Safety Notice

Medical Devices

Immucor Gamma Kleihauer Kit

Priority 2 – Warning

HPRA Safety Notice:SN2016(42) **Issue Date: 13th December 2016**

MANUFACTURER / SUPPLIER	HPRA REFERENCE
IMMUCOR Medizinische Diagnostik GmbH	V27423 / V29737

ISSUE

The HPRA issued a Safety Notice SN2016(23) on 5th August, 2016 regarding the Immucor Gamma Kleihauer Kit manufactured by IMMUCOR Medizinische Diagnostik GmbH.

Users in Ireland had reported unsatisfactory staining of patient and control material with this kit. Unsatisfactory staining was observed with a number of different lots of this device. The issue had also not occurred in a consistent manner.

The manufacturer has completed their investigation and has determined that additional information should be supplied to product users.

ACTION OR RECOMMENDATIONS

The HPRA advise that users:

1 Ensure that you are aware of the information contained in the accompanying field safety notice (FSN).

2 Maintain vigilance during use of this medical device.

3 Forward a copy of this Safety Notice to all relevant personnel.

4 Forward a copy of this Safety Notice to any other persons/organisations where these devices have been transferred.

5 Report any adverse events / incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Accident & Emergency Departments	Laboratory Directors / Managers
Chief Medical Scientists	Laboratory Technicians
Clinical Directors	Maternity wards
Clinical Nurse Managers	Neonatal units
Consultant Haematologists	Paediatric Consultants
Hospital Managers / CEOs	Public and private hospitals
Hospital personnel	Risk Managers
Intensive Care Units	Stores Managers

BACKGROUND

The Immucor Gamma Kleihauer Kit is used to detect foetal red cells in maternal blood samples. The kit is for *in-vitro* diagnostic use by trained professionals.

The manufacturer is updating the instructions for use (IFU) to provide guidance to help users avoid potential errors. Please refer to the accompanying FSN.

The HPRA is issuing this safety notice to raise awareness of this FSN and upcoming IFU update.

MANUFACTURER / AUTHORISED REPRESENTATIVE / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

IMMUCOR Medizinische Diagnostik GmbH
Robert-Bosch-Straße 32,
63303, Dreieich
Germany

Telephone: +49 (0) 6103 8056 390
Fax: +49 (0) 6103 8056 6390
E-mail: vigilance.eu@immucor.com
Website: www.immucor.com

HPRA CONTACT INFORMATION

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

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie