GENESIS

Instructions For Use

CHOLESTEROL (CHOD/PAP METHOD)

Cat no.	size
1103 101	4*25
1103 102	2*50
1103 103	4*50
1103 104	2*25

INTENDED USE

The cholesterol reagent is intended for in vitro Quantitative diagnostic determination of total cholesterol in human serum or plasma.

DIAGNOSTIC CHARACTERISTICS

Cholesterol is a steroid of high molecular weight and possesses the cyclopentanophenanthrene skeleton. Dietary cholesterol is partially absorbed and it is also synthesized by the liver and other tissues. Cholesterol is transported in plasma by lipoproteins. It is excreted unchanged into bile or after transformation to bile acids. Increased total cholesterol values are associated with a progressively escalating risk of atherosclerosis and coronary artery disease. Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Free and esterified cholesterol in the sample originates, by means of the coupled reactions described below, a coloured complex that can be measured by spectrophotometry.

Cholesterol ester + H_2O —(chol. Esterase)→ Cholesterol + Fatty acid

Cholesterol + ½ O_2 + H_2O —(chol. Oxidase)→ Cholestenone + H_2O_2

2 H_2O_2 + 4-Aminoantipyrine + Phenol —(Peroxidase)→ Quinoneimine

COMPOSITION

Reagent(R)	
Good's Buffer	35 mmol/L
Sodium cholate	0.5 mmol/L
Phenol	28 mmol/L
Cholesterol esterase	> 0.2 U/mL
Cholesterol oxidase	> 0.1 U/mL
peroxidase	> 0.8 U/mL
4-aminoantipyrine	0.5 mmol/L
Standard(S)	200 mg/dL

STORAGE.

Store at 2-8ºC.
Reagent and Standard are stable until the expiry date shown on the Vial label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION

Reagents provided are ready to use.

ADDITIONAL EQUIPMENT

-Thermostatic water bath at 37ºC
-Analyzer,spectrophotometer or photometer able to read at 546 nm.

SPECIMEN

1.Serum and EDTA plasma collected by standard procedures.
2.Cholesterol is stable for 7 days at 2-8ºC.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately. Reagent (R) contains sodium azide which may react with copper or lead plumbing.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use	⚠	CAUTION, consult instructions for use
REF	Catalogue number		Manufactured by
LOT	Lot number		

PROCEDURE

1. Bring Reagent to room temperature.
2. Pipette into labeled test tubes:

	Blank	Standard	Sample
Reagent (R)	1.0 mL	1.0 mL	1.0 mL
Standard (S)	-	10 µL	-
Sample	-	-	10 µL

3. Mix thoroughly and incubate the tubes for **10 minutes** at room temperature (16-25ºC) or **5 minutes** at 37ºC.
4. Measure absorbance (A) of Standard and Sample at 546 nm against Blank. color is stable for one hour.

CALCULATIONS

The cholesterol concentration in the sample is calculated using the following general formula:

$$\frac{\text{A Sample}}{\text{A Standard}} \times \begin{matrix} 200 = \text{mg/dL} & \text{Cholesterol} \\ 5.18 = \text{mmol/L} & \text{Cholesterol} \end{matrix}$$

REFERENCE VALUES

Up to 200 mg/dL = 5.2 mmol/L	Desirable
200-239 mg/dL = 5.2-6.21 mmol/L	Borderline High
> 240 mg/dL = > 6.24 mmol/L	High

QUALITY CONTROL

It is recommended to use The Control Serum level I and II to verify the performance of the measurement procedure.
Each laboratory should establish its own internal Quality Control .

METROLOGICAL CHARACTERISTICS

Detection limit: 0.3 mg/dL = 0.008 mmol/L
Linearity limit: 1000 mg/dL = 26.0 mmol/L
For higher values dilute sample **1/2** with physiological saline and repeat measurement.

- **Repeatability (within run):**

Mean Concentration	CV	n
121 mg/dL = 3.13 mmol/L	1.1 %	20
257 mg/dL = 6.66 mmol/L	0.9 %	20

- **Reproducibility (run to run):**

Mean Concentration	CV	n
121 mg/dL = 3.13 mmol/L	1.9 %	25
257 mg/dL = 6.66 mmol/L	1.0 %	25

INTERFERENCES

Lipemia (triglycerides 10 g/L) does not interfere.
Bilirubin (>10 mg/dL) may affect the results.
hemoglobin (>5 g/L) may affect the results.
other drugs and substances may interfere.

BIBLIOGRAPHY

1. Allain CC, Poon LS, Chan CSG, Richmond W and Fu PC. Enzymatic determination of totalserum cholesterol. ClinChem 1974; 20: 470-475.
2. Meiattini F, Prencipe L, Bardelli F, Giannini G and Tarli P. The 4-hydroxybenzoate/4-aminophenazone chromogenic system used in the enzymic determination of serumcholesterol. ClinChem 1978; 24: 2161-2165.

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