

FIELD ACTION INFORMATION – 13.12.2017

Field Action Type: PQN
Field Action Reference Number: 2017-10, Update I
Bio-Rad Division: Immunohematology

cc Chairman Medical Board and Relevant Head of Departments

PRODUCT DETAILS:

Products listed in the previous notification

Product Name	Catalog No	Lot No IHD	Lot No SAP	Expiry Date
ID-DiaCell I-II-III	004310	Potentially all lots in use		
ID-DiaCell A1A2B/I-II-III	003618			
ID-DiaCell I-II	003613			
ID-DiaCell I-II-III Asia	003614			
ID-DiaPanel	004114			
ID-DiaPanel 6 Plus	004414			

Additional products to previous notification

Product Name	Catalog No	Lot No IHD	Lot No SAP	Expiry Date
ID-Cards LISS/Coombs	004014 / 004015 / 004016 / 004017	Potentially all lots in use		
ID-DiaScreen Prophylax	004330			
ID-DiaScreen	004313			

DESCRIPTION OF THE ISSUE:

We would like to share with you an update about the issue described in the Product Quality Notification 2017-10 sent out on 27th of September 2017.

Issue description:

Since a couple of months, an increase of weak positive results in Anti-Human Globulin (AHG) tests is observed while no antibody specificity can be determined (Antibody of Undetermined Specificity - AUS).

Current status:

The investigations to identify the root cause of this issue are still ongoing. A cross functional investigation team, including people from R&D, QC, manufacturing, product support and marketing is fully dedicated to this issue since customers reports started to increase.

For the moment we suspect that the root cause is linked to several contributing factors from which a raw material used on LISS/Coombs ID-Cards is the main one.

At this stage **we are able to exclude** the following contributing factors:

- Vials (the issue is not linked to the FSCA 001-17)
- Bg status of the cells
- Deformability of the cell.

The main factor which is currently investigated is:

- The raw material used for the Coombs ID-Cards production

And to a less extent but not fully excluded yet:

- The raw material used for the ID-Cell products production
- The manufacturing process

Based on the new findings, we have started to plan for a progressive new production of LISS/Coombs ID-Cards which is expected to decrease interference with the reagent red cells and to restore the overall performance level of the Anti-Human Globulin tests.

As the ID-Card production process is complex, it will take several weeks before the new production of ID-Cards can be released and available in stock. A second update of this PQN will be send out in January to inform you about how the transition period will be managed considering the initial quantity of ID-Cards available (which will only partially cover commercial needs), the lot numbers produced and the dates at which they will become available.

Please be informed that a marketing communication to the Bio-Rad distributors has been provided end of week 49.

The Health Risk Assessment has been reassessed following these new investigation results.

We are aware of the magnitude of this problem and realize how critical the situation is for some laboratories facing a high rate of positive results of undetermined specificity.

We apologize for the inconvenience that this situation may cause and if you have any additional questions on this matter, we kindly ask you to get in touch with pqn@bio-rad.com quoting this PQN reference.

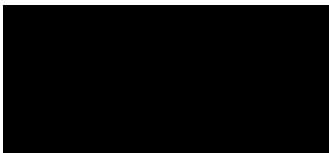
IMPLEMENTATION INSTRUCTIONS FOR RA/QA REPRESENTATIVE:

(this part is not to provide to customers)

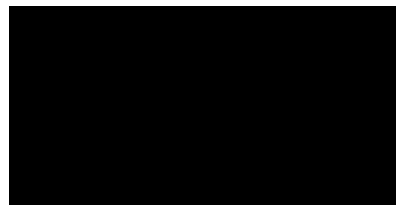
To do by the RA/QA representatives:

- Communication of this letter to the **impacted distributors**
- No need to inform actively the end-customer but could be communicated according to local needs
- Acknowledge this PQA with the templates "channel partner field action response form"
- Sent the channel partner field action response form back to pqn@bio-rad.com quoting this PQN reference until 30th of December 2017.

DATE MANUFACTURER'S FINAL REPORT EXPECTED: AS SOON AS POSSIBLE

Bio-Rad

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