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

Cressier, September 23rd, 2022

# Field Safety Notice / *FSCA 003-22*

**Affected products displaying the issue:**

| Product Name | UDI-DI | Catalog No | Version | Serial Number |
|---|---|---|---|---|
| IH-500 | 07611969167623<br>03610522063697 | 001500<br>001500RECOND | All | All |

Dear Customer,

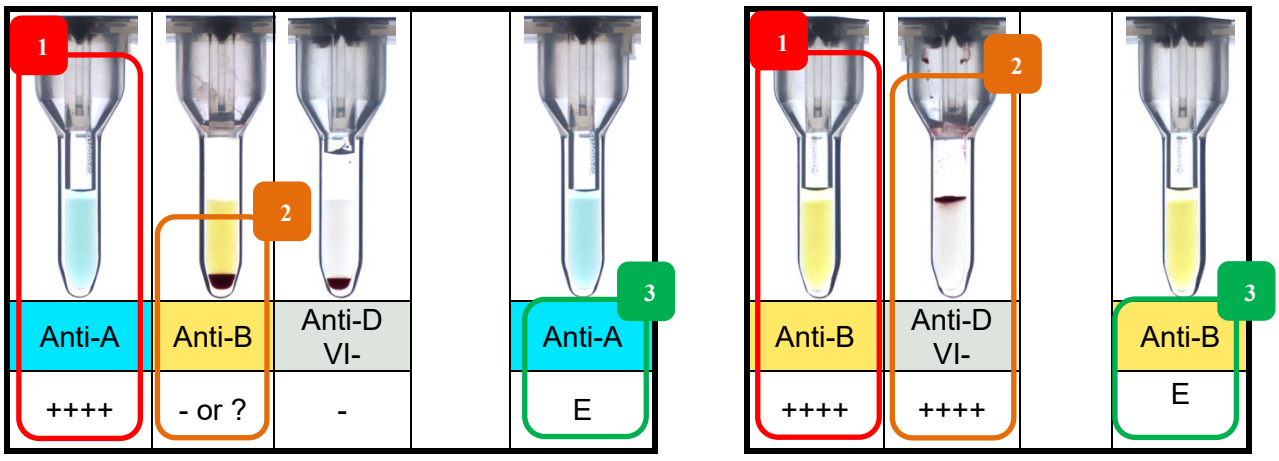
This letter contains important information that requires your immediate and urgent attention. Bio-Rad is voluntarily conducting a Field Safety Corrective Action for the products identified above.

**Description of the problem:**

We would like to share with you, and your team, information about an issue that could be observed when performing ABO grouping tests for patients and/or donors on the IH-500 instrument.

In case of absence of red blood cells (RBC) sample into the Anti-A well or Anti-B well, the reading algorithm of the IH-500 might not be able to properly detect the dispense failure and return the result as positive instead of Empty "E" as expected (See figure 1).

Out of the entire installed fleet of instruments, which includes more than 1'500 machines, only 6 cases of this type were brought to our attention in 2022, indicating a low probability of occurrence of this issue.




**(1) Unexpected behavior of IH-500: Non dispensed well returned positive "++++"**
**(2) Non dispense in a well is generally followed by a double dispense in the subsequent well (negative results displayed as "?" or "-", positive result displayed as expected)**
**(3) Expected behavior of IH-500: Non dispensed well returned "E" invalidating the result**

*Figure 1: Unexpected and expected results for empty Anti-A (left) and Anti-B (right) wells*

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

**Impact on the patient:**

| Application Subtype* | Impact on the reaction | Medical Context of Use | Mitigating Factors / Sequence of events |
|---|---|---|---|
| Combined forward and reverse grouping | False Positive | Transfusion | This situation will lead to a discrepancy between forward and reverse typing or with patient's anteriority.<br>The first time, a patient is always typed twice including a second sample prior to transfusion.<br>In case the transfusion would become urgent, crossmatch compatible O RhD negative blood units could be used pending for the final ABO/D type. |
| Combined forward and reverse grouping | False Positive | Donor Qualification | This situation will lead to a discrepancy between forward and reverse typing or donor's anteriority.<br>The first time, a donor is always typed twice and then further on, they are typed each time they donate. The blood unit would be kept on hold until the discrepancy is sorted out. |
| ABD Confirmation for patients | False positive | Transfusion | ABD Confirmation card for patient is used for patients that do have historical results available in the Laboratory Informatics System based on at least two ABO blood type determinations (forward plus reverse). In case the transfusion would become urgent, crossmatch compatible O RhD negative blood units could be used pending for the final ABO/D type. |
| ABD Confirmation for donors | False positive | Donor Qualification | ABD Confirmation card for donor is used for donors that do have historical results available in the Laboratory Informatics System based on at least two ABO blood type determinations (forward plus reverse). The blood unit would be kept on hold until the discrepancy is sorted out. |

** Remark: The ABO grouping tests for Newborn are not affected by this issue as involving a different type of dispense of the RBC suspension (50 µL of 1% RBC suspension).*

We advise you to assess this situation with your medical director 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 measure for the user:**

*We recommend to:*

1. *Ensure your preventive maintenance including needle replacement has been made according to our instructions.*
2. *As of now, verify all future results obtained on the Anti-A and Anti-B following one of the instructions below:*
    a. *Deactivate the automatic reading function in the IH-Com (this will affect all tests results)*

    *or*

    b. *Contact your field application to determine the appropriate solution (e.g. configure a reflex test in IH-COM, send an automatic comment to your LIS)*

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

If you detect a dispensing issue incorrectly interpreted, we recommend to:

1. Invalidate the result
2. Repeat the test
3. If the issue persists, contact your customer technical support representative

We ask that you ensure the transfer of this information to all the necessary people impacted in your institution and/or forward it to establishments where products may have been transferred.

*Note:* The upcoming software version 3.1 of IH-500 includes improvement of the reading algorithm for the detection of empty wells. Information regarding the new software deployment will be communicated in an FSN follow-up letter before end of 2022.

Please note that the relevant European Regulatory Agency has been advised of this Field Safety Corrective Action.

In case of any questions, as a first measure, please contact our customer technical support representative:

***[Indicate here local contact]***

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* | *International Product Manager Automated Solutions* |
| Amélie Bérard-David | Raphael Muñiz |

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

## CUSTOMER FIELD ACTION RESPONSE FORM

**Field Action Reference Number: FSCA 003-22**
**Bio-Rad Product Segment: IHD**
**Single Registration Number (SRN): CH-MF-000020826**

## PRODUCT

| Product UDI | Product Name | Catalog No | Serial No | Software Version |
|---|---|---|---|---|
| 07611969167623<br><br>03610522063697 | IH-500 | 001500<br><br>001500RECOND | All | All |

## CUSTOMER INFORMATION

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

## STATEMENT:

- ☐ No affected product received
- ☐ 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: | ***N/A*** | Number of affected products corrected/ destroyed/ returned (as applicable to the Field Action instructions): | ***N/A*** |
| If number of products corrected/ destroyed/ returned is different to the number received, please account for the difference:<br>***N/A*** | | | |

Date: Customer Signature (and Stamp if applicable)

Please return this form to: [enter local details]