PATHOZYME DIAGNOSTICS

LIPOPROTEIN (a)

(TURBIDIMETRY METHOD)

CAT No.: LPA

Reagent kit for quantitative estimation of Lipoprotein (a) in Serum.

DIAGNOSTIC SIGNIFICANCE:

Lipoprotein (a) [Lp(a)] was initially thought to be a genetic variant of low-density lipoprotein (LDL). Lp(a) is a low-density lipoprotein-like particle containing apolipoprotein B-100 disulphidelinked to one 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 hypolipidemic drugs. Since its discovery by Berg in 1963, there has been a considerable rise in interest, not only in specialized research centers but also in clinical routine 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 lipoprotein(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 quantitation of Lp(a) in serum or plasma is important for identification of individuals at risk for developing atherosclerosis.

PRINCIPLE:

This Lp(a) test is based upon the reactions between Lp(a) in the sample and latex-covalently bound rabbit antihuman Lp(a) antibodies. Lp(a) values are determined photometrically.

SPECIMEN COLLECTION:

Fresh Serum specimens should be collected by venipuncture following good laboratory practices. Lp(a) remain stable for 14 days at +2…+8°C. if the test should be performed later, it is recommended to freeze the serum. Lipemic specimens, or turbid specimens, must be clarified before the assay by high-speed centrifugation (15 min at approx. 15000 rpm).

KIT PRESENTATION:

Pack Size	1 X 26.5 ml	1 X 53 ml
R1-Lipoprotein (a) (Buffer Reagent)	1 X 22.5 ml	1 X 45 ml
R2-Lipoprotein (a) (Latex Reagent)	1 X 04 ml	1 X 08 ml
Calibrator (See Vial Label For Conc.)	1 No	1 No

REAGENT & CALIBRATOR PREPARATION:

All reagents and calibrator are ready to use.

To reconstitute the Calibrator, refer the Calibrator vial label. After reconstitution Calibrator stable for 14 days at 2-8^{0}C if store & handle properly.

REAGENT STORAGE & STABILITY:

All reagents and calibrator included in the kit are stable at 2-8^{0}C until the expiry date stated on the label.

ASSAY PARAMETERS:

Reaction	**: Fix Time**	**Sample Volume**	**: 06 µl**
Wavelength	**: 620 nm**	**R1 + R2 Volume**	**: 450 µl**
Flow Cell Temp.	**: 37^{0}C**	**Calibrator Conc.**	**: As Per Vial**
Initial Delay	**: 05 Sec**	**Zero Setting**	**: Dist. Water**
Read Time	**: 300 Sec**	**Linearity**	**: 1200 mg/L**
Reaction Slope	**: Increasing**	**Unit**	**: mg/L**

PROCEDURE:

Pipette into TT	Calibrator	Test
R1-Lipoprotein (a)	450 µl	450 µl
R2-Lipoprotein (a)	80 µl	80 µl
Lipoprotein (a) Calibrator	6 µl	--
Sample (Test)	--	6 µl

Mix immediately and read difference in absorbance between 05 seconds (AT_1) and 300 seconds (AT_2) for Calibrator and Test.

CALCULATION:

$$\text{Lipoprotein (a) (mg/L)} = \frac{\Delta\text{Abs of Test X Cocn. of calibrator}}{\Delta\text{Abs of Calibrator}}$$

Where ΔAbs = (AT_1) - (AT_2)

NORMAL VALUES:

Serum Lipoprotein (a) **:** < 300 mg/L

Each laboratory should establish its own reference range. Results should be interpreted considering all other test results and the clinical situation of the patient.

INTERFERENCE: No signification interference by Bilirubin, Hemoglobin or intralipid

PROZONE EFFECT: Not at least up to 2250 mg/L

LIMIT OF DETECTION: < 5 mg/L

SENSITIVITY: 0.43mAb / (mg/L)

LINEARITY: The method is **linear up to 1200 mg/L**.

REFERENCE:

1. Young DS. Effects of Drugs on Clinical Laboratory Test. 5th Edition, AACC Press, 2000.

2. Sonderdruck aus DG Klinische Chemie Mitteilungen 1995; 26: 207 – 224.

IFU No.: 064/00 | *Rev. No.: 00/120723*

Expiry Date | IVD In-Vitro Diagnostics Use | Storage | Mfg. Date | LOT Batch Number | REF Catalogue Number | See Package Insert

PATHOZYME DIAGNOSTICS

An ISO 9001:2015, ISO 13485:2016, CE & GMP Certified Company

A-115, Kagal Five Star MIDC, Kagal, Dist. Kolhapur-416 216.

Tel: 0231-2305072, Cell: +91 88058 67810, E-mail: contactus@pathozyme.com, Website: www.pathozyme.com