

Customer Letter VIDAS® D-DIMER EXCLUSION – ref. 30455 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 REMOVAL

VIDAS® D-DIMER EXCLUSION II – REF. 30455

LOT 1001399220

Marcy l'Etoile, date

Dear Sir, Dear Madam,

bioMérieux's records indicate that you have received our VIDAS® D-Dimer Exclusion II – ref. 30455 lot 1001399220.

Description of Issue

bioMérieux has registered two complaints on false negative results under the detection limit (<45 ng/mL) using the batch 1001399220. The investigation indicates there is the potential for a manufacturing issue to be the cause of the problem and root cause investigations are in-process. As a preventive measure, bioMérieux has decided to remove the suspect product from the field.

Impact

The impact of a false negative D-Dimer test result could be critical for the patient 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

As a consequence of this inconvenience, please complete the following actions:

1. Stop using and destroy the kits of the batch 1001399220 you may have in stock.
2. Perform a retrospective analysis of the patients tested on this batch and investigate further (e.g. final diagnosis and clinical status of the patient) if the result is < 45 ng/mL.
3. Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.
4. Send us back the attached Destruction Certificate by fax xxxxxxxx.

We shall provide replacement kits as soon as we receive the Destruction Certificate.

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) has 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

ACKNOWLEDGEMENT FORM - DESTRUCTION CERTIFICATE

TO BE RETURNED TO YOUR CUSTOMER SERVICE

fax :

Name of the laboratory:

City:

Customer number:

I acknowledge the receipt of bioMérieux letter informing of the possibility to have a false negative result on VIDAS D-Dimer Exclusion II - reference 30455 and that I have to destroy the kits still in my stock

Product : VIDAS D-Dimer Exclusion II- ref 30455 Lot 1001399220 Expiration 2013-07-08	
Number of kits destroyed	_____

DATE

SIGNATURE :