

High-Q Lipoprotein(a)

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

Intended Use: Diagnostic reagent for quantitative in vitro determination of lipoprotein (a) [Lp(a)] in serum or plasma on photometric systems

Summary:

Lipoprotein (a) [Lp(a)] is a particle consisting of a LDL molecule (LDL: low density lipoprotein) bound to apolipoprotein (a) which can have different sizes depending on the isoforms. It seems that apolipoprotein (a) can inhibit fibrinolysis competing with plasminogen due to a considerable structural homology, an effect which cannot be observed with LDL free of apolipoprotein (a). Lp(a) is considered an atherogenic risk factor which is independent of other lipid parameters and exogenous factors such as diet. Increased Lp(a) levels have a high predictive value for coronary heart disease, especially in combination with elevated LDL cholesterol. While the determination of total cholesterol and triglycerides is used for coronary risk screening, measurement of Lp(a), beside LDL-cholesterol, HDL-cholesterol, apolipoprotein A1 and apolipoprotein B, is a valuable tool for differential diagnosis of coronary heart disease.

Method:

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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)		

Reagent Preparation

The reagents are ready to use.

Lp-a Calibrator:

Lp(a) Calibrator is available as Ready to use Liquid Stable Single level Calibrator. **Reconstitution is not required.** Serial Dilution is not required. High Q-Lp(a) Calibrator values with the units mg/dL have been made traceable to the WHO/IFCC reference material SRM 2B (PRM IFCC Standard).

Storage Instructions and Reagent Stability:

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

Specimen:

Unhemolysed Serum is the preferred specimen

Stability of the specimen : 2 weeks at 4 – 8°C

3 months at –20°C

Discard contaminated specimens.

Assay Procedure: (Fixed Time)

System Parameters:

Reaction Type (Mode)	Fixed Time
Reaction Direction	Increasing
Wave Length	630 nm (600-670 nms)
Flow Cell Temp.	37°C
Delay Time	30 Seconds
Measuring Time	180 Seconds
Blank	Distilled Water
Reagent Volume (Sample Volume)	320 µl (R1) + 80 µl (R2)
Calibrator Concentration	(On the Vial- Lot Specific)
Linearity	110 mg/dL

Procedure :

Reagent	Calibrator	Sample/Control
Lp-a R1	320 µl	320 µl
Calibrator	10 µl	----
Serum Sample	—	10 µl
Mix and incubate for 5 Minutes at 37 °C		
Lp-a R2	80 µl	80 µl

Mix well and immediately aspirate in to the analyzer. Record the first absorbance (A1) at 30 seconds . Exactly 180 Seconds after the first reading record the absorbance (A2) at 37 °C.

Calculate the change in absorbance for the Calibrator and Serum Samples.

Calculations with calibrator:

$$\text{Lp(a)} = \frac{\text{A2-A1 Sample}}{\text{A2-A1 Calibrator}} \times (\text{Conc. of Calibrator in mg/dL})$$

Measuring Range

The test has been developed to determine Lp(a) concentrations within a measuring range from 3 – 110 mg/dL. If values exceed this range samples should be diluted 1 + 5 with NaCl solution (9 g/L) and the result multiplied by 6.

Prozone Limit

No prozone effect was observed up to a Lp(a) value of 400 mg/dL or 800 nmol/L.

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Specificity/Interferences:

Due to its antibodies, High-Q Lp(a) is a specific immunoassay for human Lp(a). No interference was observed by bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL, lipemia up to 2,000 mg/dL triglycerides and rheumatoid factor up to 500 IU/mL. No cross reactions with plasminogen and apolipoprotein B were seen under test conditions.

Sensitivity/Limit of Detection:

The lower limit of detection is 3 mg/dL Precision (n= 20)

Intra-assay precision	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	26.9	0.540	2.00
Sample 2	32.9	0.557	1.69
Sample 3	52.3	0.528	1.01

Intra-assay precision (single calibration)	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	26.2	0.803	3.06
Sample 2	32.2	0.720	2.24
Sample 3	52.2	1.08	2.06

Method Comparison

A comparison of High-Q Lp(a) (x) with a commercially available reagent (y) with 36 samples gave following results:
 $y = 0.952x + 2.58$ mg/dL; $r = 0.990$.

A comparison of High-Q Lp(a) (x) with a commercially available reagent (y) with 36 samples gave following results:
 $y = 1.01x + 1.89$ mg/dL; $r = 0.980$.

A method comparison of High-Q Lp(a) to the NWLRL* assay system with 20 samples gave the following results:
 $y = 0.94x + 5.50$ nmol/L; $r = 0.997$.

*Northwest Lipid Research Laboratories

Reference Range

< 30 mg/dL

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

Literature

- 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.
- 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.
















Ordering Information

Ref./Cat. No.	Pack Size	Presentation
P - LIP(a)-25	25 ml	Liquid Stable Two Reagents with Calibrator

Product Features

- Latex Enhanced Turbidimetric Immuno Assay (LETIA)
- Liquid Stable Two Reagents
- Two step Fixed Time Assay (30 Sec Delay + 180 Sec Measuring)
- Single level liquid calibrator provided
- Linearity: 3 – 110 mg/dL
- Measuring Wavelength 630 nms
- Unhemolysed Serum is the specimen
- Available as multipurpose reagents and dedicated system packs

Symbols used with IVD devices

	Date of manufacture		Manufactured by
	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)		Reagent
	Calibrator Material		Batch code
	Temperature limitation (store at)		Control
	Consult instructions for use		Keep dry Keep away from rain
	Catalog Number		

