TRYGLICERIDES MONOREAGENT LR liquid reagent

REF C4730650 6x50ml

CE **C4730650A** 6x50ml

IVD For in vitro medical device

Use

Kit for measurement of tryglicerides in serum or plasma. Colorimetric enzymatic method GPO - PAP.

Summary

Tryglicerides measurements are used in the diagnosis and treatment of hyper-lipidemia.

Principle

Tryglicerides are hidrolized, in presence of lypoproteinlipase (LPL), into fat acid and glycerol which is transformed, by glycerolchinase (GK), ATP and glicerol-3-P-oxidase (GPO), into diidroxiaceton-phopsphate and H_2O_2. The hydrogen peroxid catalyzed from peroxidase (POD) reacts with 4-aminophenazone and 4-phenol-chloride giving a coloured compound whose intensity is proportional to the concentration of triglycerides in the sample

Reagents

R1	PIPES buffer	100.0 mmol/l
	phenol	16.0 mmol/l
	lipoproteinlipase	≥ 4000 U/l
	glicerolkinase	≥ 2000 U/l
	peroxidase	≥ 2500 U/l
	ATP	0.8 mmol/l
	4-aminophenazone	1.4 mmol/l
	glicerol-3-P-oxidase	≥ 2000 U/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).
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.
- In the samples stored at 2-8°C and at -20°C the tryglicerides are stable, respectively, up to 3 days and 12 months.
- It's advisable, in presence of strongly lipoemic, jaundiced or turbid serum, to prepare a blank of the sample using saline solution.

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.

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 5' at 37°C. Measure the absorbance of sample (EC) and standard (ESTD) against the reagent blank.

Calculation

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

The reagents performance are related to 37°C, 1 cm and 510 nm.

Conversion Factor

Triyglicerides [mg/dl] x 0.01126= Tryglicerides (mmol/l)

Reference Values to 37°C

Serum – plasma	
Men	60 – 165 mg/dl (0.68- 1.86 mmol/l)
Women	40 – 140 mg/dl (0.45 – 1.58 mmol/l)

It has been noticed that the values obtained using the plasma as sample are, from 2% to 4%, lower than values obtained using the serum.
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

Reaction is linear up to a concentration of 1000 mg/dl. Samples with values exceeding this range must be diluted with saline solution. Multiply, then, the result for diluting factor.

Analytical Sensitivity

The test sensitivity in terms of detection limit is 3.50 mg/dl.

"Intra-Assay" precision (within-Run)

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

MEAN (mg/dl)	N=99.65	H=270.90
S.D.	N=2.01	H=3.78
C.V.%	N=2.01	H=1.40

"Inter-Assay" precision (between-run)

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

MEAN (mg/dl)	N=99.43	H=270.37
S.D.	N=1.75	H=3.91
C.V.%	N=1.76	H=1.45

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor **r = 0.99**

y = 0.9436 x +2.9045

Interferences

No interferences was observed by the presence of :

Bilirubin	≤ 25 mg/dl
Ascorbate acid	≤ 10 mg/dl
Hemoglobin	≤ 200 mg/dl

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

Quality controls

It's necessary, every 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

Bucolo G, David M: Clin. Chem., 19, 476 (1973).
McGowan MW, Artiss JD, Standbergh DR, Zak B: Clin. Chem., 29, 538 (1983).
Kaplan LA, Pesce AJ: "Clinical Chemistry", Mosby Ed. (1996).
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

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