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

Cressier, 19 July 2021

Field Safety Notice / *FSCA 002-21*

Affected products displaying the issue:

Product Name	Id-n°	Catalog Ref.	Lot No	SAP Batch No	Expiry Date (DD/MM/YYYY)
ID-Antigen profile II	50380	008610	50380 29 01	5947322901	31.12.2021

Note: The impacted wells of the card are anti-k and Anti-Kp^a. There is no issue with anti-Kp^b, anti-Jk^a, anti-Jk^b and ctl well.

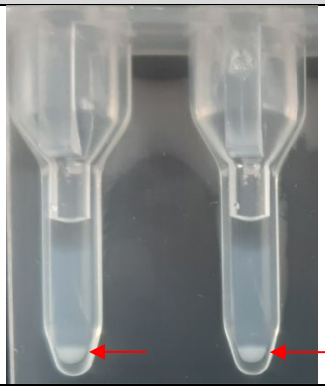
Dear Customer,

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 information about an artefact visible prior to the use of the ID-Card that could be observed when using the ID-Antigen profile II batches mentioned above.
The anti-k (KEL2) and anti-Kp^a (KEL3) wells were observed to have a whitish deposit at the bottom of the well (see image below).

Table 1: Example of unexpected whitish deposit in Gel Cards ID-Antigen profile II

Expected gel card appearance	Gel card with whitish deposit **defect**
	

The defect is present on all ID-cards of the batch 50380 29 01, can interfere with the automatic reading of reaction on IH-analyzers and readers (Saxo ID-Reader II, Banjo ID-Reader, IH-500 and IH-1000) and generate unexpected results (fig. 1) for both positive and negative samples.

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Figure 1: Examples of an expected positive (left image) and expected negative (right image) results when using the impacted ID-Cards.

Impact on the patient:

The following table summarizes the impact and the risks for each application for false positive reactions and uninterpretable reactions.

	Application	Impact
Impact on the result	Typing of k and Kp^a antigens	There is a risk of uninterpretable or false positive results for the typing of the targeted antigen when carried out with lot numbers listed above.
Risk in the context of donor typing	Typing of k antigen	***Major clinical impact:*** k negative blood is extremely scarce. An uninterpretable result would lead to delay the provision of k negative blood that could benefit to patients presenting with an anti-k and requiring a transfusion. A false positive result would lead to miss a rare blood donor that could benefit to patients presenting with an anti-k and requiring a transfusion.
	Typing of Kp^a antigen	***Negligible clinical impact:*** Uninterpretable reaction could delay the result by requiring further tests to select red cells compatible for transfusion when an anti-Kp^a is suspected. Kp^a positive red blood cell units will not be used for patient with a known anti-Kp^a.
Risk in the context of patient typing	Typing of k antigen	***Minor clinical impact*** An uninterpretable or false positive reaction could delay the result due to further investigation needed. A crossmatch will be performed prior a transfusion if the patient presents with an alloantibody. In an antenatal setting, further tests will be needed to ascertain the antibody specificity and assess its concentration by titration.
	Typing of Kp^a antigen	***Negligible to Minor Clinical Impact:*** Uninterpretable reaction could delay the result by requiring further tests to select red cells compatible for transfusion when an anti-Kp^a is suspected. Kp^a positive red blood cell units will not be used for patient with a known anti-Kp^a. In an antenatal setting, further tests will be needed to ascertain the antibody specificity and assess its concentration by titration.

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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 measure for the user:

We kindly ask you to carry out the following actions:

1. **Stop using** the ID-Cards «ID-Antigen Profile II» from lot number **50380 29 01** and discard those not used yet
2. Use another batch of "ID-Antigen Profile II" or other ID-Cards intended for the k and Kp^a antigen typing as:

Product Name	Id-n°	Catalog No
Anti-Kp^a	50290	007301
Anti-Kp^a/Kp^b	51260	006061
Anti-K/k	51220	006021

3. Fill out and sign the customers' acknowledgment of receipt form «Customer Field action response form» and send it back as well as the «Certificate of destruction» attached.

We request you transfer this information to all persons impacted in your institution and/or forward it to all locations where products may have been transferred.

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

In case of any questions, in the first instance, please contact your local technical support:

[insert local contact information/e-mail address]

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	*Marketing Director Immunohematology*
Diane Galéa	Marc Meyer

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CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Reference Number: FSCA 002-21
Bio-Rad Division: IHD

PRODUCT

Product Name	Catalog No	Lot No	SAP Lot No	Expiry Date
ID-Antigen Profile II	008610	50380 29 01	5947322901	31.12.2021

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:		Number of affected products destroyed (as applicable to the Field Action instructions):	
If number of products destroyed is different to the number received, please account for the difference:			

Date: Customer Signature (and Stamp if applicable)

Please return this form to: [enter local details]