



**Bio-Rad
Laboratories**

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

RPR 100 code : 72505
RPR 500 code : 72506

Marnes-la-Coquette, Octobre 24th 2016

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 : URGENT Field Safety Notice – Product RPR 100 (code 72505) and RPR 500 (code 72506)

Dear Valued Customer,

Please read carefully the urgent **Field Safety Notice** published by the manufacturer Trinity Biotech, regarding the products RPR 100 (code 72505) and RPR 500 (code 72506) which were distributed by Bio-Rad . Our records indicate that you have purchased the above product and we would like to share the following important information with you.

Investigations conducted by Trinity Biotech have shown that the impacted kits may fail to detect weak positive samples.

By consequence of this notification, Trinity Biotech asks users to stop using lots detailed in table 1 and to destroy them.

We remind you that these products have been replaced in our catalog by the RPR 100 (code 72515) and RPR 500 (code 72516) manufactured by Bio-Rad . These two products are not affected by this Safety Notice. Similarly the RPR cards (code 72508) are still available at Bio-Rad catalog.

Please fill and return the annex after inventory of your stocks, in order to make us able to replace the concerned products manufactured by Trinity Biotech with products manufactured by Bio-Rad.

We would like to inform you that the Authorities are aware about this notification.

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

Please forward it to whomever it may concern.

Sincerely,

Claude GIROUD
Regulatory Affairs Department



**Bio-Rad
Laboratories**

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

URGENT FIELD SAFETY NOTICE

Annexe 1

Form to fill and return to your customer service (phone number)

PRODUCT / INVOLVED LOTS (listed in the table 1)

Product name	Product reference	Batch Number	Expiration Date
Bio-Rad RPR 100	72505	D040002L	15 December 2016
		D054002L	15 December 2016
		D112042L	16 February 2017
		D113007L	22 January 2017
		D155004L	14 May 2017
Bio-Rad RPR 500	72506	D040003L	30 October 2016
		D040007L	09 December 2016
		D054001L	15 December 2016
		D113008L	09 December 2016
		D112043L	16 February 2017
		D112044L	16 February 2017
		D155005L	14 May 2017

LABORATORY / BLOOD BANK	
Undersigning Manager :	
Address :	
Phone / Fax number:	
Customer Account number :	



Following the Field Safety Notice, you are instructed to discontinue use batches of the Table 1 immediately and complete the following :

Lot Number impacted: _____ Number of kits: _____
Lot Number impacted: _____ Number of kits: _____
Lot Number impacted : _____ Number of kits: _____
Lot Number impacted : _____ Number of kits: _____
Lot Number impacted : _____ Number of kits: _____
Lot Number impacted : _____ Number of kits: _____
Lot Number impacted : _____ Number of kits: _____
Lot Number impacted : _____ Number of kits: _____
Lot Number impacted : _____ Number of kits: _____
Lot Number impacted : _____ Number of kits: _____
Lot Number impacted : _____ Number of kits: _____
Lot Number impacted : _____ Number of kits: _____

Total Number of disposed kits : _____

Disposed by : _____ Date: _____

☐ I have read information regarding the lots of products RPR 100 ref. : 72505 and RPR 500 ref. : 72506 in table 1.

☐ I need a total of _____ replacement kits .

For distributors :

☐ I have notified my customers of this urgent Filed Safety Notice : ☐ YES ☐ No

Numbers of customers notified _____

Date :

Signed and laboratory stamp :

For any other further information or support, please contact your local customer service.