respons®910

Lp(a) 21 FS*

Diagnostic reagent for quantitative in vitro determination of lipoprotein (a) [Lp(a)] in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 7139 99 10 921
4 twin containers for 100 tests 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

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
2. The reagents contain biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [8].
4. 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.
5. 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

Freeze only once! Discard contaminated specimens.

Calibrators and Controls

For the calibration the DiaSys TruCal Lp(a) 21 calibrator set is recommended. 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	3 weeks

Interfering substance	Interferences < 10%	Lp(a) [mg/dL]
Hemoglobin	up to 550 mg/dL	35.4
	up to 550 mg/dL	62.4
Bilirubin, conjugated	up to 45 mg/dL	34.4
	up to 45 mg/dL	81.9
Bilirubin, unconjugated	up to 45 mg/dL	34.8
	up to 45 mg/dL	82.1
Lipemia (triglycerides)	up to 2000 mg/dL	31.0
	up to 2000 mg/dL	99.5
Rheumatoid factor	up to 500 IU/mL	34.2
	up to 700 IU/mL	78.9
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]	16.4	28.2	78.9
Coefficient of variation [%]	3.19	1.15	0.80
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	15.1	21.7	70.8
Coefficient of variation [%]	4.58	2.83	2.42

Method comparison (n=129)	
Test x	DiaSys Lp(a) 21 FS (Hitachi 917)
Test y	DiaSys Lp(a) 21 FS (respons®910)
Slope	1.025
Intercept	–0.662 mg/dL
Coefficient of correlation	0.999

** according to NCCLS document EP17-A, vol. 24, no. 34

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. Clin Chem Lab Med 2007; 45(9): 1240–1243.

Manufacturer

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Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	LPA
Shortcut:	
Reagent barcode reference:	710
Host reference:	710

Technic	
Type:	Fixed time kinetic
First reagent:[µL]	120
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	60
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	700
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	04:48
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	2.0000
Concentration technical limits-Upper	110.0000
SERUM	
Normal volume [µL]	4.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
URINE	
Normal volume [µL]	4.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	4.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	4.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
Whole blood	
Normal volume [µL]	4.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>= <=30.00
URINE	
PLASMA	>= <=30.00
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0100
Cal. 3	0.0100
Cal. 4	0.0100
Cal. 5	0.0250
Cal. 6	0.0400
Drift limit [%]	2.00

Calculations	
Model	Cubic Spline
Degree	

* Enter calibrator value