




## CERTIFICATE OF ANALYSIS

## HDL-CHOLESTEROL

REF	1133010	2 x 40 mL	X	1133081	1 x 1 L	X	1933005	1 x 3 mL	
				1133085	1 x 5 L	X	1933080	1 x 0.5 L	
				1133088	1 x 20 L	X	1933081	1 x 1 L	
	1133050	40 ml/80 un.	x				1933006	3 ml /60 un	

Cont	R1	X	LOT	15701		2019/11	IVD	
	Standard	X	LOT					2-8°C

## PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST	SPECIFICATIONS	RESULT
Appearance	<b>R1</b> Liquid. Clear. Free of particles.	ACCEPTED X
	<b>CAL</b> Liquid. Clear. Free of particles.	ACCEPTED X

(ACCEPTED / N/A)

## FUNCTIONALITY

- Analytical parameters**  
*Blank.* Absorbance of the working reagent against water.  
*Sensitivity.*  $A_{500} / 50$  mg/dL HDL-Cholesterol<sub>Standard</sub>  
*Linearity.* Absorbance of the Internal Standard  
*Accuracy.* Ratio between assigned and obtained HDL-Colesterol values.
- 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.

<b>INSTRUMENT</b>	SHIMADZU	500 nm against reagent blank
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	0.000-0.100	ACCEPTED	ACCEPTED
Sensitivity	0.100-0.150	ACCEPTED	ACCEPTED
Linearity	200 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.

<b>This lot meets our specifications and is released for sale</b>	APPROVED	<b>Signed</b> Date of Manufacture Mayte Lázaro 2017-11-10 Quality Control Dept.
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