

BioMed- Cholesterol- SL



Enzymatic colorimetric method (CHOD-PAP)

REF:

CHO104090	(3x30 ml)	CHO104100	(5x20 ml)
CHO104120	(2x60 ml)	CHO104240	(2x120 ml)

INTENDED FOR USE:

For the quantitative determination of total cholesterol in serum and plasma

PRINCIPLE :

Under the action of Cholesterol esterase (CHE) cholesterol esters resolve in cholesterol and fatty acids.

Cholesterol Oxidase (CHOD) oxidize the above mentioned cholesterol together with the loose cholesterol releasing Cholesterol-3-one and hydrogen peroxide In presence of Peroxidase (POD), the released hydrogen peroxide reacts with a phenol substitute and 4-aminoantipyrine to form a red dye compound

The intensity of the red color produced is directly proportional to the total cholesterol in the sample when read at 500/520nm

SPECIMEN COLLECTION :

Non hemolyzed fresh serum or plasma.

Note:Cholesterol in serum or plasma is reported stable for one week at room temperature (+15-25°C.), and approximately 6 months when stored in the refrigerator at -20°C and protected against evaporation.

Shake and bring the samples at room temperature (+15-25°C)before using

REAGENTS COMPOSITION:

R1	Cholesterol Standard	200 mg/dl
R2	Good's Buffer	100 mmol/L
	Cholesterol esterase	300U/L
	Cholesterol oxidase	1500U/L
	Peroxidase	5500U/L
	4-AAP	1 mmol/L
	Phenol derivates	5mmol/L

PACKAGE : Collection and Storage .

Store at the temperature reported on the label. **Do not freeze.**

Stable till the expiration date reported upon the package.

After the unsealing and the taking of the reagent ,it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacterial contamination.

PRECAUTIONS & WARNING:

Avoid pipetting by mouth .

The preparation , according to current regulation . is classified as not dangerous.

The total concentration of non active components (preservatives , detergents ,stabilizers) is below the minimum required for citation .

Anyway handle with care , avoid ingestion , avoid contact with eyes , skin and mucous membranes The samples must be handle as potentially infected from HIV or Hepatitis .

REAGENT PREPATION & STABILITY :

Liquid reagent must be at room temperature (+15-25°C) before using.

The Reagent is limpid.

Stable until the expiration date reported upon the package.

A light reagent coloration (less than 0.030 O.D.) due to air or direct light exposure, will not impair its functioning

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instrumentations.

PROCEDURE :

Wavelength	510nm (500-546)
Optical path :	1 cm light path
Temperature :	20-25 OR 37°C
Reading :	Against blank reagent
Assay tipe :	Endpoint

Procedure : Pipetting in tubes :

	BLANK	STANDARD	SAMPLE	
Reagent (R2)	1000	1000	1000	µL
Distilled Water	10			µL
Standard		10		µL
Sample			10	µL

Mix, incubate for 5 min at 37°C or 10 sec at 20-25°C and read sample and standard absorbance Color is stable at least 30 min at room temperature.

Volumes can be proportionally modified.

This methodology describes the manual procedure to use the kit. For automated procedure, ask for specific application.

CALCULATION :

$$\text{Cholesterol mg/dl} = \frac{\text{(A) sample}}{\text{(A) Standard}} \times 200$$

Standard 200mg/dL = 5.17mmol/L

EXPECTED VALUES:

Serum, plasma:		
Recommended Intervals	< 200mg/dL	NORMAL
Suspect values	200-240mg/dL	BORDERLINE
High values	>240mg/dL	HIGH

The above mentioned values are to be considered as a reference. It is strongly recommended that each laboratory establish its own normal range according to its geographic area , according to IFCC protocol .

WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL :

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

REFERENCES :

1. Tietz N. (ed), Fundamentals of Clinical Chemistry, W.B. Saunders Co. Philadelphia, 1976.
2. Watson, D., Clin.Chem. Acta 5 (637),1960.
3. Trinder, P., Ann Clin Biochem. 6 (24),1969.

PERFORMANCE :

MEASURE INTERVAL INEARTY :	7-600 mg/dl
DETECTION LIMIT (2DS):	7.02mg/dl
SENSITIVITY:	1mg/dl=0.00179A at 510nm

INTER-ASSAY PRECISION: n=20

LOW LEVEL	M = 96.43mg/dl	C.V.=2.36 %
MEDIUM LEVEL	M = 186.93mg/dl	C.V.=1.86 %
HIGH LEVEL	M = 313.31mg/dl	C.V.=1.52 %

INTRA-ASSAY PRECISION: n=20

LOW LEVEL	M = 97.72mg/dl	C.V.2.3%
MEDIUM LEVEL	M = 192.17mg/dl	C.V.1.2%
HIGH LEVEL	M = 317.67mg/dl	C.V.2.4%
ANALIZED INTERVAL	42.5 – 383.9 mg/dl	
CORRELATION	r = 0.999	n=83
LIN. REGRESSION	y = 1.02 × +0.8	n=83



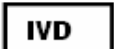


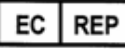



INTERFERENCE:

Interferences are negligible up to :	
Bilirubin	10 mg/dL
Triglycerides	1000mg/dL
Hemoglobin	0.5 g/L

METHOD LIMITATIONS:

For concentration higher than 600 mg/dL, repeat the measure on a sample diluted 1:2 with saline solution e multiply the results x2.

In case of highly lipemic sera, you will need to make a sample blank adding 10 ul serum to 1000 ul normal saline. Read and record absorbance against normal saline and subtract reading from sample absorbance.

	Consult Instructions for Use
	Caution, consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

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