IRISH MEDICINES BOARD
SAFETY NOTICE

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Clinitest® hCG

IMB Safety Notice: SN2011(33)
Circulation Date: 19 December 2011

MANUFACTURER/SUPPLIER
Siemens Healthcare Diagnostics (Manufacturer)
Cruinn Diagnostics 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
Lots 028619, 028924, 029997, 030240, 030431, 030602, 030826, 030998, 031332, 031460, 031662, 031798, 031924, 032106 and 032180 of the Clinitest hCG pregnancy test kits have been recalled by the manufacturer due to the potential for borderline or false positive results with commercially available controls and patient samples.

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 procedures that are contraindicated or should be avoided by pregnant women e.g. diagnostic x-rays.

SAFETY NOTICE

Siemens Healthcare Diagnostics are recalling 15 lots (listed above) of Clinitest hCG pregnancy test kits following confirmation of potential borderline or false positive results with commercially available negative controls and patient samples.

ACTION OR RECOMMENDATIONS FOR HEALTHCARE PROFESSIONALS

- Ensure that all relevant staff in your institution are informed of this recall
- Determine if you have lots 028619, 028924, 029997, 030240, 030431, 030602, 030826, 030998, 031332, 031460, 031662, 031798, 031924, 032106, and 032180 of the above product
- Locate and cease using product from the lots listed above
- Determine how much of this product has been used
- Follow the distributor / manufacturers recommendations for quarantine and disposal of product
- Follow up with patients as required.

ACTION OR RECOMMENDATIONS FOR PATIENTS

- Patients who have had a recent pregnancy test administered by a healthcare professional but are concerned that the positive result received may be incorrect should contact or seek a retest from their GP, family planning clinic or pharmacist.

ENQUIRIES

Enquiries to the distributor should be addressed to:

Cruinn Diagnostics Ltd,
5b/6b Hume Centre,
Parkwest Industrial Estate,
Nangor Road,
Dublin 12
Ireland

Telephone: +353-1-6297400
Fax: +353-1-6297401
E-mail: sean.mcgeown@cruinn.ie
Website: www.cruinn.ie

Enquiries to the manufacturer should be addressed to:

Siemens Healthcare Diagnostics Ltd,
Sir William Siemens Square,
Frimley,
Camberley GU16 8QD,
England

Telephone: 0044 (0) 1908 487600
Fax: 0044 (0) 1908 487601
Email: Anthony.walsh@siemens.com

SAFETY NOTICE

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

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

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