



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

Address
City, Date

Our reference: FSCA#5333-1

IMPORTANT:
GLOBAL FIELD SAFETY NOTICE - Correction
VIDAS® Immuno-Assays Multiple references
Substrate error - Potential delayed results
without medical impact

Dear bioMérieux Customer,

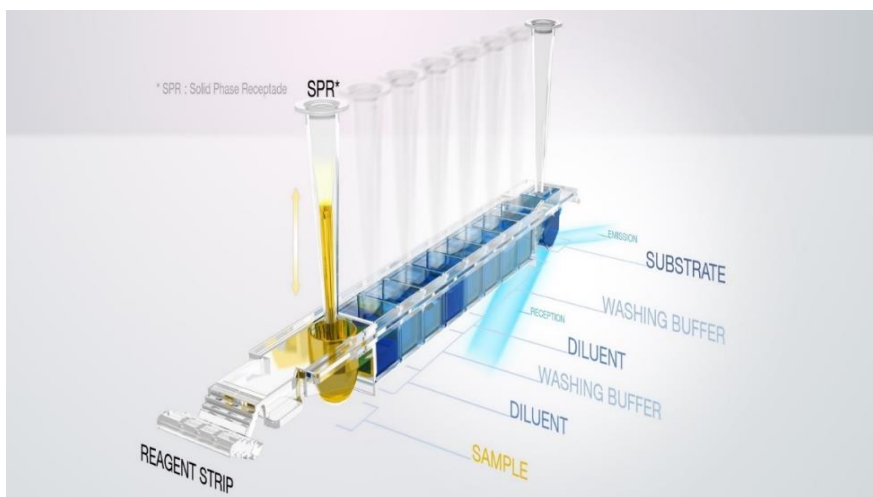
This FSCA #5333-1 is a follow-up of FSCA #5333 (released on 22-Sep-2021). FSCA #5333-1 concerns all lots of clinical VIDAS® immuno-assay product references for which a delayed result **has no medical impact but can lead to a major inconvenience for you.**

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

Description of the issue

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

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



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



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

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

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

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

- All lots impacted of VIDAS® Immuno-assays were conform to the specifications at release.
- The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using a common lot of raw material (4-MUP) that was identified as the most probable common root-cause.
- The scope of the issue was identified on all lots of VIDAS® Immuno-Assays manufactured using substrate batches containing this concerned lot of raw material. Most of the lots of VIDAS® Immuno-Assays since February 2021 were manufactured using this impacted raw material but not all of them.
- The problem is due to an accelerated degradation of the substrate. It follows a linear model over time leading to RFU acceptable limits being reached before the end of the registered shelf life of the product. This reinforced the reason why the VIDAS® Immuno-Assays with the lowest RFU limit (set at 300), were the first assays impacted : VIDAS® HIV DUO QUICK (Ref. 30447).
- Kinetic evolution analyzes were performed by measuring substrate RFU of a statistically representative number of VIDAS® immuno- assays retained batches (manufactured with the substrate containing the concerned raw material) at different shelf-lives. The model was validated on numerous data (~ 450 000) collected from the field (customers) .
- The analysis of the kinetic model allows us to predict the degradation trend of the substrate using the concerned batch of 4MUP and therefore to revise the expiry dates for each lot of impacted VIDAS® Immuno- assays finished products.
- When used until the revised expiry date, the product continues to perform per its registered performance specifications.
- Therefore, corrective actions involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products are required to ensure that the specified products will continue to perform per labelled performance specifications.
- Indeed, even if there is no medical impact in case of delayed result when using the impacted lots of clinical VIDAS® Immuno-assays listed in Table 1 below, as a conservative approach and to avoid a major inconvenience at your level, bioMérieux has decided to implement a Field Safety Corrective Action (FSCA #5333-1).



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

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

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

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

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

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

We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, your local bioMérieux Customer Service representative will be here to assist you.

Yours faithfully,

Customer Service



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

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



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