Geneva, July 17th, 2018
FCA 3976

Please forward this information to the laboratory
IMPORTANT PRODUCT CORRECTION NOTICE
VIDAS® CA 15-3 (Ref. 30429)
Standard S1 signal decrease
Lots 1006022590 and 1006251930

Reply required

Dear valued bioMérieux Customer,

This letter is intended for all customers using VIDAS CA 15-3 (Ref. 30429) lots 1006022590 and 1006251930. Our records indicate that your laboratory has received this concerned product.

Description of the issue

Following customers' complaints for calibrations out of range (Standard S1 out of range low and/or Control C1 out of range high) when using VIDAS CA 15-3 lots 1006022590 and 1006251930, investigators confirmed a defect on the identified products and reproduced the issue reported by the customers.

It has been identified that S1 signal decrease was probably due to a particular lot of raw material (bovine albumin) which is a component of standard S1, which was not performing as expected. This lot of raw material was not used for the manufacturing of any other product.

It has been established that standard S1 will continue to decrease over time, what will lead both lots of finished products to be unusable due to invalid calibrations.

Investigators showed that control C1 is conforming expected specifications. Its Relative Fluorescence Value (RFV) does not evolve overtime. The C1 out of range high reported by some customers is not linked to a signal increase but is due to Standard S1 decrease.

As the VIDAS systems trigger an alarm in case of invalid calibration, the defect is easily identified.

The identified issue can lead to delayed results. There is no risk for false results.

bioMérieux (Suisse) SA
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Tél.: + 41 (0)22 906 57 60 - Fax: + 41 (0)22 906 57 42 - www.biomerieux.ch

Impact to patient/customer:

The defect (Standard S1 signal decrease) can have two impacts on the finished product:

- Standard S1 is obtained out of range low at the opening of the kit: the kit cannot be calibrated and cannot be used, what leads to delayed results.
- Control C1 is obtained out of range high at the time of the recalibration: the kit cannot be calibrated and cannot be used, what leads to delayed results.

Required actions:

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy for your files, and forward this information to all parties that may use this product, including others to whom you may have transferred this product.
- Destroy the impacted lots: VIDAS CA 15-3 (Ref. 30429) lots 1006022590 and 1006251930.
- Complete the attached Acknowledgement Form in Attachment A and return it to your local bioMérieux representative.
- If you wish to be supplied with a replacement VIDAS CA15-3 kit, please call your bioMérieux local representative that will give your laboratory the appropriate support.

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, please contact us at 022 906 57 96.

Thank you for your continued use of bioMérieux products,

With kind regards
bioMérieux (Suisse) SA

Sabrina Wulf
Product Manager Immunoassays

Attachment A: Acknowledgement Form

Attachment A:

ACKNOWLEDGEMENT FORM

IMPORTANT PRODUCT CORRECTION NOTICE
Reply required

Please return to your bioMérieux customer service:
Email: ch_support@biomerieux.com - Fax-Nr. 022 906 57 42

FCA - 3976 – VIDAS® CA 15-3 (Ref. 30429) Standard S1 Signal decrease
Lots 1006022590 and 1006251930

Laboratory name: _____

Contact person: _____

City: _____

Customer number: _____

❑ I acknowledge receipt of this bioMérieux Important Product Correction Notice regarding **VIDAS CA 15-3 (Ref. 30429) lots 1006022590 and 1006251930** product issue.

Product : VIDAS CA 15-3 (Ref. 30429) lot 1006022590	
Number of kits received	
Number of kits destroyed	

Product : VIDAS CA 15-3 (Ref. 30429) lot 1006251930	
Number of kits received	
Number of kits destroyed	

❑ I have followed the instructions and implemented the actions as indicated in the Urgent Field Safety Notice.

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

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

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