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

Address
City, Date

Our reference: FSCA#5202-1

IMPORTANT:

URGENT FIELD SAFETY NOTICE

Ref. 30318 - VIDAS® Anti-HBs Total II

Risk of false positive results

Dear bioMérieux Customer,

Our records indicate that your laboratory received one/some of the following bioMérieux products and FSCA#5202:

Table 1: List of impacted lots:

Product	Reference	Lot #	Expiry date
VIDAS® Anti-HBs Total II	30318	1007271590	7-Dec-19
VIDAS® Anti-HBs Total II	30318	1007160480	13-Jun-20
VIDAS® Anti-HBs Total II	30318	1007180650	20-Jun-20
VIDAS® Anti-HBs Total II	30318	1007366810	11-Sep-20
VIDAS® Anti-HBs Total II	30318	1007366780	12-Sep-20
VIDAS® Anti-HBs Total II	30318	1007421640	6-Oct-20
VIDAS® Anti-HBs Total II	30318	1007439690	13-Oct-20
VIDAS® Anti-HBs Total II	30318	1007448880	19-Oct-20
VIDAS® Anti-HBs Total II	30318	1007505320	11-Nov-20
VIDAS® Anti-HBs Total II	30318	1007539450	1-Dec-20
VIDAS® Anti-HBs Total II	30318	1007568420	18-Dec-20
VIDAS® Anti-HBs Total II	30318	1007579920	23-Dec-20
VIDAS® Anti-HBs Total II	30318	1007600880	10-Jan-21
VIDAS® Anti-HBs Total II	30318	1007754100	20-Mar-21
VIDAS® Anti-HBs Total II	30318	1007889620	24-May-21
VIDAS® Anti-HBs Total II	30318	1008235530	26-Nov-21
VIDAS® Anti-HBs Total II	30318	1008443310	11-Dec-21
VIDAS® Anti-HBs Total II	30318	1008552810	28-May-22

The aim of this new communication is to inform you about the updated risk analysis related to discordant and potential false positive results with VIDAS® Anti-HBs Total II (Ref. 30318) lots listed Table 1, and to confirm you that the modification of the washing buffer composition improves the specificity of the kit by reducing the interferences and therefore reducing the risk of false positive results**.**

Description of the issue

Based on complaints received with results identified as discordant and potential false positive by some customers, bioMérieux initiated an investigation.

This initial investigation confirmed unexpected cross reactions based on the performances claimed in the Product Instructions for Use (IFU) that could lead to false positive results. The root cause of the referenced issue was identified as interferences, the exact nature of those interferences was not identified. During this investigation, the negative percent agreement with an alternative method (Roche Elecsys®) was assessed and was found similar to the one obtained during the clinical trial at launch of the VIDAS® Anti-HBs Total II (Ref. 30318) assay.

Therefore, bioMérieux has implemented a first Field Safety Corrective Action (FSCA#5202) that was released on 26-May-2021.

New complaints were reported (to date) from two customers having performed a retrospective analysis of previous results obtained with lots impacted by the Urgent Field Safety Notice associated to FSCA#5202.

A complementary investigation and new analysis of the performance data were initiated following those complaints. The data used in our initial investigation to conclude to the absence of drift regarding the specificity of the product were inaccurate. New calculations confirmed a decreased specificity for the lots impacted by the associated FSCA#5202, which led to reevaluate the Probability that the hazardous situation occurring. Taking into account the new analysis and the limitation of the method, the Probability that the hazardous situation occurring, was re-evaluated from extremely low to probable (likely to occur multiple times but not frequently over the product shelf-life).

This change in the product performance data analysis doesn't change the initial scope of affected products (listed in Table 1) nor the decisions of FSCA#5202. The actions required at your level in the Urgent Field Safety Notice of FSCA#5202 remain unchanged.

In parallel, to reduce the non-specific bindings, the composition of the washing buffer of the strip of VIDAS® Anti-HBs Total II (Ref. 30318) was modified. This new washing buffer improves the specificity of the kit by reducing the interferences. **The first lot with the new formulation not impacted by FSCA#5202 was released on 4th June 2021 (lot. #1008719940).**

Impact to customer:

The investigation showed that unexpected cross reactions (interferences) could lead to false positive results.

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 and destroy lots listed in Table 1 not already expired and remaining in your inventory if not already as required in the Urgent Field Safety Notice of FSCA#5202.
- Discuss any concerns you may have regarding previously reported patients' results obtained with one of the lots listed in Table 1 (even those already expired) 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 and/or in case of inconsistencies noticed by the clinicians.

  Note:

  It is important to keep in mind that in the absence of a gold standard method to establish the clinical immune status of a given patient (true presence of anti-HBs antibodies, as a correlate of immune protection against Hepatitis B), the confirmation of a true false positive result may require the use of more than one alternative technique.

- Despite metrological traceability, up to 20% discordant results can be observed between two competitor methods, in particular in the low range of values (*eg* between 10 and 60 mIU/mL). These discordant results are known in the literature and mentioned in our Instructions For Use: Paragraph "Limitations of the method": "Given the diversity of antibodies, the results obtained can differ depending on the assay used. If assays from different manufacturers are used with the same sample, the results can vary as much as four-fold (in rare cases as much as ten-fold)."
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.
- Please contact your local customer service if you have any question.

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 5202-1 - VIDAS® Anti-HBs Total II Ref. 30318 - 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:

❑ I acknowledge receipt of the bioMérieux letter regarding the "**VIDAS® Anti-HBs Total II Ref. 30318 - False Positive results**"

❑ I will implement the required actions, stop using and destroy the affected lots of **VIDAS® Anti-HBs Total II Ref. 30318** 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

Product	Reference	Lot #	Quantity Received	Quantity Destroyed
VIDAS® Anti-HBs Total II	30318	1008235530		
VIDAS® Anti-HBs Total II	30318	1008443310		
VIDAS® Anti-HBs Total II	30318	1008552810		

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