

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

Cont	RT	X	LOT	15816A	 	2021/01	IVD
	RD	X	LOT				
	RN	X	LOT				
	CAL	X	LOT				

2-30°C

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST	SPECIFICATIONS	RESULT
Appearance	RT	Liquid. Clear. Free of particles. ACCEPTED X
	RD	Liquid. Clear. Free of particles. ACCEPTED X
	RN	Liquid. Clear. Free of particles. ACCEPTED X
	CAL	Lyophilized. ACCEPTED X
Concentration	CAL	BT: XX.X mg/dL BD: X.X 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). Monoreagent kept at 2-8°C for a stated period of time.

INSTRUMENT	SHIMADZU / KROMA	540 nm
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	$A_{540} < 0.050$	ACCEPTED	ACCEPTED
Sensitivity	0,650-0,800 BD / 0,850-1,200 BT	ACCEPTED	ACCEPTED
Linearity	Up to 20 mg/dL	ACCEPTED	ACCEPTED
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 Francesc Guerrero 2018-04-11 Quality Control Dept.
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