

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

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

 **Store at 2-8 °C**

### **INTENDED USE**

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

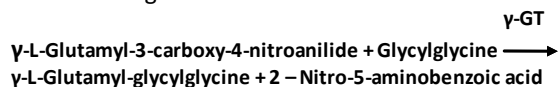
### **INTRODUCTION**

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 hepatobiliary 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:



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**

<b>R1</b>	TRIS pH 8.6	100 mmol/L
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Buffer	Glycylglycine	100 mmol/L
<b>R2</b>	L-γ -glutamyl-3-carboxy-4-nitroanilide	
Substrate		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
<b>Women</b>	4-18 U/L	5-25 U/L	7-32 U/L
<b>Men</b>	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)<sup>2</sup>: 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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	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	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