

CERTIFICATE OF ANALYSIS	Cl 100 mEq/L - P 5mg/L CHLORIDE / PHOSPHORUS STANDARD
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REF	1916005	1 x 3 mL	X	1916006	3 ml/ 60 un	x	1916081	1 x 1 L	X
	1916081	1 x 1 mL	X	1916080	1 x 0.5 L	X	1916006	3 ml/60 un.	x

Cont	R1		LOT		IVD	
	Standard	X	LOT	19795	2019-07	2-30°C

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST		SPECIFICATIONS		RESULT
Appearance	R1	Liquid. Clear. Free of particles.		N/A
	CAL	Liquid. Clear. Free of particles.		ACCEPTED X
pH	R1	1.1 ± 0.1		N/A

(ACCEPTED / N/A)

FUNCTIONALITY

- 1. Analytical parameters**
Blank. Absorbance of the Working reagent against water.
Sensitivity. A₄₇₀ / 100 mEq/L Chloride_{standard}.
Sensitivity. A₃₄₀ (UV) - A₇₄₀ (colorimetric) / 5 mg/dL Phosphorus_{standard}.
Linearity. Higher level established by the analytical performance.
Accuracy. Ratio between assigned and obtained Chloride 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 / KROMA	
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TEST	SPECIFICATIONS		RESULTS			
			FR		SR	
Blank	A ₄₇₀ < 0,050	-	N/A		N/A	
Sensitivity	0.450-0.650	A ₃₄₀ : 0.200-0.325 A ₇₄₀ : 0.240-0.370	ACCEPTED		ACCEPTED	
Linearity	70-120 mEq/L	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 2016-07-15 Quality Control Dept.
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QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485



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