Atlas Medical

γ-GT Carboxy substrate kinetic

IVD *For In-Vitro diagnostic and professional use only*

2°C 8°C Store at 2-8°C CE

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 tumours.

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 Buffer	TRIS pH 8.25	100 mmol/L
R2 Substrate	Glycylglycine L- γ -glutamyl-3-carboxy-4-nitroanilide	100 mmol/L 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)
  Dissolve one tablet of R2 Substrate in 2ml of R1 buffer
- Cap and mix gently to dissolve contents.
- 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.
- Don't use the tablet if appear broken.
- 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 absorbances at 1 minute intervals thereafter for 3 minutes.
6. Calculate the difference between absorbances 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 litere 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 0.000 U/L to linearity limit of 375 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)	40.0	199	41.6	200
SD	0.33	1.20	0.80	2.29
CV (%)	0.83	0.61	1.91	1.15

Sensitivity:

1 U/L = 0.0008 ΔA/min.

Accuracy:

Results obtained usingreagents (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): 0.99

Regression equation: y=1.2253x-2.0435

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 by Young et. Al 3,4.

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