

CERTIFICATE OF ANALYSIS	Mg 2 mg/dL-Ca 10 mg/dL MAGNESIUM / CALCIUM STANDARD
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REF	1944005	1 x 3 mL	X	1944081	1 x 1 L	X
	1944080	1 x 0.5 L	X	1944006	3 ml/ 60 un.	x

Cont	R1		LOT			IVD	
	Standard	X	LOT	19856		2020-09	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
pH	R1	7.70 ± 0.2	N/A	

(ACCEPTED / N/A)

FUNCTIONALITY

- 1. Analytical parameters**
Blank. Absorbance of the Working reagent against water.
Sensitivity. A₅₂₀ / 2 mg/dL Magnesium_{standard}.
Sensitivity. A₅₇₀ (CaOCC) + A₆₅₀ (CaAlII) / 10 mg/dL Calcium standard.
Linearity. Higher level established by the analytical performance.
Accuracy. Ratio between assigned and obtained Magnesium 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	520 nm against reagent blank
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TEST	SPECIFICATIONS		RESULTS			
			FR		SR	
Blank	0.350-0.550		N/A		N/A	
Sensitivity	0.110-0.160	A ₅₇₀ : 0.300 – 0.500 A ₆₅₀ : 0.300 – 0.550	ACCEPTED		ACCEPTED	
Linearity	Up to 10 mg/dL	Up to 22 mg/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 2017-09-01 Quality Control Dept.
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