

26/02/2021

### ACKNOWLEDGEMENT FORM

#### Urgent: Field Safety Corrective Action / FSCA 001-21

Dear Customer,

Bio-Rad is voluntarily conducting a Field Safety Corrective Action for the products identified as follows:

**Affected products displaying the issue:**

Product Name	Id-n°	Catalog No	Lot No	Expiry Date
DiaClon Anti-M/N*	51210	006011	51210 10 01	04.2021
			51210 11 01	06.2021
			51210 12 01	09.2021
			51210 12 02	10.2021
			51210 13 02	10.2021
DiaClon Anti-N	50221	007111	50221 05 01	04.2021
			50221 06 01	06.2021
			50221 07 01	07.2021
			50221 07 02	09.2021

\*The only impacted well of the card is the anti-N. There is no issue with anti-M and ctl well.

**Description of the problem:**

Unexpected reactions that could be observed when using the DiaClon anti-N and DiaClon anti-M/N mentioned above. Following customer feedback, non-specific reactions could be observed in the anti-N well (MNS2) of the above-mentioned cards with N negative samples (MNS: -2).

The table 1 shows the range of false positive reactions that may occur.

		
<i>Uninterpretable Reaction "+/-"</i>	<i>False Positive Reaction "+"</i>	<i>False Positive Reaction "++"</i>

Table 1: Example of non-specific reactions obtained on IH-500 with the impacted lots of card

The phenomenon is observed frequently when the ID-Cards are used on the IH-500. It is more rarely observed when the ID-Cards are used on IH-1000 or tested in the manual or semi-automated methods (Saxo ID-Reader II, Banjo ID-Reader, Swing TwinSampler, Classic ID-Gelstation).

#### Impact on the patient:

<b>Impact on the result</b>	There is a risk of a false positive result (up to 2+ maximum) for the typing of the N antigen when carried out with lot numbers listed above.
<b>Risk in the context of donor typing</b>	None as N positive blood units will not be used for transfusing a patient having a clinically significant anti-N
<b>Risk in the context of patient typing</b>	Delayed result - this antigen typing would be carried out for a patient presenting with a clinically significant anti-N. This inconsistency would lead to further testing.

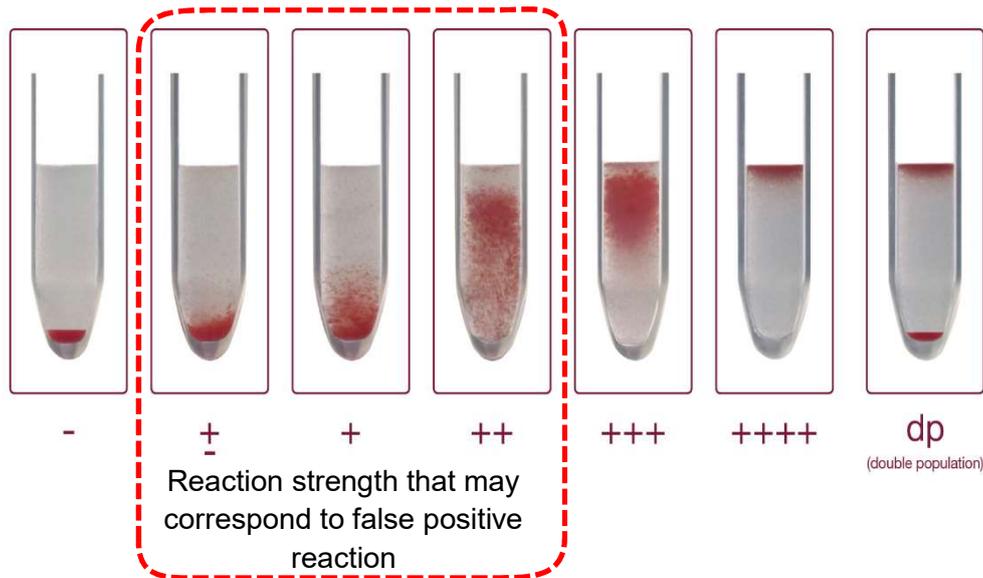
We advise you to assess this situation with your biologist to determine if retesting is deemed necessary and take the appropriate course of action depending on the patient's clinical conditions, medical history, and other relevant laboratory data.

#### Immediate protective measures:

Testing Method	Recommendation
<b>IH-500</b>	1) Stop using the impacted ID-cards on the IH-500. 2) Use one of the following methods: <ul style="list-style-type: none"> <li>• Manual method or,</li> <li>• semi-automated method or,</li> <li>• fully automated method with the IH-1000 analyzer,</li> </ul> according to recommendations described below.
<b>IH-1000 and semi-automated methods</b>	Deactivate the automatic validation of the results in IH-Com  In case of a reaction shown as +/-, + or ++ by the instrument please follow the recommendations below: <ol style="list-style-type: none"> <li>1) Invalidate the result,</li> <li>2) Repeat the test with the manual method</li> </ol>
<b>Manual Method</b>	If visual interpretation of the reaction is +/-, +, or ++ (refer to table 2): <ol style="list-style-type: none"> <li>1) Invalidate the result,</li> <li>2) Repeat the test</li> </ol> If retesting does not permit to conclude the presence or absence of the N antigen, use an alternative method such as an antigen profile determination including an incubation step at room temperature.

Any negative reaction obtained with the impacted lots should be considered as valid and indicates the absence of the corresponding antigen.

Any positive reaction obtained with the impacted lots showing a reaction strength of +++ to ++++ (refer to table 2 or instrument interpretation) should be considered as valid and indicates the presence of the corresponding antigen.



*Table 2: Reading charter for visual interpretation of reaction strength*

Please find enclosed a copy of the Field Safety Notice (F.S.N.) relating to this product for full details.

I would be grateful if you would confirm receipt of this Customer Notification by emailing a completed, signed copy of this [Acknowledgement Form](#) to [alison.smith@fannin.eu](mailto:alison.smith@fannin.eu) by the **5<sup>th</sup> March 2021**.

Please do not hesitate to contact us, should you require any further information.

We apologise for any inconvenience this notice may have caused.

Yours sincerely,

**Alison Smith**  
**Quality Department**

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Tel: +353 01 2907000

**Field Action Reference Number: FSCA 001-21**  
**Bio-Rad Division: IHD**

**CUSTOMER INFORMATION:**

Account Name:	
Undersigning Manager Name:	
Address :	
Telephone Number / Fax:	
Customer Account Number:	

**STATEMENT:**

- 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:	<i>Not applicable</i>	Number of affected products corrected/ destroyed/ returned (as applicable to the Field Action instructions):	<i>Not applicable</i>
If number of products corrected/ destroyed/ returned is different to the number received, please account for the difference: <i>Not applicable</i>			

Date:

Customer Signature (and Stamp if applicable)