DiaMed GmbH
Pra Rond 23
1785 Cressier FR / Switzerland
Phone: +41 (0)26 674 51 11
Fax: +41 (0)26 674 54 45

Cressier, 7th July, 2017

Urgent: Field Safety Notice / 002-17

Affected device:

Product Name	Catalog No	SAP Lot N°	IHD Lot N°	Expiry Date
ID-DiaCell I-II-III	004310	138478381	45184 **38 1**	31.07.2017
ID-DiaCell IP-IIP-IIIP	005310	142220381	45194 **38 1**	31.07.2017

Dear **Customer,**

This letter contains important information that requires your immediate and urgent attention.

BioRad is voluntarily recalling the products identified above. This recall is being conducted as precautionary measure.

Further to customers' complaints, supplementary tests were carried out on the above-mentioned products which revealed a performance problem with ID-DiaCell II.

Description of the problem:

The **ID-DiaCell II** of screening sets ID-DiaCell I-II-III (lot n° 45184 **38** 1) have been shown to react more weakly than expected during antibody screening with anti-E (anti-RH3).

Impact on the patient:

This may lead to unexpectedly weak or negative results in patients with weak anti-E antibodies. These results could affect the blood compatibility analysis prior to transfusion.

***Note**:*
*Even though **ID-DiaCell IIP lot 45194 38 1** was prepared from the same Blood material as the ID-Diacell II lot 45184 38 1, our investigations have demonstrated that the papain treatment allows the detection of weak form of anti-E.*
*Therefore, if you have performed your antibody screening with the **ID-Diacell P** lot 45194 38 1, the probability of not having detected a weak anti-E is remote.*

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Immediate protective measure:

We kindly ask you to carry out the following actions:

1. Destroy any remaining kits of lot 45184 38 1 and lot 45194 38 1
2. Where deemed necessary by the medical director of the laboratory, patients tested with lots n° 45184 38 1 and 45194 38 1 should be re-tested with another lot.(please refer to ***Note***)
3. Fill out and sign the attached "Reply Form and certificate of destruction for End Users" and return it to your distributor to get refund.

Please note that the relevant European Regulatory Agency has been advised of this FSCA.

In case of questions, in the first instance, please contact our Customer Service Laboratory:

slabor_cressier@bio-rad.com

Our representatives are briefed to help you manage this situation.

We apologize for any inconvenience that may have been caused by this action and we appreciate your prompt cooperation in this matter.

Yours sincerely,

[redacted]

Quality Assurance Director, Clinical Diagnostics Group – Europe

Agnes Eude Goethals

[redacted]

Vice President & General Manager Immunohematology Division

Ann Madden

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Reply Form and certificate of destruction for End Users

PRODUCT:

Product Name	Catalog No	SAP Lot N°	IHD Lot N°	Expiry Date
ID-DiaCell I-II-III	004310	138478381	45184 **38 1**	31.07.2017
ID-DiaCell IP-IIP-IIIP	005310	142220381	45194 **38 1**	31.07.2017

CUSTOMER INFORMATION:

Hospital / Laboratory	
Address (Street, Postcode, Country)	
Phone Number	
Undersigning manager name	
Customer Account Number	

STATEMENT:

I have read and understood this Field Safety Notice, and shared the information with laboratory staff to:

- Destroy the remaining stock of sets ID-DiaCell I-II-III and ID-DiaCell IP-IIP-IIIP with lots n° 45184 **38 1** and 45194 **38 1**.
- Complete the **Certificate of Destruction** below and send back this document to your customer Service (enter Local information).

CERTIFICATE OF DESTRUCTION FOR ID-DIACELL I-II-III AND ID-DIACELL IP-IIP-IIIP

LOT Number	Total Number of boxes received	Boxes Still on stock	
		Number	Date of destruction
45184.38 1			
45194 38 1			

I,.....,do hereby certify that, due to the problem reported on the ID-DiaCell I-II-III (lot number 45184 38 1) ID-DiaCell IP-IIP-IIIP (lot number 45194 38 1) and according to the instructions issued by BioRad/DiaMed GmbH, I have destroyed the above mentioned products.

Date: ..... **Signature:**

Annex I