COD 11584 1 x 50 mL	COD 11520 1 x 200 mL
STORE AT 2-8ºC	
Reagents for measurement of γ-GT concentration Only for *in vitro* use in the clinical laboratory	

GAMMA-GLUTAMYLTRANSFERASE (γ-GT)

BioSystems

CE

GAMMA-GLUTAMYLTRANSFERASE (γ-GT)
IFCC

PRINCIPLE OF THE METHOD

Gamma-glutamyltransferase (γ-GT) catalyzes the transfer of the γ-glutamyl group from γ-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[1,2,3].

γ – Glutamyl – 3 – carboxy – 4 – nitroanilide + Glycylglycine $\xrightarrow{\gamma\text{-GT}}$ γ – Glutamyl – glycylglycine + 3 – carboxy – 4 - nitroaniline

CONTENTS

	COD 11584	COD 11520
A. Reagent	1 x 40 mL	1 x 160 mL
B. Reagent	1 x 10 mL	1 x 40 mL

COMPOSITION

A. Reagent: 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: γ-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.

STORAGE

Store at 2-8ºC.

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 1.000 at 410 nm or over 1.450 at 405 nm (1 cm cuvette).

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents. Safety data sheet available for professional user on request. Disposal of all waste material should be in accordance with local guidelines. Any serious incident that might occur in relation to the device shall be reported to BioSystems S.A.

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 2-8ºC.

ADDITIONAL EQUIPMENT

– Analyzer, spectrophotometer or photometer with cell holder thermostatable at 37ºC and able to read at 405 nm or 410 nm (Note 1).

– Cuvettes with 1 cm light path.

SAMPLES

Serum and plasma collected by standard procedures.

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

PROCEDURE

1. Bring the Working Reagent and the instrument to reaction temperature.
2. Pipette into a cuvette: (Note 2)

Working Reagent	1.0 mL
Sample	100 µL

3. Mix and insert the cuvette into the photometer.
4. Record initial absorbance and at 1 minute intervals thereafter for 3 minutes.
5. Calculate the difference between consecutive absorbances, and the average absorbance difference per minute (ΔA/min).

CALCULATIONS

The γ-GT concentration in the sample is calculated using the following general formula:

$$\Delta A/min \times \frac{Vt \times 10^6}{\varepsilon \times l \times Vs} = U/L$$

The molar absorbance (ε) of 3-carboxy-4-nitroaniline at 410 nm is 7908 and at 405 nm is 9900, the lightpath (l) is 1 cm, the total reaction volume (Vt) is 1.1, the sample volume (Vs) is 0.1, and 1 U/L are 16.67 nkat/L. The following formulas are deduced for the calculation of the catalytic concentration:

	405 nm	410 nm
ΔA/min	x 1111 = U/L x 18.52 = µkat/L	x 1391 = U/L x 23.19 = µkat/L

REFERENCE VALUES

Reaction temperature	Men		Women	
	U/L	µkat/L	U/L	µkat/L
37ºC[1]	< 55	< 0.92	< 38	< 0.64

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

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

– Detection limit: 1.6 U/L = 0.03 µkat/L.

– Linearity limit: 600 U/L = 10.0 µkat/L. For higher values dilute sample 1/2 with distilled water and repeat measurement.

– Repeatibility (within run):

Mean Concentration	CV	n
31 U/L = 0.52 µkat/L	1.6 %	20
99 U/L = 1.65 µkat/L	0.5 %	20

– Reproducibility (run to run):

Mean Concentration	CV	n
31 U/L = 0.52 µkat/L	4.8 %	25
99 U/L = 1.65 µkat/L	1.4 %	25

– Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. 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[4].

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

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[5,6].

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

NOTES

1. The IFCC recommended method specify a wavelenght of 410 nm. However, measurements can also be carried out at 405 nm. In this case, the reagent initial absorbance is almost duplicated and the factor used for calculations is different (see calculations).
2. These reagents may be used in several automatic analysers. Instructions for many of them are available on request.

BIBLIOGRAPHY

1. IFCC Primary reference Procedures for the measurement of catalytic activity concentrations of enzymes at 37ºC. Part 6. Reference procedure for the measurement of catalytic concentration of γ-Glutamyltransferase. *Clin Chem Lab Med* 2002; 40:734-738.
2. IFCC reference procedures for measurement of catalytic concentrations of enzymes: corrigendum, notes and useful advice. *Clin Chem Lab Med* 2010; 48: 615-621.
3. Beleta J, Gella FJ. Método recomendado para la determinación en rutina de la concentración catalítica de la γ-glutamiltransferasa en suero sanguíneo humano. *Quim Clin* 1990; 9:58-61.
4. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
5. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. Burtis CA, Ashwood ER, Bruns DE. WB Saunders Co, 2005.
6. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.

Digitally signed by Poiata Vitalie
Date: 2025.10.02 15:20:37 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

BioSystems S.A. Costa Brava, 30. 08030 Barcelona (Spain)
www.biosystems.global