PATHOZYME DIAGNOSTICS

LIQVIPATH D-LDL CHOLESTEROL

[(Direct Method) / R1 & R2]
CAT NO.: LDL

Reagent for quantitative estimation of LDL-Cholesterol in Serum or Plasma.

DIAGNOSTIC SIGNIFICANCE:

Low-density lipoproteins (LDL) are synthesized in the liver by the action of various Lipolytic enzymes on triglycerides rich Very Low Density Lipoproteins (VLDLs). Specific LDL reactors exist to facilitate the elimination of LDL from plasma by liver parenchymal cells. It has been shown that most of the cholesterol stored in atherosclerotic plaques originates from LDL. For this reason, the LDL Cholesterol concentration is considered to be the most important clinical predictor, of all single parameter, with respect to atherosclerosis.
Accurate measurement of LDL-C is of vital importance in therapies, which focus on lipid reduction to prevent atherosclerosis or reduce its progress and to avoid plaque rupture.

PRINCIPLE:

LDL-L reagent is produced by using a combination of detergents and specific compounds which specifically bind HDL, VLDL, and chylomicron (CM) but not LDL. The combination protects HDL, VLDL and CM from the reaction by cholesterol esterase and cholesterol oxidase. Consequently LDL-cholesterol is selectively exposed to react with both enzymes.

LDL Cholesterol Esters $\xrightarrow{CE}$ Cholesterol + fatty acids

Cholesterol + O_2 $\xrightarrow{CO}$ Cholesterol-4-en-3-One + H_2O_2

$2H_2O_2$ + 4AAP+ Phenolic compd. $\xrightarrow{POD}$ Quinoneimine dye + $4H_2O$

SPECIMEN COLLECTION:

On empty stomach Serum and heparinized plasma are acceptable. EDTA plasma is acceptable, but causes decreased results. Do not freeze the samples. If any sample show precipitation, centrifuge before using.

KIT PRESENTATION:

Pack Size	1 X 20 ml	1 X 40 ml	1 X 80 ml
R1-LDL Cholesterol	1 X 15 ml	1 X 30 ml	1 X 60 ml
R2-LDL Cholesterol	1 X 5 ml	1 X 10 ml	1 X 20 ml
LDL- C Calibrator	1 No.	1 No.	1 No.

PREPARATION OF WORKING REAGENT:

R1-LDL Cholesterol & R2-LDL Cholesterol **Ready To Use**.

HDL CALIBRATOR PREPARATION & STABILITY:

For reconstitution refer the Calibrator vial label. After reconstitution Calibrator stable for 7 days at 2-8^{0}C.

REAGENT STORAGE & STABILITY:

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

NOTE:

A special surfactant, Lipid Clearing Factor (L.C.F.) is added to the Reagent to solubilize the lipemic sera (causing turbidity or opalescence) which adds to the accuracy of results.

ASSAY PARAMETERS:

Reaction	**: End point**	**Sample Volume**	**: 6 µl**
Wavelength 1	**: 620 nm**	**R1 + R2 Volume**	**: 600+200 µl**
Wavelength 2	**: 700 nm (Optional)**	**Calibrator Conc.**	**: As on vial**
Zero Setting	**: Reagent Blank**	**Linearity**	**: 1000 mg/dl**
Incubation	**: 5+5 mins. at 37 ^{0}C**	**Unit**	**: mg/dl**

PROCEDURE:

Pipette into TT	Blank	Calibrator	Test
R1–LDL Cholesterol	600 µl	600 µl	600 µl
LDL–C Calibrator	--	6 µl	--
Sample (Test)	--	--	6 µl
Mix & incubate for 5 minutes at 37 ^{0}C			
R2–LDL Cholesterol	200 µl	200 µl	200 µl
Mix & Incubation for 5 minutes at 37 ^{0}C. Read Abs of Test (T) and Calibrator(C) against Reagent Blank at 620 nm.			

CALCULATION:

Desirable	< 130 mg/dl
Borderline High Risk for CHD	130 – 159 mg/dl
High Risk for CHD	> 160 mg/dl

LDL-C (mg/dl) = Abs T ÷ Abs C X Conc. of Calibrator

NORMAL VALUES:

Each laboratory should establish its own reference range.

LINEARITY:

This procedure is linear up to 1000 mg/dl.

REFERENCES:

1. National Institute of Health Consensus Development Conference Statement: Triglycerides, High Density Lipoprotein, and coronary heart disease. Washington D.C. Feb 26-28, 1992.
2. Second Report of the Expert Panel on Detection, Evaluation, and Treatment of high Blood Cholesterol in Adults (Adult Treatment Panel II). NH Publication No. 93-3096, September 1993.

IFU No.: 033/00 | *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