

Medical Device/Equipment ALERT

Ref.MDEA(NI)2008/047

Issued: 25th June 2008

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Pregnancy test kits– Clinitest hCG Cassette, lot numbers 97552 and 97574 (professional use only), manufactured by Siemens Healthcare Diagnostics.</p>	▶ ①
<p>Problem: Recall due to the potential for false negative results.</p>	▶ ②
<p>Action by: Healthcare personnel using or distributing this device. Healthcare personnel treating patients based on results from these test kits.</p>	▶ ③
<p>Action: 1. Do not use affected lots. Discard any unused cassettes from affected lots. 2. Identify patients who have had negative pregnancy test results using these affected lots who are undergoing, or due to start, contraindicated therapies in pregnancy. 3. Consider repeating testing where clinically appropriate.</p>	▶ 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 and clinical aspects.</p>	▶ ⑥
<p style="text-align: center;">Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p> <p>Acknowledge Receipt of Alert: 27th June 2008 Action Under Way: 1st July 2008 Action Complete: 15th July 2008</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Clinitest hCG Cassette Pregnancy Test kit
Product number: 1760
Lot numbers: 97552 and 97574
Distribution date: August 2007
Expiry date of cassettes: 16/17 May 2008

This test is intended for professional use only. It is not intended for home use.

2. PROBLEM:

The manufacturer has identified, through internal product testing, that affected lots may give false negative results at the lower limit of detection (25 mIU/ml), due to decreased sensitivity of the test cassettes for hCG.

The manufacturer has recalled the affected lots (see appendix).

The MHRA is issuing an alert on this incident despite the cassettes having expired as there is a risk that women in very early stages of pregnancy may have had a false negative test and go on to have treatment contraindicated in pregnancy. In particular, women undergoing radiation or chemotherapy may be at risk.

The MHRA has not received any reports of false negative results from the affected lots.

3. ACTION BY:

Healthcare personnel using or distributing this device.

Healthcare personnel treating patients based on results from these test kits.

4. ACTION:

1. Do not use affected lots. Discard any unused cassettes from affected lots.
2. Identify patients who have had negative pregnancy test results using these affected lots who are undergoing, or due to start, contraindicated therapies in pregnancy.
3. Consider repeating testing where clinically appropriate.

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
- All wards
- Biochemistry laboratories
- Chief pharmacists
- Clinical governance leads
- Day surgery units
- Early pregnancy units
- General surgery
- Health and safety managers
- Hospital pharmacies
- Medical directors
- Medical oncologists
- Medical physics departments
- MRI units, directors of
- Nursing executive directors
- Obstetrics and gynaecology departments
- Oncology nurse specialists
- Outpatient clinics
- Point of care testing co-ordinators
- Radiation & medical oncology departments
- Radiation oncologists
- Radiation oncology, directors of
- Radiologists
- Radiology departments
- Radiology directors
- Risk managers
- Supplies managers
- Theatre managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Siemens Medical Solutions Diagnostics Ltd
Sir William Siemens Square
Frimley
Camberley
Surrey
GU16 8QD

Tel: 01276 696 680

Fax: 0845 600 1955

E-mail: dx-npt_helpdesk-uk.med@siemens.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/047 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

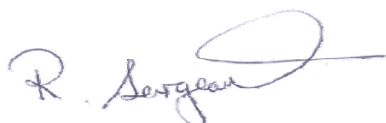
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
27th June 2008

Action Under Way:
1st July 2008

Action Complete:
15th July 2008



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)2007/01. 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)2008/047

SIEMENS

CLINITEK Status®
Analyzer

Siemens Healthcare Diagnostics Inc.

Customer Bulletin
Urgent Field Safety Notice
2008-03

Clinitest® hCG Cassette Recall

Cassette Lots 97552, 97574

Introduction

Siemens Healthcare Diagnostics has identified a potential issue with Clinitest® hCG lots 97552 and 97574.

Investigation indicates that the sensitivity of the reagent with Clinitest hCG lots 97552 and 97574 has decreased. This decrease in sensitivity has the potential to generate false negative hCG results. Shelf life of the product is also impacted by the shift in sensitivity and can no longer be guaranteed.

Actions

Examine your Clinitest hCG stock to determine if you have cassettes from lot 97552 or 97574.

If you have cassettes from these lots, discontinue use, discard the product, and immediately contact your Siemens technical support representative or distributor for replacement cassettes from a different lot.

Fill out the attached Completion Notification and return it to your technical support provider or distributor.

We apologize for any inconvenience and thank you for your immediate attention to this matter.

Trademark Information

Clinitest Status and Clinitest are trademarks of Siemens Healthcare Diagnostics.

APPENDIX to MDEA(NI)2008/047

Clinitest hCG Cassette Recall

Completion Notification

Our records indicate that Clinitest hCG cassettes were shipped to your location. Please examine your Clinitest hCG stock to determine if you have cassettes from lot 97552 or 97574.

Please dispose of any cassettes with the affected lot number and note the quantity discarded in the Quantity Discarded column. If cassettes have already been used, note the quantity in the Quantity Used column.

Part Number	Part Description	Total Quantity	Quantity Discarded (✓)	Quantity Used (✓)
1760 (06484105)	Clinitest hCG, pack of 25			

Please check two:

- We read the customer bulletin, and understand the communication.
- We checked inventory and determined that we do have Clinitest hCG lot 97552 or 97574. We discarded any unused cassettes, and listed the quantity used and discarded in the table above.
- We do not have any Clinitest hCG lot 97552 or 97574.

To signify compliance to this notification, please sign and date below and fax the signed copy of this notification to the following person.

Attention: Hannah Carmody

Fax Number: 01276 696680

When this signed notification is received, Siemens Healthcare Diagnostics will initiate an order to replace affected inventory.

Customer Signature: _____

Print name: _____

Institution: _____

Date: _____