

QUADRAPED™

CHOLESTEROL SR KIT

(CHOD / PAP Method)

(For veterinary invitro diagnostic use only)

INTENDED USE

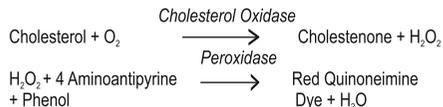
QUADRAPED™ Cholesterol SR kit is used for the determination of Cholesterol in serum or plasma.

SUMMARY

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 steroids 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.

PRINCIPLE

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.



EXPECTED VALUES

Species	Cholesterol (mg/dl)
Dog	135 - 278
Cat	71 - 156
Cow	90 - 300
Horse	75 - 220
Pig	36 - 54
Sheep	52 - 76
Goat	80 - 130
Rabbit	10 - 80
Buffalo	60 - 150

It is recommended that each laboratory establish its own range as reference ranges may vary between laboratories.

PRESENTATION

REF	1126060025
Pack Size	25 ml
L1 Cholesterol Reagent	25 ml
S Cholesterol Standard (200 mg/dl)	5 ml

COMPOSITION

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

Detergents and Preservatives.

STORAGE / STABILITY

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

REAGENT PREPARATION

Reagents are ready to use.

SAMPLE MATERIAL

Serum, EDTA / Heparin / Citrated plasma. Cholesterol is reported to be stable in serum for 7 days at 2-8°C.

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.

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

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

MATERIALS REQUIRED BUT NOT PROVIDED

Photometer analyzer with standard thermostatic cuvette holder, micropipette and appropriate laboratory equipment.

PROCEDURE

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

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

Addition Sequence	B (ml)	S (ml)	T (ml)
Cholesterol Reagent (L1)	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 mins. or at R.T. (25°C) for 15 mins. Measure the absorbance of the Standard (Abs. S) and Test Sample (Abs. T) against the Blank, within 60 mins.

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.

- Two level of control (Normal and Abnormal) are to be run on a daily basis.
- If QC results fall outside acceptance criteria, recalibration may be necessary.

- Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

LOD: 1 mg/dl

LOQ: 12.5 mg/dl

Lower Limit: 1 mg/dl

Higher Limit: 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.

Interferences:

Sample when spiked with interferent such as upto 7 mg/dl Bilirubin, 200 mg/dl haemoglobin, 1000 mg/dl intralipid does not affect the ability of the kit to determine the Cholesterol concentration.

Precision:

Within run

Within run	n	Mean	SD	% CV
Sample 1	10	156.1	1.77	1.14
Sample 2	10	285.6	1.56	0.55
Sample 3	10	589.7	1.76	0.30

Between run

Between run	n	Mean	SD	% CV
Sample 1	10	156.3	1.72	1.10
Sample 2	10	286.1	1.30	0.45
Sample 3	10	590.0	1.85	0.31

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.

NOTE

In vitro diagnostic reagent for laboratory and professional use only Not for medicinal use. The reagent contain sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water. Only clean and dry glassware must be used. Anticoagulants such as fluorides and oxalates result in false low values. Standard is Traceable to Standard Reference Material (SRM) 909b. Do not use turbid, deteriorated or leaking reagents

REFERENCES

- Trinder P., (1969) Ann. Clin. Biochem. 6:24.
- Allain C.C., et. Al., (1974) Clin. Chem. 20:470.
- Flegg H.M., (1972) Ann. Clin. Biochem. 10:79.
- Schettler Gand E. Nussel (1975) Arbeitsmed Sozialmed Praventivmed 10:25.
- Duncan and Prasse's Veterinary Laboratory Medicine: Clinical Pathology, Kenneth S. Latimer, ISBN Jane Wardrop, 6th Edition – 2010.
- Clinical Biochemistry of Domestic Animals, Sixth Edition, 2008 by Kaneko J.J., Harvey J.W. & Bruss M.L.
- Data on file: Coral Clinical Systems.

System Parameters

Reaction	: End Point	Interval	: —
Wavelength	: 505 nm	Sample Vol.	: 0.01 ml
Zero Setting	: Reagent Blank	Reagent Vol.	: 1.00 ml
Incub. Temp.	: 37°C / R. T.	Standard	: 200 mg/dl
Incub. Time	: 5 min. / 15 min.	Factor	: —
Delay Time	: —	React. Slope	: Increasing
Read Time	: —	Linearity	: 750 mg/dl
No. of read.	: —	Units	: mg/dl

SYMBOL KEYS

Store at 2-8°C	Manufacturer	In vitro Diagnostic Medical Device	Cholesterol Reagent 1	CHOD / PAP Method
Use by (Last day of stated month)	Consult Instructions for use	Batch Number	Cholesterol Standard (200 mg/dl)	This way up
Date of Manufacture	Catalogue Number			



Manufactured by:

Coral Clinical Systems

A Division of Tulip Diagnostics (P) Ltd.

BUILDING E, PLOT NO. M-46/47, PHASE III B, VERNA INDUSTRIAL ESTATE, VERNA, GOA-403 722, INDIA.

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