

CERTIFICATE OF ANALYSIS	CRP-Turbidimetric Calibrador
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3120025	1 x 50 mL	3120080 (R1)	CT31200 1x50 mL	KR31200 1x40 mL	3931205 1x1 mL	X
3120030	2 x 50 mL	3120081 (R2)	CT31212 3x50 mL	KR31202 5x40 mL	3931220 1 mL	X
3120035	2 x 200 mL	3120085 (R1)	CT31215 12x50 mL		3931220 30x1 mL	x
		3120082 (R2)	CT39201 1x1 mL	X	3931280 1x100 mL	x

Cont	Diluent (R1)	
	Latex (R2)	
	Calibrator	X

LOT 39549
 2-8°C

2020-02
IVD

PHYSICAL AND CHEMICAL CHARACYTERISTICS

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

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
LATEX (R2) DILUENT (R1)	ANALYTICAL SENSITIVITY, Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM)	$\Delta A_{540\text{ nm}} = 2.9 \text{ mA}\cdot\text{L}/\text{mg}$ This value depends on the instrument used	N/A
	LINEARITY RATE	Up to 150 mg/L This value depends on the instrument used	N/A
	PROZONE	$\Delta A_{540\text{ nm}}, 250 \text{ mg/L} > \Delta A_{540\text{ nm}}, 150 \text{ mg/L}$	N/A
	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	N/A
CALIBRATOR	TOLERANCE VALUE	45-60 mg/L	56 mg/L

(ACCEPTED / N/A)

STABILITY TEST

REAGENT	Days at 37°C	TOLERANCE	RESULT
DILUENT (R1)	7	After a stability study, the specifications remain unchanged	N/A
LATEX (R2)			
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 2018-02-19 Quality Control Department
	(APPROVED / NOT APPROVED)	

