

<b>CERTIFICATE OF ANALYSIS</b>	<b>RF-LATEX</b>
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**REF**

2355005	50 tests	X	2355015	50 tests (w/o control)	X	2355081 (1 L)	X	2923581 (100 mL)	
2355010	100 tests	X	2355020	100 tests (w/o control)	X	2355082 (0.25 L)	X	2923582 (50 mL)	
2355030	150 tests	X	2355027	150 tests (w/o control)	X	2355085 (5 L)	X	2923585 (1 L)	

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

**LOT** 23273A  
2-8°C

2019-10  
**IVD**

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

REAGENT	TEST	SPECIFICATIONS	RESULTS
RF-LATEX (R)	APPEARANCE	Homogeneous suspension free of macroscopic or flaky particles.	ACCEPTED
	COLOUR	White	
	pH	8.2 +/- 0.2	
CONTROL (+)	APPEARANCE	Liquid solution. Clear and transparent.	ACCEPTED
CONTROL (-)	APPEARANCE	Liquid solution. Clear and transparent.	ACCEPTED

(ACCEPTED / N/A)

**FUNCTIONALITY**

REAGENT	TEST	SPECIFICATIONS	RESULTS
RF-LATEX (R)	Sensitivity, against Reference Material Rheumatoid Arthritis Serum, 64/2 WHO, (NIBSC)	16-6 IU/mL	ACCEPTED
	Positive Control	3+	
	Negative Control	Negative	
CONTROL (+)	Tested with RF-Latex	3+	ACCEPTED
CONTROL (-)	Tested with RF-Latex	Negative	ACCEPTED

(ACCEPTED / N/A)

**STABILITY TEST** (14 days at 37°C)

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

(ACCEPTED / N/A)

This lot was tested by test methods described in the manufacturer's package insert.  
 These results are applicable to this lot and sequential sublots, for which a capital letter have been assigned after the lot N<sup>o</sup>.  
 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>	<b>APPROVED</b>	<b>Signed</b> <b>Date of Manufacture</b> Yolanda Vidal 2017-08-22 Quality Control Dept
	(APPROVED / NOT APPROVED)	

