

Cholesterol

(CHOD-POD: ENZYMATIC
PHOTOMETRIC METHOD)

In-vitro Diagnostic reagent/kit for quantitative determination of
Cholesterol in serum/plasma sample on Photometric System.

ORDER INFORMATION	
Cat no.	Kit Configuration
LG116-200	Reagent T1-100 ML
	Reagent T2- 5 ML
	Reagent D1- 100 ML
	Reagent D2- 5 ML
LG116-1000	Reagent T1-500 ML
	Reagent T2- 10 ML
	Reagent D1- 500 ML
	Reagent D2- 10 ML

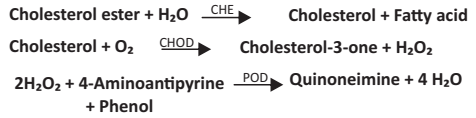
REAGENT	
Reagent : Enzyme solution	
Standard: Cholesterol 200 mg/dL.	

SUMMARY

Cholesterol is an integral part of cell membrane and a precursor for steroidal hormones and bile acids that are synthesized by cells and absorbed with food. Cholesterol is transported in blood via lipoproteins. There are different types of lipoproteins: High Density Lipoproteins (HDL), Low Density Lipoproteins (LDL), Very Low Density Lipoproteins (VLDL) and Chylomicrons. While LDL is involved in the cholesterol transport to the peripheral cells, HDL is responsible for the cholesterol uptake from the cells. The increase or decrease in value of these Lipoproteins results in increase or decrease in Cholesterol concentration in one place. This results in risk such as coronary heart disease.

PRINCIPLE

Cholesterol and its esters are released from lipoproteins by detergents. Cholesterol esterase hydrolyses the esters. In the subsequent oxidation by cholesterol oxidase, H₂O₂ is liberated. The colorimetric indicator is quinoneimine is generated from 4 aminoantipyrine and phenol by H₂O₂ under the catalytic action of peroxidase (Trinder's reaction).



STORAGE INSTRUCTIONS AND
REAGENT STABILITY

The reagent and standard is stable till the date of expiry, if stored at 2° - 8°C, protected from light and contamination is avoided. Do not freeze the reagents.
Note: Measurement is not influenced by occasionally occurring color changes.

COMPONENTS AND
CONCENTRATIONS

Reagent: Pipes Buffer pH 7.0 100 mmol/L, Phenol 1gm/L, Cholesterol esterase (CHE) ≥ 150 U/L, Cholesterol Oxidase ≥ 100 U/L, Peroxidase (POD) ≥ 500 U/L, 4-Aminoantipyrine 0.5 mmol/L
Standard: Cholesterol 200 mg/dL.

WASTE MANAGEMENT

Please refer to local legal requirements.

REAGENT PREPARATION & STORAGE

Reagents are ready to use and are stable till the expiry date when stored at recommended temperature and avoid contamination. Do not freeze the reagents!

MATERIALS REQUIRED
BUT NOT PROVIDED

NaCl solution 9 g/L.
General laboratory equipment

SPECIMEN

Serum, heparin plasma or EDTA plasma Stability:
1 months at 2° – 8 °C, 3 months at -20 °C
Only freeze once!
Discard contaminated specimens.

ASSAY PROCEDURE

Wavelength 505 (505 – 546) nm
Light path 10 mm
Temperature 37°C
Measurement Against reagent Blank

	Blank	Sample/Standard/Calibrator
Reagent	1000 µL	1000 µL
Sample	----	10 µL
Distilled water	----	----

Mix, incubate for 5 min. at 37°C. Read absorbance against thereagent blank.

CALCULATION

With Standard or Calibrator

Cholesterol (mg/dL) = $\frac{\Delta A \text{ Sample} \times \text{Conc. Of Std / Cal (mg/dL)}}{\Delta A \text{ Std. /Cal}}$

QUALITY CONTROL

For internal quality normal and abnornal controls should be assayed with each batch of samples.
Each laboratory should establish corrective action in case of deviations in control recovery.

- WARNINGS AND PRECAUTIONS
- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 - Wear suitable gloves and eye/face protection.
 - Always use safety pipettes to pull the reagents into a pipette.
 - Reagents may contain some non-reactive and preservative components. It is suggested to handle carefully, avoid direct contact with skin and do not swallow.
 - The reagents contain sodium azide (0.95g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
 - For professional use only!

PERFORMANCE CHARACTERISTICS
MEASURING RANGE

Measuring range is 5 to 1000 mg/dL. When values exceed 1000 mg/dL, the samples should be diluted 1+1 NaCl solution (9g/L) and the result multiplied by 2.

LINEARITY/LIMIT OF
MAXIMUM DETECTION

The maximum limit of detection of the assay is 1000 mg/dL.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection of the assay is 5 mg/dL.

SPECIFICITY/INTERFERENCES

No interference was observed by Ascorbic acid up to 5 mg/dL, Bilirubin up to 20 mg/dL, Triglycerides up to 2000mg/dL.

PRECISION			
Intra assay n=20	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	104.38	1.10	1.05
Sample 2	213.82	1.79	0.84
Sample 3	264.94	1.42	0.54
Inter assay n=20	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	107.04	0.98	0.91
Sample 2	224.35	1.80	0.80
Sample 3	267.97	1.52	0.57

METHOD COMPARISON

A comparison of Precision Biomed Cholesterol (y) with a commercially available test (x) using 15 samples gave following results:
y = 1.008x - 1.594; r² = 0.996.

REFERENCE RANGE	
	Cholesterol (mg/dL)
Desirable	< 200 mg/dL (5.2 mmol/L)
Borderline High Risk	200 - 240 mg/dL (5.2 – 6.2 mmol/L)
High Risk	> 240 mg/dL (> 6.2 mmol/L)

Note: It is recommended that each laboratory should establish its own reference range based on the patient population.

Labgene®

b i o t e c h

QUICK REFERENCE

Mode	Endpoint
Wavelength	505 (505 – 546) nm
Path length	10 mm
Standard conc.	200 mg/dL
Reagent volume	1000 µL
Sample volume	10 µL
Incubation time	5 min
Temperature	37°C
Blanking	Reagent blank
Normal range	< 200 mg/dL
Linearity	1000 mg/dL
Sensitivity	5 mg/dL

- LITERATURE
- Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: Saunders Company; 1999.p.809-61
 - Eur Heart J 1998: 19 1434-503.
 - Handbook of lipoprotein testing. Washington: ACC 114.
 - Handbook of lipoprotein testing. Washington: AACC 48.

INDEX OF SYMBOLS

	International Organization or Standardization		Keep out of Sunlight
	Manufacturer		For invitro diagnostic use only
	Expiry date		Read product insert before use.
	Lot (batch) number		Do not use if package is damaged
	Store between 2-8°C		Keep Away From Moisture
ART/IFU/PRC-116-01			

 Manufactured by:

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“Thanks for you”