DiaMed GmbH
Pra Rond 23
1785 Cressier FR / Switzerland
Phone: +41 (0)26 674 51 11
Fax: +41 (0)26 674 54 45

Cressier, 29 April 2019.

Urgent: Field Safety Notice / *FSCA-002-19*

Affected device:

Product Name	Catalog N°	Id N°	Batch numbers
IH-QC1	009321	08710	All lot numbers until further notice

Dear Customers,

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:

Recently we have been made aware that the anti-D (RH1) ≤ 0.05 IU/ml contained in the **IH-QC1 has given weaker reactions and sometimes negative results against D positive cells in 2 stage papain technique** (set of cells ID-DiaCell IP-IIP-IIIP, ID-DiaPanel P and ID-DiaScreen VP-VIP)**.**

The reaction level of the IH-QC1 is affected only for the control of Antibody Screening / Identification test methods performed in 2 stage papain technique in ID-Card "NaCl, Enzyme Test and Cold Agglutinins". (Id. n° 50520)

All other applications of IH-QC1 including the detection of the anti-D ≤ 0.05 IU/ml in Indirect Antiglobulin Testing (IAT) are performing according to specification.

We have also demonstrated that D positive cells of the ID-DiaCell IP-IIP-IIIP, ID-DiaPanel P and ID-DiaScreen VP-VIP reacted as expected in ID-Card "NaCl, Enzyme Test and Cold Agglutinins" when tested against the Anti-D Reference Reagent as well as the WHO Anti-D 01/572 International Standard at a concentration of 0.05 IU/ml.

Impact on the patient:

Weaker to negative results of IH-QC1 against D positive cells could result in invalidating the laboratory Quality Control for the 2 stage papain method and lead to a delayed reporting of the result.

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Immediate protective measures:

Despite extensive investigations, we have not yet identified the root cause. Until a long term solution is available, the 2 stage papain application is no longer recommended for IH-QC1 and will be removed from the product instructions for use.

In the meantime, as a positive control in 2 stage papain we recommend the anti-c (anti-RH4) in IH-QC3, which shows good enhancement compared to untreated cells in IAT

Corrective action:

Product modifications are being studied in order to make IH-QC1 usable again for the 2 stage papain application as quickly as possible.

Please note that the relevant European Regulatory Agency has been advised of this FSCA.

In case of questions, in the first instance, please contact our Technical support at:

product_support_cressier@bio-rad.com

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	**Vice President & General Manager Immunohematology Division**
Diane Galéa	***Ann Madden***

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ANNEX I / *FSCA 002-19*
Reply Form for End Users

AFFECTED DEVICE:

Product Name	Catalog N°	Id N°	Batch numbers
IH-QC1	009321	08710	All lot numbers until further notice

CUSTOMER INFORMATION:

Hospital / Laboratory	
Address (Street, Postcode, Country)	
Phone Number	
Undersigning manager name	
Customer Account Number	

STATEMENT:

I have read and understood this Field Safety Notice, and shared the information with laboratory staff to:

- Complete **the Reply Form** (Annex I) and send back this document to your Customer Service.
- Follow manufacturer's recommendations described in the FSN.

I,……..., do hereby certify that, due to the problem reported on ***IH-QC1*** and according to the instructions issued by Bio-Rad/DiaMed GmbH, I have taken all the immediate protective measures for the above mentioned product.

Date: …… **Signature:**