DiaMed GmbH
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Cressier, 2019 September 11

Urgent: Field Safety Notice / *FSCA 006-19*

Affected device:

Product name	ID number	Reference number	IHD Batch numbers	SAP Batch numbers
DC-Screening II	50560	004831 004836 004837	50560 94 01 50560 94 02 50560 94 03	3118949401 3243879402 3243909402 3243939402 3393449403

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 ID-cards DC-Screening II lots 50560 94 01, 50560 94 02 and 50560 94 03 show a reduced reactivity against samples known to contain red blood cells coated with low amounts of C3d (C3b).

Impact on the patient:
This situation may potentially lead to false negative results with samples containing red blood cells coated with low amounts of C3d/C3b only (no IgG).
These results might be contradictory with the other data (laboratory/clinical) leading to further investigations however, the final diagnosis and treatment do not rely only on the DAT (Direct Antiglobulin Testing) result.

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. The negative results obtained with the affected lots should be reassessed by the biologist and/or the clinician considering this information to determine whether further actions are required depending on the clinical context.
4. Fill out and sign the attached "**Customer Field action response form**" and return it to your distributor to get a replacement batch.

Corrective action:
Use other lots which are already available.

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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

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