

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,

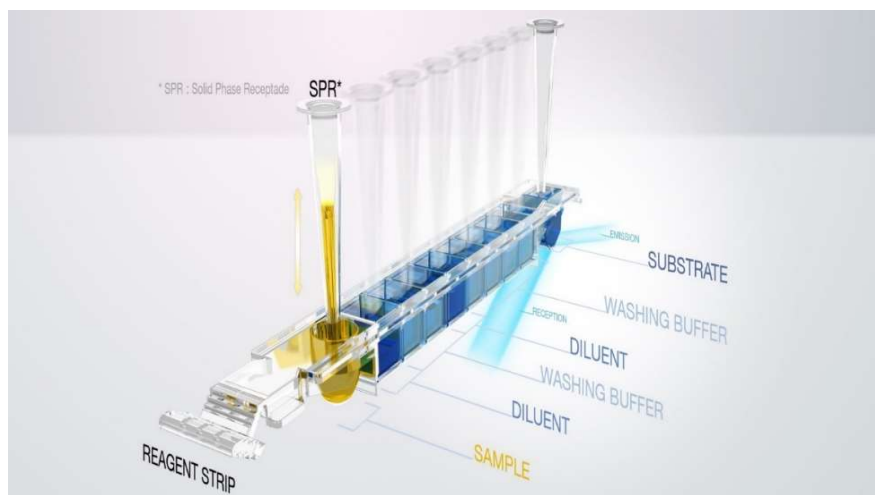
This FSCA #5333-1 is a follow-up of FSCA #5333 (released on 22-Sep-2021). FSCA #5333-1 concerns all lots of clinical VIDAS® immuno-assay product references for which a delayed result **has no medical impact but can lead to a major inconvenience for you**.

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

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