DiaMed GmbH
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Cressier, 2018 July 11

Urgent: Field Safety Notice / *FSCA 004-18*

Affected device:

Product name	Reference number	Versions
IH-Com Fullversion **IH**-Com for Reader	009000 009010	5.**1.7** and 5.**1.10**

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:
Further to a customer complaint, we have confirmed a software anomaly in **IH**-Com version 5.**1**.
This anomaly only affects the QC module for ABO forward grouping of **IH**-Com. The software allows the release of a QC result ("QC accepted") which is discrepant with the claimed result in the conditions described below:

1. Process ABO forward grouping tests with QC samples.
2. The QC result is not as expected due to a potential failure of instrument or reagents.
3. Obtain a discrepant result with the claimed result.
4. IH-Com displays a "QC passed" while it should be displayed as "QC failed".

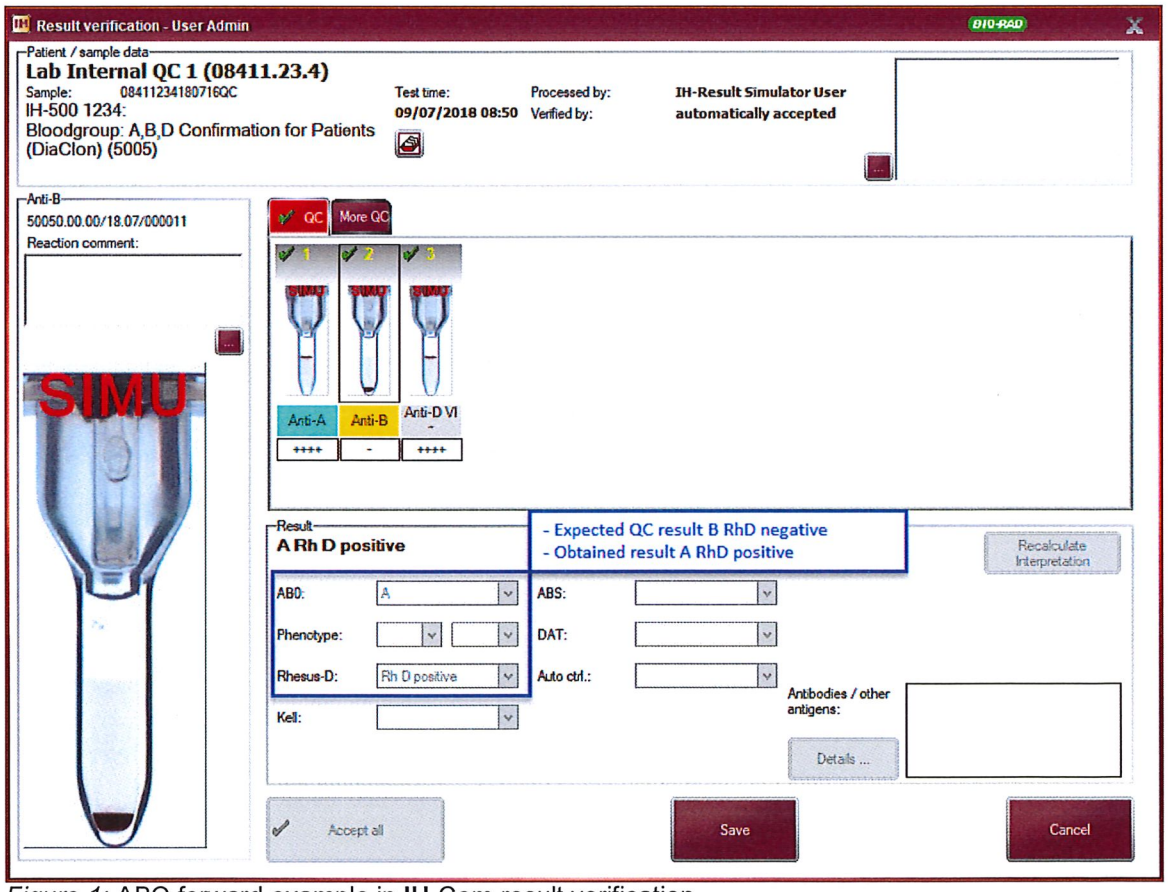

Figure 1: ABO forward example in **IH**-Com result verification.

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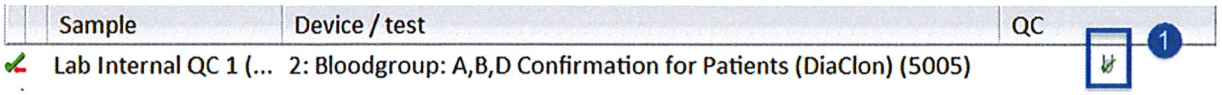
A problem occurs during the test of this QC sample, the obtained result is A Rh positive whereas the expected result is B Rh negative and this QC was accepted by IH-Com ("QC pass" shown below (1)

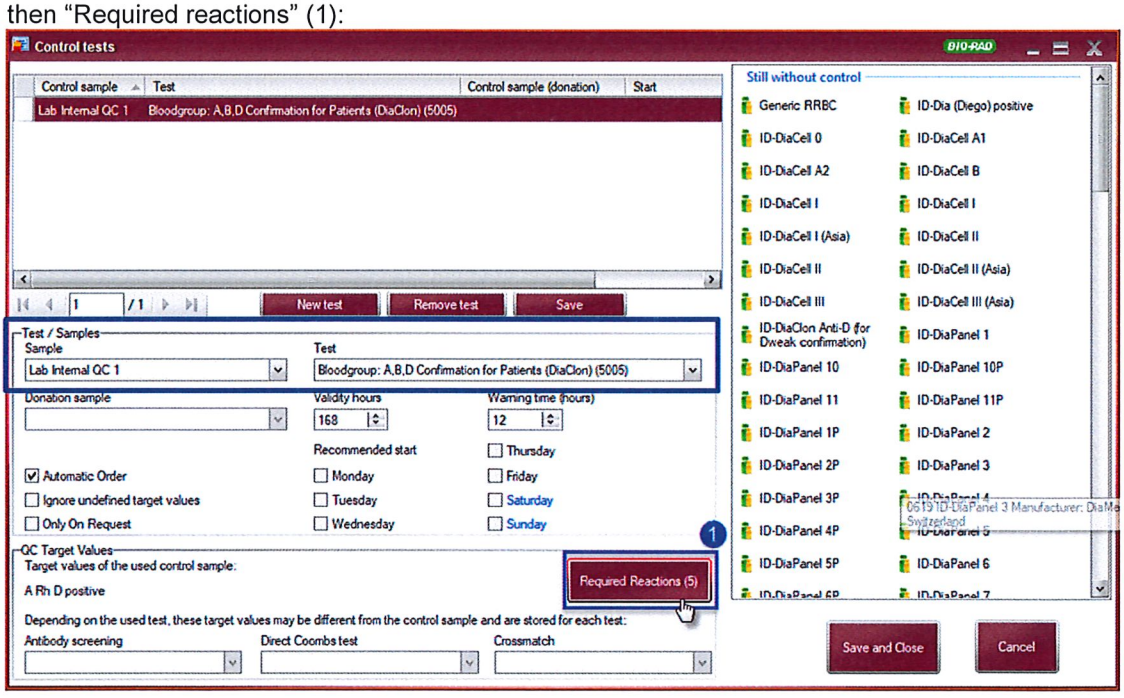


Impact on the patient:
Based on the transfusion guidelines used in most laboratories, in case of a reagent or instrument failure not detected by the routine QC, a risk remains.

Immediate preventative measures:

I. A workaround exists and consists of manually defining the claimed reaction for the QC.
It must be applied as follows:

1. Navigate to the settings "Control tests" in the QC module of **IH**-Com, select the test and the sample, then "Required reactions" (1):



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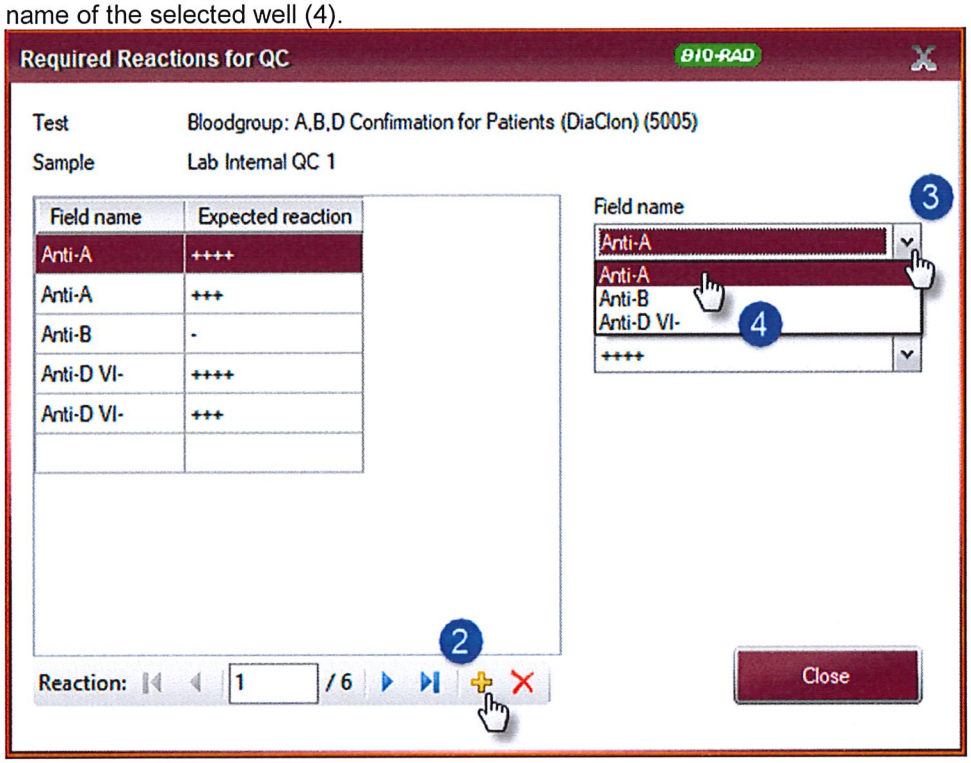
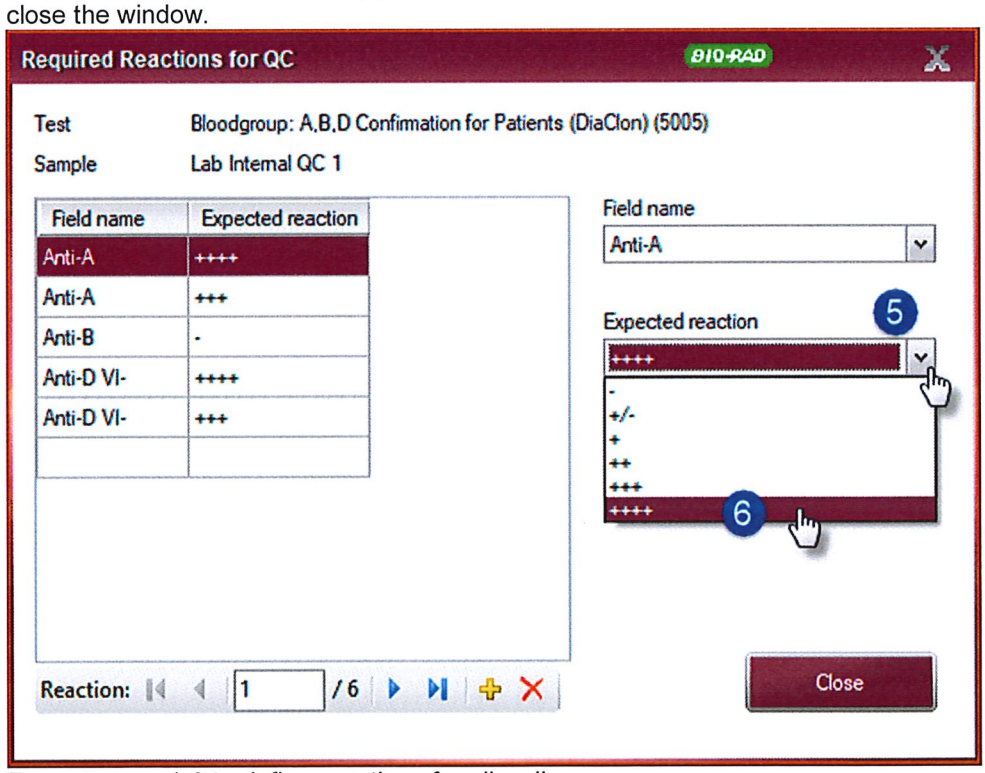
2. Select the well by clicking on "+" (2), then click on the drop down menu (3) and choose the field name of the selected well (4).



3. Click on the drop down menu (5) and select the claimed reaction for the selected field name (6) and close the window.



4. Repeat steps 1-3 to define reactions for all wells

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II. We kindly ask you to send back the reply form (Annex I) to your customer service.

Corrective action:
This anomaly will be definitively corrected by installing a service pack which will be released beginning of Q4 2018.

In case your software environment does not allow you to properly install our software correction, please maintain the immediate protective measures described in this FSN and contact immediately the Regulatory Affairs Department : RA-request_Cressier@bio-rad.com, and the International Technical Service : product_support_cressier@bio-rad.com for getting adequate assistance

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 Product support laboratory:

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

Diane Galéa

Vice President & General Manager
Immunohematology Division

Ann Madden

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Reply Form for End Users

PRODUCT:

Product name	Reference number	Versions
IH-Com Fullversion IH-Com for Reader	009000 009010	5.1.7 and 5.1.10

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 (enter Local information).
- Use the described workaround as a preventive measure.
- Update the version 5.1 with the service pack when it will be released.

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

Date: ..... **Signature:**

Annex I

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