

FIELD ACTION INFORMATION – 30.06.2017

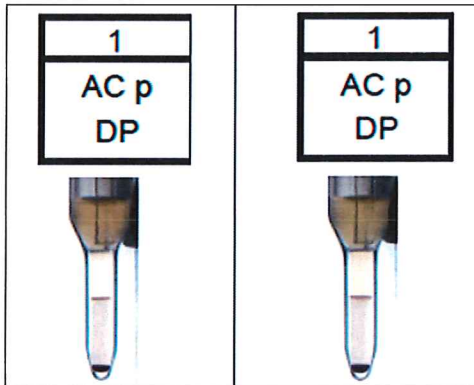
Indicate Field Action Type: PQA
Field Action Reference Number: 2017-05
Bio-Rad Division: Immunohematology

PRODUCT DETAILS:

Product Name	Issue short description	Mat. n°	Lot No IHD	Lot No SAP	Expiry Date
ID-Papain	Double population reaction	005510	Currently in date and until further notice		
	Loss of enzyme activity	005510	06311 96 1	121302961	03.07.2017
			06311 97 1	124782971	17.07.2017
			06311 99 1	141517991	31.07.2017
			06311 02 1	145832021	14.08.2017

DESCRIPTION OF THE ISSUE:

It has come to our notice that for product ID-Papain, Mat. n° 005510, shows double population reactions when the auto-control is performed in papain one stage technique (see picture 1). There is no patient risk associated with this issue; in case of a double population results in an auto control, further investigations must be carried out before concluding.



Picture 1: example for double population reactions observed within the scope of this PQN.

One of the described functions/ effects of papain is to denature/ weaken certain antigens (especially Fya, Fyb, S, s, M, N, Xga). It has been observed internally that in the last two weeks before expiry, the lots of papain mentioned above may not destroy these antigens as expected. There is no patient risk associated with this issue. The use of ID-Papain for compatibility testing and for the detection of antigens normally detected in the ID-Papain test is not impacted by this phenomenon and the papain can be used for this purpose.

If you have any additional questions on this matter, we kindly ask you to get in touch with our Complaint Handling department (email address: pqn@bio-rad.com) quoting this PQN reference.

IMPLEMENTATION INSTRUCTIONS :

We kindly ask you to carry out the following actions when you are working with ID-Papain:

- a) If the test gives unexpected positives and/ or double population reactions in the one-step technique, use preferentially the two stage method
- b) Use the most recent lot available in your stock.
- c) Use an alternative method (replace the ID-papain by one stage ID-Diluent 1)

End-users using the ID-papain on IHD automates (IH-1000, IH-500) should contact their Field Service Engineer / Application specialist for further information on available automated methods (APF's).

Lots following and including 06311 04 1 are not impacted by the loss of enzyme activity.

DATE MANUFACTURER'S FINAL REPORT EXPECTED: As soon as root cause has been identified

Bio-Rad

E Machold
30/06/2017

Emilie Machold
QA Customer Complaint officer
Immunohematology Division

F Lambercier
30.06.2017

Florian Lambercier
Division Product Support Manager
Immunohematology Division



CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Type: PQA
Field Action Reference Number: PQA 2017-05
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: _____

Date:

Customer Stamp and Signature

PLEASE RETURN THIS FORM TO YOUR LOCAL BIO-RAD CONTACT