GAMMA GT LR liquid reagent

REF C3500650/C3500650A 6x50ml

CE **C3500620/C3500620A** 6x20ml

IVD For in vitro medical device

Use

Kit for measurement of gamma glutamyl transferase (GGT) in serum or plasma. SZASZ method.

Summary

Gamma GT measurements are used in the diagnosis and treatment of liver disease such as cirrhosis, biliary obstruction and primary and secondary liver tumors.

Principle

Kinetic analysis. Gamma-glutamyl group is transferred from gamma-glutamyl-carboxy-nitroanilide to glycyglycine by gamma-glutamyltransferase (GGT) as catalist. The rate of increase in absorbance is directly proportional to sample GGT activity.

Reagents

R1	Goods buffer pH 8.25	350.0 mmol/l
	glycylglycine	180.0 mmol/l
R2	L-gamma-glutamyl-3-carboxy-4-nitroanilide	20.0 mmol/l

Reagents Preparation

Reagents are liquid and ready for use. About use as monoreagent ("sample-starter" procedure) add the entire content of one bottle of GGT **R2** in the GGT **R1** bottle and mix gently. For minor use add to every 4 ml of R1 reagent, 1 ml of R2 reagent. 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 and R2 are stable 90 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.
- Working solution stability (R1+ R2): 20 days at 2-8°C.

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 or EDTA plasma.
- Do not use samples with emolysis.
- The GGT activity is stable for 7 days at 2-8°C

Note

- The kit, according to this method, must be used in manual procedures. About automatic using 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: 405 (400 - 420) nm
Working temperature	37°C
Optical path	1 cm
Reaction	kinetic (increasing)

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

Monoreagent Procedure "sample starter"

	BLANK	SAMPLE
Working Reagent	1000 µl	1000 µl
Distilled Water	100 µl	--
Sample	--	100 µl

Mix, then incubate for 1' a 37°C. Measure the absorbance of sample (EC) against distilled water. Make at least two readings at a distance of 60". Calculate the absorbance variation ΔE/min from performed readings.

Bireagent Procedure "substrate starter"

	BLANK	SAMPLE
Reagent R1	800 µl	800 µl
Distilled Water	100 µl	--
Sample	--	100 µl

Mix, then incubate for 1' a 37°C. Then add:

Reagent R2	200 µl	200 µl

Mix , then incubate for 1' a 37°C. Measure the absorbance of sample (EC). Make at least two readings at a distance of 60". Calculate the absorbance variation ΔE/min from performed readings.

Calculation

GGT [U/l] = ΔE/min x 1159

The factor and the reagent performances are related to 37°C, 1 cm and 405 nm.

Reference Values at 37°C

Men	10 – 50 [U/l]
Women	8 – 31 [U/l]

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 800 U/l. 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 5.0 U/l.

"Intra-Assay" precision (within-Run)

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

MEAN (U/l)	N = 33.0	H = 179.20
S.D.	N = 1.94	H = 2.34
C.V.%	N = 5.88	H = 1.30

"Inter-Assay" precision (between-run)

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

MEAN (U/l)	N = 39.47	H = 180.05
S.D.	N = 1.68	H = 3.24
C.V.%	N = 4.25	H = 1.80

Correlation

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

y = 1.0189 x + 6.0325

Interferences

No interferences was observed by the presence of:

Bilirubin	≤ 25 mg/dl
Hemoglobin	≤ 250 mg/dl
Triglycerides	≤ 800 mg/dl

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

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

Committee of the Scand. Soc. for Clin. Chem. - Scand. J. Clin. Lab. Invest., 36, 119 (1976).
Szasz G: Clin. Chem., 22, 2051 (1976).
Persijn JP, van der Silk W: J. Clin. Chem. Clin. Biochem.,14, 421 (1976).
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
	Producer

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