

<b>CERTIFICATE OF ANALYSIS</b>	<b>RPR-CARBON</b>
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REF

2510010	100 tests	<b>X</b>	2510081 (1L)	<b>X</b>	2925181 (100mL)	
2510025	500 tests	<b>X</b>	2510082 (0,25L)	<b>X</b>	2925182 (50mL)	
			2510085 (5L)	<b>X</b>	2925185 ( 1L )	

<b>Cont</b>	<b>R</b>	<b>X</b>
	<b>Control (+)</b>	<b>X</b>
	<b>Control (-)</b>	<b>X</b>

**LOT** 25346  
2-8°C

2020-06  
**IVD**

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

REAGENT	TEST	SPECIFICATIONS	RESULTS
RPR-CARBON (R)	APPEARANCE	Homogeneous suspension free of macroscopic or flaky particles.	ACCEPTED
	COLOUR	Dark grey	
	pH	7.2 +/- 0.3	
CONTROL (+)	APPEARANCE	Liquid solution. Clear and transparent.	ACCEPTED
CONTROL (-)	APPEARANCE	Liquid solution. Clear and transparent.	ACCEPTED

(ACCEPTED / N/A)

**FUNCTIONALITY**

REAGENT	TEST	SPECIFICATIONS	RESULTS
RPR-CARBON (R)	Sensitivity, compared to the Reference RPR-carbon from the Centre for Diseases Control (CDC).	The same sensitivity	ACCEPTED
	Positive Control	R	
	Negative Control	Negative	
CONTROL (+)	Tested with RPR-Carbon	R	ACCEPTED
CONTROL (-)	Tested with RPR-Carbon	Negative	ACCEPTED

**STABILITY TEST** (14 days at 37°C)

REAGENT	TOLERANCE	RESULT
RPR-CARBON	After a stability study, the specifications remain unchanged	ACCEPTED
CONTROL (+)		ACCEPTED
CONTROL (-)		ACCEPTED

(ACCEPTED / N/A)

Components from human origin have been tested and found negative for the presence of antibody to HIV (1/2) as well as HBsAg and HCV. However, handle cautiously as potentially infectious.

This lot was assayed by test methods described in the manufacturer's package insert.

These results are applicable to this lot and subsequent sublots, for which a capital letter has been assigned after the lot number.

This Certificate of Analysis is a computer printout and has therefore not been signed by hand.

<b>This lot meets our specifications and is released for sale</b>	APPROVED	<b>Signed</b> <b>Date of Manufacture:</b> Pilar Montolio 2017-12-15 Quality Control Dept..
	(APPROVED / NOT APPROVED)	

