Total Cholesterol Test Kit

REF	Pack Size	Reagent
CHOLMA01	5 x 20	1 x 20ml

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

MATERIAL REQUIRED BUT NOT PROVIDED
Fully Auto Biochemistry Analyzer: LM1015-200TPH.
Calibrator
Controls.

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°C, protected from light and contamination is avoided. Do not freeze the reagent.

ON - BOARD REAGENT STABILITY-
On board reagent stability is 15 days.

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.

APPLICATION For LM1015-200 TPH

Method	End point
Blank	Reagent blank
Primary filter	510
Secondary filter	No
R1 Volume	300
R1 Position	*
Incubation time (Sec)	560
R2 Volume	-
R2 Position	-
Incubation time (Sec)	-
Sample Volume	3
Read Time	40
Calibrator Concentration	As on vial label
Mix speed set	Middle
Unit	mg/dl
Decimal	2

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CALIBRATION
For calibration, it is recommended to use any multi calibrator.

CALCULATION
Calculations Fully automated systems automatically calculate the Total Cholesterol concentration of each sample.

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.

SAFETY PRECAUTIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not use the reagent after the expiration date printed on the kit.
3.Avoid reagents contamination.
4.These Reagent kits meant for laboratory/professional use only, not for Drug use.

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 multi calibrator, calibrate the assay.
1.When using a new reagent or lot
2.When QC values are out of range

PRECISION
Reproducibility was determined using quality control sera as shown below

	Intra run		Inter run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dl)	253.15	104.9	252.96	104.9
SD	1.65	1.48	1.50	1.48
CV (%)	0.01	0.01	0.01	0.01

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

REFERENCES
Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa: WB Saunders, 1995:22-24.
Lords Data File.

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

IFU/CHO/02 Rev.: 00; Rev Date.: 22/07/2024

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