

Lp(a) 21 FS*

Diagnostic reagent for quantitative in vitro determination of lipoprotein (a) [Lp(a)] in serum or plasma on DiaSys respons[®]920

Order Information

Cat. No. 1 7139 99 10 921

4 twin containers for 100 determinations each

Method

Particle enhanced Immunoturbidimetric test

Principle

Determination of the Lp(a) concentration by photometric measurement of antigen-antibody-reaction between antibodies against Lp(a) bound to particles and Lp(a) present in the sample.

Reagents

Components and Concentrations

R1:	Glycine-buffer	pH 8.3	<1.5%
R2:	Glycine-buffer	pH 8.2	<1.5%
	Latex particles coated with anti-human lipoprotein (a) antibody (rabbit)		

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

- The reagents contain sodium azide (0.9 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
- The reagents contain biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
- To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons[®]920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
- In very rare cases, samples of patients with gammopathy might give falsified results [8].
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
- For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen

Serum, heparin plasma or EDTA plasma

Stability [1]:

2 days	at	20 – 25°C
2 weeks	at	4 – 8°C
3 months	at	-20°C

Discard contaminated specimens. Freeze only once!

Calibrators and Controls

DiaSys TruCal Lp(a) 21 calibrator set is recommended for calibration. The assigned values of the calibrator in nmol/L have been made traceable to the WHO/IFCC SRM[®]-2B reference material and the assigned values of the calibrator in mg/dL have been made traceable to a reference preparation. For internal quality control a DiaSys TruLab Lp(a) control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Lp(a) 21 (5 levels)	1 7140 99 10 059	5 x 1 mL
TruLab Lp(a) Level 1	5 9830 99 10 046	3 x 1 mL
TruLab Lp(a) Level 2	5 9840 99 10 046	3 x 1 mL

Performance Characteristics

Measuring range up to 110 mg/dL (260 nmol/L) Lp(a), depending on the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	2 mg/dL Lp(a)
No prozone effect up to 400 mg/dL (800 nmol/L) Lp(a)	
On-board stability	6 weeks
Calibration stability	4 weeks

Interferences < 10% by	
Bilirubin up to 40 mg/dL	
Hemoglobin up to 500 mg/dL	
Rheumatoid factor up to 500 IU/mL	
Lipemia (triglycerides) up to 2000 mg/dL	
For further information on interfering substances refer to Young DS [2].	

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	29.3	46.0	83.9
Coefficient of variation [%]	2.31	1.42	2.97
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	26.2	31.1	67.7
Coefficient of variation [%]	3.64	3.55	1.98

Method comparison (n=130)	
Test x	DiaSys Lp(a) 21 FS (Hitachi 917)
Test y	DiaSys Lp(a) 21 FS (respons [®] 920)
Slope	1.015
Intercept	0.50 mg/dL
Coefficient of correlation	0.998

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Reference Range

< 30 mg/dL [4]
< 75 nmol/L for Caucasians [7]

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 36-7.
2. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th. ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press, 2000.
3. Nordestgaard BG, Chapman MJ, Ginsberg HN. Lipoprotein (a): EAS Recommendations for Screening, Desirable Levels and Management. The European Atherosclerosis Society (EAS) Consensus Panel 2012.
4. Riesen WF. Lipid metabolism. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 174-5.
5. Rifai N, Bachorik PS, Albers JJ. Lipids, lipoproteins and apolipoproteins. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 809-61.
6. Marcovina SM, Koschinsky ML. Lipoprotein (a): Structure, measurement and clinical significance. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press; 1997. p. 283-313.
7. Marcovina SM, Koschinsky ML et al. Report of the national heart, lung, and blood institute workshop of Lipoprotein(a) and cardiovascular disease: recent advances and future directions. Clin Chem 2003; 49(11): 1785-96.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.



Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Lp(a) 21 FS

Application for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test	: LPA			Auto Rerun	<input type="checkbox"/>
Report Name	: Lipoprotein (a)			Online Calibration	<input type="checkbox"/>
Unit	: mg/dL	Decimal Places	: 2	Cuvette Wash	<input checked="" type="checkbox"/>
Wavelength-Primary	: 700	Secondary	: 0	Total Reagents	: 2
Assay Type	: 2-Point	Curve Type	: Cubic Spline	Reagent R1	: LPA R1
M1 Start	: 19	M1 End	: 19	Reagent R2	: LPA R2
M2 Start	: 33	M2 End	: 33	Consumables/Calibrators:	
Sample Replicates	: 1	Standard Replicates	: 3	Blank /Level 0	: 0
Control Replicates	: 1	Control Interval	: 0	Calibrator Level 1	: **
Reaction Direction	: Increasing	React. Abs. Limit	: *	Calibrator Level 2	: **
Prozone Limit %	: 97	Prozone Check	: Lower	Calibrator Level 3	: **
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000	Calibrator Level 4	: **
Technical Minimum	: *	Technical Maximum	: *	Calibrator Level 5	: **
Y = aX + b	a = : 1.0000	b =	: Calibrator 5		

* Technical limits are automatically defined by the software via the upper and lower calibrator level.

** Enter calibrator value.

Test Details		Test Volumes		Reference Ranges	
Test	: LPA				
Sample Type	: Serum				
Sample Volumes				Sample Types	
Normal	: 3.00 μ L	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum	
Increase	: 10.00 μ L	Dilution Ratio	: 1 X	<input type="checkbox"/> Urine	
Decrease	: 2.00 μ L	Dilution Ratio	: 1 X	<input type="checkbox"/> CSF	
Standard Volume	: 3.00 μ L			<input checked="" type="checkbox"/> Plasma	
				<input type="checkbox"/> Whole Blood	
				<input type="checkbox"/> Other	
Reagent Volumes and Stirrer Speed					
RGT-1 Volume	: 120 μ L	R1 Stirrer Speed	: High		
RGT-2 Volume	: 60 μ L	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: LPA				
Sample Type	: Serum				
Reference Range	: DEFAULT				
Category	: Male				
Reference Range				Sample Types	
	Lower Limit	Upper Limit		<input checked="" type="checkbox"/> Serum	
	(mg/dL)	(mg/dL)		<input type="checkbox"/> Urine	
Normal	: 0.00	: 30.00		<input type="checkbox"/> CSF	
Panic	: 0.00	: 0.00		<input checked="" type="checkbox"/> Plasma	
				<input type="checkbox"/> Whole Blood	
				<input type="checkbox"/> Other	