



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,

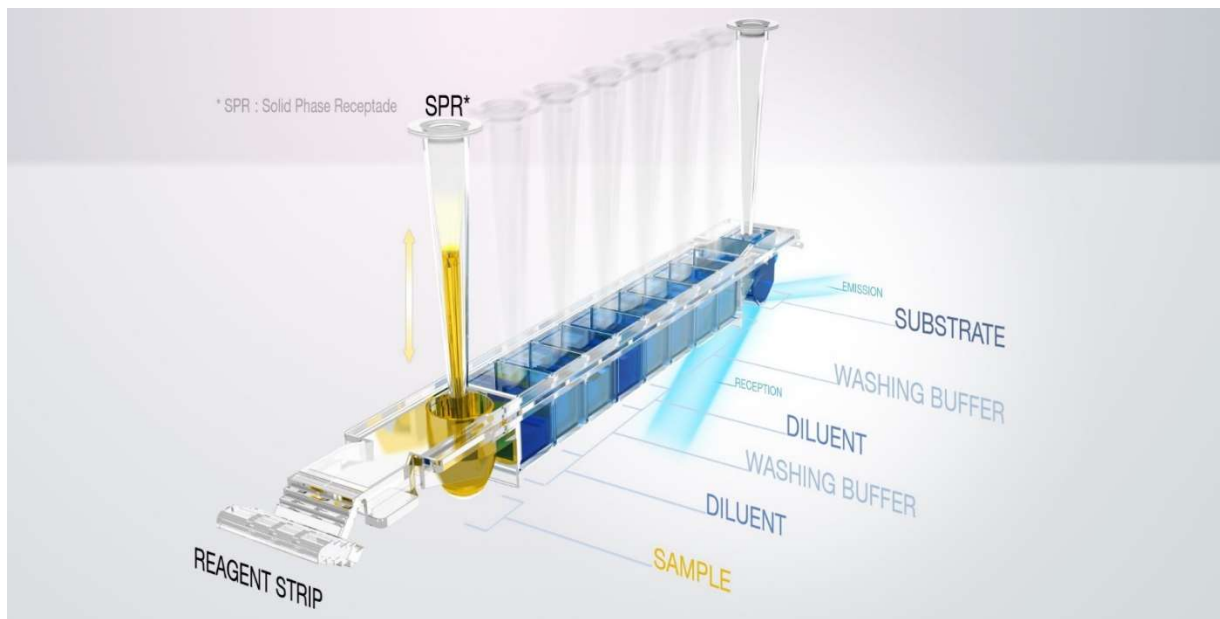
The intent of this letter is to share with you important information regarding clinical VIDAS® Immuno-Assays references products listed below in Table 1. Your laboratory received one/several of the following clinical VIDAS® Immuno-Assays references products and lots.

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)



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	Attechements
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