LDL CHOLESTEROL - DIRECT

METHOD – DIRECT HOMOGENEOUS
PRODUCT CODE – LL02

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of LDL Cholesterol in serum / plasma using Direct Homogenous method.

SUMMARY AND PRINCIPLE

Low LDL Cholesterol levels are associated with coronary heart disease. LDL partilcles regulate the cholesterol levels by uptaking and transport from liver to peripheral tissues. The reagent is for use on automated clinical chemistry analyser.

Cholesterol Esters (LDL part) $\xrightarrow{CEH}$ Cholesterol + Fatty Acids

Cholesterol + O_2 (LDL part) $\xrightarrow{CHOD}$ H_2O_2 + Cholestenone

H_2O_2 + Chromogen $\xrightarrow{POD}$ Red Dye + H_2O

KIT COMPONENTS

Reagent 1: LDL Direct Reagent 1
Reagent 2: LDL Direct Reagent 2
Reagent 3: LDL Calibrator

REAGENT PREPARATION, STORAGE & STABILITY

Reagent R1 and R2 are ready to use liquid reagent. The reagent kit should be stored at 2-8 °C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDELING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.300 O.D. against D/W at 546 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	LDL Chol
Reaction Type	End Point
Primary Wavelength	546 nm
Secondary Wavelength	630 nm
Flow Cell Temp.	37 °C
Blank setting	D.W.
Blank abs. limit	< 0.300
Linearity	400 mg/dL

Reagent 1 Volume	600 µl
Sample Volume	5 µl
1st Incubation Time	5 mins
1st Incubation Temperature	37 °C
Reagent 2 Volume	200 µl
2nd Incubation Time	5 mins
2nd Incubation Temperature	37 °C
Calibrator Conc.	On Vial

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Fasting blood is preferred for LDL Cholesterol assay. LDL Cholesterol in the serum is stable for 7 days when stored at 2-8 °C.

COMPONENTS OF REAGENT

Component	Concentration
Goods Buffer, pH 7.0	20 mmol/l
Cholesterol Oxidase	> 6000 IU/L
Cholesterol Esterase	>300 IU/L
Peroxidase	>15000 IU/L
Chromogen	3 mmol/l
Stabilizers, inactive ingredients and surface-active agents.	-

ASSAY PROCEDURE

	Calibrator	Test
Reagent 1	600 µl	600 µl
Calibrator	5 µl	
Sample		5 µl
1st Incubation: Mix the reagent and sample/calibrator in the above-mentioned ratio and incubate for 5 mins at 37 °C.		
Reagent 2	200 µl	200 µl
2nd Incubation: Add Reagent 2 & incubate for 5 mins at 37 °C.		
Aspirate the reaction mixture in the flow cell and measure abs.		
The final colour is stable for 2 hours if not exposed to light.		

CALCULATION

$$\text{LDL Cholesterol (mg/dL)} = \frac{\text{Abs. of sample x Conc. On vial label}}{\text{Abs. of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

LDL Cholesterol: <100 mg/dL. (>160 mg/dL indicates cardiac risk)

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 3.5 - 400 mg/dL. If the LDL Cholesterol value exceeds linearity limit (above 400 mg/dL), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct LDL Cholesterol value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL, Ascorbic Acid upto 4 mg/dL and Haemoglobin upto 500 mg/dL.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (mg/dL)	SD (mg/dL)	CV %	Mean (mg/dL)	SD (mg/dL)	CV %
Low Value Serum	62.8	0.66	1.0	57.45	0.93	1.6
High Value Serum	140.42	0.81	0.6	133.0	0.87	0.7

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

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 LDL Cholesterol. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

LDL reagents include ingredients which may affect magnesium assays; therefore, it is recommended to wash the cuvettes thoroughly after using the reagents. Recalibrate the instrument (with freshly reconstituted calibrator) if control sera values show inaccurate results.

BIBLIOGRAPHY

1. Rifai N, Warnick GR, McNamara JR, Belcher JD, Grinstead GF,Frantz Jr. Measurement of low density lipoprotein cholesterol in serum :a status report Clin chem 1992;38:150-160.

2. Bachoric P. Measurement of Low-density lipoprotein, 245 263in: Handbook of lipoprotein Testing (eds, Rifai, Warnick and Dominiczak), 2nd edition. AACC press 2000.

3. National cholesterol education programme Expert panel on Detection, Evaluation, and treatment of High blood cholesterol in Adults (Adult treatment panel II). NIH Publication No 93-3095, 1995.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485 : 2016
GMP
CE