DiaMed GmbH
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URGENT FIELD SAFETY NOTICE
ID-Anti-S, Ref. 007132
Test serum ID-Anti-M, N, S, s, Fya, Fyb, Ref. 008712

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 the laboratory.

Please retain this letter for your records

Date: 18/Aug/2025
Bio-Rad Reference: FSCA-004-25

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

Dear Valued Customer / Channel Partner,

This letter is to inform you about a quality issue related to false positive reactions obtained with Bio-Rad anti-S test serum. A safety issue has been identified impacting the below listed products that could pose a potential risk for patients.

Reason for the Field Safety Notice:

Bio-Rad has received complaints of false positive reactions associated with ID-Anti-S (ref. 007132). An internal investigation confirmed that the test serum ID-Anti-S was contaminated with an anti-Dia antibody. The contaminant was identified in a raw material used during the manufacture of the affected lots listed below. The presence of the contaminant may lead to false positive results.

Risk to Health:

The ID-Anti-S is intended for the antigen determination of MNS3 antigens.

S antigen typing is performed when there is a clinical suspicion of allo anti-S antibody production. Confirmation of antibody specificity requires a negative result for the corresponding antigen. Additionally, S antigen typing may be conducted prophylactically in chronically transfused patients to mitigate the risk of alloimmunization. In cases where a false positive result occurs, treatment may be delayed. However, the associated clinical impact is generally considered minor, typically resulting in temporary discomfort or transient conditions. Such instances usually necessitate the collection of an additional sample to resolve the discrepancy.

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In the context of donor qualification, S antigen typing is not routinely performed. When conducted for inventory management or to provide S-negative units, potential misclassification does not pose a direct risk to patient safety. Consequently, the associated clinical impact is considered negligible.

Affected Product Identification:

Product name	Product UDI	Catalog Number	Batch/Lot Number(s)	IHD Display Batch	Manufacture Date	Expiry Date
ID-Anti-S	07611969069514	007132	0033454701	09010.47.01	25.02.2025	31.07.2026
ID-Anti-M, N, S, s, Fy^a, Fy^b	07611969069552	008712	0050103803 0076423804 0076443805 0076463806	45460.38.03/ 08630.47.02 45460.38.04/ 08630.47.02 45460.38.05/ 08630.47.02 45460.38.06/ 08630.47.02	19.11.2024	30.04.2026

Action(s) to be taken by the Customer:
Bio-Rad is requesting that customers affected by this notice take the following action:

- Check your inventory for any remaining of the affected lots.
- If you find any affected product, dispose following your internal protocol.
- Contact Bio-Rad to request replacement for any of the affected products.
- If any patients or donors were tested with the affected lots and received a positive result, consult with your medical director to decide if further testing or other steps are needed.

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 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>*

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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
Vice President, Quality, Regulatory & Clinical Affairs
Bio-Rad Laboratories

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FIELD ACTION RESPONSE FORM

Bio-Rad Reference: FSCA-004-25

Bio-Rad Product Segment:
Single Registration Number (SRN):

PRODUCT

Product name	Product UDI	Catalog Number	Batch/Lot Number(s)	IHD Display Batch	Manufacture Date	Expiry Date
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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.
- ☐ *<Omit/include, as needed>* 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>*