HDL Cholesterol (PPT) Test Kit

REF	Pack Size	Reagent 1	Reagent 2 (Std)
PPTLMS01	2×25 ml	2×25 ml	1×2 ml

INTENDED USE

HDL cholesterol (PPT)kit is use to quantitative estimation of HDL Cholesterol in Human serum or plasma

CLINICAL SIGNIFICANCE

HDL particles serve to transport in the blood stream. HDL is known as "good cholesterol" because high levels are thought to lower the risk of heart disease and coronary artery disease. A low HDL cholesterol level is considered a greater heart disease risk. Clinical diagnosis should not be made on a single test result. It should integrate clinical and other laboratory data.

METHOD – Precipitant

TEST PRINCIPLE

Chylomicrons, LDL and VLDL are precipitated from serum by phosphotungustate in presence of magnesium ion. The HDL cholesterol remains dissolved in the supernatant and is estimated by Cholesterol SR.

$$\text{Serum/plasma} \xrightarrow[Mg^{2+}]{\text{Phosphotungustate}} \text{HDL (supernatant)} + \text{LDL, VLDL, Chylomicrones (precipitate)}$$

KIT CONTENTS/COMPONENTS

Reagent 1: HDL PPT Reagent & Reagent 2: Standard 200 mg/dl

MATERIAL REQUIRED BUT NOT PROVIDED

Cholesterol kit, Test tubes, Micropipette with tips, Analyzer, controls, Incubation chamber.

SAFETY PRECAUTIONS AND WARNINGS

1.For in-vitro diagnostics use only.
2.Do not pipette by mouth. Avoid contact with skin and eyes. If spilt thoroughly wash affected area with water.
3.Do not use the reagent after the expiration date printed on the kit.
4.HDL / LDL /CAL; components from human origin have been tested and found to be negative for the presence of HBsAg, HCV and antibody to HIV 1&2. However, handle consciously as potentially infectious.

REAGENT PREPARATION, STORAGE AND STABILITY

Reagents 1 and 2 are ready to use & are stable up to expiry date if stored at 2 – 8°C.

REAGENT DETERIORATION

Do not use reagents after the expiration date printed on the reagent label. Avoid thawing and freezing of aliquoted calibrator and lipid control.

SPECIMEN

Serum or Heparinized / EDTA plasma can be used. HDL-Cholesterol in the serum is stable for 24 hrs. when stored at 2-8° C and 30 days when stored at -20 °C.

PROGRAM

Reaction Mode	End point
Wavelength	546 nm (530 – 570 nm)
Light Path	10 mm
Blanking	Reagent Blank
Reagent Volume	1000 µl
Standard Volume	10 µl
Sample Volume	10 µl
Incubation	10 min. at 37°C.
Standard Concentration	200 mg/dl
Linearity	200 mg/dl

PROCEDURE

Addition Sequence	Sample
Sample	500µl
Reagent	500µl

Take 500 µl of Sample and 500 µl of Reagent in a glass tube and mix well, leave for 10 min. at 37°C and then centrifuge for 10 min. at 4000 rpm. After centrifugation separate supernatant solution and use for determination of HDL Cholesterol by using Cholesterol SR reagent.

Test	Blank	Standard	Supernatant
Reagent	1000 µl	1000 µl	1000 µl
Standard	-----	10 µl	-----
Sample	-----	------	10 µl

Mix & incubate for 10 min. at 37°C. Read absorbance of sample and absorbance of standard against reagent blank.

CALCULATION

Concentration (C) of HDL Cholesterol in the sample

$$C = \frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \times 200 \times 2 \text{ mg/dl}$$

Calculation of LDL cholesterol in sample

$$\text{LDL} = \text{Total Cholesterol} - \frac{\text{Triglycerides}}{5} - \text{HDL}$$

NORMAL VALUES

Male: 35 – 55 mg/dl
Female: 35 – 65 mg/dl

LIMITATIONS

If the value exceeds 200mg/dl, dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

QUALITY CONTROL AND CALIBRATION

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for HDL Cholesterol. We recommended to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

WASTE DISPOSAL

This Product is made to be used in professional laboratories.

HIGHLIGHTS

1.Bilirubin & ascorbic acid at higher concentration will interfere with the functionality of reagent. High concentration of Triglycerides interferes with the assay hence in such case sample should be diluted with saline solution prior to precipitation and assayed result should be multiplied with dilution factor.
2.Storage condition mentioned on the kit is to be used.
3.Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
4.Before testing bring the reagents to the RT.
5.Avoid reagents contamination.
6.Every time use new pipette-tips for pipetting out the reagents.
7.These Reagent kits meant for laboratory/professional use only, not for Drug use.

REFERENCE

Burtis, C.A., Ashwood, E.R., editors. Tietz textbook of clinical chemistry. 2nd ed. Philadelphia W.B Saunders company,1994, p.1028-1029.
Lords Data File.

REF	Catalog No.	Σ	Contain Sufficient for test
LOT	Batch No.		Instruction for use
	Manufacturing Date	IVD	*In-vitro* Diagnostics
	Expiry Date		Storage temperature
	Manufacturer		

IFU/PPT/01 Rev.: 01; Rev Dated.: 22/07/2024

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