LINEAR cromatest clonatest

31500 COA 25.05.14 REV02

CERTIFICATE OF ANALYSIS	MICROALBUMIN-TURBIDIMETRIC CALIBRATOR MICROALBUMIN CALIBRATOR SET

REF

	3950005	1x1 ml	x	CT39501	1x1 ml	x
	3950020	1 ml	x			

Cont			LOT				IVD	
	Diluent (R1)	X	LOT					
	Latex (R2)	X	LOT					
	Calibrator	X	LOT	39500		2019-12		2-8ºC

PHYSICAL AND CHEMICAL CHARACYTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
DILUENT (R1)	APPEARANCE	Liquid. Clear and transparent.	N/A
	pH	9.8 – 10.2	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)	$\Delta A_{650\ nm}$ = 5.64 mA·L/mg This value depends on the instrument used	N/A
	LINEARITY RATE	Up to 160 mg/L This value depends on the instrument used	N/A
	PROZONE	$\Delta A_{540\ nm}$, 1000 mg/L: > $\Delta A_{540\ nm}$, 160 mg/L	N/A
	ACCURACY, against 6-8 human urine and 2 Albumin Control	Agreement between obtained value (OV) and its expected value (EV). Rate OV/EV: 0.9 – 1.1 Control Urine: Within values interval	N/A
CALIBRATOR	ASSIGNED VALUE	68 mg/L	ACCEPTED

(ACCEPTED / N/A)

STABILITY TEST

REAGENT	Days at 37ºC	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** Montse Pérez 2017-12-04 Quality Control

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