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Cressier, 20.02.2017

## Field Safety Notice 001-17\_Follow-up letter

### Affected devices displaying the issue:

| Product Name                    | Catalog No        | Serial/ Lot No             | Expiry Date |
|---------------------------------|-------------------|----------------------------|-------------|
| ID-Dia (Diego) Positive         | 004134 / 004134VJ | All lots currently in date |             |
| 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            |                            |             |

### Other Devices from the same product range not displaying the issue but requiring your attention:

| Product Name           | Catalog No  | Serial/ Lot No             | Expiry Date |
|------------------------|---|----------------------------|-------------|
| ID-DiaCell ABO         | 003619 / 003617 / 003615 /<br>003624 / 003620 / 003621 /<br>003622 / 003623 / 003621VJ /<br>003623VJ / 003624VJ / | All lots currently in date |             |
| ID-DiaCell IP-IIP-IIIP | 005310 / 005310VJ   |                            |             |
| ID-DiaScreen VP-VIP    | 005311 / 005311VJ   |                            |             |
| ID-DiaPanel-P          | 004214 / 004214VJ   |                            |             |

Dear **Customer**,

We would like to provide additional information on the FSN 001-17 communicated on February 10<sup>th</sup>, 2017 and related to unexpected reactions that could be observed when using the above listed products.

## Description of the problem

### Applications displaying the issue:

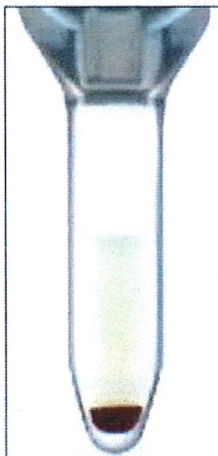
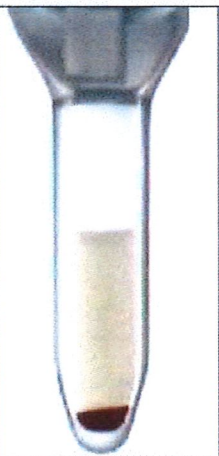
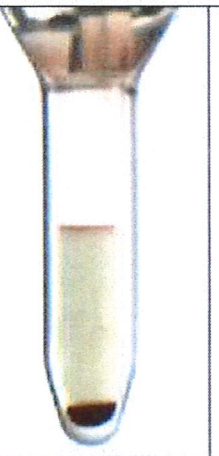
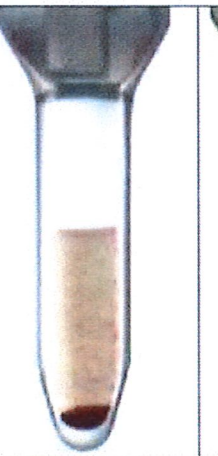
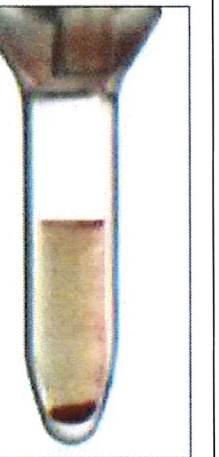
We received complaints regarding indirect antiglobulin test (IAT), especially when eluates and QC samples were tested, less frequently when patient samples were tested.

Applications that were described in the complaints received:

- **Most frequent applications**
  1. IAT for the testing of eluates subsequent to a Direct Antiglobulin Testing (DAT) positive results.
  2. Routine quality control of above listed ID-DiaCells performed in the laboratory using our internal quality controls, as well as QC samples from third parties.
- **Less frequent applications**
  3. IAT of patient samples for the screening and detection of irregular antibodies
  4. IAT for the identification of irregular antibodies performed subsequent to a positive antibody screening.

**The following are examples of the unexpected reactions (the image ① shows a normal negative for comparison)**

These images can be observed in both manual and automated methods from doubtful (images ② and ③) to false positive reaction (images ④ and ⑤).

|   |   |   |  |   |
|---|---|---|--|---|
|  |  |  |  |  |
| ①   | ②   | ③   | ④  | ⑤   |
| Negative  | Doubtful  | Doubtful  | False positive   | False positive  |

**Table 1\_Example of unexpected reactions**

The instrument may render a "?", wR, wF, (image ② and ③) or any option up to ++ (images ④ and ⑤) , depending on the intensity of the reaction.





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### **Other applications not displaying the issue so far but requiring your attention:**

Today **no cases** were reported on the following applications:

5. Antibody screening using papain treated ID-DiaCells
6. Antibody identification using papain treated ID-DiaPanel
7. ABO Reverse group using ID-DiaCell ABO

If you are facing the described unexpected results with these applications, please contact immediately our Customer Service Laboratory at [slabor\\_cressier@bio-rad.com](mailto:slabor_cressier@bio-rad.com) to report the case and provide any necessary data allowing its proper handling.

### **Impact on the patient**

A risk assessment has concluded that unexpected reactions (from doubtful to false positive as illustrated in table 1) require further confirmation testing before a final decision for transfusion is made.

The impact of the unexpected reaction is described below for each application:

| Application |   | Impact of doubtful to false positive results  |
|-------------|---|---|
| 1           | IAT for the testing of eluates  | Impossibility to identify an antibody of a DAT positive patient sample (eluate).  |
| 2           | Quality Control of above listed ID-DiaCells   | Impossibility to validate your QC tests due to unexpected positive results compared to the expected QC sample reactivity pattern. |
| 3           | IAT of patient samples for the screening of irregular antibodies                                    | Results requiring further confirmation through antibody identification.   |
| 4           | IAT for the identification of irregular antibodies  | Impossibility to identify an irregular antibody detected during screening test.   |
| 5           | Enzyme test with papainized cells of patient samples for the screening of irregular antibodies      | Results requiring further confirmation through antibody identification.   |
| 6           | Enzyme test with papainized cells of patient samples for the identification of irregular antibodies | Impossibility to identify an irregular antibody detected during screening test.   |
| 7           | ABO Reverse group   | Discrepant results between reverse grouping and ABO forward grouping which require further investigation.                         |

### **Immediate protective measure:**

Please re-test any unexpected reactions (see table 1) with a new kit.

If the results are not conclusive, we recommend using an alternative method.

We advise the Medical Director to review the previous results of the Laboratory and assess the needs to take further actions.

**Important note:** Negative results obtained with the concerned ID-DiaCell's are valid.



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Please note that the relevant European Regulatory Agencies have been advised of this FSN follow-up letter.

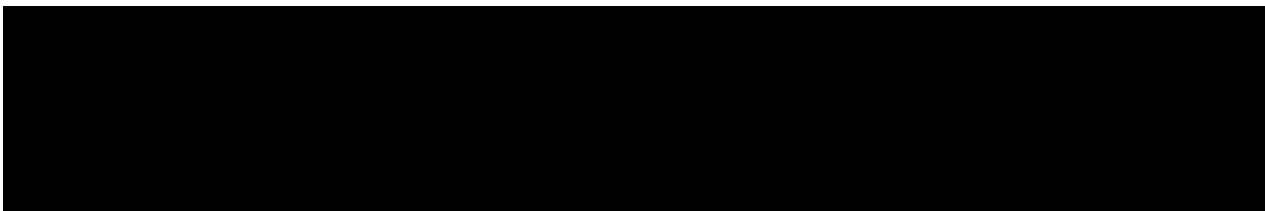
In case of any questions, in the first instance, please contact our Customer Service Laboratory:

**[slabor\\_cressier@bio-rad.com](mailto: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,



Quality Assurance Director, Clinical  
Diagnostics Group - Europe

Agnes Eude Goethals

Vice President and General Manager,  
Immunohematology Division

Ann Madden