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

| REF | Lot # | Product Name | Current Expiry date | Revised Expiry date |
|----------|------------|-----------------------------------|---------------------|---------------------|
| 30450 | 1008661450 | VIDAS BRAHMS PROCALCITONIN 60T | 21-Sep-2022 | 26-Oct-2021 |
| 30450 | 1008722440 | VIDAS BRAHMS PROCALCITONIN 60T | 27-Oct-2022 | 30-Nov-2021 |
| 30450 | 1008741790 | VIDAS BRAHMS PROCALCITONIN 60T | 07-Nov-2022 | 30-Nov-2021 |
| 30450 | 1008769030 | VIDAS BRAHMS PROCALCITONIN 60T | 24-Nov-2022 | 31-Dec-2021 |
| 30450 | 1008796890 | VIDAS BRAHMS PROCALCITONIN 60T | 11-Dec-2022 | 31-Dec-2021 |
| 30450 | 1008784200 | VIDAS BRAHMS PROCALCITONIN 60T | 30-Nov-2022 | 09-Jan-2022 |
| 30450 | 1008817120 | VIDAS BRAHMS PROCALCITONIN 60T | 15-Dec-2022 | 24-Jan-2022 |
| 30450 | 1008886330 | VIDAS BRAHMS PROCALCITONIN 60T | 18-Jan-2023 | 08-Feb-2022 |
| 30450 | 1008926040 | VIDAS BRAHMS PROCALCITONIN 60T | 08-Feb-2023 | 21-Mar-2022 |
| 30450-01 | 1008647850 | VIDAS BRAHMS PROCALCITONIN 60T | 14-Sep-2022 | 18-Oct-2021 |
| 30450-01 | 1008748010 | VIDAS BRAHMS PROCALCITONIN 60T | 14-Nov-2022 | 30-Nov-2021 |
| 30450-01 | 1008888030 | VIDAS BRAHMS PROCALCITONIN 60T | 19-Jan-2023 | 12-Feb-2022 |
| 30450-01 | 1008903210 | VIDAS BRAHMS PROCALCITONIN 60T | 31-Jan-2023 | 21-Feb-2022 |



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



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333 - VIDAS® BRAHMS PROCALCITONIN 60T (Ref. 30450, 30450-01 & 30450-86) and VIDAS® BRAHMS PROCALCITONIN 30T (Ref. 30450-30) - Substrate Error

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “VIDAS® BRAHMS PROCALCITONIN 60T (Ref. 30450, 30450-01 & 30450-86) and VIDAS® BRAHMS PROCALCITONIN 30T (Ref. 30450-30) – Substrate Error”

- I will implement the required actions regarding impacted lots of VIDAS® BRAHMS PROCALCITONIN 60T (Ref. 30450, 30450-01 & 30450-86) and VIDAS® BRAHMS PROCALCITONIN 30T (Ref. 30450-30) as indicated in the Urgent Field Safety Notice.

- Have you encountered impact on patients’ results, or reports of illness or injury related to the identified issue ?
 - Yes No

DATE

SIGNATURE :



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

Address
City, Date

Our reference: FSCA#5333

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

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

Required actions:

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



We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify products listed in Table 1,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® D DIMER EXCLUSION II 60T (Ref. 30455, 30455-02), VIDAS® D DIMER EXCLUSION II 60T US (Ref. 30455-01) and VIDAS® D DIMER EXCLUSION II 30T (Ref. 30455-30) at 2-8°C as described in Product Instructions for Use.

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.

- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible.

We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Yours faithfully,
Customer Service



Table 1 : Product with remaining shelf life (taking into account the revised expiry date)

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



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



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

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

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the "VIDAS® D DIMER EXCLUSION II 60T (Ref. 30455, 30455-02), VIDAS® D DIMER EXCLUSION II 60T US (Ref. 30455-01) and VIDAS® D DIMER EXCLUSION II 30T (Ref. 30455-30) - Substrate Error"
I will implement the required actions regarding impacted lots of VIDAS® D DIMER EXCLUSION II 60T (Ref. 30455, 30455-02), VIDAS® D DIMER EXCLUSION II 60T US (Ref. 30455-01) and VIDAS® D DIMER EXCLUSION II 30T (Ref. 30455-30) as indicated in the Urgent Field Safety Notice
Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue ?
Yes No

DATE

SIGNATURE :



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

Address
City, Date

Our reference: FSCA#5333

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® NT-PROBNP 2 60 TESTS (Ref. 30458)
and VIDAS® NT-PROBNP 2 30 TESTS (Ref.
30458-30)
Substrate Error – Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1 or Table 2.

- **For products with No remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify impacted lots in Table 1,
 - Stop using the listed impacted lots
 - Destroy the remaining lots in your inventory.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 2:**
 - Identify products listed in Table 2,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 2.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® NT-PROBNP 2 60 TESTS (Ref. 30458) and VIDAS® NT-PROBNP 2 30 TESTS (Ref. 30458-30) at 2-8°C as described in Product Instructions for Use.

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.

- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible.

We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Yours faithfully,
Customer Service



Table 1: Product with NO remaining shelf life (taking into account the revised expiry date).

| REF | Lot # | Product Name | Current Expiry date | Revised Expiry date |
|----------|--------------|----------------------------|---------------------|---------------------|
| 30458 | 1008693930** | VIDAS NT-PROBNP 2 60 TESTS | 15-Apr-2022 | 13-Sep-2021 |
| 30458-30 | 1008699310** | VIDAS NT-PROBNP 2 30 TESTS | 15-Apr-2022 | 13-Sep-2021 |

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

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

| REF | Lot # | Product Name | Current Expiry date | Revised Expiry date |
|----------|------------|----------------------------|---------------------|---------------------|
| 30458 | 1008747590 | VIDAS NT-PROBNP 2 60 TESTS | 04-May-2022 | 11-Oct-2021 |
| 30458 | 1008776240 | VIDAS NT-PROBNP 2 60 TESTS | 01-Jun-2022 | 26-Oct-2021 |
| 30458 | 1008838180 | VIDAS NT-PROBNP 2 60 TESTS | 30-Jun-2022 | 17-Nov-2021 |
| 30458 | 1008851520 | VIDAS NT-PROBNP 2 60 TESTS | 30-Jun-2022 | 17-Nov-2021 |
| 30458 | 1008886400 | VIDAS NT-PROBNP 2 60 TESTS | 20-Jul-2022 | 22-Dec-2021 |
| 30458 | 1008894100 | VIDAS NT-PROBNP 2 60 TESTS | 27-Jul-2022 | 04-Jan-2022 |
| 30458 | 1008894140 | VIDAS NT-PROBNP 2 60 TESTS | 27-Jul-2022 | 04-Jan-2022 |
| 30458-30 | 1008776230 | VIDAS NT-PROBNP 2 30 TESTS | 01-Jun-2022 | 26-Oct-2021 |
| 30458-30 | 1008897360 | VIDAS NT-PROBNP 2 30 TESTS | 27-Jul-2022 | 04-Jan-2022 |



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

**FSCA 5333 - VIDAS® NT-PROBNP 2 60 TESTS (Ref. 30458)
and VIDAS® NT-PROBNP 2 30 TESTS (Ref.
30458-30) - Substrate Error**

**TO BE RETURNED TO YOUR BIO-MERIEUX 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® NT-PROBNP 2 60 TESTS (Ref. 30458) and VIDAS® NT-PROBNP 2 30 TESTS (Ref. 30458-30) – Substrate Error**”

- I will implement the required actions regarding impacted lots of **VIDAS® NT-PROBNP 2 60 TESTS (Ref. 30458) and VIDAS® NT-PROBNP 2 30 TESTS (Ref. 30458-30)** as indicated in the Urgent Field Safety Notice.

- Have you encountered impact on patients’ results, or reports of illness or injury related to the identified issue ?
 - Yes No

DATE

SIGNATURE :



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

Address
City, Date

Our reference: FSCA#5333

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® HIGH SENSITIVE TROPONIN I 60 TESTS
(Ref. 415386) and VIDAS® HS TROPONIN I 30
TESTS (Ref. 415386-30)
Substrate Error – Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1 or Table 2.

- **For products with No remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify impacted lots in Table 1,
 - Stop using the listed impacted lots
 - Destroy the remaining lots in your inventory.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 2:**
 - Identify products listed in Table 2,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 2.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® HIGH SENSITIVE TROPONIN I 60 TESTS (Ref. 415386) and VIDAS® HS TROPONIN I 30 TESTS (Ref. 415386-30) at 2-8°C as described in Product Instructions for Use.

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.

- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible.

We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Yours faithfully,
Customer Service



Table 1: Product with NO remaining shelf life (taking into account the revised expiry date).

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

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

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

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



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



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

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

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

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “**VIDAS® HIGH SENSITIVE TROPONIN I 60 TESTS (Ref. 415386) and VIDAS® HS TROPONIN I 30 TESTS (Ref. 415386-30) – Substrate Error**”

- I will implement the required actions regarding impacted lots of **VIDAS® HIGH SENSITIVE TROPONIN I 60 TESTS (Ref. 415386) and VIDAS® HS TROPONIN I 30 TESTS (Ref. 415386-30)** as indicated in the Urgent Field Safety Notice.

- Have you encountered impact on patients’ results, or reports of illness or injury related to the identified issue ?
 - Yes No

DATE

SIGNATURE :



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

Address
City, Date

Our reference: FSCA#5333

IMPORTANT:
URGENT FIELD SAFETY NOTICE
VIDAS® HEV IGM 30T (Ref. 418115)
Substrate Error – Potential delayed results

Dear bioMérieux Customer,

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

Description of the issue:

Based on an unusual rate of complaints from the field for “substrate error” leading to a potential delayed results on different VIDAS® references tested on all VIDAS® systems, bioMérieux initiated an investigation.

The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using the common lot of raw material (4-MUP). The only potential risk associated with the substrate error is a delayed result as you need to run another test. There is no risk of false results. The investigation demonstrates that the issue occurs over the product shelf-life. The analyzes of the kinetic model allowed to define a revised expiry date for each impacted lot of VIDAS® Immuno-Assays finished products. When used until the revised expiry date, the product continues to perform per its registered performance specifications

Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products impacted by the issue, is required to ensure the specified products will continue to perform per registered performance specifications.

Impact to Customer/Patient:

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

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



Required actions:

We request you to take the following actions at this time:

Following receipt of this Urgent Field Safety Notice, check inventory to determine if lots are listed in Table 1.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify products listed in Table 1,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
 - Continue product use until revised expiry date.

- Contact your local bioMérieux representative to order the replacement products when appropriate,

- As a reminder, please store the VIDAS® HEV IGM 30T (Ref. 418115) 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 |
|------------|--------------|---------------------|----------------------------|----------------------------|
| 418115 | 1008652560 | VIDAS HEV IGM 30T | 19-Sep-2022 | 23-Feb-2022 |
| 418115 | 1008776540 | VIDAS HEV IGM 30T | 28-Nov-2022 | 28-Apr-2022 |
| 418115 | 1008868900 | VIDAS HEV IGM 30T | 16-Jan-2023 | 14-Jun-2022 |



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5333 - VIDAS® HEV IGM 30T (Ref. 418115) - Substrate Error

**TO BE RETURNED TO YOUR BIO-MERIEUX 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 IGM 30T (Ref. 418115) - Substrate Error**”
- I will implement the required actions regarding impacted lots of **VIDAS® HEV IGM 30T (Ref. 418115)** 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 :