

CERTIFICATE OF ANALYSIS	LDL-CHOLESTEROL
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REF	1133105	1 x 5 mL	X	1133180	1 x 1 L	X	1933105	1 x 3 mL	X	1933181	1 x 1 L	
							1933180	1 x 0.5 L		1933006	3 ml/60 un.	

Cont	R1	X	LOT	15593A		2019-05	IVD	
	Standard	X	LOT					2-8°C

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST		SPECIFICATIONS	RESULT	
Appearance	R1	Liquid. Clear. Free of particles.	ACCEPTED	X
	CAL	Liquid. Clear. Free of particles.	ACCEPTED	X

(ACCEPTED / N/A)

FUNCTIONALITY

<p>1. Analytical parameters <i>Blank.</i> Absorbance of the working reagent against water. <i>Sensitivity.</i> A₅₀₀ / 50 mg/dL LDL-Cholesterol_{Standard} <i>Linearity.</i> Absorbance of the Internal Standard <i>Accuracy.</i> Ratio between assigned and obtained LDL-Cholesterol values.</p> <p>2. Stability Testing <i>Fresh Reagents (FR).</i> Items kept at 2-8°C. <i>Stressed Reagents (SR).</i> Items kept at 37/42°C for a stated period of time.</p>
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INSTRUMENT	SHIMAZDU	500 nm against reagent blank
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TEST	SPECIFICATIONS	RESULTS	
		FR	SR
Blank	A ₅₀₀ < 0.070	ACCEPTED	ACCEPTED
Sensitivity	0.200-0.300	ACCEPTED	ACCEPTED
Linearity	Up to 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.

This lot meets our specifications and is released for sale	APPROVED	Signed Date of Manufacture Mayte Lázaro 2017-04-21 Quality Control Dept.
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