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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 10 -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 (10-DiaCell ABO and 10-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,

... ...



DiaMedGmbH Pra Rond 23

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### ANNEX 1

# <u>Urgent: Field Safety Notice / 001-17-Follow-up Letter ||</u> <u>Reply Form for Customers</u>

### **PRODUCT:**

Product Name	Catalog No	
ID-Dia (Dieqo) Positive	004134 / 004134VJ	
ID-DiaCell SF	003640	
1D-DiaCell Pool	003630 / 003631	
1D-DiaCell AB0/1-11	003610	
ID-DiaCell AB0/1-11-111	003618	
ID-DiaScreen 1-11-111-IV-VP-VIP	004316	
ID-DiaCell 1-11	003613	
	003613VJ	
ID-DiaPanel	004114	
	004114VJ	
ID-DiaCell 1- 11- 111	004310 / 004310VJ	
1D-DiaScreen 1-11-111-IV	004311	
ID-DiaCell 1-11-111 Asia	003614	
1D-DiaScreen Prophylax	004330	
ID-DiaPanel Plus 6	004414	

### **CUSTOMER INFORMATION:**

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

### STATEMENT:

1 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 I Customer Stamp I Signature	e <i>:</i>

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







# Appendix 1-8

Please find hereunder our Red Blood Cell Product delivery schedule: if you need information about your group of countries please contact your local customer service.

### Group B

The group of countries B will receive their first delivery with these vials starting from lots numbers listed in the table 1 and according to yearly delivery schedule.

Shii:,ping Date: (Please enter the delivery week for your customer)

### Table 1

Product Name	Catalog No	Lot No	Expiry Date
ID-Dia (Diego) Positive	004134 / 004134VJ	05980.79.2	03/07/2017
ID-DiaCell SF	003640	06060.56.1	17/07/2017
ID-DiaCell Pool	003630 / 003631	06070.74.2	03/07/2017
ID-DiaCell AB0 /1-11	003610	45002.84.1	03/07/2017
ID-DiaCell AB0 /1-11-111	003618	45012.84.1	03/07/2017
ID-DiaScreen1-11-111-IV-VP-VIP	004316	45070.53.2	03/07/2017
ID-DiaCell 1-11	003613	45151.81.1	03/07/2017
	003613VJ	4515.81.02	03/07/2017
1D-DiaPanel	004114	45161.10.1	03/07/2017
	004114VJ	4516.10.02	03/07/2017
ID-DiaCell 1-11-111	004310 / 00431OVJ	45183.70.2	03/07/2017
1D-DiaScreen 1-11-111-IV	004311	45200.53.2	03/07/2017
ID-DiaCell 1-11-111 Asia	003614	45330.25.2	03/07/2017
1D-DiaScreen Prophylax	004330	45660.80.1	03/07/2017
ID-DiaPanel Plus 6	004414	45670.91.1	31/07/2017



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### Appendix 1- A

Please find hereunder our Red Blood Cell Product delivery schedule: if you need information about your group of countries please contact your local customer service.

#### Group A

The group of countries A will receive their first delivery with these vials starting trom lots numbers listed in the table 2 and according to yearly delivery schedule.

Shipping Date: (Please enter the delivery week tor your customer)

### Table 2

Product Name	Catalog No	Lot No	Expiry Date
ID-Dia (Dieqo) Positive	004134 / 004134VJ	05980.80.1	17/07/2017
1D-DiaCell SF	003640	06060.56.1	17/07/2017
1D-DiaCell Pool	003630 / 003631	06070.75.1	17/07/2017
ID-DiaCell AB0/1-11	003610	45002.85.1	17/07/2017
ID-DiaCell AB0/1-11-111	003618	45012.85.1	17/07/2017
1D-DiaScreen 1-11-111-IV-VP-VIP	004316	45070.54.1	17/07/2017
ID-DiaCell 1-11	003613	45151.82.1	17/07/2017
	003613VJ	N/A	N/A
ID-DiaPanel	004114	45161.11.1	17/07/2017
	004114VJ	N/A	N/A
ID-DiaCell 1-11-111	004310 / 004310VJ	45184.27.1	17/07/2017
ID-DiaScreen 1-11-111-IV	004311	45200.54.1	17/07/2017
ID-DiaCell 1-11-111 Asia	003614	45330.26.1	17/07/2017
ID-DiaScreen Prophylax	004330	45660.80.2	17/07/2017
ID-DiaPanel Plus 6	004414	45670.91.2	31/07/2017