IRISH MEDICINES BOARD

MEDICAL DEVICE

SAFETY NOTICE

Clearview HCG Pregnancy Test Kit

IMB Safety Notice: SN2007(02)

SAFETY NOTICE

MANUFACTURER / SUPPLIER

Unipath Limited, Bedford, United Kingdom (Manufacturer)
Fannin Healthcare, Dublin, Ireland (Distributor)
Promed / Prodent Limited, Kerry, Ireland (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

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.

BACKGROUND

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.

ACTION OR RECOMMENDATIONS FOR <u>HEALTHCARE PROFESSIONALS</u>

- 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 <u>PATIENTS</u>

- 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

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Unipath Limited
Priory Business Park
Bedford
United Kingdom

SAFETY NOTICE

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

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