

REF NO **DESCRIPTION**
CS603 **CHOLESTEROL**

PACKAGE SIZE

CS 603-1	1 X 1000 ML	CS 603-6	6X 20 ML
CS 603-2	2 X 500 ML	CS 603-7	1 X 100 ML
CS 603-3	3 X 100 ML	CS 603-8	2 X 50 ML
CS 603-4	6 X 50 ML	CS 603-9	1 X 50 ML
CS 603-5	1 X 200 ML	CS 603-10	10 X 100 ML

INTENDED USE

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

INTENDED USER: Professional Use Only

CLINICAL SIGNIFICANCE

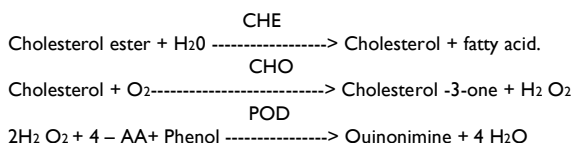
Cholesterol is a fat-like substance called a lipid that is found in all body cells. The liver makes all of the cholesterol the body needs to form cell membranes and to make certain hormones.

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 (H₂O₂) , In a coupled reaction catalyzed by peroxidase (POD), Quinonimine dye (red) is formed from (H₂O₂), 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 (Liquid) Reagent

Phosphate buffer, (pH 6.50)	30 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	: 546nm
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	<5.1mmol/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 contain 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 are also oxidized. However, these analogs do not normally occur in any appreciable amounts in serum

SYMBOL ON LABELS

IVD in vitro diagnostics	 manufacturing date
LOT lot number	 expiry date
REF catalogue number	 manufacturer
 temperature limit	 instruction for use

BIBLIOGRAPHY

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



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CS603-CHOL
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EC **REP**

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