

CERTIFICATE OF ANALYSIS	LDL CHOLESTEROL DIRECT
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REF	1142005	40 mL	X	CT10290	1x60 mL	X	1142080	1x1.5 L	X	1142050	30 ml/80 un.	x
	1142010	320 mL	X	KR10290	5x40 mL	X	1142081	1x0.5 L	X	1142055	10 ml/80 un.	x
	1142025	80 mL	x	KR10292	1x40 ml	x				1142060	80 ml/40 un.	x
										1142065	80 ml/40 un.	x

Cont	R1-R2	x
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LOT	R1 15863 R2 15864	2019-11
	2-8°C	IVD

QUALITATIVE CONTROLS

TEST	SPECIFICATIONS	RESULT		
Physical appearance	R1	Liquid. Clear. Free of particles. Light yellow	Complying	x
	R2	Liquid. Clear. Free of particles. Colorless	Complying	x
pH	R1 6.5 ± 0.2 R2 6.5 ± 0.2	Complying		x

QUANTITATIVE CONTROLS

1. Analytical parameters
Blank. Absorbance of Working reagent against water.
Linearity. Higher level established by the analytical performance.
Sensitivity. Absorbance of a dilution 1:75:25 sample/reagents at 600 nm, 100 mg/dL of cholesterol
Accuracy. Ratio between assigned and obtained values.

TEST	SPECIFICATIONS	RESULTS
Blank	$A_{600} R1 \leq 0.120 / R2 \leq 0.080$	Conforms
Linearity	Up to 250 mg/dL	Conforms
Sensitivity	0.090/0.150	Conforms
Accuracy (mg/dL)	80.7 ± 13.7	81.5
	125.1 ± 21.3	125.9
	166.1 ± 28.2	167.8

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 Quality Control Dept. 02/11/ 2017
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