

FIELD ACTION INFORMATION – 27.09.2017

Indicate Field Action Type: PQA
Field Action Reference Number: 2017-10
Bio-Rad Division: Immunohematology

PRODUCT DETAILS:

Product Name	Cat. ref. n°	Lot No IHD	Lot No SAP	Expiry Date
ID-DiaCell I-II-III	004310	All lots currently in date		
ID-DiaCell A1A2B/I-II-III	003618			
ID-DiaCell I-II	003613			
ID-DiaCell I-II-III Asia	003614			
ID-DiaPanel	004114			
ID-DiaPanel 6 Plus	004414			

DESCRIPTION OF THE ISSUE:

We have been made aware that the above-mentioned products of cells may show antibody of (antibody undetermined specificity) undetermined specificity (AUS) in IAT method which are not confirmed by further testing's.

The company is fully aware of the magnitude of this problem and the level of distress that this is causing in the field. A risk assessment has been performed and no patient risk has been identified. A team of experts is currently working on this issue as an absolute priority. We will let you know about any updates of this issue.

We kindly ask you to keep your samples showing this phenomenon and to contact your local Bio-Rad contact (CTS).


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 :

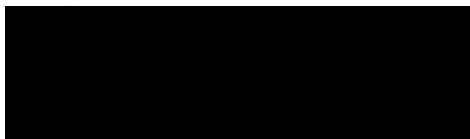
Collect the forms:

- channel partner field action response
- customer field action response
- regional field action closure

DATE MANUFACTURER'S FINAL REPORT EXPECTED: N/A

Bio-Rad

Emilie Machold
QA Customer Complaint officer
Immunohematology Division



Florian Lambercier
Division Product Support Manager
Immunohematology Division



CUSTOMER FIELD ACTION RESPONSE FORM

cc Chairman Medical Board and Relevant Head of Departments

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Bio-Rad Division: IHD Immunohematology Division

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CUSTOMER INFORMATION

Account Name:	
Undersigning Manager Name:	
Address :	
Telephone Number / Fax :	
Customer Account Number :	

STATEMENT:

- I am aware of information about the field action concerning the above reference product(s) and have proceeded according to the instructions issued by Bio-Rad.

Number of affected kits/systems: N/A

Date:

Customer Stamp and Signature

PLEASE RETURN THIS FORM TO: [ENTER LOCAL DETAILS]