

PRODUCT CODE CS005

INTENDED USE

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

CLINICAL SIGNIFICANCE

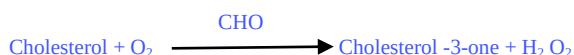
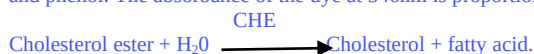
Cholesterol is a fat-like substance called a lipid that is found in all body cells. The liver makes all of the cholesterol the body needs to form cell membranes and to make certain hormones.

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 (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	50 mmol/L
buffer, (pH 6.50) Phenol	5 mmol/L
4-Aminoantipyrine	0.25 mmol/L
Cholesterol Esterase	>350 U/L
Cholesterol Oxidase	>140 U/L
Peroxidase	>10 U/L

REAGENT

PREPARATION Reagent is

ready for use.

REAGENT STORAGE AND STABILITY

The reagent 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.

PRUCEDURE

APPLICATION ON AUTO BIO CHEMISTRY

BR-160 AUTO BIOCHEMISTRY ANALYZER					
TEST NAME	CHOL		SAMPLE VOLUME	3	
FULL NAME	CHOLESTEROL				
	PRI.	SEC.	REAGENT VOLUME	R1	R2
WAVE LENGTH	546	NONE	300	NONE	
ASSAY /POINT	1 POINT END	START	END		
		1	25		
DECIMAL PLACE	2				
UNIT	mg/dl				
LINEARITY RANGE	LOW	HIGH			
	0	750			

BR-120 AUTO BIOCHEMISTRY ANALYZER					
TEST NAME	CHOL		SAMPLE VOLUME	3	
FULL NAME	CHOLESTEROL				
WAVE LENGTH	PRI.	SEC.	REAGENT VOLUME	R1	R2
	546	NONE		300	NONE
ASSAY /POINT	1 POINT END	START	END		
		6	24		
DECIMAL PLACE	2				
UNIT	mg/dl				
LINEARITY RANGE	LOW	HIGH			
	.0	750			

PRECAUTION

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

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

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 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

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.
- Roeshlau, 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.

