IRISH MEDICINES BOARD

Notice Information: Medical Devices - Recall 12 June 2007

Part 1. Product Information

a)	Title:	Clearview HCG Pregnancy Test Kit
b)	Product Name/Type:	Clearview HCG Pregnancy Test Kit
c)	Reference:	SN2007(02)
d)	Manufacturer/Supplier:	Unipath Limited, Bedford, United Kingdom (Manufacturer) Fannin Healthcare, Dublin, Ireland (Distributor) Promed / Prodent Limited, Kerry, Ireland (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:	Lot HG0050 of the Clearview HCG pregnancy test kit (cat number 500158) 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 Clearview HCG pregnancy test kit is intended for professional use only in hospitals / clinics and is not sold in pharmacies for home use. The Clearview 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 Unipath Limited is recalling lot HG0050 of Clearview HCG pregnancy test kits following identification of a manufacturing defect. The manufacturer reports that this defect affects a small proportion of lot number HG0050 only. The fault in this product may result in incorrect results e.g. false negative or void (no lines) results. The IMB have 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. Note: The Clearblue pregnancy test kit, which is manufactured by Unipath for self-testing in the home, is not affected by 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 number HG0050 of the above product Locate and cease using product from lot number HG0050 Determine how much of this product has been used Follow the distributor / manufacturer 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:	Enquiries to the manufacturer should be addressed to: Unipath Limited Priory Business Park Bedford United Kingdom Contact: Mr. Steven Swales Telephone: 0044-1234-835-928 Email: steven.swales@unipath.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: medicaldevices@imb.ie Website: www.imb.ie SN2007(02): Clearview HCG Pregnancy Test Kit

Part 7. Keywords

a) Keywords: Clearview HCG Pregnancy Test Kit