PATHOZYME DIAGNOSTICS

LIQVIPATH D-HDL CHOLESTEROL

[(Direct Method) / R1 & R2]

CAT NO.: HDL

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

DIAGNOSTIC SIGNIFICANCE:

High- Density Lipoproteins (HDL) are one of the major classes of plasma lipoproteins. They are composed of a number of heterogeneous particles, including cholesterol and vary with respect to size and content of lipid and apolipoprotein. HDL serves to remove cholesterol from the peripheral cells of the liver, where the cholesterol is converted to bile acids and excreted into the intestine. An inverse relationship between HDL – Cholesterol (HDL-C) levels in serum and the incidence/prevalence of Coronary Heart Disease (CHD) has been demonstrated in a number of epidemiological studies. The importance of HDL-C as a risk factor for CHD is now recognized. An accurate measurement of HDL-C is of vital importance when assessing patient risk from CHD.

PRINCIPLE:

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

HDL 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 - HDL Cholesterol	1 X 15 ml	1 X 30 ml	1 X 60 ml
R2 - HDL Cholesterol	1 X 5 ml	1 X 10 ml	1 X 20 ml
HDL- C Calibrator	1 No.	1 No.	1 No.

PREPARATION OF WORKING REAGENT:

R1-HDL Cholesterol & R2-HDL 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 solubilise 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**	**: 250 mg/dl**
Incubation	**: 5+5 mins. at 37 ^{0}C**	**Unit**	**: mg/dl**

PROCEDURE:

Pipette into TT	Blank	Calibrator	Test
R1 - HDL Cholesterol	600 µl	600 µl	600 µl
HDL–C Calibrator	--	6 µl	--
Sample (Test)	--	--	6 µl
Mix & Incubate for 5 minutes at 37 ^{0}C			
R2 – HDL 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:

Male: 35 - 80 mg/dl	**Female**: 42 - 88 mg/dl

HDL-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 250 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.

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

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