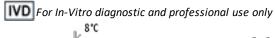
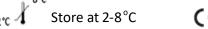


y-GT Carboxy substrate kinetic





INTENDED USE

For the quantitative determination of gamma-glutamyl transferase (y-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:

ν-GT

γ-L-Glutamyl-3-carboxy-4-nitroanilide + Glycylglycine -----

y-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	Glycylglycine	100 mmol/L
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)
 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:
- 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.

- 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 (ΔΑ/min).

CALCULATIONS

($\Delta A/Min$) X 1190 = U/L of γ -GT

Units: One international unit (IU) is the amount of enzyme that transforms 1 μ mol 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	Conversion factor to		
temperature	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)	
Mean (U/L)	40.0	199
SD	0.33	1.20
CV (%)	0.83	0.61

Inter-assay (n=20)			
41.6	200		
0.80	2.29		
1.91	1.15		

Sensitivity:

1 U/L = $0.0008 \Delta A/min$.

Accuracy:

Results obtained using 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): 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

- Gendler S. y-GT. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984;1120-1123,
- 2. Persijn J P et al. J Clin Chem Clin Biochem 1976: (14) 9: 421 427.
- 3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
- 4. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.

- 5. Burtis A et al. Tietz Texbook of Clinical Chemistry, 3rd ed AACC 1999.
- 6. Tietz N W et al. Clinical Guide to laboratory Tests, 3rd ed AACC 1995.

ATLAS Medical
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany

Tel: +49 - 33708 - 3550 30 Email: Info@atlas-medical.com

PPI1633A01

Rev A (02.09.2019)

REF	Catalogue Number	1	Temperature limit
IVD	In Vitro diagnostic medical device	\triangle	Caution
Σ	Contains sufficient for <n> tests and Relative size</n>	(i	Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
Ī	Fragile, handle with care		Use-by date
4	Manufacture r fax number	(8)	Do not use if package is damaged
	Manufacturer telephone number	*	Date of Manufacture
漆	Keep a way from s unlight	今	Keep dry