IRISH MEDICINES BOARD

MEDICAL DEVICE

SAFETY NOTICE

Clinitest® hCG Cassette Pregnancy Test Kit

IMB Safety Notice: SN2008(05)

SAFETY NOTICE

MANUFACTURER/SUPPLIER

Siemens Healthcare Diagnostics (Manufacturer)
Allphar Services Limited (Distributor)

TARGET GROUPS

Accident & Emergency Departments
Chemotherapy Nurses / Consultants
Day Surgery / Endoscopy Units
Directors of Anaesthetics
Family Planning Clinics
General Practitioners
Health Service Executive
Hospital Chief Executive Officers
Medical Directors
Nursing Executive Directors
Laboratory Managers
Obstetrics and Gynaecology Consultants / Departments
Oncology / Radiotherapy Departments
Pharmacy Departments
Point of Care Managers / Coordinators
Procurement Departments
Relevant Wards
Risk Managers
Theatre Managers
X-Ray Departments

ISSUE

Lot 97552 and lot 97574 of the Clinitest hCG pregnancy test kits has been recalled by the manufacturer due to the potential for false negative results i.e. a negative result obtained in pregnancy.

BACKGROUND

The Clinitest hCG pregnancy test kit is intended for professional use only in hospitals / clinics and is not sold in pharmacies for home use. The Clinitest hCG pregnancy test may be carried out to:

a) Determine pregnancy
b) As part of the investigation of certain patient symptoms
c) To rule out pregnancy before treatments or diagnostic x-rays / procedures that are contraindicated or should be avoided by pregnant women

Siemens Medical Solutions Diagnostics are recalling lot 97552 and lot 97574 of Clinitest hCG pregnancy test kits following identification of a manufacturing defect. The manufacturer reports that the sensitivity of the reagent with Clinitest hCG lot 97552 and lot 97574 has decreased and that this decrease in sensitivity has the potential to generate false negative hCG results. The shelf life of lot 97552 and lot 97574 is impacted by the shift in sensitivity and can no longer guarantee.

The Irish Medicines Board (IMB) has been advised by the Irish distributors that all public and private hospitals / clinics that have received the affected lot have been advised of this recall.

ACTION OR RECOMMENDATIONS FOR <u>HEALTHCARE PROFESSIONALS</u>

- Ensure that all relevant staff in your institution are informed of this recall
- Determine if you have lot 97552 and lot 97574 of the above product
- Locate and cease using product from lot 97552 and lot 97574
- Determine how much of this product has been used
- Follow the distributor / manufacturers recommendations for quarantine and disposal of product
- Follow up patients as required

ACTION OR RECOMMENDATIONS FOR <u>PATIENTS</u>

- Patients who have had a recent pregnancy test in hospital but are concerned that the negative result received may be incorrect should contact or seek a retest from their GP, family planning clinic or pharmacist

ENQUIRIES

Enquires to the manufacturer should be addressed to:

Siemens Medical Solutions Diagnostics Europe Limited
Chapel Lane
Swords
Co. Dublin

SAFETY NOTICE

Telephone: +33 1 49229905
Fax: +33 1 49223248
Email: sylvie.legledic@siemens.com

United Kingdom Branch

Telephone: 1800 409 904
Fax: +44 1276 696680
Email: dx-npt_helpdesk-uk.med@siemens.com

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Medical Devices Department
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

If you have any enquiries, you may contact the Medical Devices Department at:

Telephone: +353-1-6764971
Fax: +353-1-6344033
Email: vigilance@imb.ie
Website: www.imb.ie

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