

#### PRODUCT CODE

**CS005**

#### INTENDED USE

This reagent is intended for in vitro quantitative determination of Cholesterol in serum & plasma

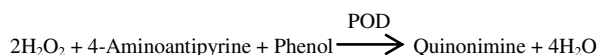
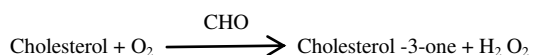
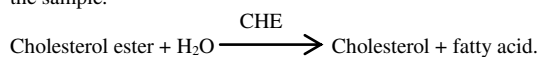
#### CLINICAL SIGNIFICANCE

Cholesterol is a fat-like substance called a lipid 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.

#### PRINCIPLE

Cholesterol Esterase (CHE) catalysis the hydrolysis of cholesterol esters, to produce cholesterol, which is oxidized by Cholesterol Oxidase (CHO) to yield Hydrogen Peroxide (H<sub>2</sub>O<sub>2</sub>). In a coupled reaction catalyzed by peroxidase (POD), Quinonimine dye (red) is formed from (H<sub>2</sub>O<sub>2</sub>), 4 Amino Antipyrine (4-AA) and phenol. The absorbance of the dye at 546nm is proportional to the concentration of cholesterol in the sample.



#### REAGENT COMPOSITION

##### Cholesterol Reagent

Pipes buffer, (pH 6.80)	50 mmol/L
Phenol	5 mmol/L
4-Aminoantipyrine	0.25 mmol/L
Cholesterol Esterase	>350 U/L
Cholesterol Oxidase	>140 U/L
Peroxidase	>10 U/L

##### Cholesterol Standard

Cholesterol standard concentration 200 mg/dL or 5.14 mmol/L

#### REAGENT PREPARATION

Reagent and standard are ready for use.

#### REAGENT STORAGE AND STABILITY

The reagents are stable, if protected from light, up to the stated expiry date when stored at 2 - 8° C.

#### SPECIMEN

Serum, heparinized or EDTA plasma. Cholesterol levels are stable for 7 days at 2 - 8°C. Fluoride or oxalate will interfere.

#### PRECAUTION

To avoid contamination, use clean laboratory wares. Avoid direct exposure of reagent to light.

#### ASSAY

Wavelength	:	546 nm
Cuvette	:	1 cm light path
Temperature	:	20-25°C or 37°C
Measurement	:	Against reagent blank

#### PROCEDURE

Pipette into cuvettes	Blank	Standard	Sample
Cholesterol reagent	1000 µL	1000 µL	1000 µL
Standard	--	10 µL	--
Sample	--	--	10 µL

Mix and incubate for 10 minutes at 20-25°C or 5 minutes at 37°C  
Measure the absorbance of the sample (As) and the standard (Astd) against the reagent blank

#### CALCULATION

$$\text{Cholesterol Conc. (mg/dL)} = \frac{\Delta A \text{ sample}}{\Delta A \text{ standard}} \times 200 \text{ (Std.conc.)}$$

To convert mg/dL to mmol/L divide by 38.9

#### Linearity:

This reagent is linear up to 750 mg/dL or 19.30 mmol/L. If the concentration is greater than linearity (750 mg/dL), dilute the sample 1+2 with physiological saline (0.9%) and repeat the assay. Multiply the result by 3.

#### NORMAL RANGE

Desirable	<200mg/dL	<5.1 mmol/L
Suspect	200 – 240mg/dL	5.1 – 6.2 mmol/L
High	> 240mg/dL	> 6.2 mmol/L

#### QUALITY CONTROL

All control sera with Cholesterol value estimated by this method can be used.

#### NOTES

- The test is not influenced by haemoglobin values up to 200mg/dl or by bilirubin values up to 5 mg/dl.
- The reagent contains sodium azide as preservative (0.05%) Do not swallow and avoid contact with skin and mucous membranes.
- Cholesterol oxidase is not totally specific for cholesterol. Other analogs of cholesterol such as 7 – dihydro and 20 – hydroxyl cholesterol is also oxidized. However, these analogs do not normally occur in any appreciable amounts in serum

#### SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
	Catalogue Number		Pack Size
	Expiry Date		Volume
	Storage Condition		Lot Number
	Instruction for Use		In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests		For Single Use Only
	EC Representative		European conformity

#### BIBLIOGRAPHY

- Richmond, W.; Clin Chem. 19, 1350.1973.
- Roerschlau, P. et al.; Clin Chem llin. Biochem. 12,226,1974.
- Trinder, P. Ann. Clin. Biochem, 6,24,1969.
- Allain, C.C. et al.; Clin. Chem., 20, 470, 1974.

