TURBICHEM LIPOPROTEIN (a)

(Turbilatex method)

KIT NAME	KIT SIZE	CAT. NO
Turbichem - Lp(a)	1 x 50 ml	TLpa01050M

GENUINE BIOSYSTEM

INTRODUCTION

Lipoprotein (a) (Lp(a)) is intended for Invitro quantitative determination of Lp(a) in human serum. Lp(a) is a subclass of lipoprotein discovered in 1963 by Kare Berg. It is similar to LDL in that it contains a single ApoB protein along with cholesterol and other lipids. The similarities in components of Lp(a) to that of LDL and plasminogen suggests that Lp(a) may be associated with atherosclerosis and thrombosis. Numerous studies suggested that Lp(a) level is an important risk factor that may contribute to coronary artery disease independently or cooperatively with other risk factor. Lp(a) values should be interpreted with clinical evaluation and other lipoprotein tests when assessing atherosclerotic cardiovascular disease.

METHOD PRINCIPLE

The Kit utilizes latex-enhanced immunoturbidimetry to measure the Lp(a) level in human serum or plasma. During the test, Lp(a) in the sample binds with the specific anti Lp (a) antibody to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry, analyzer. The change in absorbance is proportional to the level of Lp (a) in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

KIT CONTENTS

R1 - LP (a) Buffer	1 x 40 ml
R2 - LP (a) Antibody	1 x 10 ml
R3 - LP (a) Calibrator	1 vial

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 7-10 days on board the analyser at 2-10°C. Protect from light and avoid contamination.

WORKING REAGENT PREPARATION AND STABILITY

Assay can be performed with use of separate R1-Lp (a) and R2-Lp (a) reagents of 4 parts of R1-Lp (a) with 1 part of R2-Lp (a). Avoid foaming.

CONCENTRATIONS IN THE TEST

R1 - Glycine buffer solution.

R2 - 0.4% suspension with latex particles sensitized with anti-Lp(a) antibodies

Warnings and notes

1. The Kit is for in vitro diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed

ADDITIONAL EQUIPMENT

- Automatic analyzer or photometer able to read at 630 nm
- Thermostat at 37ºC
- General laboratory equipment

SPECIMEN

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2- 4° C for up to 3 days or at -20° C for up to 1 months. Avoid repeated freezing and thawing.

PLOTTING OF MULTIPOINT CURVE

The Turbichem Lp(a) is based on Non-Linear Reactions, hence it is strongly recommended to run Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

Serial Dilution Step

	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50 µl from 1st Tube	50 µl from 2nd Tube	50 µl from 3rd Tube	50 µl from 4th Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dillution	Neat	1/2	1/4	1/8	1/16

PROCEDURE

These reagents may be used both for manual assay and in several automatic analyzers. Applications for them are available on request.

Wavelength	630 nm
Temperature	37°C
Cuvette	1 cm

Pipette into the cuvette:

Reagent	Calibrator (C)	Test (T)
R1 LP (a) Buffer	800 µl	800 µl
Caibrator	15 µl	-
Sample	-	15 µl
Mix well and incubate for 5 mins at 37° C		
R2 LP (a) Latex	200 µl	200 µl

Mix well & incubate for 5 min. at 37°C. Measure the absorbance of calibrator & sample.

CALCULATION

$$\text{LP (a) concentration} = \frac{\text{Abs.Test}}{\text{Abs.Calibrator}} \times \text{Calibrator Concentration}$$

REFERENCE VALUES

Upto 30 mg/dl

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

PERFORMANCE CHARACTERISTICS

- **Linearity:** 0.2 to 100 mg/dl
- **Precision:** within Run CV $\leq$ 4 %
- **Specificity / Interferences**

  No interference detected for bilirubin upto 60 mg/dL and hemoglobin 10 g/L, triglycerides 1000 mg/dL

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Berg, K. A new serum type system in man: the Lp system. Acta Pathol Microbiol Scand 1963; 59:362-382.
2. Hajjar KA, Nachman RL. The role of lipoprotein(a) in atherogenesis and thrombosis. Ann Rev Med 1996; 47: 423-442.
3. Marcovina SM, Koschinsky ML, hegele RA. Lipoprotein(a) and coronary heart disease risk. Curr Cardiol Rep 1999; 1: 105-11.
4. Kostner GM, Avogaro P, Cazzolate G, Marth E, Bittolo-Bon G,Qunici GB. Lipoprotein Lp(a) and the risk for myocardial infarction.
5. Armstrong VW, Cremer P, Eberle E, Manke A, Schulze F, Wieland H, Kreuzer H, Seidel D. The association between serum Lp(a) concentrations and angiographically assessed coronary atherosclerosis. Atherosclerosis 1986; 62: 249-257.

SYSTEM PARAMETERS

Method	End Point
Wavelength	630 nm
Zero Setting	Reagent Blank
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	5 mins + 5 mins
Delay Time	----
Read Time	----
No. of Reading	2
Interval Time	----
Sample Volume	0.015 ml (10 ul)
Reagent Volume	1.0 ml (1000 ul)
Standard Concentration	Refer Calibrator vial
Units	mg/dl
Factor	----
Reaction Slope	Increasing
Linearity	100 mg/dl

IVD CE

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