HDL-CHOLESTEROL
DIRECT ENZYMATIC CHOLORIMETRIC

INTENDED USE:

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

PRINCPLE:

Direct determination of serum HDL (high-density lipoprotein cholesterol) levels without the need for any pre-tr atment or Centrifugation of the sample .
The method depends on the properties of a detergent which solubillizes only the HDL so that HDL-c is released to react with the cholesterol esterase, cholesterol oxidase and chromogens 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 color formed is proportional to the HDL concentration 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 and 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° to 8°C or 21 days at -20°.

GENERAL SYSTEM PARAMETERS:

Reaction type	Endpoint
Wave lenght	546 nm
Light Path	1 Cm
Reaction Temperature	37°C
Blank / Zero Setting	Reagent
Reagent volume	1 ml
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

ASSAY PROCEDURE:

	Blank	Calibrator	Sample
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 10 minutes incubation at 37°C.

CALCUTION:

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

LINEARITY:

Reagent is Linear up to 200 mg/dl.
Dilute the sample appropriately and re-assay if HDL-C Concentration exceeds 200 mg/l.

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.

QUALTYCONTROL:

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

LIMITATION & PRECAUTIONS:

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

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