Atlas Medical CE

γ-GT Carboxy substrate kinetic.Liquid Quantitative determination of gamma-glutamyl transferase (γ-GT)

IVD ***For in -vitro diagnostic use only***

2°C 8°C **Store at 2-8 °C**

INTENDED USE

For the quantitative determination of gamma-glutamyl transferase (γ-GT) in human serum.

INTRODUCTION

Gamma-glutamyl transferase (γ-GT) is a cellular enzyme with wide tissue distribution in the body, primarily in the kidney, pancreas, liver and prostate. Measurements of gamma-glutamyl transferase (γ-GT) activity are used in the diagnosis and treatment of hepatobillary diseases such biliary obstruction, cirrhosis or liver tumors.
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE

Gamma-glutamyl transferase (γ-GT) catalyses the transfer of γ-glutamyl group from γ-glutamyl-p-nitroanilide to acceptor glycylglycine, according to the following reaction:

γ-L-Glutamyl-3-carboxy-4-nitroanilide + Glycylglycine —(γ-GT)→ **γ-L-Glutamyl-glycylglycine + 2 – Nitro-5-aminobenzoic acid**

The rate of 2-nitro-5-aminobenzoic acid formation, measured photometrically, is proportional to the catalytic concentration of γ-GT present in the sample.

MATERIALS

REAGENTS

R1	TRIS pH 8.6	100 mmol/L
Buffer	Glycylglycine	100 mmol/L
R2 Substrate	L-γ -glutamyl-3-carboxy-4-nitroanilide	3 mmol/L

EQUIPMENTS NEEDED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 405 nm.
- Thermostatic bath at 25°C, 30°C, 37°C (±0.1°C)
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

PREPARATION

- Working reagent (WR)
  Mix: 4 vol. (R1) Buffer + 1 vol. (R2) Substrate
- Stability: 21 days at 2-8 °C or 5 days at room temperature 15-25 °C.

STORAGE AND STABILITY

- All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8 °C, protected from light and contamination is prevented during their use.
- Do not use reagents over the expiration date
- Signs of reagent deterioration:
  - Presence of particles and turbidity.
  - Blank absorbance (A) at 405 nm ≥ 1.80.

SAMPLES

Serum. γ -GT is stable for at least 3 days at 2-8 °C, 8 hours at 15-25 °C and 1 month at – 20°C.

PROCEDURE

1. Assay conditions:
   Wavelength ……405nm.
   Cuvette…… 1 cm light path.
   Constant temperature …….25°C /30°C/ 37°C.
2. Adjust the instrument to zero with distilled water or air.
3. Pipette into a cuvette.

WR (ml)	1.0
Sample (µL)	100

4. Mix, wait for 1 minute.
5. Read initial absorbance (A) of the sample, start the stopwatch and read absorbance at 1 minute intervals thereafter for 3 minutes.
6. Calculate the difference between absorbance and the average absorbance differences per minute (ΔA/min).

CALCULATIONS

(ΔA/Min) X 1190 = U/L of γ -GT

Units: One international unit (IU) is the amount of enzyme that transforms 1 µmol of substrate per minute. In standard conditions. The concentration is expressed in units per litre of sample (U/L).

TEMPERATURE CONVERSION FACTORS

To correct results to other temperatures multiply by:

Assay temperature	Conversion factor to		
	25°C	**30°C**	**37°C**
25°C	1.00	1.37	1.79
30°C	0.73	1.00	1.30
37°C	0.56	0.77	1.00

REFERENCE VALUES

	25°C	**30°C**	**37°C**
Women	4-18 U/L	5-25 U/L	7-32 U/L
Men	6-28 U/L	8-38 U/L	11-50 U/L

NOTE

These values are for orientation purpose; each laboratory should establish its own reference range.

QUALITY CONTROL

- If control values are found outside the defined range, check the instrument, reagents and technique for problems.
- Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

PERFORMANCE CHARACTERISTICS

Measuring range:

From detection limit of 2U/L to linearity limit of 300 U/L.

If the results obtained were greater than linearity limit, dilute the sample 1/10 with NaCl 9 g/L and multiply the result by 10.

Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (U/L)	38.3	190	40.1	198
SD	0.39	0.53	0.82	2.30
CV (%)	1.03	0.28	2.05	1.16

Sensitivity:

1 U/L = 0.0008 ΔA/min.

Accuracy:

Results obtained using Atlas reagents (y) did not show systematic differences when compared with other commercial reagents (x).

The results obtained using 50 samples were the following:

Correlation coefficient $(r)^2$: 0.99990

Regression equation: y=1.334x-1.493.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Plasma should not be used, anticoagulants inhibit the enzyme. Gross haemolysis interferes in the assay.

A list of drugs and other interfering substances with γ -GT determination has been reported.

REFERENCES

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry