

FIELD ACTION INFORMATION – 27.07.2018

Field Action Type: PQN
Field Action Reference Number: 2018-13
Bio-Rad Division: Immunohematology

PRODUCT DETAILS:**Impacted product**

Product Name	Catalog No	Lot No IHD	Lot No SAP	Expiry Date
IH-QC 5	009325	08750.54.1	279955541	13.08.2018

DESCRIPTION OF THE ISSUE:

We have been made aware that the internal control IH-QC 5 of the above-mentioned lot may react differently than expected (3 to 4 +) with a potential double population or a weaker reaction when used to control anti-D reagents. This situation could lead to an invalid internal quality control.

This lot of IH-QC 5 should not be used for controlling the reactions with anti-D, but is fit for purpose for the other applications.

We confirm that this unexpected situation does not introduce any patient risk. All valid results obtained until now with this lot are valid.

Please note that the lot 08750.53.1 is available for replacement by ordering through the usual channels, quoting this PQN reference number.

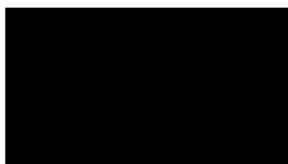
We apologize for the inconvenience that this situation may cause and if you have any additional questions on this matter, we kindly ask you to get in touch with pqn@bio-rad.com quoting this PQN reference.

IMPLEMENTATION INSTRUCTIONS FOR RA/QA REPRESENTATIVE (this part is not to provide to customers):

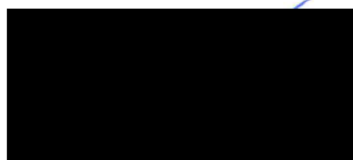
To do by the RA/QA representatives:

- The event has not been reported to European authorities
- Communication of this letter to the **end users** receiving this lot
- Acknowledge this PQA with the templates "channel partner field action response form", " regional field action closure form"
- Sent the response form back to pqn@bio-rad.com quoting this PQN reference until 10th of August 2018.

DATE MANUFACTURER'S FINAL REPORT EXPECTED: N/A

Bio-Rad

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