

CERTIFICATE OF ANALYSIS	UREA STANDARD 50 mg/dL
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REF	1158005	2 x 50 mL	1158085 (R1)	1 x 4 L	CT10382	3 x 50 mL	1958005	1 x 3 mL	X
	1158010	3 x 100 mL	1158086 (R2)	1 x 1 L	CT10385	12 x 50 mL	1958080	1 x 500 mL	x
			1158087 (R3)	1 x 20 L	KR10382	5 x 40 mL	1958081	1 x 1 L	x
			1158088 (R4)	1 x 5 L	KR10385	11 x 40 mL	1958006	3 ml/60 un.	x
	1158055	20 ml/80 un	1158060	80 ml/40 un	1158065	60 ml/40 un	1158050	40 ml/80 un	x

Cont	R1		LOT						
	R2		LOT						
	R3		LOT						
	Standard	X	LOT	19838	2020-05	2-8°C	IVD		

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST	SPECIFICATIONS	RESULT
Appearance	R1 R2 R3	Liquid. Clear. Free of particles. N/A
	CAL	Liquid. Clear. Free of particles. ACCEPTED X
pH	R1: 6.8 ± 0.2 R2: 6.9 ± 0.2 R3: 12 ± 0.2	N/A

(ACCEPTED / N/A)

FUNCTIONALITY

- 1. Analytical parameters**
Blank. Absorbance of Working reagent against water.
Sensitivity. A₆₀₀ (Urea Berth.) + A₃₄₀ (BUN) / 50 mg/dL Urea^{Standard}
Linearity. Higher level established by the analytical performance.
Accuracy. Ratio between assigned and obtained Urea 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	SHIMADZU / BS 300
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	A ₆₀₀ ≤ 0.110	N/A	N/A
Sensitivity	A ₆₀₀ : 0.350 – 0.475 A ₃₄₀ : 0.140 – 0.170	ACCEPTED	ACCEPTED
Linearity	Up to 300 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 2017-05-15 Quality Control Dept.
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