

|                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------|
| COD 12520 5 x 40 mL + 5 x 10 mL                                                                                   |
| STORE AT 2-8°C                                                                                                    |
| Reagents for measurement of $\gamma$ -GT concentration<br>Only for <i>in vitro</i> use in the clinical laboratory |

**GAMMA-  
GLUTAMYLTRANSFERASE**  
( $\gamma$ -GT)



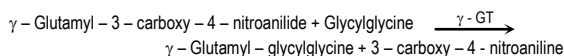
**BioSystems**



**GAMMA-GLUTAMYLTRANSFERASE ( $\gamma$ -GT)**  
IFCC

## PRINCIPLE OF THE METHOD

Gamma-glutamyltransferase ( $\gamma$ -GT) catalyzes the transfer of the  $\gamma$ -glutamyl group from  $\gamma$ -glutamyl-3-carboxy-4-nitroanilide to glycylglycine, liberating 3-carboxy-4-nitroaniline. The catalytic concentration is determined from the rate of 3-carboxy-4-nitroaniline formation<sup>1,2,3</sup>.



## COMPOSITION

A. Reagent: 5 x 40 mL. Glycylglycine 206.25 mmol/L, sodium hydroxide 130 mmol/L, pH 7.9.

**WARNING: H315: Causes skin irritation. H319: Causes serious eye irritation. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332+P313: If skin irritation occurs: Get medical advice/attention.**

B. Reagent: 5 x 10 mL.  $\gamma$ -Glutamyl-3-carboxy-4-nitroanilide 32.5 mmol/L.

**WARNING: P302+P352 - IF ON SKIN: Wash with plenty of soap and water. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P362 - Take off contaminated clothing and wash before reuse.**

For further warnings and precautions, see the product safety data sheet (SDS).

## STORAGE

Store at 2-8°C.

Reagents are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Indications of deterioration:

– Reagents: Presence of particulate material, turbidity, absorbance of the blank over the limit indicated in "Assay parameters".

## AUXILIARY REAGENTS

Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

## REAGENT PREPARATION

Working Reagent: Pour the contents of the Reagent B into the Reagent A bottle. Mix gently. Other volumes can be prepared in the proportion: 4 mL Reagent A + 1 mL Reagent B. Stable for 2 months at 2-8°C.

Reagent open and kept in the refrigerated compartment of the analyzer is stable 20 days.

## SAMPLES

Serum and plasma collected by standard procedures.

Gamma-glutamyltransferase in serum and plasma is stable for 5 days at 2-8°C. Use heparin or EDTA as anticoagulant.

## REFERENCE VALUES

| Reaction temperature | Men  |             | Women |             |
|----------------------|------|-------------|-------|-------------|
|                      | U/L  | $\mu$ kat/L | U/L   | $\mu$ kat/L |
| 25°C                 | < 22 | < 0.37      | < 15  | < 0.25      |
| 30°C                 | < 35 | < 0.59      | < 24  | < 0.40      |
| 37°C <sup>1</sup>    | < 55 | < 0.92      | < 38  | < 0.64      |

Values at 25°C and 30°C are obtained from those at 37°C by using a conversion factor. These ranges are given for orientation only; each laboratory should establish its own reference ranges.

## CALIBRATION

A calibration is recommended at least every 20 days, after reagent lot change or as required by quality control procedures.

## ASSAY PARAMETERS

|                             |                     | A25          | A15          |
|-----------------------------|---------------------|--------------|--------------|
| GENERAL                     | Test name           | GGT          | GGT          |
|                             | Analysis mode       | mon. kinetic | mon. kinetic |
|                             | Sample type         | SER          | SER          |
|                             | Units               | U/L          | U/L          |
|                             | Reaction type       | increasing   | increasing   |
|                             | Decimals            | 0            | 0            |
|                             | No. of replicates   | 1            | 1            |
| Test name in patient report |                     | -            | -            |
| PROCEDURE                   | Reading             | monoch.      | monoch.      |
|                             | Volumes             |              |              |
|                             | Sample              | 30           | 30           |
|                             | Reagent 1           | 300          | 300          |
|                             | Reagent 2           | -            | -            |
|                             | Washing             | 1.2          | 1.2          |
|                             | Predilution factor  | -            | -            |
| Filters                     | Postdilution factor | 2            | 2            |
|                             | Main                | 405          | 405          |
|                             | Reference           | -            | -            |

| Times       | Reading 1<br>Reading 2<br>Reagent 2 | 60 s<br>195 s<br>- | 72 s<br>216 s<br>- |
|-------------|-------------------------------------|--------------------|--------------------|
| CALIBRATION | Calibration type                    | multiple           | multiple           |
|             | Calibrator replicates               | 3                  | 3                  |
|             | Blank replicates                    | 3                  | 3                  |
|             | Calibration curve                   | -                  | -                  |
| OPTIONS     | Blank absorbance limit              | 1.450              | 1.450              |
|             | Kinetic blank limit                 | -                  | -                  |
|             | Linearity limit                     | 600                | 600                |

## QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, 18009 and 18042) and II (cod. 18007, 18010 and 18043) to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

## METROLOGICAL CHARACTERISTICS

The following data were obtained using an A25 analyser. Results are similar with A15. Details on evaluation data are available on request.

– Detection limit: 5.8 U/L = 0.10  $\mu$ kat/L.

– Linearity limit: 600 U/L = 10.0  $\mu$ kat/L.

– Repeatability (within run):

| Mean Concentration         | CV    | n  |
|----------------------------|-------|----|
| 37 U/L = 0.62 $\mu$ kat/L  | 1.4 % | 20 |
| 225 U/L = 3.75 $\mu$ kat/L | 1.0 % | 20 |

– Reproducibility (run to run):

| Mean Concentration         | CV    | n  |
|----------------------------|-------|----|
| 37 U/L = 0.62 $\mu$ kat/L  | 4.7 % | 25 |
| 225 U/L = 3.75 $\mu$ kat/L | 1.8 % | 25 |

– Trueness: Results obtained with this procedure did not show systematic differences when compared with a reference procedure. Details of the comparison experiments are available on request.

– Interferences: Hemoglobin (> 5 g/L), bilirubin (> 10 g/L) and lipemia (triglycerides > 4 g/L) may affect the results. Other drugs and substances may interfere<sup>4</sup>.

## DIAGNOSTIC CHARACTERISTICS

Gamma-glutamyl transferase is found in highest concentration in liver, the renal tubules and intestines although it is also present in other tissues such as the pancreas, prostate, salivary glands, seminal vesicles, brain and heart.

Gamma-glutamyl activity is elevated in any and all forms of liver disease, showing highest values in cases of intra or posthepatic biliary obstruction. High elevations are also observed in patients with metastatic neoplasm of the liver. In pancreatitis and some pancreatic malignancies, enzyme activity may be moderately elevated<sup>5,6</sup>.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

## BIBLIOGRAPHY

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