

FIELD ACTION INFORMATION – 31.08.2017

Indicate Field Action Type: PQA
Field Action Reference Number: 2017-06
Bio-Rad Division: Immunohematology

PRODUCT DETAILS:

Product Name	Mat. n°	Lot No IHD	Lot No SAP	Expiry Date
ID-DiaCell I- II-III Asia	003614	45330 29 1	167516291	09.10.2017
		45330 29 2	168117292	23.10.2017

DESCRIPTION OF THE ISSUE:

We have been made aware that unexpected positive reactions may occur with the cell III of the product ID-DiaCell I-II-III Asia, IHD lot n° 45330 29 1 and 45330 29 2 (delivery under way). We kindly ask you to scrap any remaining goods of the IHD lots 45330 29 1 and 45330 29 2. We are sending the lots 45330 30 1 respectively 45330 30 2 as a replacement in week 36.

A risk assessment has been performed and no patient risk has been identified.

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 let know us **no later than the end of week 37** the quantity of products (certificate of destruction) that has been destroyed at the end-users' so that we can arrange an additional production to cover this gap and sent it back to pqn@bio-rad.com.

DATE MANUFACTURER'S FINAL REPORT EXPECTED: 31.08.2017

Bio-Rad


31/08/2017
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QA Customer Complaint officer
Immunohematology Division


31.08.2017
Florian Lambercier
Division Product Support Manager
Immunohematology Division