

FIELD ACTION INFORMATION – 06.03.2018**Field Action Type: PQA****Field Action Reference Number: 2018-04****Bio-Rad Division: Immunohematology****PRODUCT DETAILS:**

Product Name	Mat. n°	Lot No IHD	Lot No SAP	Expiry Date
ID-DiaCell I-II-III	004310	45184 07 1	229094071	09.04.2018

DESCRIPTION OF THE ISSUE:

We have been made aware that the cell III of the product, ID-DiaCell I-II-III, lot 45184 07 shows sign of hemolysis (see picture 1).



Picture 1: ID-DiaCell I-II-III, Cell III showing hemolysis

Increased testing has shown that this haemolysis has no impact on the performance or the results obtained whether using the cells manually or on the instruments. The cell continues to react as claimed in the IFU.

It has been proved that even if the cell shows hemolysis with the lot 45184 07 1, is reacting as claimed in the IFU. The reaction strength for Fya, Fyb, S/s, M and N is not decreased. The performances of the product are not impacted.

You may continue to use the hemolysed cells as long as they give the expected results. This lot will be carefully monitored internally until the end of shelf life.

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 your local Bio-Rad contact quoting this PQN reference.

DATE MANUFACTURER'S FINAL REPORT EXPECTED: N/A**Bio-Rad**

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