



LIQUID CHOLESTEROL (CHOD/POD method)

IVD For in -vitro diagnostic use only

2°C  8°C
Store at 2-8°C 

INTENDED USE

For the measurement of cholesterol in human serum or plasma.

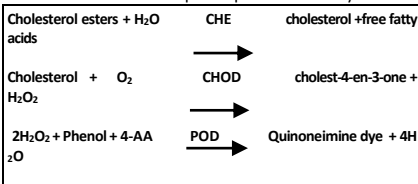
INTRODUCTION

Cholesterol is one of the lipids found in the blood stream. High level of cholesterol in blood-hypercholesterolemia - is a major risk factor of coronary heart disease, which may lead to heart attacks.

METHODOLOGY: CHOD/POD method.

PRINCIPLE OF THE METHOD

The enzyme cholesterol esterase is used to hydrolyze the cholesterol esters present in serum into free cholesterol and free fatty acids. The enzyme cholesterol oxidase, in the presence of oxygen, oxidizes cholesterol to cholest-4-en-3-one and hydrogen peroxide. Hydrogen peroxide oxidizes phenol and 4-aminoantipyrine to produce red color that can be measured spectrophotometrically.



The intensity of the color formed is proportional to the cholesterol concentration in serum.

REAGENTS COMPOSITION

R	PIPES PH 6.8	90mmol/L
	Phenol	26mmol/L
	4-Aminophenazone(4-AA)	0.4mmol/L
	Cholesterol esterase(CHE)	1000U/L
	Cholesterol oxidase(CHOD)	300U/L
	Peroxidase(POD)	650U/L
Cholesterol STD	Cholesterol aqueous primary standard 200mg/dl	

EQUIPMENTS NEEDED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 505 nm.
- Matched cuvettes 1.0cm light path
- General laboratory equipment.

PREPARATION

- Reagents and standards provided are ready to use.

STORAGE AND STABILITY

- All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminants during their use.
- Do not use reagents after the expiration date.
- SIGNS OF REAGENT DETERIORATION
 - Presence of particles and turbidity.
 - Blank absorbance against water at 505 nm ≥ 0.26

PRECAUTION

1. This reagent is for in vitro diagnostic and professional use.
2. Protective clothing should be worn when handling the reagents. Also, wash the area of contact with water immediately if contact occurs.
3. Do not pipette by mouth. Flash with water if contact occurs.
4. Specimens should be considered infectious and handled appropriately.
5. Do not use the reagents if damaged and discard the contents immediately.

6. Test materials and samples should be discarded in a biohazards container.
7. Wash hands and the test table top with water and soap once the testing is done.

COLLECTING AND HANDLING OF SPECIMENS

Use serum, or plasma preserved in EDTA.

Determination of lipid constituent in plasma or serum are normally done on blood drawn from patients fasting for 12 to 16 hours. Stability of the sample is 7 days at 2-8°C. Freezing at -20°C will keep samples stable for 3 months. Freezing at -60°C provides the longest stable storage and may allow for Reproducible results even after a year or more.

ASSAY PARAMETERS

Reaction	End point	Sample Vol.	0.01ml
Wavelength	505 nm	Reagent Vol.	1.0ml
Zero Settings	Reagent blank	Standard	200mg/dl
Incub. Temp.	37°C/R.T	linearity	Up to 600 mg/dl
Incub. Time	5 min/10 min		
Reac. Slope	increasing		
Units	mg/dl		

ASSAY PROCEDURE

1. Wavelength..... 505 nm (500-550)
2. Cuvette.....1cm.light path
3. Tempe.....37°C/25°C
4. Adjust the instrument to zero with distilled water.
5. Pipette into clean dry test tubes labeled as Blank (B), Standard(S), and Test (T):

	B	S	T
Reagent(ml)	1.0	1.0	1.0
Standard(μL)	-	10	-
Sample (μL)	-	-	10

6. Mix well and incubate at 37°C for 5min or at R.T. (25°C) for 10min.

- Measure the absorbance of the standard and test sample against blank.
- After incubation the color is stable for at least 60 min.

CALCULATIONS

Cholesterol (mg/dl) = $\frac{A}{A_{STD}} \times 200$ mg/dl (STD Conc.)

(A) STD

Conversion factor: mg/dL x 0.02586= mmol/L.

QUALITY CONTROL

To ensure adequate quality control, it is recommended that each run includes assayed normal and abnormal controls. If control values are found outside the defined range, check the instrument calibration, and reagent for problems.

REFERENCE VALUES

Serum or plasma:

Classification	Total cholesterol (mg/dl)
Desirable	<200
Borderline to high risk	200-239
High risk	≥ 240

These values are for guidance purposes, each laboratory should establish its own reference range, according to its own geographic area.

PERFORMANCE CHARACTERISTICS

Measuring range (Linearity):

The assay is linear between 10 mg/dl and 600 mg/dl. If the results obtained were greater than linearity limit, dilute the sample to half with NaCl 9g/L and multiply the result by 2.

Sensitivity:

1 mg/dl = 0.0016 (A)

Accuracy:

Results obtained using this reagent compared well with other commercial reagents.

Precision:

The results of the performance characteristics depend on the analyzer used.

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (mg/dl)	84.256	199.395	99.58	217.02
STD	1.46	6.46	1.12	6.21
C.V%	1.73%	3.2%	1.12%	2.86%

INTERFERENCES

No interferences were observed to hemoglobin up to 5 g/L and up to 10mg/dl. A list of drugs and other substances interfering with cholesterol determination has been reported.

NOTES

















- LCF (Lipid Clearing Factor) is integrated in the reagent that clears the turbidity caused by lipemic sample and thus avoids overestimation of Cholesterol.
- Calibration with the aqueous standard may cause a systematic error in Automatic procedures. In these cases, it is recommended to use a serum Calibrator.
- Use clean disposable pipette tips for its dispensation.

REFERENCES

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PPI1444A01
Rev A (02.09.2019)

	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry