DiaMed GmbH
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URGENT FIELD SAFETY NOTICE

ID-DiaCell I-II-III, 004310

This letter contains important safety information. Please ensure all impacted users in your facility are made aware of this letter and the recommended actions.

For the attention of professional users in laboratory

Please retain this letter for your records

Date: March 27, 2025
Bio-Rad Reference: FSCA 003-25

Legal Manufacturer:
DiaMed GmbH, SRN: CH-MF000020826
GLN: 7601001392533

Dear Valued Customer / Channel Partner,

The purpose of this letter is to inform you about a quality issue related to ID-DiaCell I-II-III, which may pose a potential safety risk to patients.

Reason for the Field Safety Notice:

Following a customer complaint, we have confirmed that nonspecific reactions and slight hemolysis may occur when using **ID-DiaCell I-II-III**, Lot **991885841** (Expiration Date: **2025-04-14)**.

Our investigation confirmed that **Cell I** of the affected lot may lead to unexpected weak positive reactions during antibody screening, both manually and using automated systems.

The following are examples of the type of image that can be seen when the problem occurs (well II and III show a normal negative reaction; well I shows the unexpected weak reaction).

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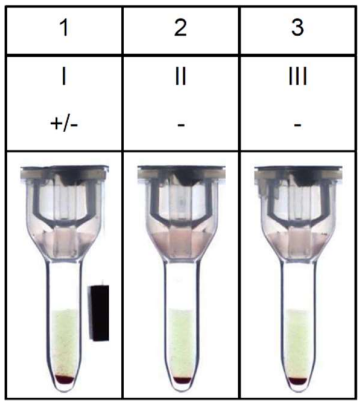

Figure 1: Example of unexpected positive reaction in IAT with cell I (well I)

Risk to Health:

In accordance with the testing protocols implemented in your laboratory, an uninterpretable antibody screening result will require additional investigation to confirm or exclude the presence of clinically significant alloantibodies. The use of reagent red blood cells from the affected lot may lead to false-positive reactions. This can result in unnecessary follow-up testing, extended turnaround times, and additional laboratory workload, particularly in the context of donor qualification, antenatal screening of pregnant women, or pre-transfusion testing, where accurate antibody detection is critical.

Affected Product Identification:

ID-DiaCell I-II-III, Id-n° 45184
The ″ID-DiaCell I-II-III″ are Reagent Red Blood Cells intended to be used for screening of irregular red blood cell antibodies in human donor and patient serum or plasma for immunohematology testing.

Product UDI	Catalog Number	Batch/Lot Number	Manufacture Date (YYYY-MM-DD)	Expiry Date (YYYY-MM-DD)
07611969000968	004310	991885841	2025-01-27	2025-04-14

Action(s) to be taken by the Customer:

Bio-Rad is requesting that customers affected by this notice take the following action:

- If a suspected nonspecific reaction is identified during result validation, please discard the unused impacted products (Lot 991885841) and use a different lot from your standing orders.

- Please ensure that this notice is shared with all relevant individuals within your organization. If you have forwarded or transferred any of the affected product(s) listed above to another organization, kindly provide them a copy of this letter.

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- Please complete and return the attached response form as soon as possible to confirm receipt of this important communication.

Resolution by Bio-Rad:

Bio-Rad takes product quality and safety very seriously, and investigations are ongoing to determine how our quality control can be improved to avoid the recurrence of this issue.

The National Competent (Regulatory) Authority has been informed of this field safety notice.

Contact Information:
Please contact Bio-Rad Technical Support if you have any questions regarding this communication.

- *<Bio-Rad support numbers / email>*

Bio-Rad would like to assure you that our highest priority is maintaining a high level of safety and quality. We regret any inconvenience caused by this issue.

Elizabeth Platt
Bio-Rad VP, Quality, Regulatory & Clinical Affairs

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FIELD ACTION RESPONSE FORM

Bio-Rad Reference: FSCA 003-25
Bio-Rad Product Segment: IH
Single Registration Number (SRN): CH-MF000020826

PRODUCT

Product UDI	Product Name	Catalog No	Lot No	Expiry Date (YYYY-MM-DD)
07611969000968	ID-DiaCell I-II-III	004310	991885841	2025-04-14

CUSTOMER / CHANNEL PARTNER INFORMATION

Account Name:	
Undersigning Manager Name:	
Address:	
Telephone Number / Fax:	
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.
- ☐ For completion by Channel Partners: All customers have been informed about this field action and have proceeded according to the instructions issued by Bio-Rad. Number of customers informed: _____

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 / Channel Partner Signature (and Stamp if applicable):

Please return this form to: *<enter local details, e.g. return email address>*