Lp(a) 21 FS*

Diagnostic reagent for quantitative in vitro determination of lipoprotein (a) [Lp(a)] in serum or plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 7139 99 10 966
R1: 2 x 100 tests
R2: 2 x 100 tests

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 lipoprotein (a) antibody (rabbit)	anti-human	

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 trays.

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 calibration, DiaSys TruCal Lp(a) 21 calibrator set is recommended. The assigned values of the calibrator have been made traceable to the WHO/IFCC reference material SRM® 2B (nmol/L) or to the Immuno LEIA® Lp(a) Reference Standard Human (mg/dL). 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 from up to 110 mg/dL (260 nmol/L) Lp(a), at least up to 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**	1 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

Interferences < 10% by
Bilirubin up to 60 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]	12.1	45.7	79.2
Coefficient of variation [%]	2.00	1.82	1.29
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	13.0	66.7	84.2
Coefficient of variation [%]	1.96	1.99	2.11

Method comparison (n=80)	
Test x	DiaSys Lp(a) 21 FS (Hitachi 917)
Test y	DiaSys Lp(a) 21 FS (BM6010/C)
Slope	0.962
Intercept	-0.591 mg/dL
Coefficient of correlation	0.9925

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

Reference Range

< 30 mg/dL [3]
< 75 nmol/L for Caucasians [4]

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

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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. Riesen WF. Lipid metabolism. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 174-5.
4. 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.
5. Nordestgaard BG, Chapman MJ, Ginsberg HN. Lipoprotein (a): EAS Recommendations for Screening, Desirable Levels and Management. The European Atherosclerosis Society (EAS) Consensus Panel 2012.
6. 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.
7. 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.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
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BioMajesty

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Chemistry code 10 713

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.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	40
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	2.0
Sample vol (U)	2.0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	23
S-DET.P.r	24
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	LP(a)
Digits	2
M-wave L.	694
S-wave.L	****
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	2.0	2.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting

Formula	Spline	**Axis Conv**	No conv
Blank	Blank-any value	**Points**	6

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	2.0	No dil	0	0	0	9.999	-9.999
1	#	2.0	No dil	0	0	0	9.999	-9.999
2	#	2.0	No dil	0	0	0	9.999	-9.999
3	#	2.0	No dil	0	0	0	9.999	-9.999
4	#	2.0	No dil	0	0	0	9.999	-9.999
5	#	2.0	No dil	0	0	0	9.999	-9.999

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