

CHOLESTEROL SL

Enzymatic Colorimetric Method

Liquid reagent ready to use

REF 12230240 R 12X20mL

IVD

PRODUCT CODE: CHO-12D20

INTENDED USE

Quantitative determination of Total Cholesterol in serum and plasma.

PRINCIPLE

Esterified cholesterol is hydrolyzed into free cholesterol and fatty acid by cholesterol esterase (CHE). Cholesterol oxidase (CHOD) oxidizes the free cholesterol into cholestene-3-one with formation of hydrogen peroxide. In presence of peroxidase (POD), hydrogen peroxide reacts with a derivative of phenol and 4-aminoantipyrine to produce a colored complex whose color intensity is directly proportional to the total cholesterol concentration in the sample.

SAMPLE

Serum, plasma.

Avoid samples with high concentrations of ascorbic acid.

Cholesterol in the sample is stable 3 days at 2-8°C and one month at -20°C.

KIT COMPONENTS

Reagent (A) Vol = 100/250/1000 ml	Buffer	100 mmol/l
	4-AAP	1 mmol/l
	CHE	300 U/l
	CHOD	300 U/l
	POD	1500 U/l
Standard Vol = 5 ml	Derivative of phenol	1 mmol/l
	Cholesterol	Value on label

The reagents are stable until the expiration date indicated on the label if

stored at 2-8°C and protected from light. Do not use over expiry date.

Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided. Do not freeze. Keep bottles closed when not in use.

A slight color of the reagent (less than 0.040 O.D) due to air or light does not affect its operation.

REAGENT PREPARATION

Liquid Reagent, bring to room temperature (15-25°C) before use.

PRECAUTIONS AND WARNINGS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Use the normal precautions required in the laboratory.

Dispose of waste according to local laws.

PROCEDURE

Wavelength:	510 nm (500 – 520)
Lightpath :	1 cm
Temperature:	37°C
Reading:	against blank reagent
Method:	Increasing End Point
Sample/Reagent:	1/100

pipette:	blank	sample	standard
Reagent (A)	300 µl	300 µl	300 µl
water	3 µl		
sample		3 µl	
standard			3 µl

Mix, incubate at 37°C for 5 minutes, and read against blank reagent the absorbance of the sample (Ax) and the standard (As).

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RESULTS CALCULATION

Serum/plasma:

Cholesterol mg/dl = $A_x/A_s \times 200$ (standard value)

Conversion factor: mg/dl x 0.02586 = mmol/l

EXPECTED VALUES

Serum, plasma:

Low Risk:	< 200 mg/dl (< 5.17 mmol/l)
Moderate Risk:	200–240 mg/dl (5.17 - 6.20 mmol/l)
High Risk:	> 240 mg/dl (> 6.20 mmol/l)

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of Sicurobio control sera: ACUTROL 1 (REF. SB-8334) and ACUTROL 2 (REF. SB-8335).

PERFORMANCE

Sensitivity: the sensitivity of the method is : 7 mg/dl.

Linearity: the method is linear up to 700 mg/dl. For higher values, dilute the sample 1:5 and multiply the result by 5.

Precision intra-assay:

	Level1	Level 2	Level 3
Mean (mg/dl)	79.72	187.5	271.4
SD	0.37	1.51	1.96

CV %	0.47	0.81	0.72
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Precision inter-assay:

	Level1	Level 2	Level 3
Mean (mg/dl)	83.53	194.2	310.5
SD	1.21	2.25	4.14
CV %	1.44	1.16	1.33

Interferences: bilirubin does not interfere up to 20 mg/dl. Hemoglobin does not interfere up to 500 mg/dl.

Triglycerides up to 800 mg/dl do not interfere.

Correlation against a reference method:

$Y = 1.0087x + 4.3902$ $r = 0.9929$

REFERENCES

1. Trinder P., Ann. Clin. Biochem. 6, 24 (1969)
2. Kaplan LA, Pesce AJ, Clinical Chemistry, Mosby Ed. 1989
3. Vassault A. et al., Ann. Biol. Clin., 44, 686 (1986).



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