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

URGENT FIELD SAFETY NOTICE

Reagents for antibody screening tests

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 laboratories

Please retain this letter for your records

Date: 07.03.2024
Bio-Rad Reference: FSCA 003-24

Legal Manufacturer:
DiaMed GmbH
Single Registration Number (SRN): CH-MF000020826
GLN: 7601001392533

Dear Valued Customer / Channel Partner,

The purpose of this letter is to inform you about a quality issue we are facing with Bio-Rad reagent intended for antibody screening.

Reason for the Field Safety Notice:

We have been able to confirm an increased level of complaints and adverse events related to weak non-specific reactions when using ID-System screening reagents in Indirect Antiglobulin Testing (IAT) for QC, donor, and patient samples.

Customers using both the manual and instrument methods reported weak positive reaction results (identified as “?”, “wR”, “+/-“, and sometimes “+” on instruments) instead of an expected clearly negative “-“ reaction in IAT.

These doubtful reactions or in some cases weak positive reactions may occur randomly among batches.

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The investigations so far point out that a possible enhancer of the phenomenon is the combination of certain lots of reagents red blood cells with certain lots of associated ID-Cards.

Risk to Health:

In accordance with the guidelines implemented in your laboratory, a non-interpretable and/or weak positive screening result leads to further investigation prior to any transfusion. Investigation of uninterpretable screening results may cause potential delay in the reporting of the result.

Affected Product Identification:

The increased level of complaints involves the products listed below:

ID-DiaCell I-II-III, Id-n° 45184 **ID-DiaCell I-II-III Asia**, Id-n° 45330 **LISS/Coombs,** Id-n° 50531 **Coombs Anti-IgG,** Id-n° 50540
Reagents red blood cells and ID-Cards intended to be used for antibody screening in indirect antiglobulin testing in patient and/or donors.

Product UDI	Catalog Number	Batch/Lot Number(s)	Manufacture/Distribution Dates	Expiry Date
07611969000968	004310	**All lots currently in use and future lots until further notice***		
07611969014521	004310VJ			
07611969012060	003614			
07611969000845	004014			
07611969010080	004017			
07611969000869	004016			
07611969000852	004015			
07611969014736	004015VJ			
07611969233045	004015VC			
07611969071487	004023			
07611969000876	004024			
07611969010097	004027			
07611969000890	004026			
07611969000883	004025			
07611969014743	004025VJ			

*The occurrence of the issue varies depending on the combination of certain lots of reagents red blood cells with certain lots of associated ID-Cards.

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Action(s) to be taken by the Customer:

The capacity of impacted reagents to detect clinically significant antibodies is not affected by the issue described above. For that reason, you may continue to use these products for their intended purpose.

In case you would experience non-specific reaction impacting your ability to render results, Bio-Rad is requesting that customers affected by this notice take the following action:

1. If available in your laboratory, repeat the test with another lot of ID-Cards

   If the issue persists or if you do not have other lot of ID-Cards available,

2. Switch to another lot of cells that you have received within your standing order.

We thank you to continue reporting any issues to our support team, where the team will liaise with the laboratory to collect the relevant information.

This may include:

- The Daily Journal with images
- Information on the Instrument used or manual testing
- Information on the reagents lots used (ID-Cards and ID-Cells)
- The frequency of “wR”’s or weak reactions observed versus the total amount of screening tests per day
- IH-QC samples impacted
- Patient/Donor samples impacted

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:

Bio-Rad takes product quality and safety very seriously, and we have been diligently investigating all issues raised. We continue to investigate the root cause of this issue and the corrective measures to address them.

Bio-Rad continues to ensure the delivery of your products according to the standing orders. We will keep you informed of any significant developments and updates regarding the issue.

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

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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.

Mario Wijker
Bio-Rad SVP, RAQA

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FIELD ACTION RESPONSE FORM

Bio-Rad Reference: FSCA 003-24
Bio-Rad Product Segment: IHD
Single Registration Number (SRN): CH-MF000020826

PRODUCT

Product UDI	Product Name	Catalog No	Serial/ Lot No	Expiry Date
07611969000968	ID-DiaCell I-II-III	004310	**All lots currently in use and future lots until further notice**	
07611969014521	ID-DiaCell I-II-III	004310VJ		
07611969012060	ID-DiaCell I-II-III Asia	003614		
07611969000845	LISS/Coombs	004014		
07611969010080	LISS/Coombs	004017		
07611969000869	LISS/Coombs	004016		
07611969000852	LISS/Coombs	004015		
07611969014736	LISS/Coombs	004015VJ		
07611969233045	LISS/Coombs	004015VC		
07611969071487	Coombs Anti-IgG	004023		
07611969000876	Coombs Anti-IgG	004024		
07611969010097	Coombs Anti-IgG	004027		
07611969000890	Coombs Anti-IgG	004026		
07611969000883	Coombs Anti-IgG	004025		
07611969014743	Coombs Anti-IgG	004025VJ		

CUSTOMER / CHANNEL PARTNER INFORMATION

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

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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>*