

PRIVELEDGED AND CONFIDENTIAL

Dear Customer

**RECALL NOTICE
IN VITRO DIAGNOSTIC TEST KITS**

PRODUCT: CLEARVIEW SIMPLIFY D-DIMER
PRODUCT CODE: 505285
KIT LOT NUMBERS: PT030A and PT031A
(Containing Test Device Batch Number: 682-024)

Unipath Ltd (a division of Inverness Medical) is recalling the above lots of CLEARVIEW SIMPLIFY D-DIMER TEST KITS. This action follows advice from the original manufacturer that these lots are experiencing a decrease in sensitivity. False negative results are possible on low-level D-dimer samples which may incorrectly influence the clinical diagnostic decision.

Accordingly would you please cease using any product from the above lots for patient testing with immediate effect. If you have removed test devices from the original kit box you should stop using devices labelled with the number 682-024. In addition please confirm to us the quantities of product from these lots that you currently hold via the enclosed Faxback Form.

Please arrange for all such material, including complete kits or part used kits, to be returned to the address below. Prior to returning any product please can you contact [REDACTED] (Tel: 01234 [REDACTED] email: [REDACTED]@unipath.com) or [REDACTED] (Tel: 01234 [REDACTED] email: [REDACTED]@unipath.com) to confirm the quantity of product to be returned and to request a Returns No. which is required to accompany the goods.

Unipath Ltd (returns number...)
Priory Business Park
Bedford
MK44 3UP
United Kingdom Attn: [REDACTED] (QA Manager)

As soon as we have received the returned product then we will arrange for credit to be raised. Should you require extra stocks as a result of this activity then please place an order. Such orders will be shipped and invoiced at normal prices.

I can confirm that the MHRA, as the UK Competent Authority, are being notified of the details of this recall.

I apologise on behalf of Unipath and Inverness Medical for the inconvenience that this may cause you and I would also like to thank you for your continued support of Unipath and Inverness Medical and our products.

For UNIPATH LTD
[REDACTED]
[REDACTED]

15/02/2007

FAX Back Form

Please Complete This Form & Fax Back To: -

To: Unipath Ltd.
F.A.O.: [REDACTED] (QA Manager)
Fax No.: +44 (0)1234 835003
Postal Address: Unipath Ltd.
Priority Business Park
Bedford
MK44 3UP
United Kingdom
Subject: Recall of Clearview Simplify D-dimer
Product Code: 505258
Lot Numbers: PT030A and PT031A
Containing Test Device Batch Number: 682-024

From: Tel. No:
Company:

We *do / do not have any stock which is subject to this recall * denote as applicable

Lot No.:	PT030A	PT031A
Number Of Complete Kits For Return:		
Number Of Part Used Kits For Return:		
Total Number Of Kits For Return:		

Signed: - Dated: -