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To the Laboratory Manager
To the attention of the Healthcare Center Chairman
To the attention of the Reactovigilance correspondent

bioMérieux UK Ltd
UK VIGILANCE
UKVIGILANCE@biomerieux.com

Our ref.: 3749 - FSCA – VIDAS and miniVidas Clinical –QCV Alert

Basingstoke, 09th January 2018

IMPORTANT : PRODUCT SAFETY CORRECTION NOTICE
3749 - FSCA - VIDAS And miniVIDAS Clinical - QCV Alert

Dear bioMérieux Customer,

Our records indicate that your laboratory operates one or more VIDAS® and/or mini VIDAS® instruments.

The VIDAS® and mini VIDAS® are automated, multiparametric immunodiagnostic testing instruments intended to be used by trained and qualified laboratory professionals for *In vitro* Diagnostic (IVD) purpose. The VIDAS® and mini VIDAS® instruments are intended to execute immunoassay protocols and to release results according to the package insert of the specific assay kits.

The VIDAS® and mini VIDAS® instruments contain several sub-assemblies that contribute to the overall functionality of the device:

- Electronic control - power supplies and circuitry provide the power and instructions to each component within the instrument.
- Motion - motors, belts and various other hardware provide for the movement of the assay strip trays, the optics assembly and Solid Phase Receptacles (SPR®) block.
- Optics – scanner head detecting and transmitting the fluorescence readings from the assay reactions in the assay strip.
- Reagent pipetting or liquid pipetting- performed via one pipettor module (pump) per each section; each pump performs all fluid transfer operations using the assay strip contents and the Solid Phase Receptacles.

The VIDAS® and mini VIDAS® are composed of multiple sections that allow the user to run multiple independent immunoassay tests. VIDAS® contains five (5) separate sections, while the mini VIDAS® contains two (2) separate sections. **It is important to note that each of these sections contains a separate pump.**

To ensure the instruments function as intended and provide accurate results, two (2) methods of control are available to the user.

1. For the instrument functionality, the Quality Control VIDAS® (QCV®) assay has been designed to detect pump related issues, including abnormal operation of pipette mechanisms (reagent handling) that may affect test results, and to alert this to the user:
    a. This control is based on a testing principle that corresponds to successive aspirations/dilutions of fluorescent substrate solutions which are standardized and have varying levels of concentration.

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b. The aspirations are performed at different speeds to check pump aspiration capability and determine whether there is a potential pipetting issue that could impact results.
c. QCV® must be performed on all positions to ensure that the whole instrument has been checked.
d. The sensitivity of QCV® allows for detectability of pump issues before impacting the biological test results. If QCV® alerts the user, the corresponding instructions in the Instrument User Manual should be followed, up to and including contacting bioMérieux support. The Manual recommends that you perform a retrospective analysis of all patient specimens processed since the last successful QCV® test (currently monthly).

2. For the laboratory testing, External Quality Controls (EQC) are intended as a Quality Control to monitor precision of laboratory testing and must be used in accordance with the package insert, laboratory policy and in compliance with Governmental Regulations & Accreditation Requirements. Please note that External QC is not specifically intended to detect pump anomalies.

Table 1 : Impacted VIDAS® and mini VIDAS® systems:

Ref	System	In combination with	
		Product Name	Ref
99174, 99733, 99734, 99737, 99739, 410416, 410417, W1421	mini VIDAS®	Quality Control VIDAS® (QCV®)	30706
93296, 93297, 99011, 99444, 99735, W3205	VIDAS®		

Description of the issue:
Based on a review of relevant data and feedback from users following QCV alert on VIDAS® / mini VIDAS®, we have identified there are due to some pump clogging and displacement of the color-coded SPR® label (DOT). These pump clogging and DOT displacement could contribute to erroneous results for any assay performed on the VIDAS® and mini VIDAS® system due to a decrease of pipetted volume.

In response, bioMérieux is taking action to help ensure the instruments perform as intended:
1. Pumps have to be changed every 7 years.
2. bioMérieux will systematically clean the VIDAS® / mini VIDAS® pumps during the yearly Preventive Maintenance.

Required customer actions:
In addition to the actions taken by bioMérieux defined above, we also need your support to implement the following permanent changes to how you manage your VIDAS® or mini VIDAS® system.

1. Increase the frequency of the Quality Control VIDAS® (QCV®) testing to weekly rather than monthly to reduce the period of potential retrospective analyses needed. In the event of QCV® test alert, it is recommended to review previous patient results with the laboratory medical director, and perform a retrospective analysis of all patient specimens processed since the last successful QCV® test (now weekly). Consequently the QCV® frequency change from monthly to weekly will reduce the retrospective analysis in case of a QCV® alert. Please note that bioMérieux will update the User Manual to reflect this new requirement.

2. As indicated within the Instructions For Use, continue to conduct a visual inspection of the SPR® after each run (including patient sample test and QCV® test) to ensure that the dot on the SPR® is still in place. If a SPR does not have its color-coded dot, perform the following.
    i. Reject the result corresponding to the defective SPR®.
    ii. Check that the color-coded DOT is not adhered to the SPR® block or seal; if it is, remove it.
    iii. Repeat the assay.
    iv. Contact bioMérieux Technical Assistance or your bioMérieux representative.

3. Continue to perform External QC testing in accordance with laboratory policy and in compliance with Governmental Regulations & Accreditation Requirements. bioMérieux is not requesting that you perform additional EQC testing.
   NOTE: While EQC can qualify overall test and/or instrument performance, please be aware that EQC testing cannot detect pump issues in other sections than the section(s) where EQC is performed.

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4. Please insure this letter is distributed to, and reviewed by, all appropriate personnel within your organization.

5. Please store this letter with your bioMérieux VIDAS® and /or mini VIDAS® documentation.

6. Please complete and return the Acknowledgement Form in Attachment A by Fax to confirm receipt of this notice.

bioMérieux SA is committed to providing our customers with the highest quality products, and we apologize for any inconvenience this has caused your institution. If you have any questions or concerns, please contact your local bioMérieux representative.

Thank you for your continued use of bioMérieux products,

bioMérieux
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Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE

FSCA 3749 – mini VIDAS® and VIDAS® - QCV alert

TO BE RETURNED TO UKVIGILANCE AT THE FOLLOWING

EMAIL ADDRESS : UKVIGILANCE@BIOMERIEUX.COM

OR ALTERNATIVELY BY POST:

BIOMERIEUX UK LTD
GRAFTON WAY,
BASINGSTOKE,
HAMPSHIRE,
RG22 6HY

CUSTOMER INFORMATION:

ORGANIZATION NAME:	
CITY, STATE AND POSTAL CODE:	
CONTACT NAME:	
CONTACT TITLE:	

Customer number:

❑ I acknowledge the receipt of bioMérieux Urgent Product Correction Notice informing this company regarding the mini VIDAS® and VIDAS® - QCV alert.

❑ I have followed the instructions and implemented the actions as indicated in the Urgent Product Correction Notice.

Have you received reports of illness or injury related to the identified issue?
❑ Yes or ❑ No

DATE ..... **SIGNATURE : .....**

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