CHOLESTEROL SL

Enzymatic Colorimetric Method

Liquid reagent ready to use

REF. 0045/50 4x 50 ml
REF. 0045 4x100 ml
REF. 0035 2x100 ml
REF. 0093 4x250 ml

CE
IVD

Azienda certificata DNV

GIESSE DIAGNOSTICS

INTENDED USE

Quantitative determination of Total Cholesterol in serum and plasma.

PRINCIPLE

Esterified cholesterol is hydrolized 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) Volume = 50/100/250 ml	Buffer 4-AAP CHE CHOD POD Derivative of phenol	100 mmol/l 1 mmol/l 300 U/l 300 U/l 1500 U/l 1 mmol/l
Standard Volume = 5 ml	cholesterol	200 mg/dl

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C and protected from light. Do not freeze. Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided.

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)	1000 µl	1000 µl	1000 µl
water	10 µl		
sample		10 µl	
standard			10 µl

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

Reaction volumes can be proportionally varied.

This method describes the manual procedure to use the kit.

For automated procedure, ask for specific applications.

RESULTS CALCULATION

Serum/plasma:

Cholesterol mg/dl = Ax/As x 200 (standard value)

EXPECTED VALUES

Serum, plasma:

Low Risk:	**< 200**	**mg/dl**
Moderate Risk:	**200 – 240**	**mg/dl**
High Risk:	**> 240**	**mg/dl**

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 control sera: PRECISENORM (REF.6000) and PRECISEPATH (REF.6001).

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
DS	0.37	1.51	1.96
CV %	0.47	0.81	0.72

Precision inter-assay:

	Level1	Level 2	Level 3
Mean (mg/dl)	83.53	194.2	310.5
DS	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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