

Lipoprotein(a) (Lp(a)) Control

✓ **REFERENCE**



Lp (a) Control	LPCON-002	1 x 2 ml	2-8 °C
Human biological fluid containing Lp(a) standardized from a secondary preparation of human Lipoprotein(a), sodium azide (< 1g/l)			
Batch number :	21E07		
Expiry date :	05/2022		
Control date :	27/05/21		
Control report number :	DGM-QAC-REP-21106		
Document prepared and signed by :	L.Ginneberge		

✓ **ANALYTICAL PERFORMANCES**

See the corresponding reagents technical sheet.

✓ **PREPARATION AND REAGENTS STABILITY**

The control is ready for use ; once opened, it is stable until expiry date if stored stoppered in appropriate temperature conditions and without any contamination (avoid pipetting and decantation).

✓ **METHOD OF ANALYSIS AND CALCULATION**

See the corresponding reagents technical sheet.

✓ **QUALITY CONTROL**

Accuracy and reproducibility : analytical performances can be checked with the internal quality control serum of the laboratory.

✓ **BIBLIOGRAPHY**

- (1) Tate, J.R. et al. International Federation of Clinical Chemistry standardization project for the measurements of lipoprotein (a). Phase I. Evaluation of the analytical performance of lipoprotein (a) assay systems and commercial calibrators. Clin. Chem. 44:8, (1998) 1629-1640
- (2) Kostner, G.M. et al. Preparation of a stable fresh frozen primary lipoprotein(a) (Lp(a)) standard. Journal of Lipid Research. 40, (1999) 2255-2263
- (3) Marcovina, S.M. et al. Use of Reference Material Proposed by the International Federation of Clinical Chemistry and Laboratory Medicine to Evaluate Analytical Methods for the Determination of Plasma Lipoprotein(a). Clin. Chem. 46:12, (2000) 1956-1967

✓ **SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

✓ **COMPOSITION**

The lipoprotein(a) control is a human biological fluid containing human Lp(a) at fixed value and sodium azide (<1g/l) as preservative.

✓ **PRINCIPLE OF TEST**

The human Lp(a) reacts upon a specific antibody for human LP(a) and the turbidity induced by the formation of immune complexes is recorded at 340 nm. The turbidity measured is directly proportional to the Lp(a) concentration of the control which can be used for the validation of the calibration curve and the stability during time of this curve in immunoturbidimetry.

✓ **PRECAUTIONS**

For in vitro single diagnostic use. To be handled by entitled Personnel. Products from human source were tested and found free from HBsAg and antibodies to HCV and HIV but this material should be treated just as carefully as potentially infective. Products containing sodium azide have to be handled with care ; avoid ingestion and contact with skin and mucous membranes. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

























LPCON 21E07 IFU EN v05 31/05/21


	CONTROL	
	mg/dl	
	Target	Range
Lipoprotein (a)	30	24 - 36

Values assigned from a secondary preparation of human Lipoprotein(a)

Symbols

The following symbols may appear on the packaging and labelling :

	<i>Batch code</i>		<i>Buffer</i>
	<i>Use by</i>		<i>Calibrator</i>
	<i>Manufacturer</i>		<i>High</i>
	<i>In Vitro Diagnostics Medical Device</i>		<i>Medium</i>
	<i>Temperature limitation (store at)</i>		<i>Low</i>
	<i>Catalogue number</i>		<i>4 levels</i>
	<i>Consult instructions for use</i>		<i>5 levels</i>
	<i>Reagent</i>		<i>6 levels</i>
	<i>Kit</i>		<i>Control</i>
	<i>Contents</i>		<i>This product meets the requirements of European Directive 98/79 CE concerning diagnostic medical devices in vitro</i>
	<i>Antibody or Antiserum</i>		<i>Track version changes</i>

	<i>DiAgam Belgium: Rue du Parc Industriel 40, 7822 Ghislenghien, Belgium</i>
<i>DiAgam Headquarters</i>	<i>Avenue Louis Lepoutre 70, 1050 Bruxelles, Belgique</i>
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