



23 September 2014

Dear Sir / Madam

Our Reference : VIDAS Anti HBs Total II – Ref: 30318 – Lots : see Table
IMPORTANT: Product Correction Notice

Our records indicate you have received the VIDAS Anti HBs Total II – Ref.30318 – lots. see Table below

REF #	Product Name	Lot/ KIT	Lot (Strip)	Expiry date	Release date	Distribution beginning date	Distribution End date
30318	VIDAS® Anti-HBs Total II	1002578500	141029-0	29-OCT-2014	10-FEB-2014	11-FEB-2014	Still ongoing
30318	VIDAS® Anti-HBs Total II	1002755610	141216-0	16-DEC-2014	10-FEB-2014	26-FEB-2014	
30318	VIDAS® Anti-HBs Total II	1002837540	150205-0	05-FEB-2015	07-MAR-2014	11-JUN-2014	
30318	VIDAS® Anti-HBs Total II	1002903980	150323-0	23-MAR-2015	23-APR-2014	10-JUN-2014	

Description of Issue:

In the Instruction for Use (IFU), the paragraph “Specimen stability” states, “the stability of the sample separated from the clot has been validated using samples in stoppered tubes: at 18-25°C for 3 days”. Further review identified that the data study of stability mentioned in the Product Review Development report file (Ref. VR11) is “for stoppered tubes, at 18-25°C for 8 hours”. The information referenced in the current IFU is incorrect with regards to Specimen stability for samples in stoppered tubes. The Instructions for Use should state: “the stability of the sample separated from the clot has been validated using samples in stoppered tubes at 18-25°C for 8 hours”.

Impact:

The product is performing as intended and there is no quality issue associated with the performance of the product. There is no impact of this issue on the customer/patient safety.

Cont....



Required actions:

We request you to take the following actions:

1. Ensure this letter has been distributed and reviewed by all appropriate personnel within your organisation.
2. When using the VIDAS® Anti-HBs Total II kits (REF 30318), please reference the correct information in the customer letter associated with Specimen stability.
3. Fill out and return the Acknowledgement Form for the attention of Customer Service Department to fax number 0044 (0) 1256 816863

bioMérieux can advise that the Competent Authorities have been advised of this action.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologise for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact our Technical Service Department on 0044 (0) 1256 461881.

Thank you for your continued use of bioMérieux products.

Yours faithfully

Customer Service Department

Attachment A: Acknowledgement Form

FIELD NOTICE

FCA 2210 –VIDAS Anti HBs Total II – Ref.30318 – Multiple lots – IFU error

To be returned for the attention of Customer Service Department to fax number: 0044 (0) 1256 816863

I acknowledge the receipt of bioMérieux letter informing about the IFU error for **VIDAS Anti HBs Total II – Ref.30318- Lots. See below**

Reference	Product Name	Lot/ KIT
30318	VIDAS® Anti-HBs Total II	1002578500
30318	VIDAS® Anti-HBs Total II	1002755610
30318	VIDAS® Anti-HBs Total II	1002837540
30318	VIDAS® Anti-HBs Total II	1002903980

In order to comply with Competent Authority Regulations it is important that you complete and return this Acknowledgement Form for the attention Customer Service Department to fax no. 0044 (0) 1256 816863

DATE:

SIGNATURE :

14135 (CA)