

FIELD ACTION INFORMATION – 27.09.2017

Indicate Field Action Type: PQA
Field Action Reference Number: 2017-07_update
Bio-Rad Division: Immunohematology

PRODUCT DETAILS:

Status on 06th September 2017

Product Name	Mat. n°	Lot No IHD	Lot No SAP	Expiry Date
DiaMed Q.C. System	009948	45950 46 1	166035461	25.09.2017
		45950 47 1	172383471	09.10.2017

Current status

Product Name	Mat. n°	Lot No IHD	Lot No SAP	Expiry Date
DiaMed Q.C. System	009948	45950 46 1	166035461	25.09.2017
		45950 47 1	172383471	09.10.2017
		45950 48 1	174297481	23.10.2017
		45950 49 1	180341491	06.11.2017
		45950 50 1	180343501	06.11.2017

DESCRIPTION OF THE ISSUE:

We would like to inform you about the replacement related to the issue we had with the product DiaMed Q.C. System, IHD lot n° 45950 46 1, 45950 47 1 and 45950 48 1 showing hemolysis in samples 1 and 4 and weakly in sample 2 according to PQN 2017-07, sent out on 06th of September.

IHD lot n° 45950 49 1, SAP lot n° 180341491 (expiry date 06.11.2017) and IHD lot n° 45950 50 1, SAP lot n° 180343501 are currently going to be shipped this week (week 39). These products are still showing a slight hemolysis but they are nevertheless usable. You may continue to use the hemolysed cells as long as they give the expected results. We are continuing to work to determine the root cause and will update them as soon as possible.

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 :

Collect the forms:

- channel partner field action response
- customer field action response
- regional field action closure
- certificate of destruction

Please send back the completed forms to pqn@bio-rad.com.

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

Emilie Machold
QA Customer Complaint officer
Immunohematology Division



Florian Lambercier
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