DiaMed GmbH
Pra Rond 23
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Cressier, April 25, 2022

Field Safety Notice / *FSCA 001-22*

Affected products displaying the issue:

UDI	Product Name	Catalog No	IHD Lot n°	SAP Lot n°	Expiry Date
(01)07611969231515 (17)220516(10)709953721	IH-QC 3	009323	08730 72 1	709953721	May 16, 2022

Dear Customer,

This letter contains important information that requires your immediate and urgent attention. Bio-Rad is voluntarily conducting a Field Safety Corrective Action for the products identified above.

Description of the problem:

We would like to share with you, and your team, information about a quality issue detected with the IH-QC 3 lot 08730 72 1.

Following customers' feedback, we have been able to confirm that the results obtained with this IH-QC 3 batch may not be as expected. Different issues were observed which may cause QC failed results:

- Positive reactions may be observed in Direct Antiglobulin Tests (DAT)
- Weaker or in worse case false negative reactions may occur with RH:4 cells in Indirect Antiglobulin Test (IAT) and in 2-stage papain technique
- When testing the impacted batch of IH-QC3 with ID-Cards containing anti-c, a double population with anti-c (RH:4) can be observed

Impact on the patient:

The unexpected and false negative reactions described above can all lead to a QC failed result, to investigations by the laboratory, and subsequently, can cause a delayed reporting of patients' results.

Immediate protective measure for the user:

We recommend you carry out the following actions:

1. Stop using the IH-QC 3 from lot 08730 72 1 and discard those not used yet
2. Use another lot of IH-QC 3 available. A new lot 08730 75 1 is now available (week 17)

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3. Complete and sign the "*Customer field action response form*" attached and return it to your local contact

Would you need any additional kits to cover your needs, please contact us rapidly in order to organise the shipment.

We demand you to transfer this information to all persons impacted in your institution and/or forward it to establishments where products may have been transferred.

Please note that the relevant European Regulatory Agency has been advised of this Field Safety Corrective Action.

In case of any questions, in the first instance, please contact your customer technical support representatives:

[Indicate here local contact]

Our representatives are briefed to help you manage this situation.

We apologize for any inconvenience that may have been caused by this action and we appreciate your prompt cooperation in this matter.

Yours sincerely,

Quality Assurance Representative	Marketing Manager Reagents
Diane Galéa	Inger-Anne Torsheim

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CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Reference Number: FSCA 001-22
Bio-Rad Product Segment: IHD
Single Registration Number (SRN): CH-MF-00020826

PRODUCT

Product UDI	Product Name	Catalog No	Lot No	Expiry Date	Software Version
(01)07611969231515 (17)220516(10)709953721	IH-QC 3	009323	08730 72 1 *(SAP 709953721)*	May 16, 2022	N/A

CUSTOMER INFORMATION

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

Number of affected products received:		Number of affected products destroyed (as applicable to the Field Action instructions):	
If number of products destroyed is different to the number received, please account for the difference:			

Date: Customer Signature (and Stamp if applicable)

Please return this form to: [enter local details]