

INTENDED USE : This reagent kit is intended for "in vitro" quantitative determination of High - Density Lipoprotein Cholesterol (HDL-C) in serum & plasma.

CLINICAL SIGNIFICANCE : The 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 risk. Clinical diagnosis should not be made on a single test result; it should integrate with clinical and other laboratory data.

PRINCIPLE : Direct determination of serum HDL (High - Density Lipoprotein Cholesterol) levels without need for any pre-treatment of centrifugation of the sample. The method depends on the property of a detergent which solubilizes only the HDL so that HDL cholesterol is released to react with the Cholesterol esterase, Cholesterol oxides and chromogenes to give colour. The non-HDL lipoprotein LDL, VLDL and chylomicrons are inhibited from reacting with the enzymes due to absorption of the detergents on their surfaces. The intensity of the colour form proportional to the concentration of HDL Cholesterol in the sample.

REAGENT COMPOSITION :

Reagent 1 : Buffer Reagent

Reagent 2 : Substrate Reagent

HDL-C Calibrator : Concentration Printed on the Vial.

SAMPLES : Serum or heparinized plasma, free of hemolysis, removed from the blood clot as soon as possible. Anticoagulants containing citrate should not be used.

WORKING REAGENT PREPARATION & STABILITY : Reagent 1 & Reagent 2 are Ready to use & are stable up to the expiry date stated on the label.

HDL-C Calibrator : Dissolve with distilled water (Qty Printed on the vial). Cap and mix gently to dissolve contents. Reconstituted calibrator is stable for 7 days at 2°C to 8°C or 21 days at -20°C.

ASSAY PROCEDURE :

	Blank	Calibrator	Blank
Reagent 1	750 µl	750 µl	750 µl
Calibrator	-	10 µl	-
Sample	-	-	10 µl

Mix and incubate for 5 Minutes at 37°C and then add

Reagent 2	250 µl	250 µl	250 µl
-----------	--------	--------	--------

Mix and read the optical density (A) after 5 minutes incubation at 37°C.

CALCULATION :

$$\text{HDL-C (mg/dl)} = \frac{\text{OD of Sample}}{\text{OD of Calibrator}} \times \text{Conc. of Calibrator}$$

GENERAL SYSTEM PARAMETERS :

Reaction Type	End Point (Two Step)
Wavelength	546 nm
Light Path	1cm
Reaction Temperature	37°C
Blank / Zero Setting	Reagent
Reagent Volume	1000 µl (750 µl + 250 µl)
Sample Volume	10 µl
Incubation Time	10 Min.
Calibrator Concentration	Printed on vial
Low Normal at 37°C	35 mg/dl
High Normal at 37°C	88 mg/dl
Linearity	200 mg/dl

LINEARITY : Reagent is linear upto 200 mg/dl.

Dilute the sample appropriately and re-assay if HDL-C Concentration exceeds 200 mg/dl.

REFERENCE NORMAL VALUE :

Adult male : 35 - 79.5 mg/dl

Adult female : 42 - 88 mg/dl

It is recommended that each laboratory should assign its own normal range.

QUALITY CONTROL : For accuracy it is necessary to run known controls with every assay.

SENSITIVITY / LIMIT OF DETECTION : The Lower Limit of detection is 1.0 mg/dl.

LIMITATION & PRECAUTIONS:

- Storage conditions as mentioned on the kit to be adhered.
- Do not freeze or expose the reagent to high temperature as it may affect the performance of the kit.
- Before the assay bring all the reagents to room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust or debris.

BIBLIOGRAPHY :

- 1) Natio H K Cholesterol Kaplan A et al. Clin. Chem. The C. V. Mosby Co. St Louis. Toronto. Princeton 1984; 1207-1213 and 437.
- 2) US National Cholesterol Education Program of the National Institutes of Health.
- 3) Young DS. Effects of Drugs on Clinical Lab. Tests 4th ed AACC Press, 1995.
- 4) Young DS. Effects of diseases on Clinical Lab. Tests 4th ed AACC 2001.
- 5) Burlis A et al. Tietz Textbook of clinical Chemistry, 3rd ed AACC 1999.
- 6) Tietz N. W. et al, Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

Mfd. In India By:

PRECILAB REAGENTS & CHEMICALS PVT. LTD.

A / F-6 & F-8, Udyog Bhawan - 2, Plot K - 3, MIDC, Ambarnath (E), Thane, Maharashtra - 421506, INDIA.