HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

FLUOROCELL PLT

Priority 2 – Warning

HPRA Safety Notice: SN2017(30) **Issue Date: 1st September 2017**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Sysmex	V33047

ISSUE
Sysmex is recalling 15 lots of Fluorocell PLT after observing false low PLT-F results caused by certain cartridges of these lots. A field safety notice (FSN) has been issued advising customers of the appropriate actions to take. Please refer to the accompanying FSN for details of the affected lots.

ACTION OR RECOMMENDATIONS
The HPRA advises that users: 1 Refer to the accompanying FSN and follow the instructions provided by the manufacturer. 2 Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred. 3 Report any adverse events/incidents associated with this device to the manufacturer and the HPRA.

TARGET GROUPS

Chief Medical Scientists	Laboratory staff
Clinical Directors	Medical Scientists
Consultant Haematologists	Private hospitals
Hospital Managers / CEOs	Private Medical Practitioners
Hospital personnel	Purchasing Managers
Intensive Care Units	Risk Managers
Laboratory Managers	Supplies Managers

BACKGROUND

Sysmex initiated a recall of 15 affected lots of Fluorocell PLT following the identification of false low PLT-F results in certain cartridges.

Sysmex advised that PLT-F results were significantly lower than PLT-I results on isolated cartridges of the affected lots. Sysmex also advised that whilst the flag 'PLT Abn Scattergram' was triggered in some cases, in other cases it was not. The manufacturer also indicated that the false low PLT-F value was associated with a false classification of the PLT population in the PLT-F scattergram.

Internal tests performed by the manufacturer with fresh human blood samples showed a decrease of side fluorescence (SFL) for samples measured in the PLT-F channel when the affected lots of Fluorocell PLT were used. As a consequence, the PLT-F population was not counted as PLT and thus the PLT-F results became false low. In addition, the diagnostic parameters IPF (IPF %) and IPF# (IPF count) were potentially affected as well.

Sysmex advised that this issue may lead to wrong diagnostic and patient treatment decisions and serious outcomes for patients.

Sysmex advised that if a replacement lot of Fluorocell PLT is not available, customers may need to continue to use affected lots, in which case it is mandatory to follow the 'plausibility check' for every PLT-F result.

Please refer to the accompanying FSN for further details.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

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

Sysmex Europe GmbH
Bornbarch 1
Norderstedt 22848
Germany

Telephone: +49-40-52726-111
E-mail: vigilance@sysmex-europe.com

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

Aquilant Services
Aquilant House,
21 Fonthill Business Park,
Fonthill Road,
Clondalkin,
Dublin 22

Telephone:+353-1-4048330
E-mail:
Shauna.McFadden@aquilantservices.com

Sysmex Ireland
Aquilant House,
Fonthill Business Park,
Fonthill Road,
Clondalkin,
Dublin 22

Telephone:+44-870-9029216
E-mail: Productmail@sysmex.co.uk
Website: www.sysmex.co.uk

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