[redacted]

URGENT FIELD SAFETY NOTICE FOLLOW-UP

Reagents for Indirect Antiglobulin Testing

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: 20.09.2024
Bio-Rad Reference: FSCA 003-24 Follow-up

[redacted]

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 Indirect Antiglobulin Testing (IAT).

Reason for the Field Safety Notice:

In a previous communication, we informed you about a quality issue we are experiencing with some of our reagents used for antibody screening testing. This follow-up notice is to update the scope of the impacted products and applications.

We can confirm that, both in manual and automated methods, weak positive reaction results may be obtained (identified as "?", "wR", "+/-", and sometimes "+" on instruments) instead of an expected clearly negative "-" reaction **in any application of IAT**.

At this stage of our investigation, we can confirm that reagent red blood cells are excluded from the primary root cause. However, we cannot eliminate that those reagents, associated with impacted ID-Cards, are contributory factors that enhance the frequency of the observed

phenomena. This is why antibody screening and identification are the most affected applications.

Risk to Health:

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

Affected Product Identification:

LISS/Coombs, Id-n° 50531 **Coombs Anti-IgG,** Id-n° 50540 **DiaScreen***, Id-n° 50571
ID-Cards intended to be used for indirect antiglobulin testing with patients' and/or donors' samples.

Product name	Product UDI	Catalog Number	Batch/Lot Number(s)	Manufacture/ Distribution Dates	Expiry Date
LISS/Coombs	07611969000845	004014	**All lots currently in use and future lots until further notice****		
	07611969010080	004017			
	07611969000869	004016			
	07611969000852	004015			
	07611969014736	004015VJ			
	07611969233045	004015VC			
Coombs Anti-IgG	07611969071487	004023			
	07611969000876	004024			
	07611969010097	004027			
	07611969000890	004026			
	07611969000883	004025			
	07611969014743	004025VJ			
DiaScreen*	07611969001095	004704			
	07611969010134	004707			
	07611969001118	004706			
	07611969001101	004705			
	07611969233120	004705VJ			

* For DiaScreen ID-Cards, only the Anti-IgG+C3d wells are impacted
**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.

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 another 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, ID-Cells, etc)
- The frequency of “wR”'s or weak reactions observed versus the total amount of 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 are now able to exclude the reagents red blood cells as the primary root cause. Further analyses are ongoing as part of the extensive investigation on the components and each different step of the manufacturing processes of ID-Cards.

We remain committed to identifying the root cause as a top priority and implementing corrective measures to prevent recurrence.

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.

Contact Information:

The Bio-Rad Technical Support is consistently updated with the latest information on the investigation and the possible actions to be taken to help you manage this situation.

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.

FIELD ACTION RESPONSE FORM

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

PRODUCT

Product UDI	Product Name	Catalog No	Serial/ Lot No	Expiry Date
07611969000845	LISS/Coombs	004014	**All lots currently in use and future lots until further notice**	
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		
07611969001095	DiaScreen	004704		
07611969010134	DiaScreen	004707		
07611969001118	DiaScreen	004706		
07611969001101	DiaScreen	004705		
07611969233120	DiaScreen	004705VJ		

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>*