DiaMed GmbH
Pra Rond 23
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Cressier, 2019 May 20

Urgent: Field Safety Notice / *FSCA 003-19*

Affected device:

Product name	ID number	Reference number	IHD Batch numbers	SAP Batch numbers
ID-DiaCell I-II-III Asia	45330	003614	45330 52 1 45330 52 2	375053521 378425522

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 product identified above.

Description of the problem:
Further to customer's reports, we have been able to confirm that the cell III of ID-DiaCell I-II-III Asia lots 45330 52 1 and 45330 52 2 shows a reduced reactivity against samples known to contain anti-Mi^a.

Impact on the patient:
This situation may potentially lead to false negative results with samples containing weak forms of anti-Mi^a antibody.
This result could thereafter affect the blood compatibility analysis prior to transfusion as well as the assessment for the need to refer to foetal medicine specialist during the pregnancy.

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. Use **another** lot number.
3. Where deemed necessary by the medical director of the laboratory, patients tested with lots n° 45330 52 1 and 45330 52 2 should be re-tested with another lot.
4. Fill out and sign the attached "**Customer Field action response form**" and return it to your distributor to get refund.

Corrective action:
The lot 45330 53 will be available week 22.

H006001 07.12

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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 Technical support at:

product_support_cressier@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

Diane Galéa

Vice President & General Manager
Immunohematology Division

Ann Madden

H006001 07.12

CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Reference Number: FSCA 003-19

Bio-Rad Division: IHD

PRODUCT

Product UDI	Product Name	Catalog No	Serial/ Lot No	Expiry Date	Software Version
NA	ID-DiaCell I-II-III Asia	003614	45330 52 1	17.06.2019	NA
NA	ID-DiaCell I-II-III Asia	003614	45330 52 2	01.07.2019	NA

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 corrected/ destroyed/ returned (as applicable to the Field Action instructions):	
If number of products corrected/ destroyed/ returned 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]