GAMMA GT SL

Kinetic Method (Szasz-Tris)

Liquid reagents ready to use

REF 18210160 R1 8X20mL
REF 12003040 R2 8X5mL

IVD

PRODUCT CODE: GAM-8D25

Company with Quality System ISO 9001 – ISO 13485 Certified by LMS

INTENDED USE

Quantitative determination of glutamyltransferase (γ-GT) in serum.

PRINCIPLE

The γ-GT, in the presence of glycyl-glycine, splits the L-γ-glutamyl-3-carboxy-4-nitroanilide (carboxi-glupa) in L-γ-glutamyl-glycyl-glycine and 5-amino-2-nitrobenzoate. The absorbance change in time unit measured at 405 nm is proportional to the enzyme activity in the sample.

SAMPLE

Serum, plasma EDTA. Avoid hemolysis.

The γ-GT in serum is stable one week at 2-25°C. Store at -20°C for prolonged periods.

KIT COMPONENTS

Reagent (A) γ-GT Volume = 80 ml	Tris buffer Glycyl-glycine	50 mmol/l 125 mmol/l
Reagent (B) γ-GT Volume = 20 ml	L-γ-glutamyl-3-carboxy-4-nitroanilide	6 mmol/l

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C and protected from light. Do not use over expiry date.

Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided. Do not freeze.

Keep bottles closed when not in use.

REAGENT PREPARATION

Liquid Reagents, bring to room temperature (15-25°C) before use.

For **useasmonoreagent**: add a part of Reagent (B) to 4 parts of Reagent (A).

The working solution (A+B) is stable 1 weeks at 2-8°C.

PRECAUTIONS AND WARNINGS

Reagents may contain some non-reactive and preservative components.

It is suggested to handle carefully it, avoiding contact with skin and swallow. Use the normal precautions required in the laboratory.

Dispose of waste according to local laws.

PROCEDURE

Wavelength:	405 nm
Lightpath:	1 cm
Temperature:	37°C
Reading:	against distilled water
Method:	Increasing kinetic

Use as monoreagent:

pipette:	
Working solution (A+B)	300µl
sample	24µl

Mix, incubate at 37°C for 1 minute, read the initial absorbance against water. Make 3 readings at a distance of 60 seconds. Calculate the average value of the absorbance variations per minute. (ΔA/min).

Use as bireagent:

pipette:	
Reagent (A)	240µl
sample	24µl
mix and after 1 minute add:	
Reagent (B)	60µl

Mix, incubate at 37°C for 1 minute, read the initial absorbance against water. Make 3 readings at a distance of 60 seconds. Calculate the average value of the absorbance variations per minute. (ΔA/min).

RESULTS CALCULATION

Perform calculation in Units per litre, multiplying the ΔA/min by the factor as it is indicated:

activity in U/L: ΔA/min x 1422**(*)**

(*) Factor calculated in our laboratories. We recommend the use of SicuroBio calibrator Acucal (Ref. SB-8327) to verify that this factor is correct for your test system.

EXPECTED VALUES

Men: **≤ 49 U/L**

Women: **≤ 32 U/L**

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of Sicurobio control sera: ACUTROL 1 (REF. SB-8334) and ACUTROL 2 (REF. SB-8335).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 2 U/L

Linearity: the method is linear up to 1200 U/L. For higher values, dilute the sample 1:10 and multiply the result by 10.

Precision intra-assay:

	Level 1	Level 2	Level 3
Mean (U/l)	21.40	147.1	307.0
SD	0.819	1.792	1.414
CV %	3.83	1.22	0.46

Precision inter-assay:

	Level 1	Level 2	Level 3
Mean (U/l)	21.21	152.5	322.5
SD	0.619	1.958	1.958
CV %	2.92	1.28	0.61

Interferences: bilirubin does not re up to 30 mg/ dl. Ascorbic does not interfere up to 50 mg/dl. The presence of hemolysis causes an underestimation proportional to the degree of hemolysis.

The commonly used anticoagulants inhibit the activity of γ-GT.

Anticonvulsants (phenytoin, barbiturates) cause a false increase in γ-GT.

Correlation against a reference method:

Y = 1.0399x + 2.1657 r = 0.9994

REFERENCES

1. Szasz G., Clin. Chem. 22,2051 (1976).
2. Vassault, A. et al. Ann. Biol. Clin., 44,686 (1986).
3. Young, D.S., et al., Clin. Chem. 21:1D (1975).

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