Safety Notice

Medical Devices

ID-DiaCells

(Multiple Products)

Priority 2 – Warning

HPRA Safety Notice: SN2017(10) **Issue Date: 24/02/2017**

MANUFACTURER / SUPPLIER	HPRA REFERENCE
DiaMed GmbH	V30834

ISSUE

The HPRA has received reports from users in Ireland regarding intermittent non-specific reactions produced by ID-DiaCells. Non-specific cell reactions can result in suspect false-positive results leading to a delay in determining irregular antibody identification. This issue may also result in repeat testing.

The manufacturer issued a customer communication on 20th January 2017. A field safety notice (FSN) was subsequently issued on 10th February 2017 informing users of this issue. A follow-up FSN has also been issued by the manufacturer, providing additional information regarding this issue. Refer to accompanying FSNs for further information.

ACTION OR RECOMMENDATIONS

The HPRA advise that users:

1 Refer to the accompanying FSNs and follow the instructions provided.

2 Forward a copy of this Safety Notice and the accompanying FSNs to all relevant personnel.

3 Forward a copy of this Safety Notice and the accompanying FSNs to any other persons/organisations where these devices have been transferred

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

TARGET GROUPS	
Chief Medical Scientists	Blood Establishments
Clinical Directors	Laboratory Directors / Managers
Clinical Nurse Managers	Laboratory Technicians
Consultant Haematologists	Public and private hospitals
Hospital Managers / CEOs	Risk managers
Hospital personnel	Stores managers

BACKGROUND

Unsatisfactory cell reactions have been observed in a number of different laboratories for a range of test panels and lot numbers. Unsatisfactory cell reactions may be recorded erroneously on instruments as false-positives.

The manufacturer's investigation into this issue is ongoing. The HPRA is issuing this safety notice to raise awareness of the FSNs.

The HPRA may provide an update on this issue, if further information becomes available.

MANUFACTURER / AUTHORISED REPRESENTATIVE / DISTRIBUTOR CONTACT INFORMATION

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

DiaMed GmbH	Telephone:	+41-26-674 5236
Pra rond 23	Fax:	+41-26-674 5469
1785 Cressier FR	E-mail:	RA-request_Cressier@bio-rad.com
Switzerland	Website:	www.diamed.com

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

Fannin	Telephone:	+353-1-290 7000
Fannin House	E-mail:	quality@fannin.eu
South County Business Park	Website:	www.fannin.eu
Leopardstown,		
Dublin 18.		

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: +353-1-676 4971
Fax: +353-1-634 4033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie