

CERTIFICATE OF ANALYSIS	TOTAL and DIRECT BILIRUBIN STANDARD
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REF	1112005	2 x 100 mL		1912005	1 x 1mL	X
				1912081	30 x 1 mL	X

Cont	RT		LOT		 	IVD	
	RD			LOT			
	RN			LOT			
	CAL	X		LOT			19881

2021-01 2-8°C

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST		SPECIFICATIONS	RESULT	
Appearance	RT	Liquid. Clear. Free of particles.	N/A	
	RD	Liquid. Clear. Free of particles.	N/A	
	RN	Liquid. Clear. Free of particles.	N/A	
	CAL	Lyophilized.	ACCEPTED	X
Concentration	CAL	BT: 11 mg/dL	BD: 3.4 mg/dL	ACCEPTED X

(ACCEPTED / N/A)

FUNCTIONALITY

- 1. Analytical parameters**
Blank. Absorbance of the working reagent against water.
Sensitivity. Absorbance of the Bilirubin Standard against the blank.
Linearity. Absorbance of the Internal Standard.
Accuracy. Ratio between assigned and obtained DIRECT and TOTAL Bilirubin 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	BS-300	540 nm
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	$A_{540} < 0.050$	N/A	N/A
Sensitivity	0,250-0,450 BD / 0,700-1,200 BT	ACCEPTED	ACCEPTED
Linearity	Up to 20 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 2017-12-29 Quality Control Dept.
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