

CERTIFICATE OF ANALYSIS	CRP-TURBIDIMETRIC
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REF	3120025	1 x 50 mL	X	3120080 (R1)	X	3931205	CT31200 1x50 mL	KR31200 1x40 mL	X
	3120030	2 x 50 mL	X	3120081 (R2)	X	3931220	CT31212 3x50 mL	KR31202 5x40 mL	X
	3120035	2 x 200 mL	X	3120085 (R1)	X		CT31215 12x50 mL		
				3120082 (R2)	X				

Cont	Diluent (R1)	X	LOT	31095		2019-07	IVD 	2-8°C
	Latex (R2)	X	LOT	31096		2019-07		
	Calibrator	X	LOT					

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
DILUENT (R1)	APPEARANCE	Liquid. Clear and transparent.	ACCEPTED
	pH	8.2 +/- 0.1	ACCEPTED
LATEX (R2)	APPEARANCE	Liquid. Homogeneous suspension free of macroscopic or flaky particles.	ACCEPTED
	pH	7.8 – 8.3	ACCEPTED
CALIBRATOR	APPEARANCE	Liquid. Yellowish, clear and transparent.	ACCEPTED

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
LATEX (R2) DILUENT (R1)	SENSITIVITY, against Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM)	Blank (540 nm): < 0.900 Δ A 540 nm, 75 mg/L: 0.200 – 0.300 Δ A 540 nm, 150 mg/L: 0.400 – 0.600	ACCEPTED
	LINEARITY RATE (150/75)	2.0 (1.8 – 2.2)	ACCEPTED
	PROZONE	Δ A 540 nm, 250 mg/L: > Δ A. 150 mg/L	ACCEPTED
	ACCURACY, against 6-8 human sera and 2 CRP Control Sera	Agreement between obtained value (OV) and its expected value (EV). Rate OV/EV: 0.9 – 1.1 Control Serums: Within values interval	ACCEPTED
CALIBRATOR	TOLERANCE VALUE	45-60 mg/L	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: Yolanda Vidal 2018-01-04 Quality Control Department
	(APPROVED / NOT APPROVED)	

