

CERTIFICATE OF ANALYSIS	MICROALBUMIN-TURBIDIMETRIC
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REF	3150005	1 x 50 mL	x	3150080 (R1)	X	3950005	CT32000 1x50 mL	KR32000 1x40 mL	
				3150081 (R2)	X	3950020	CT32002 3x50 mL	KR32002 5x40 mL	
				3150082 (R1)	X				
				3150085 (R2)	X				

Cont	Diluent (R1)	X	LOT	31129		2019-10	IVD	2-8°C
	Latex (R2)	X		31130		2019-10		
	Calibrator	X						

PHYSICAL AND CHEMICAL CHARACTYTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
DILUENT (R1)	APPEARANCE	Liquid. Clear and transparent.	ACCEPTED
	pH	9.8 – 10.2	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)	ANALYTICAL SENSITIVITY, Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM)	$\Delta A_{650\text{ nm}} = 5.64 \text{ mA}\cdot\text{L}/\text{mg}$ This value depends on the instrument used	ACCEPTED
	LINEARITY RATE	Up to 160 mg/L This value depends on the instrument used	ACCEPTED
	PROZONE	$\Delta A_{540\text{ nm}}, 1000 \text{ mg/L} > \Delta A_{540\text{ nm}}, 160 \text{ mg/L}$	ACCEPTED
	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	ACCEPTED
CALIBRATOR	ASSIGNED VALUE	60 – 70 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)			N/A
CALIBRATOR	10		

(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 2018-04-13 Quality Control
	(APPROVED / NOT APPROVED)	

