DiaMed GmbH
Pra Rond 23
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Phone: +41 (0)26 674 51 11
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Cressier, September 8th, 2022

Field Safety Notice / *FSCA 002-22*

Affected products displaying the issue:

UDI	Product Name	Catalog No	IHD Lot n°	SAP Lot n°	Expiry Date
(01)07611969231560 (17)220919(10)746258821	IH-QC8	009328	08780 82 1	746258821	2022-09-19

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 product identified above.

Description of the problem:

We would like to share with you, and your team, information on our product **IH-QC8 lot 08780 82 1**.

Following two customer complaints, it has been confirmed that tubes from the impacted lot may present clots of red blood cells and turbid supernatant.

The clots may interfere with the reaction leading to uninterpretable results in the manual or the automated method.

In automated method, these clots may lead to an obstruction of the fluidic circuit during the pipetting process. To prevent this issue, our systems IH-500, IH-1000 and Swing TwinSampler II are equipped with a clot detection function. In case a clot is detected, an alarm message will be displayed to the user and the system will request the retest.

Impact on the patient:

The uninterpretable reaction described above can lead to a QC failed result, to an investigation by the laboratory, and subsequently, cause a delay in the reporting of patients' results.

On automated systems, the presence of clots will lead to an alarm requiring repeating the Quality Control and subsequently, can cause a delay in the reporting of patients' results.

Immediate protective measure for the user:

In case clots are detected in the tube, we recommend to:

1. Stop using the impacted lot of IH-QC8 and discard the affected lot
2. Use another lot of IH-QC8. Lot **08780 84 1** is now available.

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We ask that you ensure the transfer of 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 our 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*
…	…

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CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Reference Number: FSCA 002-22
Bio-Rad Product Segment: IHD
Single Registration Number (SRN): CH-MF-000020826

PRODUCT

Product UDI	Product Name	Catalog No	IHD Lot No	SAP Lot No	Expiry Date
(01)07611969231560 (17)220919(10)746258821	IH-QC8	009328	08780 82 1	746258821	2022-09-19

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 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 Signature (and Stamp if applicable)

Please return this form to: [enter local details]