IRISH MEDICINES BOARD

Notice Information: - Advisory
19 December 2011

Part 1. Product Information

a)	Title:	Clinitest® hCG
b)	Product Name/Type:	Clinitest® hCG
c)	Reference:	SN2011(33)
d)	Manufacturer/Supplier:	Siemens Healthcare Diagnostics (Manufacturer) Cruinn Diagnostics Limited (Distributor)

Part 2. Target Audience

a)	Target Audience:	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

Part 3. Problem/Issue

a)	Problem/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.

Part 4. Background Information

a)	Background Information:	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. 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.

Part 5. Action to be taken

a) Action to be taken:

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.

Part 6. Enquiries

a) All enquiries should be made to:

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

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

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

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