

**FIELD ACTION INFORMATION – 25.10.2018**

**Field Action Type: PQN**  
**Field Action Reference Number: 2018-14**  
**Bio-Rad Division: Immunohematology**

Cc Chairman Medical Board and relevant Head of Departments

**PRODUCT DETAILS:**  
**Impacted product**

Product Name	Catalog No	Lot No IHD	Lot No SAP	Expiry Date
IH-QC 3	009323	08730.70.1	311514701	19/11/2018

**DESCRIPTION OF THE ISSUE:**

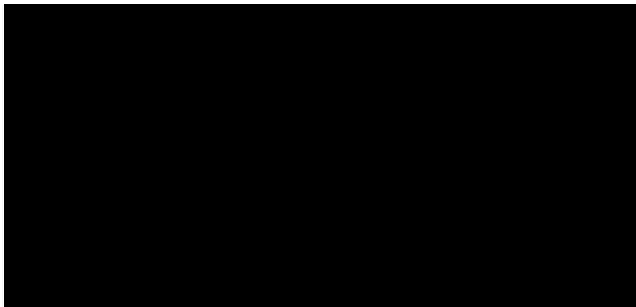
We have been made aware that the internal control IH-QC 3 of the above-mentioned lot may react differently than expected (3+ to 4 +) with a potential double population when used to control anti-B reagents. This situation could lead to an invalid internal quality control.

We confirm the problem, but this unexpected situation does not introduce any patient risk.

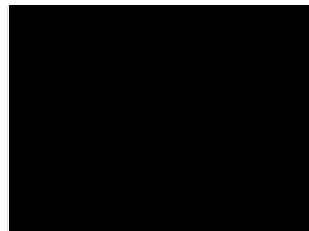
Please note that the lot 08730.71.1 is available for replacement by ordering through the usual channels, quoting this PQN reference number.

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](mailto:pqn@bio-rad.com) quoting this PQN reference.

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



Temimi Hiba  
QA Complaint Officer  
Immunohematology Division



Remco Tieleman  
Division Product Support Manager  
Immunohematology Division