

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/21

Issued: 9th March 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Coagulation point of care test: Clearview Simplify D-dimer. Kit lot numbers PT030A and PT031A containing test devices of batch number 682-024.</p>	▶ ①
<p>Problem: Increased risk of false negative results.</p>	▶ ②
<p>Action by: Healthcare personnel supplying, using or managing these devices. Medical staff treating patients based on the results of these devices.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Stop using affected product • Identify and quarantine all remaining stock of affected product. • Consider the need to review patients previously tested negative with affected product. • Follow the actions set out in the manufacturer's two notices (see appendix). 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC In accordance with PEL(06)17 acknowledgment of assurance should be given:-</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

The Clearview Simplify D-dimer point of care test is manufactured by Unipath Limited (a division of Inverness Medical).

Boxes of ten individual foil pouches bear the kit lot numbers PT030A and PT031A.

Individual foil pouches bear the batch number 682-024.

NB. It is understood that none of these devices have been supplied by the Northern Ireland distributor, but the product is available directly from the UK and Southern Ireland.

2. PROBLEM:

The Clearview Simplify D-dimer test is intended as an aid in the diagnosis of disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT) and pulmonary embolism. The D-dimer test is intended to be used to help diagnose or exclude thrombotic diseases and conditions and to decide on the need for further treatment or investigation.

The manufacturer has reported a decrease in sensitivity in the affected product. False negative results are possible, which may incorrectly influence clinical decisions. For example, a negative result may be used to rule out DVT and discharge patients without further investigation or treatment.

The manufacturer has recalled affected product and their investigation into the root cause of this problem is ongoing.

3. ACTION BY:

Healthcare personnel supplying, using or managing these devices.

Medical staff treating patients based on the results of these devices.

4. ACTION:

- Stop using affected product
- Identify and quarantine all remaining stock of affected product.
- Consider the need to review patients previously tested negative with affected product.
- Follow the actions set out in the manufacturer's two notices (see appendix).

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- A&E departments
- Ambulance services directors
- Ambulance staff
- Anaesthetic nursing staff
- Anaesthetists
- Anti-coagulation clinics
- Cardiothoracic departments
- Chief biomedical scientists (haematology and coagulation)
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Day surgery units
- Haematologists
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA
- Intensive care units
- Laboratory managers (haematology and coagulation)
- Medical directors
- Outpatient clinics
- Paramedics
- Point of care testing co-ordinators
- Purchasing managers
- Risk managers
- Staff supporting patients receiving haemodialysis at home
- Supplies managers

6. CONTACTS:

Enquires to the manufacturer should be addressed to:

John Wisson
Unipath Limited
Priory Business Park
Bedford
MK44 3UP

Tel: 01234 835 583

Fax: 01234 835 009

E-mail: john.wisson@unipath.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/21 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

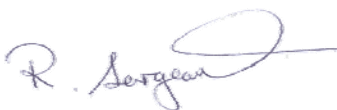
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

Deadline (Email received)	: 12 March 2007
Deadline (action underway)	: 16 March 2007
Deadline (action complete)	: 23 March 2007



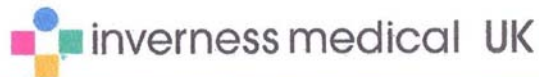
Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

APPENDIX to MDEA(NI)2007/021



Professional Diagnostics

Unipath Limited
Priory Business Park
Bedford, MK44 3UP, UK
T: +44 (0)1234 835000
F: +44 (0)1234 835009

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 Debbie Petersen (Tel: 01234 835141, email: debbie.petersen@unipath.com) or Nicola Emerton (Tel: 01234 835148, email: nicola.emerton@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: Colin Hook (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.

A handwritten signature in blue ink that reads 'C Hook'.

Colin Hook – QA Manager
15/02/2007

FAX Back Form

Please Complete This Form & Fax Back To: -

To: Unipath Ltd.
F.A.O.: Mr. Colin Hook (QA Manager)
Fax No.: +44 (0)1234 835003
Postal Address: Unipath Ltd.
Priory 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: -

End User Fax Back Form

Professional Diagnostics

Priory Business Park
Bedford, MK44 3UP, UK
t: +44 (0)1234 835000
f: +44 (0)1234 835009

1st March 2007

Dear Partner

This is a supplementary communication regarding the recent recall of Clearview Simplify D-dimer. Unipath Ltd would like to provide you with the following recommendation.

As you are aware a recent investigation has shown Clearview Simplify D-dimer lots PT030A and PT031A (containing device lot number 682-024) to have a decrease in sensitivity and as a result both lots have been recalled (refer to letter dated 14th/15th February 2007). False negative results are possible on low-level D-dimer samples tested since November 6th 2006, which may incorrectly influence the clinical diagnostic decision.

As a precaution, Unipath recommend that the healthcare professional or healthcare authority consider following up patients who previously tested negative with either of these affected lots. A subsequent decision to recall and possibly re-test a patient should consider current clinical signs and symptoms. As stated in the instructions for use for this product, 'Clinical diagnosis should not be based on the result of Clearview Simplify D dimer alone.'

If a patient is re-tested it should be noted that a positive result at re-test cannot be compared to a previous negative result as this positive result may be due to a new thrombotic event.

Yours Sincerely



For Unipath Ltd
Colin Hook
QA Manager