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

Cressier, 30-08-2023

Field Safety Notice / *FSCA 004-23*

Affected products displaying the issue:

Product Name	UDI	Catalog No	IHD Lot n°	SAP lot n°	Expiration Date
ID-DiaCell I-II-III 3x10 ml	(01)07611969000968(17)230918(10)843989501	004310	45184.50.1	843989501	18.09.2023
	(01)07611969000968(17)230918(10)844911531		45184.53.1	844911531	

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 product identified above.

Description of the problem:

Nonspecific reactions may be observed when using the following batches of ID-DiaCell I-II-III 3x10 mL:

- Lot 843989501 / 45184.50.1 (Cell I impacted)
- Lot 844911531 / 45184.53.1 (Cell III impacted)

Cell I (lot 843989501 / 45184.50.1) and cell III (lot 844911531 / 45184.53.1) of ID-DiaCell I-II-III may produce unexpected weak positive reactions instead of a clear negative result. The anomaly is observable during Quality Control sample testing with manual and automated methods.

Impact on the patient:

In accordance with the guidelines implemented in your laboratory, an uninterpretable screening result should lead to further investigation prior to any transfusion. Investigation of an uninterpretable screening result may cause potential delay in the reporting of results.

Immediate Actions:

In the case of a suspected nonspecific reaction identified during result validation, please discard the unused impacted products (lot 843989501 / 45184.50.1 and 844911531 / 45184.53.1), and use a different lot.

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

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 technical support representatives:

[Indicate here local contact]

We regret any inconvenience this may cause, and we appreciate your prompt cooperation in this matter.

Yours sincerely,

Quality Assurance Representative	*Marketing Manager Reagents*
Amélie Berard	Inger Anne Torsheim

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CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Reference Number: FSCA 004-23
Bio-Rad Product Segment: IH
Single Registration Number (SRN): CH-MF-000020826

PRODUCT

Product Name	UDI	Catalog No	IHD Lot n°	SAP lot n°	Expiration Date
ID-DiaCell I-II-III 3x10 ml	(01)07611969000968(17)230918(10)843989501	004310	45184.50.1	843989501	18.09.2023
	(01)07611969000968(17)230918(10)844911531		45184.53.1	844911531	

CUSTOMER INFORMATION

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

STATEMENT:

- ☐ No affected product received
- ☐ 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 corrected/ destroyed/ returned (as applicable to the Field Action instructions):	
If number of products corrected/ destroyed/ returned is different to the number received, please account for the difference:			

Date: Customer Signature (and Stamp if applicable)

Please return this form to: [enter local details]