

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

2375005	50 tests	X	2375020	100 tests (w/o control)	X	2375081 (1 L)	X	2923781 (100 mL)	
2375010	100 tests	X	2375027	150 tests (w/o control)	X	2375082 (0.25 L)	X	2923782 (50 mL)	
2375030	150 tests	X				2375085 (5 L)	X	2923785 (1 L)	

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

<b>LOT</b>	23272A
	2-8°C

	2019-10
<b>IVD</b>	

**PHYSICAL AND CHEMICAL CHARACTERISTICS**

REAGENT	TEST	SPECIFICATIONS	RESULTS
RF-WAALER (R)	APPEARANCE	Homogeneous suspension free of macroscopic or flaky particles.	ACCEPTED
	COLOUR	Red	
	pH	7.0 +/- 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-WAALER (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- Waaler	3+	ACCEPTED
CONTROL (-)	Tested with RF-Waaler	Negative	ACCEPTED

(ACCEPTED / N/A)

**STABILITY TEST** (14 days at 37°C)

REAGENT	TOLERANCE	RESULT
RF-WAALER	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 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 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 2017-08-04 Quality Control Dept
	(APPROVED / NOT APPROVED)	

