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

Address
City, Date

Reference: FSCA 4592

IMPORTANT:

URGENT FIELD SAFETY NOTICE

VIDAS® VZG (ref 30217) – batches 1007410330 and 1007393380- Invalid calibration

Dear valued Customer,

You are a VIDAS® Varicella-Zoster IgG (VZG, ref 30217) user and we thank you for your continued confidence. Our records indicate that your laboratory is using bioMerieux VIDAS® VZG batches 1007410330 and 1007393380 (expiry date 08 FEB 2020).

VIDAS® VZG is an automated qualitative test for use on the instruments of the VIDAS family, for the detection of IgG antibodies to varicella zoster virus in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). VIDAS VZG is intended as an aid in the determination of immunological experience with varicella-zoster virus.

Description of the issue :

Following customers complaints for invalid calibration (Relative Fluorescence Value "RFV" Calibrator S1 too high and out of RFV range of MLE data) when using one kit of VIDAS® VZG (ref 30217) batch 1007410330, the investigation (PR#1663066) was initiated.

The tests confirmed the invalid calibration on the customer's kit with an increase of the Calibrator S1 signal.

The tests performed internally showed a signal heterogeneity within the lot of Solid Phase Receptacle (SPR®) included in the kits VIDAS® VZG batches 1007410330 and 1007393380.

The root cause has not been identified yet, the investigation is still ongoing.

Impact to customer:

Using VIDAS® VZG (ref 30217) batches 1007410330 and 1007393380, you could observed two situations :

- If the calibration is invalid; you would have an alert on the VIDAS® instrument. The impact of the issue is a delayed result on patient's sample.
- If the calibration is valid; the risk is to have VZG false positive result on samples.

Required actions:

We request you to take the following actions at this time:

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- Stop using the VIDAS® VZG batches 1007410330 and 1007393380 and destroy the remaining products.
- Discuss any concerns you may have regarding previously reported patient results obtained with your Laboratory Medical Director to determine the appropriate course of action. Results should be reviewed and interpreted in the context of the overall clinical picture. Assess the need for retesting in case of patients at risk after Varicella Zoster virus contact.
- Contact your local customer service if you have observed the issue and if you have a doubt regarding your results.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.

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 your local bioMérieux Customer Service representative.

Yours faithfully,
Customer Service

Attachment A: Acknowledgement Form.

FIELD SAFETY NOTICE
VIDAS® VZG (ref 30217) - batches 1007410330 and 1007393380
Invalid calibration

TO BE RETURNED TO YOUR BIOMÉRIEUX CUSTOMER SERVICE AT THE FOLLOWING FAX NUMBER : XXXXXXXX

Name of the laboratory:

City:

Customer number:

❑ I acknowledge receipt of the bioMérieux letter regarding the **"VIDAS® VZG (ref 30217) - batches 1007410330 and 1007393380- Invalid calibration"**

❑ I will implement the required actions as indicated in the Urgent Product Safety Correction Notice.

REF #	Product Name	SN #
30217	VIDAS® VZG	1007410330
30217	VIDAS® VZG	1007393380

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