Customer Letter VIDAS® D-Dimer Exclusion II™– ref. 30455 and 30455-01 English version

To the attention of the Laboratory Manager

To the attention of the Healthcare Center Chairman

To the attention of the Vigilance Correspondent

IMPORTANT : PRODUCT CORRECTION

VIDAS® D-DIMER EXCLUSION II™ – REF. 30455 and 30455-01

ALL LOTS

Marcy l'Etoile, date

Dear Sir, Dear Madam,

bioMérieux's records indicate that you have received our product VIDAS® D-Dimer Exclusion II™ – references 30455 and 30455-01

REF 30455	Lots	Expiration date
30455	1001408170	16-May-2013
30455	1001246710	16-May-2013
30455	1001479890	15-Jun-2013
30455	1001345580	15-Jun-2013
30455	1001399220	08-Jul-2013
30455	1001490580	09-Aug-2013
30455	1001531500	11-Sep-2013
30455	1001632240	26-Sep-2013
30455	1001735180	26-Sep-2013
30455	1001704040	29-Oct-2013
30455	1001743890	13-Nov-2013
30455	1001820290	18-Dec-2013
30455	1001817830	12-Dec-2013
30455	1002001060	12-Dec-2013
30455	1001860670	11-Jan-2014
30455	1001902620	06-Feb-2013

30455	1001985490	11-Feb-2014
30455	1002112180	11-Feb-2014
REF 30455-01	Lots	Expiration date
30455-01	1001625210	09-Aug-2013
30455-01	1001715580	26-Sept-2013
30455-01	1001711530	11-Sept-2013
30455-01	1001789540	29-Oct-2013
30455-01	1001932680	12-Dec-2013
30455-01	1002010290	11-Jan-2014
30455-01	1002082290	06-Feb-2014

Description of Issue

bioMérieux has registered some customer complaints about not reproducible results below the detection limit (<45 ng/mL) on the above listed lot numbers.
Our internal investigation after testing in-house titrated samples has not reproduced this result.
The specific root cause has not yet been identified, however the investigation into this issue is still in progress.

Impact

The potential risk associated to this issue is reporting false negative results for VIDAS D-Dimer Exclusion II™.
The impact of a false negative D-Dimer test result could be critical for the patient with a low or moderate clinical pretest probability for deep vein thrombosis (DVT) or pulmonary embolism (PE) because it could prevent further diagnostic workup for venous thromboembolism and withholding anticoagulant treatment when it is actually needed, resulting in a negative impact to patient care.

Actions

Please complete the following actions:.

1. Repeat all results less than < 45 ng/mL obtained with the kit VIDAS® D-Dimer Exclusion II™ ref. 30455 and 30455-01.
2. Determine if retrospective analysis of results of the patients is required and investigate further (e.g. final diagnosis and clinical status of the patient) if the result is < 45 ng/mL.
3. Complete and return the Acknowledgement Form in Attachment A by Fax to confirm receipt of this notice

An additional insert will be added to newly manufactured lots to require a confirmation of the results below the detection limit (< 45 ng/mL).

If you have additional questions about the retest, please contact your Local bioMérieux Representative.

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.

The French Competent Authority (ANSM) and Food and Drug Administration (FDA) have been informed of this 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 sincerely,

Customer Service

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA - 1684 – VIDAS® D-DIMER EXCLUSION II™

Customer Information:

Customer Account Number: _____ Organization Name: _____

Street Address: _____

City, State and Postal Code: _____

Contact Name: _____

Contact Title: _____

Phone Number: _____

Product Information:

Catalog Number	Description