Pariksha Biotech
A game changer in IVD

Lipoprotein(a) Estimation Kit

High-Q Lipoprotein(a)

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

HIGH®
Command on Quality

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 LDLcholesterol. 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:
Latex Enhanced Turbidimetric Immuno Assay (LETIA)

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: Calibrator is available as Lyophilized Calibrator.. **Reconstitute Calibrator with 1.0 ml of Distilled Water and keep it for 20 Minutes.** Mix gently and make a uniform suspension. Reconstituted Calibrator is stable for 60 Days once stored properly at 2-8°C. Aliquot it in to small volumes and store at 2-8°C for the contamination free use and for good reconstitution stability. Calibrator is stable for 6 Months when frozen at -20°C if the repeated freeze and thaw cycles are avoided. Calibrator needs to be serially diluted as per the procedure mentioned in the Calibrator insert.High-Q Lp(a) Calibrator values with the units mg/dLhave been made traceable to the WHO/IFCC reference materialSRM 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- 5 point Spline Calibration with 5 Calibrator Levels):

System Parameters:

Reaction Type (Mode)	Fixed Time- Linear
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	320 µl (R1) + 80 µl (R2)
Sample Volume)	10 µl
Calibrators Concentrations	(On the Vials Lot Specific)
Linearity	110 mg/dL

Procedure :

Reagent	Calibrator	Sample/Control
Lp-a R1	320 µl	320 µl
Calibrators (1,2,3,4,5)	10 µl	----
Serum Sample	—	10 µl
Mix and incubate for 5 Minutes at 37 °C		
Lp-a R2	80 µl	80 µl

1) Read absorbance A1 after 30 Seconds. (Delay)
2) Incubate and Read the absorbance A2 after 180 Seconds (Measuring)
3) Calculate the absorbance differences ΔA=A2–A1 for each point of the calibration curve, controls and all unknown samples.
4) The concentration of Lp-a in the unknown sample can be calculated from ΔA=A2–A1
5) Using a 3rd order polynomial mathematical model where abscissa (X) is the ΔA=A2–A1 and ordinate (Y) is the concentration of Lp-a or plotting the values of ΔA=A2–A1 obtained for every concentration level of the calibrator against the Lp-a concentration and interpolating the individual ΔA=A2–A1 of every sample in the calibration curve.

Calculations with Calibrators/ Calibration Curve/ Result Interpretation:
The concentration of Lp-a in unknown samples is derived from a calibration curve using an appropriate mathematical model such as spline. The calibration curve is obtained with 5 calibrators at different levels. Stability of calibration: 6 weeks**Performance Characteristics**

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 = 0.952 x + 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 = 1.01 x + 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 = 0.94 x + 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

1. 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.
2. 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.

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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)**
- **Lyophilized 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
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

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Manufactured in India by :
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AN ISO 13485 Certified Company

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