



CERTIFICATE OF ANALYSIS

TOTAL PROTEIN STANDARD 7 g/dL

REF	1153005	2 x 50 mL	1153085	1 x 5 L	CT10352	6 x 40 mL	1953005	1 x 3 mL	X
	1153010	4 x 100 mL	1153088	1 x 20 L	CT10355	10 x 60 mL	1953080	1 x 0.5 L	X
	1153020	4 x 250 mL			KR10352	8 x 30 mL	1953081	1 x 1 L	x
			CT10350	2 x 40 mL	KR10355	18 x 30 mL	1953006	3 ml/60 un.	x
	1153050	50 ml/80 un.	1153055	100 ml/40 un.	1153060	250 ml/28 un.			

Cont	R1		LOT		IVD
	Standard	X	LOT	19817	2020-01
					
					2-8°C

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST		SPECIFICATIONS	RESULT
Appearance	R1	Blue. Liquid. Clear. Free of particles.	N/A
	CAL	Liquid. Clear. Free of particles.	ACCEPTED X

(ACCEPTED / N/A)

FUNCTIONALITY

1. Analytical parameters

Blank. Absorbance of the Working reagent against water.

Sensitivity. $A_{540} / 7 \text{ g/dL Total protein}_{\text{standard}}$.

Linearity. Higher level established by the analytical performance.

Accuracy. Ratio between assigned and obtained Total protein values.

2. Stability Testing

Fresh Reagents (FR). Items kept at 2-8°C.

Stressed Reagents (SR). Items kept at 37/42°C for a stated period of time.

INSTRUMENT	SHIMAZDU	540 nm against reagent blank
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	$A_{540} < 0.150$	N/A	N/A
Sensitivity	0.300-0.450	ACCEPTED	ACCEPTED
Linearity	Up to 12 g/dL	N/A	N/A
Accuracy	Within the expected values	ACCEPTED	ACCEPTED

(ACCEPTED / N/A)

This lot was assayed by the test method described in the manufacturer's package insert.

These results are applicable to this lot and subsequent sublots, for which a capital letter has 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 Mayte Lázaro 2017-01-17 Quality Control Dept.
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