

Marnes La Coquette, 2019 July 4th

Ref. letter Field Action PQA 13-19 IDD

Product Quality Notice

This information is intended for the end user of this product
If you are not the end user, please forward this information to
the appropriate laboratory personnel

Subject: Platelia Toxo IgA TMB Ref. 72737 - lot 8G2036 - Expiry date 2019/11/27

Dear Valued Customer,

Following reported cases for run failures due to a low positive control R4b signal, (OD <0.5) when the antigen solution R6a is used after freezing/thawing step, we performed some investigations and we confirmed this issue with the following product and lot:

Ref. **72737** Platelia Toxo IgA TMB 96 tests - **lot 8G2036** - Expiry date 2019/11/27

As a consequence, we ask you to:

- Use only freshly reconstituted R6a solution (1 vial allow to run 3 strips; 4 vials within a kit).
- In case you run less than 3 strips, do not freeze unused volume of R6a reconstituted solution but discard it.
- Contact your local customer support to find an alternative solution, in case you use frozen R6a in your routine.

The investigations to determine the root cause showed that the diluent R7 of the product mentioned above, influences significantly the activity of the reconstituted and frozen antigen solution. To avoid any new event, a new functional control has been implemented in manufacturing to control activity of the reconstituted and frozen antigen solution for each new lot.

We apologize for the inconvenience, and remain at your disposal for any further information.

Please forward to whomever it may concern.

Sincerely,

Hélène ESVAN | Int. Product Support Manager

Infectious Disease Division



**Bio-Rad
Laboratories**

3, boulevard Raymond Poincaré
92430 Marnes-la-Coquette, France
Téléphone : +33 (0) 1 47 95 60 00
Télécopie : +33 (0) 1 47 41 91 33

CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Reference Number: 13-19

Bio-Rad Division: IDD

PRODUCT

Product UDI	Product Name	Catalog No	Serial/ Lot No	Expiry Date
	Platelia Toxo IgA TMB 96 tests	72737		2019/11/27

CUSTOMER INFORMATION

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

STATEMENT:

- ☐ I am aware of the 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 products received:		Number of tests discarded due to impossible freezing process of reconstituted R6	
If number of products discarded is different to the number received, please account for the difference:			

Date:

Customer Signature (and Stamp if applicable)