Pariksha Biotech
A game changer in IVD

Lp-PLA2 Estimation Kit

High-Q Plac Lp-PLA2

LETIA

HIGH Q
Command on Quality

Intended Use:
Diagnostic reagent for quantitative in vitro determination of Lp-PLA2 (Lipoprotein-associated phospholipase A2) in serum and plasma on photometric systems

Summary:
As per the experts " Lipoprotein-associated phospholipase A2 (Lp-PLA2) appears to be a specific marker of plaque inflammation that may play a direct role in the formation of rupture-prone atherosclerotic plaque ". High-Q Plac Test (Test for Lp-PLA2 or PAF acetylhydrolase) is the blood test (non-invasive and inexpensive) to aid in assessing risk for both coronary heart disease and ischemic stroke associated with atherosclerosis. The PLAC blood test, works by measuring an enzyme called Lp-PLA2 or otherwise also known as platelet activating factor (PAF)-acetylhydrolase. This enzyme is made by a type of white blood cell called a macrophage. Macrophages make more of this enzyme due to vascular inflammation and release it into the blood when a person has coronary heart disease or rupture-prone atherosclerotic plaque. This is a simple blood test and no fasting is needed

Lipoprotein-associated phospholipase A2 (Lp-PLA2), also known as platelet-activating factor acetylhydrolase (PAF-AH), is a calciumindependent phospholipase released by inflammatory cells in atherosclerotic plaques. In circulation, Lp-PLA2 is predominantly associated with LDL particles whereas only a small portion of enzyme is associated with HDL. Lp-PLA2 hydrolyzes oxidized LDL to generate two pro-atherogenic and pro-inflammatory compounds: Lysophosphatidylcholine (lyso-PC) and oxidized free fatty acids (oxFFA). Both substances play a major role in the development of vulnerable atherosclerotic plaques. Concentration of Lp-PLA2 is independent of the presence of other cardiovascular risk factors, shows minimal biovariability and is not elevated in systemic inflammatory reactions. Lp-PLA2 is a beneficial indicator for cardiovascular disease (CVD) risks, and may represent a potential therapeutic target for the reduction of such risks.

Principle:
Lp-PLA2 in patient sample and its corresponding antibody sensitization latex particles in solution meet, agglutination, produce certain turbidity, within the scope of the linear antibodies to exist the certain amount of turbidity height is proportional to the content of antigen, under 546 nm wavelength, by measuring the turbidity of compared with same processing calibration is tasted, can calculate the Lp-PLA2 level in the sample

Components:
Composition Initial concentration of solutions

Reagent 1:
Disodium hydrogen phosphate dodecahydrate 0.9 g/L
Sodium dihydrogen phosphate dihydrate 6.5 g/L
PEG 6000 20 g/L

Reagent 2:
Latex particle suspension of mouse anti human Lp-PLA2 antibody 50mL/L

Calibrator :
Tris 6.05g/L
BSA50g/L
Trehalose 20g/L
Lp-PLA2 Appropriate amount

Storage and stability:
Lp-PLA2 Reagents are stored at 2-8°C. The reagents and are stable when stored as instructed until the expiration date on the label.

Lp-PLA2 Calibrators:

High Q Lp-PLA2 Calibrators are available as ready to use liquid stable 5 Level Calibrators and are stable till the expiry date mentioned on the labels when properly stored at 2-8°C

Lp-PLA2 Controls: (Optional)

High Q Lp-PLA2 Controls are available as ready to use liquid stable 2 Level Controls and are stable till the expiry date mentioned on the labels when properly stored at 2-8°C

Specimen:
Fresh Serum.
The sample should be tested for Lp-PLA2 on the same day blood collection. Lp-PLA2 can be stable for 7 days at 2-8°C and stable for 3 months at -20°C when frozen and freeze thaw cycles are avoided

Assay Procedure:
System Parameters:

Calibration Method	**Multi Point -Linear- Spline**
Reaction Type (Mode)	Fixed Time /Two Point
Reaction Direction	Increasing
Wave Length	546 nm
Flow Cell Temp.	37°C
Delay Time	10 Seconds
Measuring Time	240 Seconds
Blank	Distilled Water Blank
Reagent Volume	320 µl (R1) + 80 µl (R2)
Sample Volume)	10 µl
Calibrator Concentrations	(On the Vials Lot Specific)
Linearity	800 ng/mL

Procedure

Reagent	**Calibrator**	**Sample/Control**
Lp-PLA2 R1	**320 µl**	**320 µl**
Calibrator(1,2,3,4,5)	**10 µl**	**----**
Sample	**—**	**10 µl**
Lp-PLA2 R2	**80 µl**	**80 µl**

1) Read absorbance A1 after 10 Seconds. (Delay)
2) Incubate and Read the absorbance A2 after 240 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-PLA2 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-PLA2 or plotting the values of ΔA=A2–A1 obtained for every concentration level of the calibrator against the Lp-PLA2 concentration and interpolating the individual ΔA=A2–A1 of every sample in the calibration curve.

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Calculations with Calibrators/ Calibration Curve/ Result Interpretation:

Calculation:

The concentration of Lp-PLA2 in unknown samples is derived from a calibration curve using an appropriate mathematical models such as Multi Point / Linear/Spline. The calibration curve is obtained with 5 calibrators at different levels. Stability of calibration: 4 weeks

Reference range:

Serum :

Desirable : Less than 175 ng/mL.

Moderate Risk : 175 to 200 ng/mL

(At this stage other cardiac risk markers like Apo-A1, Apo-B, Apo-B/Apo-A1 Ratio, Lipoprotein(a), hS-CRP should be evaluated.

High Risk : More than 200 ng/mL

(At this stage patient should be advised for 2D ECHO and simultaneously for the assessment of risk for both coronary heart disease and any possibility of Myocardial Ischemia because of rupture prone atherosclerotic plaque.)

The above classification is only the indicator but the final diagnosis should be made on the other clinical findings

The test results will be affected by age, sex, weight and etc. It is recommended that each laboratory should establish its own reference range

Linearity : 10-800 ng/mL

Limitations of testing method

1. The test results only reflect the sampling state at that time, and clinicians need to combine clinical and other test indicators to judge;
2. If the concentration of interfering substances in the sample satisfies the following requirements, the test results will not be affected:

Ascorbic acid ≤ 0.5g/L;
Bilirubin ≤ 0.5g/L;
Hemoglobin ≤ 5.0g/L;
Triglyceride ≤ 10g / L.

3.LOD ≤ 10 ng/mL
4.Precision: CV ≤ 8%; inter-batch deviation: <10%;
5.Accuracy: The measured value shall be fallen within the range of quality control target value.

Method Comparison:

A comparison of High-Q Lp-PLA2 (y) with an activity test (x) using 97 samples gave following results: y = 0.909 x – 4.28 U/L; r = 0.999

Literature

1. Ridker, P.M.; MacFadyen, J.G.; Wolfert R.L.; Koenig W. Relationship of lipoprotein-associated phospho-lipase A2 mass and activity with incident vascular events among primary prevention patients allocated to placebo or to statin therapy: An analysis from the JUPITER trial. Clin Chem 2012; 58(5):877–886.

2. Münzel, T.; Gori, T. Lipoprotein-associated phospholipase A2, a marker of vascular inflammation and systemic vulnerability. Eur Hear J 2009; 30:2829–2831.

3. Madjid, M.; Ali, M.; Willerson, J.T. Lipoprotein-associated phospholipase A2 as a novel risk marker for cardiovascular disease. Tex Heart Inst J 2010; 37(1): 25–39.

Ordering Information

Ref./Cat. No.:	Pack Size	Presentation
P - Lp-PLA2-25	25 ml	Liquid Stable two reagents with Calibrator

Product Features

- **Liquid Stable Two Reagents**
- **Two step Fixed Time Assay**
- **5 Level Calibrators provided**
- **Linearity: 800 ng/mL**
- **Measuring Wavelength 546 nm**
- **Serum is the preferred specimen**
- **Available as multipurpose reagents and dedicated system packs**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic medical device		Keep away from sunlight
	Do not freeze		This way up
	Use-by date		Do not use if package is damaged
	Keep dry	LOT	Batch Code
	Consult instructions for use	R	Reagent
eIFU Indicator	Consult electronic instructions for use	CAL	Calibrator Material
REF	Catalogue number		
	Caution		

eIFU Indicator

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Manufactured in India by :
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