

01.12.2016

**Product Quality Notification 2016-07**

**PRODUCT DETAILS:**

Product Name	Catalog No	Serial/ Lot No	Expiry Date	Cell
ID-DiaPanel	004114v	45161.95.x	19.12.2016	Cell 3, donor 980602
ID-DiaPanel P	004214v	45171.95.x		

Dear valued customers,

Following some customers' feedbacks, we have been able to observe and confirm inconsistent reactions with some anti-E on the above mentioned cell, without however any evidence that the E-antigen on this cell is a partial-E.

We would advise you that, in the case that you have a positive reaction with the cell II of the screening cells, but a negative result with cell 3 of the panel, the possibility of an anti-E should not be excluded.

This information will be placed in the 'Screen and panel antigen notice' list in the Marketing area II of the Secret area.

In addition, this cell will be blocked for further use

Please ensure that the end users are informed of this PQN

We apologize for the inconvenience that this situation may cause and we remain at your disposal should you need any additional information

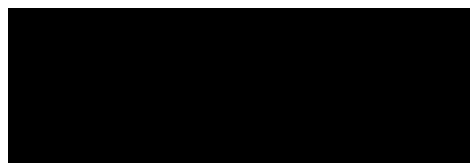
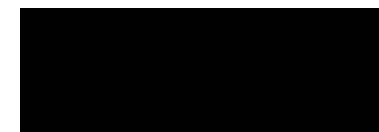
With best regards,

**Bio-Rad**

Emilie Machold  
QA Customer Complaint officer  
Immunohematology Division

Florian Lambercier  
Division Product Support Manager  
Immunohematology Division

02/12/2016





## SMI PQA RESPONSE FORM

**PQA Reference Number:** 2016-07

**Manufacturing Division:** IHD

### PRODUCT DETAILS

Product Name	Catalog No	Serial/ Lot No	Expiry Date	Cell
ID-DiaPanel	004114v	45161.95.x	19.12.2016	Cell 3, donor 980602
ID-DiaPanel P	004214v	45171.95.x	19.12.2016	

### CUSTOMER INFORMATION

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

### STATEMENT:

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

☐ All customers have been informed about this product quality action and have proceeded according to the instructions issued by Bio-Rad.

Number of customers informed: \_\_\_\_\_

Number of affected kits/ systems: \_\_\_\_\_

Date:

SMI Stamp and Signature:

**PLEASE RETURN THIS FORM TO: (ENTER LOCAL DETAILS)**