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).



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

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

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

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

* All impacted lots of VIDAS® Immuno-assays were conform to the specifications at release.
* The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using a common lot of raw material (4-MUP) that was identified as the most probable common root-cause.
* The scope of the issue was identified on all lots of VIDAS® Immuno-Assays manufactured since February 2021 using substrate batches manufactured with this concerned lot of raw material
* The problem is due to an accelerated degradation of the substrate, which follows a linear model over time leading to RFU acceptable limits being reached before the end of the registered shelf life of the product.
* Kinetic evolution analyzes were performed by measuring substrate RFU of a statistically representative number of VIDAS® immuno-assays retained batches (manufactured with the substrate containing the concerned raw material) at different shelf-lives.
* 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](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30118-01 |
| 30125 | VIDAS® C. difficile GDH | [See attachment 2](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30125-01 |
| 30211 | VIDAS® TOXO Compétition | [See attachment 3](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30308 | VIDAS® Anti-HCV | [See attachment 4](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30314 | VIDAS® Anti-HBc Total II | [See attachment 5](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30315 | VIDAS® HBs Ag Ultra | [See attachment 6](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30318 | VIDAS® Anti-HBs Total II | [See attachment 7](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30405 | VIDAS® HCG | [See attachment 8](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30409 | VIDAS® Progesterone | [See attachment 9](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30409-01 |
| 30421 | VIDAS® CK-MB | [See attachment 10](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30439 | VIDAS® HBc IgM II | [See attachment 11](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30443 | VIDAS® HIV DUO Ultra | [See attachment 12](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30446 | VIDAS® Myoglobin | [See attachment 13](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30447 | VIDAS® HIV DUO Quick | [See attachment 14](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30450 | VIDAS® B•R•A•H•M•S PCT™ | [See attachment 15](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30450-01 |
| 30450-30 |
| 30450-86 |
| 30455 | VIDAS® D-Dimer Exclusion II™ | [See attachment 16](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30455-01 |
| 30455-02 |
| 30455-30 |
| 30458 | VIDAS® NT-proBNP2 | [See attachment 17](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 30458-30 |
| 30603 | VIDAS® Digoxin | [See attachment 18](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 415386 | VIDAS® High sensitive Troponin I | [See attachment 19](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 415386-30 |
| 418115 | VIDAS® Anti-HEV IgM | [See attachment 20](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 421172-03 | VIDAS® NEPHROCHECK® | [See attachment 21](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 423077 | VIDAS® DENGUE NS1 Ag | [See attachment 22](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |
| 423078 | VIDAS® Anti-DENGUE IgM | [See attachment 23](https://doclink/livelink/llisapi.dll?func=ll&objId=213014417&objAction=browse&viewType=1) |