Lp(a) Multi-Purpose (MPR) Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
GL409LP	1 x 50 ml	Lp(a) - 1	2-8°C
	1 x 14 ml	Lp(a) - 2	
GL419LP	5 x 50 ml	Lp(a) - 1	2-8°C
	5 x 14 ml	Lp(a) - 2	

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of Lp(a) in serum on automated and semi-automated analysers.

SUMMARY AND EXPLANATION:

Lipoprotein (a) [Lp(a)] was initially thought to be a genetic variant of low density lipoprotein (LDL). It is in fact a low density lipoprotein-like particle containing apolipoprotein B-100 disulphide-linked to the large glycoprotein called apolipoprotein (a). Apolipoprotein (a) has been shown to have a considerable degree of homology with human plasminogen. The characteristic feature of lipoprotein (a) is that it is distinct from all other serum proteins and apolipoproteins. This protein is believed to be inherited as an autosomal dominant trait and appears to be insensitive to either diet, lifestyle or most hypolipidaemic drugs. Since its discovery by Berg in 1963, there has been a considerable rise in interest, not only in specialised research centres but also in clinical laboratories, in the accurate measurement of lipoprotein (a) in blood. This interest was stimulated by reports indicating that levels above 0.2 – 0.3 g/l, present in approximately 25% of the population, are associated with an increased risk of coronary heart disease. Many investigators have confirmed that a high Lp(a) concentration represents an indicator of risk for cardiovascular disease, especially when the serum LDL-Cholesterol or APO B are elevated. Therefore a convenient and reliable method for the quantification of Lp(a) in serum or plasma is important for identification of individuals at risk for developing atherosclerosis.

PRINCIPLE OF THE TEST:

This assay is based on the reaction between antigen and antibody. This reaction forms an insoluble complex producing a turbidity, which is measured spectrophotometrically. The amount of complex formed is directly proportional to the amount of Lp(a) in the sample.

Lp(a) Antigen + Anti-Lp(a) Antibodies ⟶ Antigen/Antibody complex

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Clear, colourless liquid
Reagent 2: White turbid appearance
Any significant changes could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety precautions:
This product is not hazardous under EU specifications. Contains Sodium Azide. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument application procedures are available upon request.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent 1	Glycine Buffer pH9.0 with protein stabilisers	0.1M
	PRESERVATIVE	---
Reagent 2	Glycine Buffer pH8.2	0.1M
	NaCl	0.15M
	BSA	0.5%
	Anti Lp(a) antibody	---
	PRESERVATIVE	---

REAGENT PREPARATION AND STABILITY:

Reagent 1 and 2 are ready for use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly:
- Unopened components are stable until expiry date stated on the label.
- Once open, components are stable for 1 month at 2-8°C.

TYPE OF SPECIMEN:

Use serum as specimen. *Very lipemic or turbid specimen must be clarified before the assay*.

It is recommended to follow CLSI procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Serum should be separated from cells within 2 hours after collection.
Stability: Up to 2 weeks at 2-8°C.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
Lp(a) Calibrator	GL9622	General Laboratory Equipment	N/A
Lipid Control Level 1	GL9009	Saline solution 0.9 g/l NaCl	N/A
Photometer	N/A		

Assay procedure:
Wavelength: λ: 500 - 600 nm
Temperature: 37°C
Optical path: 1 cm light path.

	Blank	**Calibrator**	**Sample**
Reagent 1	1.25 ml	1.25 ml	1.25 ml
Sample	----	----	10 µl
Calibrator	----	10µl	----
Gently mix and Incubate at 37°C Measure the Optical Density (OD1) after 5 minutes, against the blank.			
Reagent 2	350 µl	350 µl	350 µl
Gently mix and Incubate at 37°C Measure the Optical Density (OD2) after further 10 minutes, against the blank.			

Calibration:
Using recommended Calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure.
- At intervals established by the Laboratory QC programme.

CALCULATION:

$$\text{Lp(a) sample} = \frac{\Delta Abs_{Sample} - Abs_{Blank}}{\Delta Abs_{Calibrator} - Abs_{Blank}} \times \text{Concentration}_{\text{Calibrator}}$$

(Conversion Factor: Qty in mg/l = Qty in mg/dl x 10)

EXPECTED VALUES:

Normal range	<300 mg/l (<30 mg/dl)

Each laboratory should establish its own reference range. Lp(a) results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance evaluation can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
Linear up to 800mg/L (80 mg/dL).
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/L) and re-assay. Multiply result by 2.

Interfering substances:
Haemolysis: No interference up to 10 g/L Haemoglobin
Lipemia: No interference up to 0.5% Intralipid
Bilirubin: No interference up to 440 µmol/L Bilirubin

Sensitivity:
The Lowest Detectable Level was estimated < 6.83 mg/L (0.68 mg/dL).

Precision:

Within Run N = 20	Mean *(mg/L)*	*% CV*	*Between RunN = 10*	Mean *(mg/L)*	*% CV*
Level 1	134.15	1.80	Level 1	133.80	2.83

Method Comparison:
Using 30 samples, a comparison, between this Lp(a) test (y) and another commercially available test (x), gave the following results:

y = 1. 0034x – 0.7822	r^2 = 0.9854

BIBLIOGRAPHY:

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SYMBOLS:

The following symbols are used in the labelling of Glenbio systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard
CE	CE Mark - Device comply with the Directives 98/79/EC		
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

GLENBIO LTD
10 Kilbegs Road, Antrim, Co. Antrim, BT41 4NN
Tel/Fax: +44(0)2879659842
Email: info@glenbio.com
Web: www.glenbio.com

EC REP
GLENBIO IRELAND LTD
17b Fota Business Park, Carrigtwohill, Co. Cork,
T45 PK77, Ireland

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