



GENESIS

Instructions For Use

γ - GT (IFCC Method) (4+1)

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

INTENDED USE

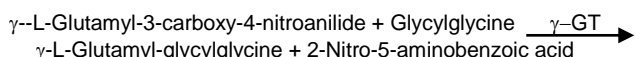
γ - GT reagent is intended for the in vitro quantitative, diagnostic determination of gamma-glutamyl transferase (γ-GT) in human serum.

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 as 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:



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 | 100 mmol/L |
| | Glycylglycine | 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 2-8°C, 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 2-8°C or for 5 days at 15-25°C. 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 2-8°C and for at least 2 months when frozen.

PRECAUTIONS AND WARNINGS

- Do not ingest or inhale.
- 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 | | Manufactured by |
| LOT | | Lot number | | Temperature Limit |
| | | Consult instructions for use | | |

PROCEDURE

- Bring the reagent to room Temperature
- Pipette into a cuvette:

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

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

- CALCULATIONS

With factor.

$$(\gamma\text{-GT}) \text{ U/L} = \Delta A/\text{min} \times 1450$$

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) | SD | CV (%) | |
| 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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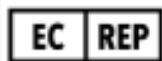
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