

CERTIFICATE OF ANALYSIS CERTIFICADO DE ANALISIS	CC STANDARDS AND CONTROLS CC ESTÁNDARES Y CONTROLES
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REF	MULTICALIBRATOR CC/H			HDL/LDL CALIBRATOR			HUMAN MULTISERA NORMAL			HUMAN MULTISERA ABNORMAL		
	1975005	5 x 5 mL			1972005	1 x 1 mL	X	1980005	5 x 5 mL		1985005	5 x 5 mL
1975080	30 x 5 mL			1972081	30 x 1 mL	X	1980080	30 x 5 mL		1985080	30 x 5 mL	
CT19750	8 x 3 mL						CT19800	8 x 3 mL		CT19850	8 x 3 mL	
1975006	5 ml/ 60 un			1972006	1 ml/ 60 un	x	1980006	5 ml/ 60 un		1985006	5 ml/ 60 un	

Cont	HDL/LDL CALIBRATOR	X	LOT	19900		2020-01		2-8°C	IVD
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QUALITATIVE CONTROLS

TEST	SPECIFICATIONS	RESULTS			
		PASS	X	FAIL	
APPEARANCE	Lyophilised	PASS	x	FAIL	
SOLUBILITY SPEED	< 2 Minutes	PASS	X	FAIL	
ASSIGNED VALUES	HDL 42.8 mg/dL LDL 70.1 mg/dL	PASS	X	FAIL	

<i>HUMAN SOURCE PLASMA</i>	HBs Ag, Anti-HIV 1/2 and Anti HCV Nonreactive when units tested individually.
<i>STORAGE TEMPERATURE</i>	Refrigerate 2-8°C.
<i>STABILITY</i>	The expiry date is illustrated on the side of each pack.
<i>SAFETY</i>	Because no test method can offer complete assurance that products derived from human source will not transmit infectious agents, it is recommended that this product be handled with the same precautions used for patients specimens.
<i>USE</i>	Use of this product is only recommended together with the enclosed batch specific document which contains analytical data and stability information.

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. 05/02/2018
	(APPROVED / NOT APPROVED)	

