Cholesterol Test Kit

CHOD-PAP Method

Quantitative determination of Total Cholesterol in serum/plasma
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
PCHO 25	1 X 25 mL
PCHO 50	1 X 50 mL
PCHO 100	2 X 50 mL
PCHO 100	1 X 100 mL
PCHO 500	1 X 500 mL
PCHO 1000	1 X 1000 mL
PCHO 5000	1 X 5000 mL
PCHO 10000	1 X 10000 mL

CLINICAL SIGNIFICANCE

Cholesterol is a fat-like substance that is found in all body cells. The liver makes all of the cholesterol the body needs to form 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

"CHOD-PAP": enzymatic photometric test

PRINCIPLE

Cholesterol esters are hydrolyzed to produce cholesterol. Hydrogen Peroxide is then produced from oxidation of cholesterol by cholesterol oxidase. The indicator quinoneimine is formed from hydrogen peroxide and 4-aminoantipyrine in the presence of phenol and peroxide. The absorption of the red quinoneimine dye is proportional to the concentration of cholesterol in the sample.

REAGENT

Reagent : Cholesterol Reagent
Cholesterol standard : 200 mg/dL

REAGENT PREPARATION

The Reagent is ready to use.

REAGENT STORAGE AND STABILITY

The Reagent is stable till expiry when stored at 2 - 8°C.
Store protected from light.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum, heparin plasma or EDTA plasma

Stability: 7 days at 4 – 8°C
3 months at –20°C
Discard contaminated specimens! Freeze only once!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	505nm (490-550nm)
Reaction Type	End point
Cuvette	1 cm light path
Reaction Temperature	37°C
Measurement	Against Reagent Bl
Sample Volume	10 µl
Reagent Volume	1000 µl
Incubation	5 minutes
Maximum Blank Absorbance	< 0.30
Low Normal at 37°C	< 200 mg/dl
High Normal at 37°C	> 240 mg/dl
Linearity at 37°C	1000 mg/dl

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	Blank	Standard	Test
Reagent	1000µL	1000µL	1000µL
Water	10µL	--	--
Standard	--	10µL	--
Sample	--	--	10µL

- Mix, Incubate for 5 mins. at 37°C (or 10 mins. at 20 - 25°C)
- Measure absorbance of Sample (AT) and Standard (AS) against Reagent blank at 505nm.
- The colour is stable for at least 30 mins.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 1000 mq/dL.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION

$$\text{Cholesterol mg/dL} = \frac{\text{Abs.of Sample (AT)}}{\text{Abs.of Standard (AS)}} \times \text{Standard Value}$$

CLIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of **Cholesterol standard** have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS).

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Norm	115.88	3.46	2.99%
Path	183.11	6.73	3.68%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Norm	115.58	2.97	2.57%

Path	183.11	6.04	3.31%

LINEARITY

The method is linear upto a concentration of 1000 mg/dl. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Cholesterol is 3 mg/dL.

METHOD COMPARISON

A comparison of Paramcare Cholesterol with a commercially available assay (x) using 59 samples gave following results: $R^2 = 0.991$

REFERENCE VALUES

Normal	< 200 mg/dl
Borderline - High	220 - 239 mg/dl
High	> 240 mg/dl

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Bilirubin: No interference found upto Bilirubin 15mg/dl.
- Hemoglobin: No interference found upto 500 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

Tietz N.W., White, W.L.Mosby, CO St.Louis, P.Young.D.S, Henry, R,J., Chem. (1964), 10, 533.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



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