

CERTIFICATE OF ANALYSIS	RF-TURBIDIMETRIC
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REF	3130025	1 x 50 mL	X	3130080 (R1)	X	3931305	CT31300 1x50 mL	KR31300 1x40 mL	X
	3130030	2 x 50 mL	X	3130081 (R2)	X	3931320	CT31312 3x50 mL	KR31302 5x40 mL	X
	3130035	2 x 200 mL	X	3130085 (R1)	X		CT31315 12x50 mL		
				3130082 (R2)	X				

Cont	Diluent (R1)	X	LOT	31120		2019-09	IVD		2-8°C	
	Latex (R2)	X		LOT		31121				2019-09
	Calibrator	X		LOT						

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
DILUENT (R1)	APPEARANCE	Liquid. Clear and transparent.	ACCEPTED
	pH	8.4 ± 0.1	ACCEPTED
LATEX (R2)	APPEARANCE	Liquid. Homogeneous suspension free of macroscopic or flaky particles.	ACCEPTED
	pH	8.2 ± 0.2	ACCEPTED
CALIBRATOR	APPEARANCE	Liquid. Yellowish, clear and transparent.	ACCEPTED

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
LATEX (R2) DILUENT (R1)	ANALYTICAL SENSITIVITY, Rheumatoid Arthritis Serum 1 st British Standard NIBS Code: 64/002	$\Delta A_{650\text{ nm}} = 3.0 \text{ mA}\cdot\text{mL}/\text{IU}$ <small>This value depends on the instrument used</small>	ACCEPTED
	MEASUREMENT RANGE	20 – 160 IU/mL <small>This value depends on the instrument used</small>	ACCEPTED
	PROZONE	$\Delta A_{650\text{ nm}}, 800 \text{ IU/mL} > \Delta A_{650\text{ nm}}, 160 \text{ IU/mL}$	ACCEPTED
	ACCURACY, against 6-8 human sera and 2 RF Control Sera	Agreement between obtained value (OV) and its expected value (EV). Rate OV/TV: 0.9 – 1.1 Control Serums: Within values interval	ACCEPTED
CALIBRATOR	TOLERANCE VALUE	150-180 IU/mL	ACCEPTED

(ACCEPTED / N/A)

STABILITY TEST

REAGENT	Days at 37°C	TOLERANCE	RESULT
DILUENT (R1)	7	After a stability study, the specifications remain unchanged	ACCEPTED
LATEX (R2)			ACCEPTED
CALIBRATOR	10		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.

This lot meets our specifications and is released for sale	APPROVED	Signed Date of Manufacture Marta Vilaró 2018-02-22 Quality Control Department
	(APPROVED / NOT APPROVED)	

