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

Cressier, 27 October 2021

Field Safety Notice / *FSCA 003-21*

Affected products displaying the issue:

Product Name	Catalog No	Lot n°	Expiry Date	UDI
ID-DiaCell I-II-III	004310	45184 **52 1** *(SAP 645823521)*	2021-11-15	(01)07611969000968 (17)211115(10)645823521
ID-DiaCell IP-IIP-IIIP	005310	45194 **52 1** *(SAP 646733521)*	2021-11-15	(01)07611969001293 (17)211115(10)646733521

Dear Customer,

This letter contains important information that requires your immediate and urgent attention. Bio-Rad is voluntarily conducting a Field Safety Corrective Action for the products identified above.

Description of the problem:

We would like to share with you, and your team, information about the above-mentioned red blood cells product.

Further to customer reports, we have been able to confirm that marked hemolysis can be observed with the ID-DiaCell I-II-III and ID-DiaCell IP-IIP-IIIP lot 52 1, particularly with the cell II and IIP.

This marked hemolysis may interfere with the automatic reading and lead to a “?” result instead of negative.

Figure 1_Image of the impacted lot of cells

Impact on the patient:

A risk assessment has been conducted and hereunder are the outcomes per application:

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Context of use	Impact on the reaction	Impact on the result
Transfusion	Uninterpretable reaction "?" instead of negative	This situation may lead to further testing and a delay in result.
Donor qualification		Should lead to further investigations which may delay the reporting of the final result

Results obtained with this lot should not be questioned, if quality control reacted within the expected range.

In addition, our stability monitoring indicates that the product still reacts according to our specifications.

Immediate protective measure for the user:

As an immediate action, we recommend you:

- Stop using the impacted lot 45184 **52 1** and 45194 **52 1**
- Start using the new lot 45184 **69 1** and 45194 **69 1** that you have received within your standing orders.

We demand you to transfer this information to all persons impacted in your institution and/or forward it to establishments where products may have been transferred.

Please note that the relevant European Regulatory Agency has been advised of this Field Safety Corrective Action.

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

CTS.benelux@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,

xxx

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CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Reference Number: FSCA 003-21
Bio-Rad Division: IHD

PRODUCT

Product UDI	Product Name	Catalog No	Serial/ Lot No	Expiry Date
(01)07611969000968 (17)211115(10)645823521	ID-DiaCell I-II-III	004310	45184 52 1 (SAP 645823521)	2021-11-15
(01)07611969001293 (17)211115(10)646733521	ID-DiaCell IP-IIP-III	005310	45194 52 1 (SAP 646733521)	2021-11-15

CUSTOMER INFORMATION

Account Name:	
Undersigning Manager Name:	
Address :	
Telephone Number / Fax :	
Customer Account Number :	

STATEMENT:

☐ I am aware of the information about the field action concerning the above reference product(s) and have proceeded according to the instructions issued by Bio-Rad.

Number of affected products received:		Number of affected products destroyed:	
If number of products destroyed is different to the number received, please account for the difference:			

Date: Customer Signature (and Stamp if applicable)

Please return this form to: CTS.benelux@bio-rad.com