

Cressier, 2018 July 11

Urgent: Field Safety Notice / FSCA 004-18

Affected device:

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

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".

The screenshot shows the 'Result verification - User Admin' window. The patient/sample data is 'Lab Internal QC 1 (08411.23.4)' with sample 'IH-500 1234' and blood group 'A,B,D Confirmation for Patients (DiaClon) (5005)'. The test time is '09/07/2018 08:50' and the result is 'IHL-Result Simulator User automatically accepted'.

On the left, there is a 'SIMU' (simulated) image of a test tube. The 'Anti-B' section shows '50050.00.00/18.07/000011' and a 'Reaction comment' field.

The main area displays three test tubes for 'QC' (Quality Control) with results: 'Anti-A: +++++', 'Anti-B: -', and 'Anti-D VI: +++++'. Below this, the 'Result' section shows 'A Rh D positive'. A warning box indicates: '- Expected QC result B RhD negative' and '- Obtained result A RhD positive'. The 'ABO' dropdown is set to 'A', 'Phenotype' is empty, 'Rhesus-D' is 'Rh D positive', and 'Kell' is empty. The 'ABS' dropdown is empty, 'DAT' is empty, and 'Auto ctrl.' is empty. There is a 'Recalculate Interpretation' button.

At the bottom, there are buttons for 'Accept all', 'Save', and 'Cancel'.

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

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))

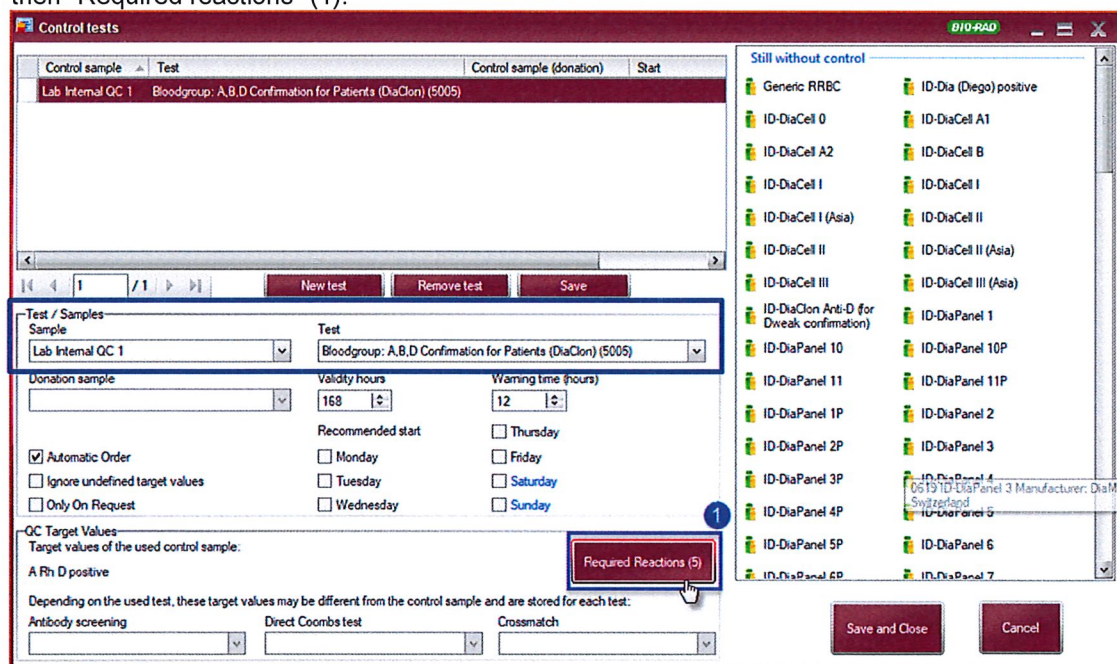
Sample	Device / test	QC
Lab Internal QC 1 (... 2: Bloodgroup: A,B,D Confirmation for Patients (DiaClon) (5005)		 1

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):



The screenshot shows the 'Control tests' window in the IH-Com software. The window is divided into several sections. At the top, there is a table with columns for 'Control sample', 'Test', 'Control sample (donation)', and 'Start'. Below this, there is a list of control samples, including 'Lab Internal QC 1'. The 'Test / Samples' section is highlighted, showing 'Lab Internal QC 1' and 'Bloodgroup: A,B,D Confirmation for Patients (DiaClon) (5005)'. The 'Required Reactions (5)' button is highlighted with a red box and a circled '1'. The 'QC Target Values' section shows 'A Rh D positive'. The 'Antibody screening' section shows 'Direct Coombs test' and 'Crossmatch'.

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).

Required Reactions for QC

Test: Bloodgroup: A,B,D Confirmation for Patients (DiaClon) (5005)
Sample: Lab Internal QC 1

Field name	Expected reaction
Anti-A	++++
Anti-A	+++
Anti-B	-
Anti-D VI-	++++
Anti-D VI-	+++

Field name: Anti-A (selected)

Reaction: 1 / 6

Close

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

Required Reactions for QC

Test: Bloodgroup: A,B,D Confirmation for Patients (DiaClon) (5005)
Sample: Lab Internal QC 1

Field name	Expected reaction
Anti-A	++++
Anti-A	+++
Anti-B	-
Anti-D VI-	++++
Anti-D VI-	+++

Field name: Anti-A

Expected reaction: ++++ (selected)

Reaction: 1 / 6

Close

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

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

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Reply Form for End Users

PRODUCT:

Product name	Reference number	Versions
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IH-Com for Reader	009010	

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