

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

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".

🛄 Result verification - User Admin				810- 8 40	x
Patient / sample data Lab Internal QC 1 (08411.2 Sample: 08411234180716QC IH-500 1234: Bloodgroup: A,B,D Confirmation f (DiaClon) (5005)	Test time: 09/07/2018 08:50	Processed by: Venfied by:	IH-Result Simulator User automatically accepted		
Reaction comment:	Anti-A Anti-A Anti-A Anti-B Anti-A				
	A Rh D positive		result B RhD negative It A RhD positive	Recalculate Interpretation	
	B0: A 🗸	ABS:	v		
Pi Pi	henotype:	DAT:	~		
R	thesus-D: Rh D positive 🗸	Auto ctrl.:	Antibodies / other	r	7
Ка	iel:		antigens:		description of the second second
			Details		Loc scale in parts and
	Accept all		Save	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		4	
1	Lab Internal QC 1 (2: Bloodgroup: A,B,D Confirmation for Patients (DiaClon) (5005)		W		-

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):

Control tests		and the state of the second second	although the second	No she had been a second	(810-RAD) _ E X
Control sample A Test		Control sample (donation)	Start	Still without control	· · · · · · · · · · · · · · · · · · ·
Lab Internal QC 1 Bloodgroup: A,B,D Confirm	ation for Patients (DiaClon) (500	5)		🖡 Generic RRBC	🚦 ID-Dia (Diego) positive
				👔 ID-DiaCell 0	🚺 ID-DiaCell A1
				🚺 ID-DiaCell A2	👔 ID-DiaCell B
				🚦 ID-DiaCell I	🖡 ID-DiaCell I
				📔 ID-DiaCell I (Asia)	🚺 ID-DiaCell II
<			2	🚺 ID-DiaCell II	📔 ID-DiaCell II (Asia)
	New test Remov	ve test Save		🚺 ID-DiaCell III	👸 ID-DiaCell III (Asia)
-Test / Samples	Test			Dveak confirmation	🔋 ID-DiaPanel 1
Lab Internal QC 1	1	mation for Patients (DiaClon) (50)5) 🗸	🚺 ID-DiaPanel 10	📙 ID-DiaPanel 10P
Donation sample	Validity hours	Warning time (hours)		🚺 ID-DiaPanel 11	📔 ID-DiaPanel 11P
v		12		D-DiaPanel 1P	🚺 ID-DiaPanel 2
✓ Automatic Order	Recommended start	Thursday		👔 ID-DiaPanel 2P	E ID-DiaPanel 3
Ignore undefined target values	Tuesday	Saturday		1D-DiaPanel 3P	061910-UlaPanel 3 Manufacturer: Dia
Only On Request	Wednesday	Sunday	0	1D-DiaPanel 4P	Switzerland
-QC Target Values Target values of the used control sample:	****		ed Reactions (5)	1D-DiaPanel 5P	1D-DiaPanel 6
A Rh D positive		Hequi	eu neactions (o)	In. Nis Panal 60	ID_DisPanal 7
Depending on the used test, these target values m	ay be different from the control s	ample and are stored for each te	st:		
	ct Coombs test	Crossmatch		Save ar	nd Close Cancel
v		Y	Y		



H006001 07.12

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).

est		mation for Patients (DiaClon) (5005)
ample	Lab Internal QC 1	Field name
Field name	Expected reaction	
Anti-A	++++	Anti-A Anti-A
Anti-A	+++	Anti-B
Anti-B		Anti-D VI-
Anti-D VI-	++++	
Anti-D VI-	+++	
		9
		Close

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

Sample Lab Internal QC 1 Field name Expected reaction Anti-A ++++	
Actia	
Anti-A +++	F
Anti-B - Expected reaction	5
Anti-D VI- ++++	
Anti-D VI- +++ +/-	
+ ++	
····	10
	7
	Close



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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

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Vice President & General Manager Immunohematology Division

Ann Madden





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Urgent: Field Safety Notice / FSCA 004-18 Reply Form for End Users

PRODUCT:

Product name	Reference number	Versions
IH-Com Fullversion	009000	5. 1.7 and 5. 1.10
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