Total Cholesterol Test Kit

REF	Pack Size	Reagent 1	Reagent 2 (Std)
CHOLMS01	4×25 ml	4×25 ml	1×2 ml
CHOLMS02	4×50 ml	4×50 ml	1×2 ml
CHOLMS03	5×100 ml	5×100 ml	2×3 ml
CHOLMS04	2×25 ml	2×25 ml	1×2 ml

INTENDED USE
Cholesterol reagent is used for the quantitative estimation of cholesterol in human serum or plasma.

CLINICAL SIGNIFICANCE
Cholesterol is fat like substance that is found in all body cells. The liver makes all the cholesterol the body need to forms cell membranes and to make certain hormones. The determination of serum cholesterol is one of the important tools in the diagnosis and classification of lipemia. High blood cholesterol is one of the major risk factors for heart disease. Clinical diagnosis should not be made on a single test result: it should integrate clinical and other laboratory data.

METHOD
Enzymatic, CHOD–POD Method, End Point, Single reagent chemistry.

TEST PRINCIPLE
Cholesterol esterase hydrolyses cholesterol esters into cholesterol and fatty acids.

$$\text{Cholesterol ester} \xrightarrow{\text{CHOE}} \text{Cholesterol + Fatty acids}$$

$$\text{Cholesterol + } O_2 \xrightarrow{\text{CHOD}} H_2O_2\text{+Cholest-4-en-3one}$$

$$2H_2O_2\text{+ Antipyrine + Phenol} \longrightarrow \text{Red Quinonimine Dye}$$

KIT CONTENTS / COMPONENTS
Reagent 1 : Buffered Enzymes
Reagent 2 : Standard Cholesterol (200 mg/dl)
The reagent and standard are ready to use and are stable at 2 – 8°C up to the expiry date mentioned on the label.

MATERIAL REQUIRED BUT NOT PROVIDED
Laboratory instrumentation, spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi-automated, calibrated micropipettes, glass or high-quality polystyrene cuvettes, test tubes/rack, heating bath, controls, saline.

SAFETY PRECAUTIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not pipette by mouth. Avoid contact with skin and eyes. If spilt thoroughly wash affected area with water.
3.Do not use the reagent after the expiration date printed on the kit.

REAGENT PREPARATION, STORAGE AND STABILITY
The reagent is stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8℃, protected from light and contamination is avoided. Do not freeze the reagent.

REAGENT DETERIORATION
Discard the reagent if absorbance exceeds 0.300 against distilled water at 505 nm.

SPECIMEN
Use fresh unhemolysed serum. serum or plasma should be separated from the cell as soon as possible. Use heparine or EDTA as anticoagulant. Serum/plasma stable for 7 days at 2 - 8°c.

PROGRAM

Reaction mode	End point
Wavelength	505 nm(470-560nm)
Light path	10 mm
Blanking	Reagent blanking
Reagent volume	1000 µl
Standard volume	10 µl
Sample volume	10 µl
Incubation	10 min. at 37°C
Standard Concentration	200 mg/dl
Linearity	700 mg/dl

PROCEDURE

Test	Blank	Standard	Sample
Reagent	1000 µl	1000 µl	1000 µl
Standard	----	10 µl	----
Sample	----	----	10 µl

Mix well & incubate for 20 minutes at Room Temperature or for 10 minutes at 37°C. Read absorbance of sample and absorbance of standard against reagent blank.

CALCULATION
Concentration of Cholesterol (C) in the sample

$$C = \frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \times 200 \text{ mg/dl (Conc. Of std)}$$

NORMAL VALUES
Normal Cholesterol: < 200 mg/ dl

LIMITATIONS
If the value exceeds 700mg/dl dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

QUALITY CONTROL AND CALIBRATION
It is recommended to perform internal quality control with assayed normal and assayed abnormal, to confirm the validity of the test and assure the accuracy of patient result. Using the recommended calibrator or the Standard included, calibrate the assay.
1.When using a new reagent or lot
2.When QC values are out of range

WASTE DISPOSAL
This Product is made to be used in professional laboratories.

HIGHLIGHT
1.The Reagents are sensitive to light & higher temperature. Reagents may develop a slight pink coloration on ageing which does not interfere with the functionality of reagent.
2.If the volume of the reagent is not sufficient to fill the cuvette, double all the specified volumes.
3.Storage condition mentioned on the kit is to be used.
4.Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
5.Before testing bring the reagents to the RT.
6.Avoid reagents contamination.
7.Every time use new pipette-tips for pipetting out the reagents.
8.These Reagent kits meant for laboratory/professional use only, not for Drug use.

REFERENCE
Tietz N.W., ed. Clinical Guide to laboratory Tests, 3rd ed. Philadelphia, Pa: W.B. Saunders.
Lords Data File.

REF	Catalog No.	Σ	Contain Sufficient for test
LOT	Batch No.		Instruction for use
	Manufacturing Date	IVD	*In-vitro* Diagnostics
	Expiry Date		Storage temperature
	Manufacturer		

IFU/CHO/01Rev.: 03; Rev Dated.: 22/07/2024

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