

Notice Information: Medical Devices - Recall 15 April 2008

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

- a) Problem/Issue:

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: Determine 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 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.

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 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 Patients
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

a) 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 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 SN2008(05) - Clinitest#174; hCG Cassette Pregnancy Test Kit

Part 7. Keywords

a) Keywords:

Clinitest® hCG Cassette Pregnancy Test Kit