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

Cressier, November 27th, 2012

Urgent: Field Safety Notice / 004-12

Dear valued customer and IH-Com user,

This letter contains important information concerning an issue that requires your immediate attention.

Affected device

Product name: **IH-Com kit Fullversion** (Data Management and Result Interpretation Software)

Product REF: **009000**

Software versions: **03.0.43 / 03.0.52 / 03.0.59**

Description of the problem

In case of not interpretable results in the anti-AB well (ABO3) of ID-Cards intended for ABO forward grouping, the IH-Com software doesn't include the reaction of this well (result code -30) when sending the results to the laboratory Host.

The issue can only occur if the following conditions are met:

1. IH-Com Software is connected to the laboratory Host through ASTM* communication mode and,

2. an "ABO not interpretable" result is obtained due to a reaction "?" or "+/-" or "dp" in the anti-AB well of an ID-Card** intended for ABO forward grouping (see point *a.* on the illustration on p.2) and,

3. the "Second reading" option is deactivated and IH-Com results are directly sent to the Host,

or

3'. the "Second reading" option is activated but the "not interpretable" result obtained in IH-Com is directly saved and sent to the Host without a manual selection by the user in the ABO scrollbar (see point *b.* on the illustration on p.2)

** Please note that you are not concerned if you are working with Maestro emulation communication mode between IH-Com and your Host or if you are using IH-Com software without any connection to a Host.*

*** List of concerned ID-Cards (ID n°/Test code): 50001/PR01; 50031/PR01B; 50961/SV07; 50071/MO30B; 51011/MO02; 50012/MO01&MI35A; 50411/MO33A; 50481/MO01A.*

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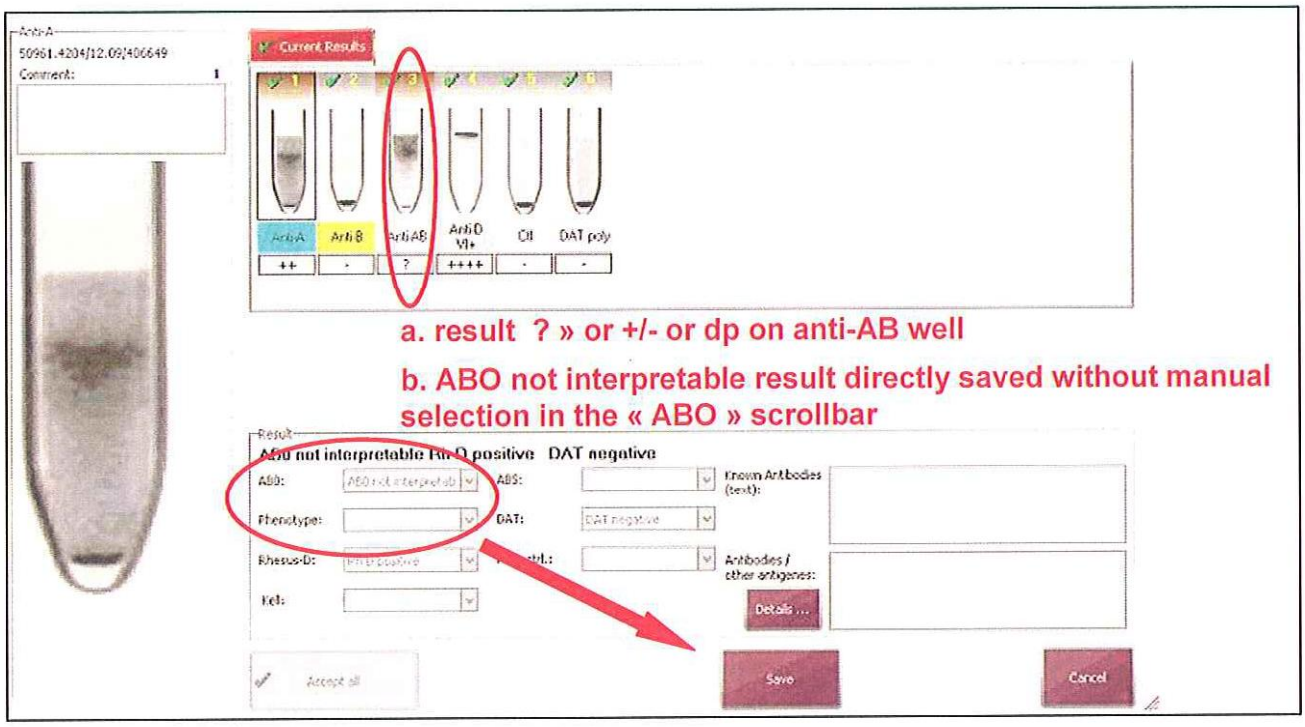

Illustration of IH-Com -"Second reading" option

Impact on the patient

The described issue could lead to the interpretation of the ABO group only based on the results of the anti-A and anti-B wells without taking into account the result of the anti-AB well of the concerned ID-Cards.

The analysis of this issue led to the conclusion that a residual risk exists for Newborns for whom ABO group is only determined through ABO forward grouping (no reverse grouping performed). In the worst case scenario, a mixed field result ("dp") in the anti-AB well in addition to a non detectable mixed field in the other wells (anti-A or anti-B), could lead to assigning a wrong ABO group to the newborn based on the mother's group.

The probability of occurrence of such case is extremely remote. Nevertheless, considering that the residual risk could affect the test results for these patients, we inform you so that you can take the appropriate protective measures.

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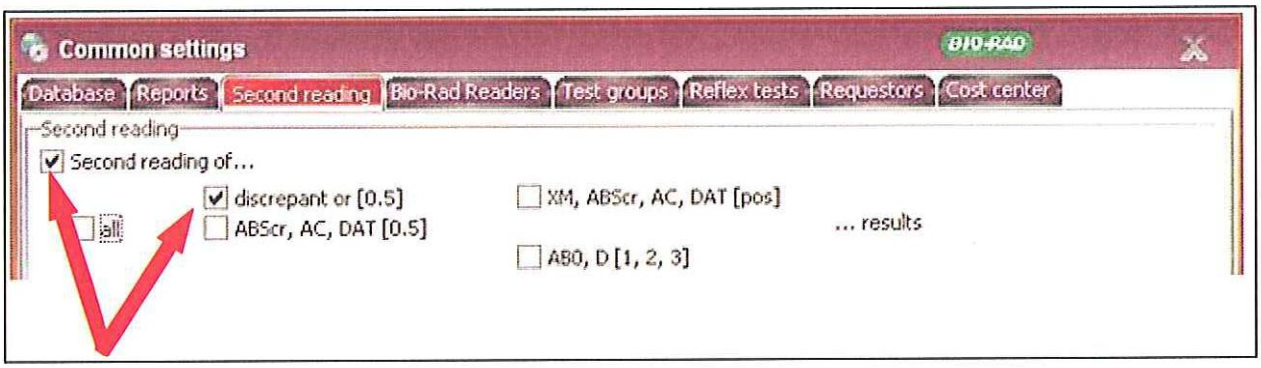
Immediate protective measure

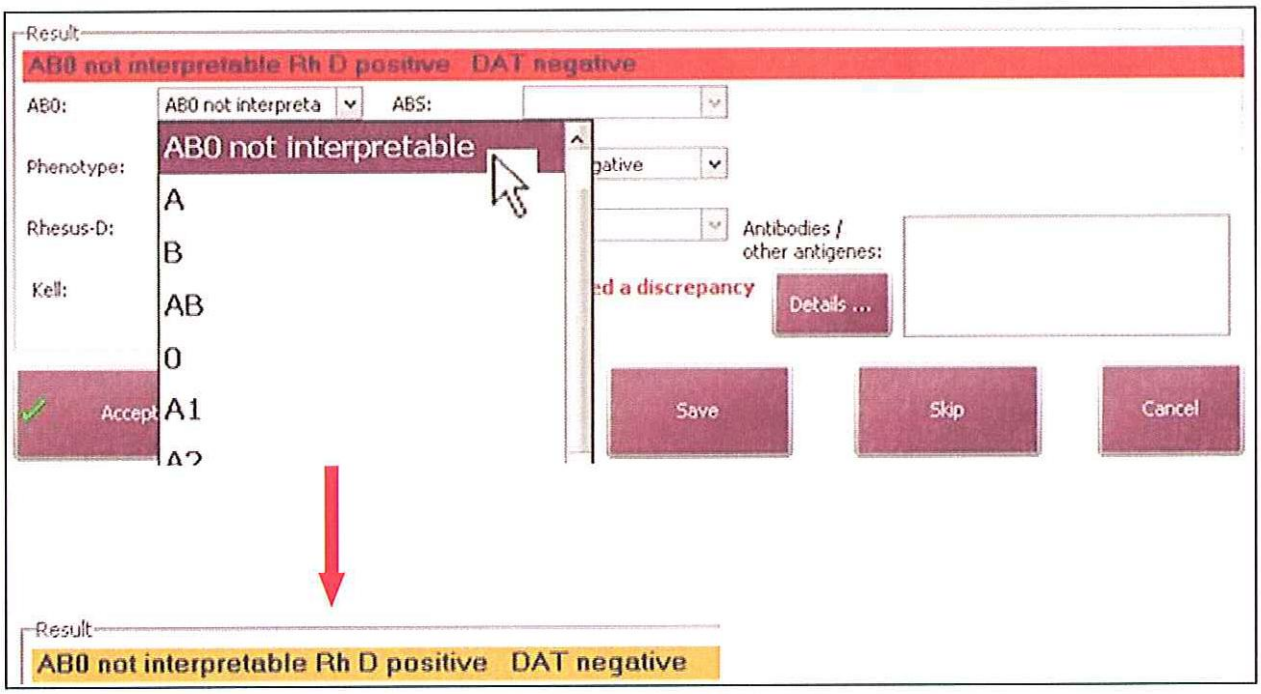
This issue will be permanently corrected through the deployment of the new IH-Com software version.

In the meantime to exclude the residual risk, we advise you to immediately implement the following protective measures:

1. **Ensure that the "Second reading" option of IH-Com is activated at least on discrepant results (as illustrated below),**



2. **In case of "ABO not interpretable" in IH-Com due to a reaction "?" or "+/-"or "dp" in the anti-AB well, the operator must open the "ABO" scrollbar and select manually "ABO not interpretable" before saving and sending the result to the Host.** (see illustration below - The manually selected interpretation will be highlighted in yellow)



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Actions to be taken by the distributor / Subsidiary

- Please translate into your national language(s) the above text and share this information with the concerned customers.
- Please complete the Field Safety Notice Reply Form (Annex I) and return to DiaMed GmbH.
- Retain this notification as part of your Quality System documentation as well as the completed Field Safety Notice forms of your respective customers (Annex II).

Actions to be taken by the customer

- Please complete the Field Safety Notice reply form (Annex II) and return to your distributor.
- Please share this information with the relevant laboratory staff, to ensure that the appropriate protective measure is taken.

In case of questions, in the first instance, please contact our Help desk:

+41 (0) 26 674 51 60
support.instr_cressier@bio-rad.com

Our collaborators are briefed to help you manage this situation.

We apologize for any inconvenience and would like to thank you in advance for your cooperation.

Yours sincerely,

DiaMed GmbH
RA/QA Manager
Agnes Eude Goethals

DiaMed GmbH
BU Marketing Manager
Armin Köchli

H006001 10.10

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Annex I

Urgent: Field Safety Notice Reply Form for Distributors / Subsidiaries / 004-12

Product name:	**IH-Com kit Fullversion** **(Data Management and Result Interpretation Software)**
Product REF:	**009000**
Software versions:	**03.0.43 / 03.0.52 / 03.0.59**

Please fill out and sign the information below and return the completed form to DiaMed GmbH including a copy of the translated letter within 10 working days:

- by email at RA-request_Cressier@bio-rad.com
- by Fax at: **+ 41 26 674 54 69**

I have read and understood this Field Safety Notice, and shared this information with concerned laboratories.

_____

Distributor / Subsidiary Name

_____

Address

_____

Phone Number

_____

Completed by: Name / Signature / Title / Date

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Annex II

Urgent: Field Safety Notice Reply Form for Customers / 004-12

Product name:	**IH-Com kit Fullversion** (Data Management and Result Interpretation Software)
Product REF:	**009000**
Software versions:	**03.0.43 / 03.0.52 / 03.0.59**

Please fill out and sign the information below and return the completed form to your distributor within 10 working days.

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

_____

Hospital / Laboratory

_____

Address

_____

Phone Number

_____

Completed by: Name / Signature / Title / Date