HDL CHOLESTEROL KIT (DIRECT SINGLE REAGENT)

Homogeneous PVS / PEGME Selectivity Method

Product Code: 10031 (Previously mislabeled as Ferritin)	**Reaction Type:** End Point Method
Pack Size: 40 ml	**Matrix Target:** Human Serum & Fasting Plasma
Storage Temp: 2–8°C (Ready to Use)	**Wavelength:** 620 nm (Alternative to 560 nm)

INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This liquid diagnostic reagent system is configured for the direct, single-reagent quantitative in vitro determination of High-Density Lipoprotein (HDL) Cholesterol concentration in human serum or plasma by a direct homogeneous method.

Clinical Significance: Plasma lipoproteins transport cholesterol and triglycerides in the bloodstream. They are structurally classified into Chylomicrons, VLDL, LDL, and HDL. HDL plays a vital role in transporting cholesterol from peripheral tissues back to the liver (reverse cholesterol transport), serving as an inverse protective marker against coronary artery disease (CAD) risks. Routine direct measurement ensures consistent therapeutic tracking.

METHOD PRINCIPLE

The assay utilizes a modified homogeneous methodology combining polyvinyl sulfonic acid (PVS) and polyethylene-glycol-methyl ether (PEGME) alongside selective detergents. This matrix renders LDL, VLDL, and chylomicrons (CM) structurally inaccessible to Cholesterol Oxidase (CHOD) and Cholesterol Esterase (CHER). Only HDL fractions specifically react, yielding hydrogen peroxide which is detected colorimetrically via peroxidase activity:

$$\text{HDL Cholesterol Esters} + H_2O \xrightarrow{\text{PVS/PEGME Selectivity}} \xrightarrow{\text{CE/CHOD}} H_2O_2 + \text{Cholestenone}$$

$$H_2O_2 + \text{Chromogen Mixture} \xrightarrow{\text{POD}} \text{Blue Quinone Dye complex} + H_2O$$

The intensity of the final color shift is quantified photometers-side at 620 nm and is directly proportional to the HDL concentration.

STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

Reagent / Component Line	Blank (B)	Standard (S)	Test (T)
R1 - HDL Direct Reagent	1000 µl	1000 µl	1000 µl

Reagent / Component Line	Blank (B)	Standard (S)	Test (T)
HDL Liquid Calibrator (Lot Specific Concentration)	—	10 µl	—
Patient Specimen (12–14 hr Fasting Matrix)	—	—	10 µl

Operational Directive: Mix well and incubate for exactly 5 minutes at 37°C. Read the absolute optical absorbance of the Calibrator (C) and Test (T) against the Reagent Blank (B) at 620 nm.

STEP 2: CALCULATIONS & DATA TRACKING

> HDL Concentration (mg/dL) = ***[Abs. of Test / Abs. of Std.] × HDL Calibrator Concentration***

TECHNICAL PARAMETERS & CLINICAL SUPPORT MATRIX

Universal Safeguards	Professional in vitro diagnostic use only. Reagents are ready to use and stable up to the printed expiration dates when protected at 2–8°C. Utilize separate micro pipette tips to guarantee zero sample cross-contamination paths.
Expected Range	HDL Cholesterol Reference Interval: 35 to 80 mg/dL. Each individual laboratory must independent-side establish its own specific reference range.
Analytical Linearity	Direct method is linear up to 250 mg/dL. Samples exceeding this parameter must be diluted with standard saline and re-assayed, multiplying the output by the dilution factor.

Manufactured by: M/s. SAWIN BIOMEDICALS PVT. LTD.
Plot No: M82/2, Medical Devices Park, Sultanpur, Ameenpur Mandal, Sangareddy Dist-502 319, Hyderabad, Telangana, INDIA.
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