

# Notice Information: Medical Devices - Recall 15 April 2008

#### Part 1. Product Information

a) Title: Clinitest® hCG Cassette Pregnancy Test Kit

b) Product Name/Type: Clinitest® hCG Cassette Pregnancy Test Kit

c) Reference: SN2008(05)

d) Manufacturer/Supplier: Siemens Healthcare Diagnostics (Manufacturer) Allphar Services Limited (Distributor)

#### Part 2. Target Audience

a) Target Audience: Accident & 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: 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.

### 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: pregnancy As part of the investigation of certain patient symptoms To rule out pregnancy before treatments or diagnostic x-rays / procedures that are contraindicated or should be avoided by pregnant 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.

#### Part 5. Action to be taken

a) Action to be taken:

<em>Action or Recommendations For Healthcare Professionals
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 <em>Action or Recommendations For Patients </em> 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

## Part 6. Enquiries

 All enquiries should be made to:

Enquires to the manufacturer should be addressed to: Siemens Medical Solutions Diagnostics Europe Limited Chapel Lane Swords Co. Dublin Telephone: +33 1 49229905 Fax: +33.149223248 Email: sylvie.legledic@siemens.com United Kingdom Branch Telephone: 1800 409 904 Fax: +44 1276 696680 Email: dx-npt helpdeskuk.med@siemens.com All adverse incidents relating to a medical Irish Medicines Board Medical device should be reported to the: 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: SN2008(05) - Clinitest® hCG www.imb.ie Cassette Pregnancy Test Kit

# Part 7. Keywords

a) Keywords:	Clinitest® hCG Cassette Pregnancy Test Kit	
a) Keywords:	Cliniteste nCG Cassette Pregnancy Test Kit	