CHOLESTEROL

METHOD – CHOD-PAP
PRODUCT CODE – LC04

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Cholesterol in serum / plasma using CHOD-PAP method.

SUMMARY AND PRINCIPLE

Cholesterol levels are important in the diagnosis and classification of hypolipoproteinaemias. Measurement of serum cholesterol levels can serve as an indicator of liver function, biliary function, intestinal absorption, tendency towards coronary artery disease, thyroid function and adrenal disease. Cholesterol is a reagent set for determination of Total Cholesterol based on enzymatic method using Cholesterol Esterase, Cholesterol Oxidase and Peroxidase.

$$\text{Cholesterol esters} \xrightarrow{\text{CEH}} \text{Cholesterol + Fatty Acids}$$

$$\text{Cholesterol + } O_2 \xrightarrow{\text{CHOD}} H_2O_2 + \text{Cholestenone}$$

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

KIT COMPONENTS

Reagent 1: Cholesterol Reagent
Reagent 2: Cholesterol Standard (200 mg/dL)

REAGENT PREPARATION, STORAGE & STABILITY

Cholesterol is single ready to use reagent. No preparation of working solution is required prior to use. The 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	Cholesterol
Reaction Type	End Point
Wavelength	546 nm
Flow Cell Temp.	37 °C
Blank setting	Reagent
Blank abs. limit	< 0.300

Reagent Volume	1000 µl
Sample Volume	10 µl
Incubation Temperature	37 °C
Incubation Time	10 min.
Standard Conc.	200 mg/dL
Linearity	1000 mg/dL

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 Cholesterol assay. Cholesterol in the serum is stable for 7 days when stored at 2 -8 ^{0}C and 60 days if stored at -20 ^{0}C.

COMPONENTS OF REAGENT

Component	Concentration
Buffer, pH 7.5	100 mmol/l
Cholesterol Oxidase	>10 IU/L
Cholesterol Esterase	>135 IU/L
Peroxidase	>495 IU/L
Chromogen	0.5 mmol/l
Stabilizers and inactive ingredients.	-

ASSAY PROCEDURE

	Blank	Standard	Test
Reagent	1000 µl	1000 µl	1000 µl
Standard	NA	10 µl	NA
Sample	NA	NA	10 µl
Mix the reagent and sample/standard in the above-mentioned ratio.			
Incubate the assay mixture for 10 minutes at 37 °C.			
Aspirate reaction mixture into flow cell and measure the absorbance.			
The final colour is stable for 2 hours if not directly exposed to light.			

CALCULATION

$$\text{Total Cholesterol (mg/dL)} = \frac{\text{Abs. of sample x 200}}{\text{Abs. of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

Desirable Cholesterol - <200 mg/dL.
Borderline High Cholesterol - 200-239 mg/dL.
High Cholesterol - >240 mg/dL.

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 10 - 1000 mg/dL. If the Cholesterol value exceeds linearity limit (above 1000 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 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	104.4	1.26	1.2	106.0	0.94	0.9
High Value Serum	249.6	0.49	0.2	255.0	0.67	0.3

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

PRECAUTIONS

1. Discard the working reagent if its absorbance exceeds 0.300 at 546 nm against distilled water.
2. If Cholesterol value exceeds 1000 mg/dL then dilute the specimen suitably with normal saline & repeat the assay. In such case the results obtained should be multiplied by dilution factor to obtain the correct Cholesterol value.
3. The standard is a viscous solution. Use broad mouth pipette for accurate pipetting.

BIBLIOGRAPHY

1. Richmond W., Clin. Chem. 19, 1350 (1973).
2. Tarbutton P.N., Gunter C.R., Clin. Chem, 20,724 (1974).
3. Allain C.C. et al, Clin Chem. 20,470 (1974).
4. Young D.S. et. al, 21, D (1975).

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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