

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/ 56

Issued: 12 June 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section								
Medical Device/Equipment: Pregnancy test kits: Clearview HCG, product code 500158, lot number HG0050.	▶ ①								
Problem: Possibility of false negative pregnancy test results.	▶ ②								
Action by: Healthcare personnel using or distributing this device.	▶ ③								
Action: <ul style="list-style-type: none"> Do not use lot HG0050 of the affected product. Quarantine and dispose of all affected product in accordance with the manufacturer's recall letter (see appendix). Develop a local policy for the review of patients tested with affected product. 	▶ ④								
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td></td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table> For onward distribution see Section 5	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust		Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
Chief Executive of each HSS Board	General Medical Practitioners								
Chief Executive of each HSS Trust									
Chief Executive of each Agency									
NIAIC Liaison Officers									
Contacts Details of manufacturer contacts and NIAIC contact for technical aspects.	▶ ⑥								
Feedback Requirements to NIAIC In accordance with PEL(06)17 acknowledgment of assurance should be given:-	▶ ⑦								

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

1. DEVICE/EQUIPMENT:

Clearview HCG
Product code: 500158
Lot number: HG0050
Manufactured by Unipath Ltd (a division of Inverness Medical)

This test is intended for professional use only. It is not intended for direct sale to members of the public.

2. PROBLEM:

The NIAIC has been informed of a patient who received false negative test results when tested with Clearview HCG lot HG0050.

The manufacturer has recalled this lot of product (see appendix).

The manufacturer has determined that this problem was caused by a single manufacturing fault that was not detected by routine quality control checks.

Around 80,000 tests from lot HG0050 were distributed in Europe in March and April 2007. The manufacturer has determined that it is unlikely that more than 44 tests have been affected by the manufacturing fault.

3. ACTION BY:

Healthcare personnel using or distributing this device.

4. ACTION:

- Do not use lot HG0050 of the affected product.
- Quarantine and dispose of all affected product in accordance with the manufacturer's recall letter (see appendix).
- Develop a local policy for the review of patients tested with affected product.

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:

- Accident & emergency departments
- Adult intensive care units
- All wards
- Biochemistry laboratories
- Chemotherapy nurses / consultants
- Chief pharmacists
- Clinical governance leads
- Directors of anaesthetics
- Early pregnancy units
- Family planning clinics
- Health & safety officers
- Medical directors
- Medical Oncology departments
- Microbiology laboratories
- Nursing executive directors
- Obstetrics and gynaecology departments
- Pathology managers
- Pharmacy departments
- POCT co-ordinators / managers
- Radiation oncology departments
- Radiology departments
- Risk managers
- Theatre managers
- Independent Health and Social Care Providers – Private Clinics & Hospitals through RQIA
- Community hospitals
- Directors of public health
- District nurses
- Family planning clinics
- General medical practitioners
- Health visitors
- Lead nurses
- Pharmaceutical advisors
- Pharmacists
- Practice nurses

6. CONTACTS:

Enquires to the manufacturer should be addressed to:

Steven Swales
Unipath Ltd
Priory Business Park
Bedford
MK44 3UP

Tel: 01234 835 928

Fax: 01234 835 009

E-mail: steven.swales@unipath.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/56 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

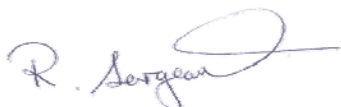
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

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

Deadline (Email received)	: 13 June 2007
Deadline (action underway)	: 14 June 2007
Deadline (action complete)	: 27 June 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/XX

<Letterhead>

<Addressee>

**RECALL NOTICE
IN VITRO DIAGNOSTIC TEST KITS**

PRODUCT: CLEARVIEW HCG
PRODUCT CODE: 500158
KIT LOT NUMBER: HG0050

Dear Customer,

Unipath Ltd (a division of Inverness Medical) is recalling the above lot of CLEARVIEW HCG TEST KITS. This action follows the identification of a manufacturing defect affecting a small proportion of the above lot. This issue has been identified following completion of a customer complaint investigation into reported false negative results. The cause of the defect is associated with the incorrect assembly of some of the devices in this lot. The impact of this defect is to produce either 'False Negative' or 'Void' (no lines) devices when tested with a positive sample.

Please inspect your stocks and identify all units from the above lot number. The lot number is identifiable from printing on the original kit box and also, for any that may have been removed from the original kit box, on individual pouched devices.

Accordingly would you please cease using any product from the above lot with immediate effect.

We would request that you please carry out the following: -

1. Block all materials from the above product lot that you may still have in stock.
2. Dispose of this product to prevent any further use.
3. Complete the enclosed Fax Back Form with the following information and details: -
 - Number Of Kits Received
 - Number Of Kits Blocked & Destroyed
4. Sign and date the Fax Back form to confirm that all affected product has been disposed of and send to Unipath Ltd using the contact details provided.
5. On receipt of the completed Fax Back form we will raise and issue replacement product on a 'Free Of Charge' basis.
6. We would kindly request that any outstanding invoice for the original supplied product still be paid so that 'Free Of Charge' replacement product can be provided.

Recall Letter 3

On behalf of Unipath and Inverness Medical I apologise for the inconvenience that this may cause you and am grateful for your help in expediting resolution of this issue. I would also like to thank you for your continued support of Unipath and Inverness Medical and our products.

For UNIPATH LTD

Colin Hook
QA Manager
31/05/2007

For further information please contact the following: -

<u>Technical Support</u>	Tel: +44 (0)1234 835928 Email: Steven.swales@unipath.com
<u>Customer Services</u>	Tel: +44 (0)1234 835700 Email: Unipath.customercare@unipath.com
<u>Quality Assurance</u>	Tel: +44 (0)1234 835563 Email: Colin.hook@unipath.com

Recall Letter 3