DiaMed GmbH
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Cressier, 03/05/2017

Field Safety Notice 001-17_Follow-up letter II

Dear Customer,

Through the investigations performed, we were able to identify the main root cause and contributory factors leading to the unexpected results described in the FSN 001-17.

The root cause is a non-homogeneous silicone coating process into the glass vials. As a permanent correction, another source of vials will be used for the production of the ID-cells listed as "affected devices displaying the issue".

These vials allow recovering the full quality of the product, starting from lots numbers listed according to Appendix I and for any subsequent lots numbers.

For already delivered products, FSN recommendations still apply.

Concerning the other devices from the same product range (ID-DiaCell ABO and ID-DiaCell papainized cells), we have performed a close monitoring and will keep doing. So far, no event has been reported, confirming these products are most probably out of scope.

In case of any questions, in the first instance, please contact our Customer Service Laboratory:

slabor_cressier@bio-rad.com

Our representatives are briefed to help you in managing 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,

[redacted]

Site Quality Management Representative, Immunohematology Division

Diane Galea

[redacted]

Vice President and General Manager, Immunohematology Division

Ann Madden

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ANNEX 1

Urgent: Field Safety Notice / 001-17
Reply Form for Customers

PRODUCT:

Product Name	Catalog No
ID-Dia (Diego) Positive	004134 / 004134VJ
ID-DiaCell SF	003640
ID-DiaCell Pool	003630 / 003631
ID-DiaCell ABO/I-II	003610
ID-DiaCell ABO/I-II-III	003618
ID-DiaScreen I-II-III-IV-VP-VIP	004316
ID-DiaCell I-II	003613 003613VJ
ID-DiaPanel	004114 004114VJ
ID-DiaCell I-II-III	004310 / 004310VJ
ID-DiaScreen I-II-III-IV	004311
ID-DiaCell I-II-III Asia	003614
ID-DiaScreen Prophylax	004330
ID-DiaPanel Plus 6	004414

CUSTOMER INFORMATION:

Hospital / Laboratory	
Address (Street, Postcode)	
Country	
Phone Number	
Undersigning manager name	
Customer Account Number	

STATEMENT:

I am aware of information about the field action concerning the above reference product(s) and have proceeded according to the instructions issued by Bio-Rad.

*Date / Customer Stamp / Signature:*_____

Please return this form to your customer service: [enter local details]