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

Cressier, 4th October, 2016

Urgent: Field Safety Notice / 004-16

Affected device:

Product Name	Catalog No	Serial/ Lot No	Expiry Date
ID-DiaCell I-II	003613	45151.61.1	24.10.2016
ID-DiaCell ABO/I-II	003610	45002.66.1	24.10.2016

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 and ID-DiaCell ABO/I-II (lot n° 45151.61.1 and lot n° 45002.66.1) has been shown to react much more weakly than expected during antibody screening with anti-E (anti-RH3).

An antigen E variant is highly suspected.

Impact on the patient:

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

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Immediate protective measure:

We kindly ask you to carry out the following actions:

1. Destroy any remaining kits of lots 45151.**61.1** and 45002.**66.1**
2. The ID-Diacell I-II will be immediately replaced with lot 45151.**63.1**, exp. date 21.11.2016 and 45002.**68.1**, exp. date 21.11.2016.
3. Please use Annex II, *Reply Form and certificate of destruction for Customers* for this purpose.
4. Where deemed necessary by the medical director of the laboratory, patients tested with lots 45151.**61.1** and 45002.**66.1** should be re-tested.

Please fill out and sign the Field Safety Notice reply form and the Certificate of destruction (Annex II) and return the completed form to your distributor by the 19th of October 2016.

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

DiaMed GmbH
CH-1785 Cressier FR

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Please fill out and sign this document until the end of the 19th of October 2016.

Urgent: Field Safety Notice / 004-16
Reply Form and certificate of destruction for Customers

PRODUCT:

Product Name	Catalog No	Serial/ Lot No	Expiry Date
ID-DiaCell I-II	003613	45151.61.1	24.10.2016
ID-DiaCell ABO/I-II	003610	45002.66.1	24.10.2016

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 and ID-DiaCell ABO/I-II with the lot numbers 45151.61.1 and 45002.66.1
- Complete the **Certificate of Destruction** below and send back this document to the distributor.

CERTIFICATE OF DESTRUCTION FOR ID-DIACELL I-II

LOT Number	Total Number of boxes received	Boxes Still on stock	
		Number	Date of destruction
45151.61.1			
45002.66.1			

I,.....,do hereby certify that, due to the problem reported on the ***ID-DiaCell I-II (lot number*** 45151.61.1**)** and ***ID-DiaCell ABO/I-II (lot number*** 45002.66.1**)** and according to the instructions issued by BioRad/DiaMed GmbH, I have destroyed the above mentioned products.

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