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: 07.02.2025
Bio-Rad Reference: FSCA 001-25

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 of Bio-Rad ID-DiaCell I-II-III. A safety issue has been identified that could pose a risk for patients.

Reason for the Field Safety Notice:

Following a customer complaint, we have confirmed that nonspecific reactions could be observed when using the product ID-DiaCell I-II-III, lot 974360541 (expiration date 17.02.2025).

Investigations were performed and confirmed that the **cell II** of the kit ID-DiaCell I-II-III lot 974360541 presents a high expression of HLA Class I antigen (Bg^a). Therefore, this cell detects antibodies which are generally not clinically significant.

This may give unexpected weak positive reactions during antibody screening with both manual and all automated methods.

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

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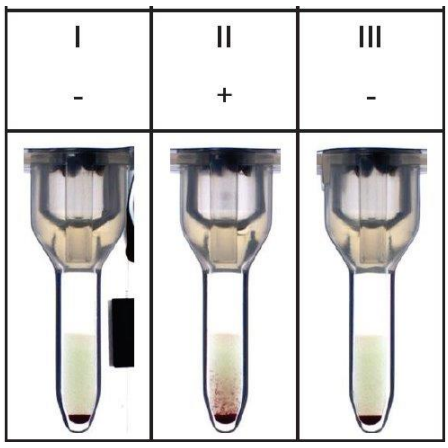

Figure 1: Example of unexpected positive reaction with cell II (well II)

Risk to Health:

In accordance with the guidelines implemented in your laboratory, an uninterpretable screening result would lead to further investigation for the follow-up of pregnant women or before any transfusion.
This situation could lead to additional workups, unnecessary crossmatching, or could delay the identification of clinically significant alloantibodies.

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(s)	Manufacture Dates	Expiry Date
07611969000968	004310	974360541	18.11.2024	17.02.2025

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Action(s) to be taken by the Customer:

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

In the case of a suspected nonspecific reaction identified during result validation, please discard the unused impacted products (lot 974360541) and use a different lot that you have received within your standing orders.

Please ensure this notice is passed to all those who need to be aware within your organization or to any organization where the impacted devices have been transferred.

Please complete and return the attached response form as soon as possible so that we are assured you have received this important communication.

Resolution by Bio-Rad:

As a corrective action, the donor has been blocked in our database to avoid further use in our reagents red blood cells.

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, RACA

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FIELD ACTION RESPONSE FORM

Bio-Rad Reference: FSCA 001-25
Bio-Rad Product Segment: IH
Single Registration Number (SRN): CH-MF000020826

PRODUCT

Product UDI	Product Name	Catalog No	Lot No	Expiry Date
07611969000968	ID-DiaCell I-II-III	004310	974360541	17.02.2025

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>*

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