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

Cressier, 10.02.2017

Urgent: Field Safety Notice / 001-17

Affected device:

Product Name	Catalog No	Serial/ Lot No	Expiry Date
ID-Dia (Diego) Positive	004134	All lots currently in date	
ID-DiaCell SF	003640		
ID-DiaCell Pool	003630 / 003631		
ID-DiaCell ABO/I-II *	003610		
ID-DiaCell ABO/I-II-III *	003618		
ID-DiaScreen I-II-III-IV-VP-VIP	004316		
ID-DiaCell I-II	003613		
ID-DiaPanel	004114		
ID-DiaCell I-II-III	004310		
ID-DiaScreen I-II-III-IV	004311		
ID-DiaCell I-II-III Asia	003614		
ID-DiaScreen Prophylax	004330		
ID-DiaPanel Plus 6	004414		
ID-DiaCell I-II	003613VJ		
ID-DiaPanel (1-11)	004114VJ		
ID-Dia Positiv	004134VJ		
ID-DiaCell I-II-III	004310VJ		

** Vials ID-DiaCell I, ID-DiaCell II, ID-Diacell III only (ID-DiaCell ABO out of scope)*

Dear **Customer,**

This letter contains important information that requires your immediate attention.

Description of the problem:

We would like to share with you, and your team, information about unexpected reactions primarily on eluates and QC samples but also with some patient samples when using the above mentioned products.
This phenomenon is observed randomly between batches, and also within single batches.

Impact on the patient:

A risk assessment has been done, and the conclusion is that this unexpected result requires further confirmation testing before a final transfusion decision is made and. Negative results can be reliably accepted as negative.

Immediate protective measure:

In case of doubtful reactions, please re-test with a new kit. If the results remain in doubt, we would advise you to send the sample to a reference laboratory and if an urgent transfusion is required, perform a crossmatch.

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A team of internal and external experts has been and continues working to identify the root cause and determine corrective actions.

Further investigations are still ongoing and will continue until we can provide a solution.

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,

Quality Assurance Director, Clinical Diagnostics Group - Europe	Vice President and General Manager, Immunohematology Division
Agnes Eude Goethals	Ann Madden

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Please fill out and sign this document until 2017-02-17

Urgent: Field Safety Notice / 001-17
Reply Form for Customers

PRODUCT:

Product Name	Catalog No	Serial/ Lot No	Expiry Date
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** Vials ID-DiaCell I, ID-DiaCell II, ID-Diacell III only (ID-DiaCell ABO out of scope)*

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.

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

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Annex II