CHOLESTEROL MONOREAGENT LR liquid reagent

REF 2236100 6x100 ml
CE **2230650** 6x50 ml
IVD For in vitro medical device

10Use

Kit for measurement of cholesterol in serum or plasma
Colorimetric enzymatic method CHOD - PAP.

Summary

Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood, and of lipid and lipoprotein metabolism disorders.

Principle

End point analysis. Free cholesterol and cholesterol released from its esters after enzymatic hydrolysis are oxidized enzymatically (CHE). The free cholesterol is oxidized by cholesterol oxidase (CHOD) to colest-4-en-3-one giving hydrogen peroxide. The indicator quinoneimine is formed from hydrogen peroxide that in presence of peroxidase (POD), reacts with 4-aminophenazone and phenol to form a coloured compound. The colour intensity is directly proportional to the cholesterol total concentration in the tested sample.

Reagents

R1	Goods buffer pH 6.8	100.0 mmol/l
	cholesterol esterase	≥ 500 U/l
	cholesterol oxidase	≥ 800 U/l
	phenol	20.0 mmol/l
	peroxidase	≥ 2500 U/l
	4-aminophenazone	1.6 mmol/l

Reagents Preparation

Reagent is liquid and ready to use. Keep out the reagents from refrigerator only for the use and recap them immediately.

Storage And Stability

Store the kit at 2-8°C.

- After opening, the vials R1 is stable 90 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent amendments) and Directive 88/379/CEE and subsequent amendments to the classification-packaging and labeling of dangerous substances.
However the reagent should be handled with care, according to good laboratory practice.
Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contact with skin, eyes and mucous membranes.

Waste Management

Please refer to the local legal requirements.

Specimen Collection and Preparation

- Serum-heparinized plasma or EDTA plasma.
- After picked up, serum and plasma must be separated, as soon as possible, from red cells. Avoid anticoagulants as fluoride, citrate and oxalate.
- The cholesterol is stable in the samples for 7 days if stand at 15-25°C or 28 days at 2-8°C.

Note

- The kit, according to this method, must be used in manual procedures. About automatic use follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the singles vials.

Procedures

Wavelength	λ: 510 (500- 550) nm
Working temperature	37°C
Optical path	1 cm
Reaction	"end point" (increasing)

Bring the reagents at 15-25°C before use them.

Monoreagent Procedure "sample starter"

	BLANK	STD	SAMPLE
Working reagent	1000 µl	1000 µl	1000 µl
Distilled Water	10 µl	--	--
Sample	--	--	10 µl
Standard	--	10 µl	--

Mix, then incubate for 10' at 37°C. Measure the absorbance of sample (EC) and standard (ESTD) against the reagent blank.

Calculation

Cholesterol (mg/dl) or (mmol/l) =
EC/ESTD x Conc. STD

Conversion Factor

Cholesterol [mg/dl] x 0.02586=Cholesterol (mmol/l)

Reference Values to 37°C

Serum – plasma
180 -220 mg/dl

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity

The reaction is linear in concentration range between 2,8 and 800 mg/dl. Samples with values exceeding this range must be diluted with saline solution. Then, multiply,the result for diluting factor.

Analytical Sensitivity

The test sensitivity in terms of detection limit is 2.80 mg/dl.

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor **r = 0.9877**

y = 0.95 x +1.155

Interferences

No interferences was observed by the presence of

Bilirubin	≤ 15 mg/dl
Haemoglobin	≤ 200 mg/dl
Triglycerides	≤ 800 mg/dl

For a comprehensive review of interfering substances, refer to the publication by Young.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal-High). Results:

MEAN (mg/dl)	N=150.10	H=286.55
S.D.	N=3.08	H=5.18
C.V.%	N=2.05	H=1.81

"Inter-Assay" precision (between-run)

Determined on 20 samples for each control (N-H). Results:

MEAN (mg/dl)	N=150.28	H=281.27
S.D.	N=2.78	H=3.80
C.V.%	N=1.85	H=1.35

Quality controls

It's necessary, each time the kit is used, to perform quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Kaplan LA, Pesce AJ: "Clinical Chemistry", Mosby Ed. (1996). Barham D, Trinder P: Analyst, 97 142 (1972).
Fossati P, Prencipe L, Berti G: Clin. Chem., 26(2) 227 (1980).
Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5th ed. 2000.

Symbols

CE	CE Mark (98/79 CE regulation)
IVD	in vitro medical device
LOT	Batch Code
	Use by
	Storage temperature limits
	Read instruction for use
	Gesan Production srl