



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

Our reference: FSCA 5202

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 the following bioMérieux products :

Table 1:

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

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



Description of the issue

Based on complaints received with results identified as false positive by the customers (in relation to the clinical status of the patients and/or in relation to another technique), bioMérieux initiated an investigation.

This investigation did not confirm a degraded global specificity for the product VIDAS® Anti-HBs Total II Ref. 30318. However, the investigation showed unexpected interferences that had not been described in the Instructions for Use and that could lead to false positive results.

Based on the above, and even if the probability of occurrence of false positive results has been assessed as extremely low, as a conservative approach BioMérieux has decided to implement a Field Safety Corrective Action.

In parallel, as part of continuous improvement of our products, to reduce the interferences, the composition of the washing buffer of the strip of VIDAS® Anti-HBs Total II Ref. 30318 has been modified to decrease non-specific bindings and therefore decrease the risk of false positive results. The first lot with this new formulation will be released in the coming weeks.

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.
- 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.
- 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 - VIDAS® Anti-HBs Total II Ref. 30318 - False Positive Results

TO BE RETURNED TO YOUR BIO-MERIEUX CUSTOMER SERVICE AT THE FOLLOWING
FAX NUMBER : XXXXXXXXX

Name of the laboratory:

City:

Customer number:

- 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 :