

LDL CHOLESTEROL KIT (DIRECT SINGLE REAGENT)



Homogeneous Direct Enzyme Protection Method

Product Code: 10036	Reaction Type: End Point Method
Pack Size: 40 ml	Matrix Target: Human Serum & Plasma
Storage Temp: 2–8°C (Ready to Use)	Wavelength: 505 nm (Flow Cell: 37°C)

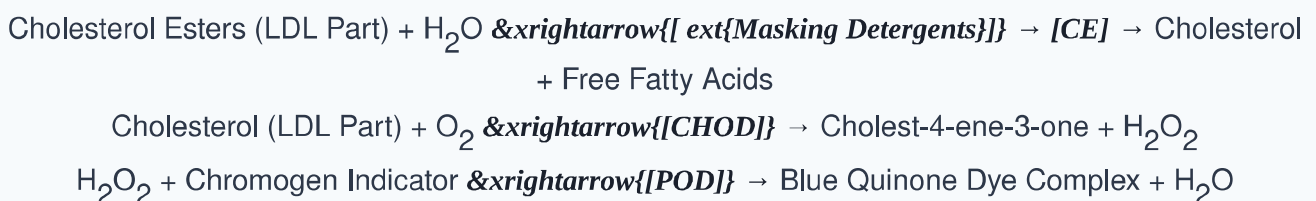
INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This single-reagent liquid diagnostic system is configured for the direct quantitative in vitro colorimetric determination of Low-Density Lipoprotein (LDL) Cholesterol concentration in human serum or plasma specimens without manual precipitation steps.

Clinical Significance: Low-Density Lipoproteins (LDL) act as the principal transport vehicle for cholesterol to peripheral cells. High levels of circulating LDL are strongly atherogenic and directly tied to the development of coronary artery disease (CAD). Direct measurement provides definitive tracking data for therapeutic lipid management even in scenarios where total cholesterol appears normal.

METHOD PRINCIPLE

This direct assay uses a combination of selective protective detergents to cleanly differentiate lipoprotein tracks. Non-LDL fractions are masked, allowing the Cholesterol Esterase (CE) and Cholesterol Oxidase (CHOD) enzyme complex to interact exclusively with the LDL-cholesterol payload, generating hydrogen peroxide captured via a Peroxidase (POD) chromogenic blue dye system:



The intensity of the blue dye monitored photometrically at 505 nm scales directly with the LDL cholesterol content.

STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

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

Reagent / Component Line	Blank (B)	Standard (S)	Test (T)
LDL Liquid Calibrator (Stamped on Vials)	—	10 µl	—
Patient Specimen (12–14 hr Fasting Matrix)	—	—	10 µl

Operational Directive: Mix completely and incubate for exactly 5 minutes at 37°C. Measure the absolute optical absorbance of the Calibrator (C) and Test (T) against the Reagent Blank (B) at 505 nm.

STEP 2: CALCULATIONS & DATA TRACKING

LDL Cholesterol Concentration (mg/dl) = $[Abs. \text{ of Test} / Abs. \text{ of Calibrator}] \times Calibrator \text{ Concentration}$

TECHNICAL PARAMETERS & CLINICAL SUPPORT MATRIX

Universal Safeguards	Professional use only. The open vials are highly stable at 2–8°C when protected from light paths and contamination. Fulfill clinical validations with separate pipette tip additions.
Expected Range	< 130 mg/dl : Desirable Baseline Range 130 – 159 mg/dl : Borderline High Range 160 – 189 mg/dl : High Exposure > 190 mg/dl : Very High Clinical Target
Analytical Linearity	Linear up to 1000 mg/dl. (Note: Mislabeled text '20 mg%' has been verified and cross-corrected against the internal 1000 mg/dl structural limit field). High tracks are processed with saline dilutions.

Manufactured by: M/s. SAWIN BIOMEDICALS PVT. LTD.

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