SBio CHOLESTEROL KIT

(CHOD / PAP Method)

(For invitro diagnostic use only)

REF	90292075	90282150
Pack Size	75 ml	2 x 150 ml

CE

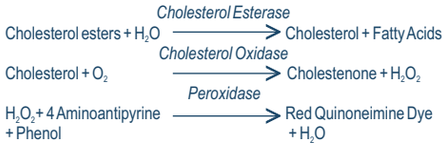
8°C 2°C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	L2 Enzyme Reagent 2	This way up
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	S Cholesterol Standard (200 mg/dl)	EC REP Authorised Representative in the European Community
Date of Manufacture	REF Catalogue Number	L1 Enzyme Reagent 1	CHOD/PAP CHOD/PAP Method	

INTENDED USE

Cholesterol Kit is used for the determination of cholesterol in serum or plasma.

PRINCIPLE OF THE TEST

Cholesterol esterase hydrolyses esterified cholesterols to free cholesterol. The free cholesterol is oxidised to form hydrogen peroxide which further reacts with phenol and 4-aminoantipyrine by the catalytic action of peroxidase to form a red coloured quinoneimine dye complex. Intensity of the colour formed is directly proportional to the amount of cholesterol present in the sample.



CLINICAL SIGNIFICANCE

Cholesterol is the main lipid found in blood, bile and brain tissues. It is the main lipid associated with arteriosclerotic vascular diseases. It is required for the formation of steriods and cellular membranes. The liver metabolizes the cholesterol and it is transported in the blood stream by lipoproteins. Increased levels are found in hypercholesterolaemia, hyperlipidaemia, hypothyroidism, uncontrolled diabetes, nephrotic syndrome and cirrhosis. Decreased levels are found in malabsorption, malnutrition, hyperthyroidism, anemias and liver diseases.

PRESENTATION	75 ml	2 x 150 ml
L1 : Enzyme Reagent 1	60 ml	2 x 120 ml
L2 : Enzyme Reagent 2	15 ml	2 x 30 ml
S : Cholesterol Standard (200 mg/dl)	5 ml	5 ml

COMPOSITION

Goods buffer 50 mM; pH 7.0; CHE ≥ 100 U/L; CHO ≥ 100 U/L; POD ≥ 1000 U/L; 4-AAP 0.3 mM; Phenol 4 mM; Non Reactive Stabilizers, Detergents and Preservatives.

STORAGE / STABILITY

Contents are stable at 2-8°C till the expiry mentioned on the labels.

SAMPLE REQUIRED

Serum, EDTA plasma.

REAGENT PREPARATION

Reagents are ready to use.

Working reagent: Pour the contents of 1 bottle of L2 (Enzyme Reagent 2) into 1 bottle of L1 (Enzyme Reagent 1). This working reagent is stable for at least 8 weeks when stored at 2-8°C. Upon storage the working reagent may develop a slight pink colour however this does not affect the performance of the reagent.

Alternatively for flexibility as much of working reagent may be made as and when desired by mixing together 4 parts of L1 (Enzyme Reagent 1) and 1 part of L2 (Enzyme Reagent 2). Alternatively, 0.8 ml of L1 and 0.2 ml of L2 may also be used instead of 1 ml of the working reagent directly during the assay.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength/filter : 505 nm (Hg 546 nm) / Green
Temperature : 37°C / R.T.
Light path : 1 cm

MATERIALS REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

Pipette into clean dry test tubes labeled as Blank (B), Standard (S) and Test (T):

Addition Sequence	B (ml)	S (ml)	T (ml)
Working Reagent	1.0	1.0	1.0
Distilled Water	0.01	--	--
Cholesterol Standard (S)	--	0.01	--
Sample	--	--	0.01

Mix well and incubate at 37°C for 5 minutes or at R.T. (25° C) for 15 minutes. Measure the absorbance of the Standard (Abs. S) and Test Sample (Abs. T) against the Blank within 60 minutes.

CALCULATIONS

$$\text{Cholesterol in mg/dl} = \frac{\text{Abs. T}}{\text{Abs. S}} \times 200$$

QUALITY CONTROL

The following process is recommended for QC during the assay of Cholesterol. *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

This procedure is linear upto 750 mg/dl. If the value exceeds this limit, dilute the serum with normal saline (NaCl 0.9%) and repeat the assay. Calculate the value using the proper dilution factor.

Limit of detection:

The limit of detection for Cholesterol is 1 mg/dl.

Interferences:

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

Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	92.0	5.61	93.81	2.68	185.8	8.29
Control 2	193.5	1.56	202.00	2.01	395.52	3.57

Method comparison:

Comparative studies were done to compare our reagent with another commercial Cholesterol Assay. No significant differences were observed. Details of the comparative studies are available on request.

REFERENCE RANGE

Serum / Plasma (Suspicious) : 220 mg/dl and above
(Elevated) : 260 mg/dl and above

It is recommended that each laboratory establish its own normal range representing its patient population*.

NOTE

Cholesterol is reported to be stable in sample for 7 days when stored at 2-8°C. The sample should preferably be of 12 to 14 hours fasting. Anticoagulants such as flourides and oxalates result in false low values. The test is not influenced by Hb values upto 20 mg/dl and bilirubin upto 10 mg/dl. The reagent may be used in several automated analyzers. Instructions are available on request.

Standard is traceable to standard reference material (SRM) 909b. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. Trinder P., (1969) Ann. Clin. Biochem. 6:24.
2. Allain C.C., et. Al., (1974) Clin. Chem. 20:470.
3. Flegg H.M., (1972) Ann. Clin. Biochem. 10:79.
4. Schettler, Gand E. Nussel (1975) Arbeitsmed Sozialmed Praventivmed 10:25.

Mfd. for:

Singapore SB Biosciences PTE Ltd.

11 Yishun Street 51, # 04-23, The Criterion, Singapore 767971.

EC REP

CMC Medical Devices & Drugs S.L.,
C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain.

CHO1(SBio)/0420/VER-02