Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Laboratory Medical Director

Address
City, Date

Our reference: FSCA#5731

IMPORTANT:

URGENT FIELD SAFETY NOTICE

VIDAS® Anti-HEV IgM (HEVM) Ref. 418115

False positive results

Dear bioMérieux Customer,

Our records indicate that your laboratory received at least one of the lots listed in table 1 below:

Table 1: List of impacted lots

Lot number	Product name	Product reference	Expiry date
1008971220	VIDAS® Anti-HEV IgM (HEVM)	418115	17-AUG-2022
1009082540			11-MAY-2023
1009176230			18-JUN-2023
1009299760			11-SEP-2023
1009421100			14-NOV-2023

Description of the issue

Following complaints from the field for false positive results when using some lots of VIDAS® Anti-HEV IgM (HEVM), bioMérieux initiated an investigation to assess product issue and identify the root-cause,

While the investigation is still ongoing the followings were identified:

- ⇨ The analysis of data retrieved from some impacted customers and tests performed internally allowed to highlight five lots (listed in Table 1) that potentially gave false positive results with patient samples.
- ⇨ The issue occurred only with some specific patient samples. The tests done on internal samples gave conform results.

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com
Legal notice / Mentions légales de la société émettrice

- ⇨ The investigation identified a potential root cause that is non-specific binding to the Solid Phase Receptacle with some patient samples associated to a common raw material (specific peptide lot) used for the manufacturing of these five lots.

- ⇨ The tests done with other lots of VIDAS® Anti-HEV IgM (HEVM) manufactured with another raw material have confirmed that these lots are still conform to the product specifications. Consequently, you can be confident in using other lots of VIDAS® Anti-HEV IgM (HEVM) available on the market.

Impact to customer:

Based on the investigation results, there is a potential of false positive result when using lots of VIDAS® Anti-HEV IgM (HEVM) listed in Table 1.

Required actions:

We request you to take the following actions:

- 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 and discard kits of impacted lots listed in Table 1 remaining in your inventory**.**
- Discuss any concerns you may have regarding previously reported patients' results obtained with any of the lots listed in Table 1 with your Laboratory Medical Director to determine the appropriate course of action.

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.

URGENT FIELD SAFETY NOTICE

FSCA 5731 - VIDAS® Anti-HEV IgM (HEVM) – False positive results

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TO BE RETURNED TO YOUR BIOMERIEUX 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® Anti-HEV IgM (HEVM) Ref. 418115 – False positive results".

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

❑ Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue ?

❑ Yes ❑ No

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