GENESIS

Instructions For Use

γ - GT (IFCC Method) (4+1)

Cat no.	size
1211 101	2*25
1211 102	5*20

INTENDED USE

γ - GT reagent is intended for the in vitro quantitative, diagnostic determination of gamma-glutamyl transferase (γ–GT) in human serum.

DIAGNOSTIC CHARACTERISTICS

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 tumours. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data

PRINCIPLE OF THE METHOD

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 $\xrightarrow{\gamma\text{–GT}}$ 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.

COMPOSITION

Reagent (R1)	TRIS pH 8.6 Glycylglycine	100 mmol/L 100 mmol/L
Reagent (R2)	L-γ-glutamyl-3-carboxy-4-nitroanilide	3 mmol/L

STORAGE AND STABILITY.

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contaminations prevented during their use. Do not use reagents over the expiration date.

REAGENT PREPARATION

Working reagent- : Mix 4 mL of R1 + 1 mL of R2. Stable for 3 weeks at 2-8ºC or for 5 days at 15-25ºC. Protect from light.

ADDITIONAL EQUIPMENT

− Analyzer, spectrophotometer able to read at 405 nm.

SPECIMEN

Serum or EDTA plasma free of hemolysis. Fluoride, citrate and oxalate inhibit γ-GT activity.

The enzyme in the sample is stable for at least 1 week at 2-8ºC and for at least 2 months when frozen.

PRECAUTIONS AND WARNINGS

- Do not ingest or inhalate.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water.
- In case of severe injuries; seek medical advice immediately.
- Avoid use of hemolysed samples.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by
	Consult instructions for use		Temperature Limit

PROCEDURE

1. Bring the reagent to room Temperature
2. Pipette into a cuvette:

Working Reagent	1 ml
Sample/Calibrator (optional)	100 µL

3. Mix and incubate for 60 seconds.
4. Read initial absorbance (A) of the sample, start the stopwatch and read absorbance at 1minute intervals thereafter for 3 minutes.
5. Calculate the difference between absorbances and the average absorbance differences per minute (ΔA/min).

- **CALCULATIONS**

With factor.

(γ–GT) U/L = ΔA/min x 1450

REFERENCE VALUES

Male	7-32 U/L
Female	11-50 U/L

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

QUALITY CONTROL

It is recommended to use the Control Serum level I And II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control.

METROLOGICAL CHARACTERISTICS

Measuring range:

- detection limit of 2 U/L.
- 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)	40.03	200.1	39.98	200
SD	065	1.58	0.73	1.68
CV (%)	1.62	0.79	1.81	0.84

Sensitivity: 1 U/L = 0.0008 ΔA/min.

Accuracy: Results obtained using Genesis 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

- Lipemia (intralipid >2.5 g/L) may affect the results.
- Bilirubin (> 10 mg/dL) may affect the results.
- Hemoglobin (> 8 g/L) may affect the results.
- Other drugs and substances may interfere.

BIBLIOGRAPHY

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IFU-GGT-13
Rev. (2) 17/09/2023

ISO 13485:2016 Medical Devices

CE

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