DiaMed GmbH
Pra Rond 23
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Tel : +41 (0)26 674 51 11
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Cressier, 2018 July 11

Urgent: Field Safety Notice / *FSCA 003-18*

Affected device:

Product name	ID number	Reference number	Batch numbers
Anti-Jk^a	17610	104301	17610 81 01 17610 82 01 17610 83 01

Dear **Customer,**

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

Description of the problem:
Further to customer's complaints, we have been able to confirm that the test sera anti-Jk^a (ref. 104301) Jk^a lots 17610.83.01, 17610.82.01 and 17610.81.01 shows a reduced reactivity potentially leading to false negative results, with some cells expressing a single dose of Jk^a antigen Jk (phenotype(a+b+)).

Impact on the patient:
Most guidelines recommend carrying out Jka phenotyping twice on two samples distant in time and with 2 different sources of reagents.
In addition including known positive samples in the quality controls perform in the laboratory would allow to detect the reduced reactivity.
Nevertheless, transfusion risks associated to an incorrect determination of Jk^a phenotype for patients who have an anti-Jka that is below detection limit or showing dosage cannot be completely excluded.

Immediate protective measures:
We kindly ask you to carry out the following actions:

1. Stop using the affected lots and destroy* those not used yet.
2. In case the tests is not carried out twice using a second reagent or the result is not checked against an available anteriority, we recommend you to review the phenotypes Jk(a-b+) that were obtained with these lot numbers.

Corrective action:
Until the availability of new lot of Anti-Jk^a, we recommend you to use one of the product alternatives listed below:
a. DiaClon Anti-Jk^a (ref. 104352)
b. Seraclone Anti-Jk^a (ref. 808179)
c. ID-Card DiaClon Anti-Jk^a (ref. 007321)
d. ID-Card DiaClon Anti-Jk^a/Jk^b (ref. 006051)

*Confirmation form and destruction form to be sent back to your relevant Bio-Rad / Diamed local representatives.

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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 department:

cdg_techsupport_EEMEA@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	Vice President & General Manager Immunohematology Division
Diane Galéa	*Ann Madden*

DIAMED GMBH
BIO-RAD
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Annex I
Reply Form and destruction form for End Users

PRODUCT:

Product name	ID number	Reference number	Batch numbers
Anti-Jk[a]	17610	104301	17610 81 01 17610 82 01 17610 83 01

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 **the Reply Form** (Annex I) and send back this document to your customer Service (enter Local information).
- Destroy all the remaining affected lots in stock.

Number of lot destroyed : ……,
Replacement catalogue number needed : ……..

I,…….....,do hereby certify that, due to the problem reported on the Anti-Jk[a] and according to the instructions issued by BioRad/DiaMed GmbH, I have taken all the immediate protective measures and destroy the above mentioned products.

Date: …… **Signature:**