

# BioMed - $\gamma$ - Gamma GT



## kinetic

REF: GGT124060 ( 10 x 6 ml )  
GGT124100 (10 x 10 ml)

### INTENDED FOR USE:

For the quantitative determination of  $\gamma$ -glutamyl transferase in serum .

### PRINCIPLE :

Kinetic determination of  $\gamma$ -glutamyl transferase in human serum according to the following reaction :

L -  $\gamma$ -glutamyl - 3-carboxy-4-nitroanilide + glycylglycine



L -  $\gamma$  - glycylglycine + 5-amino-2-nitrobenzoate .

The amount of 5-amino-2- nitrobenzoate formed is proportional to  $\gamma$ -GT activity in the sample .

Shake and bring the samples at room temperature ( +15-25°C ) before using.

### SPECIMEN COLLECTION:

#### Serum :

#### Notes :

$\gamma$ -GT activity is inhibited by most anticoagulants .

$\gamma$ -GT in serum is stable 7 days at +2-8°C and up to 2 months frozen at -20°C and protected from evaporation .

### REAGENT COMPOSITION:

<b>R1</b>	<i>Buffer reagent (Liquid)</i>	
	Tris buffer pH 8.2	120 mmol/l
	Glycylglycine	120 mmol/l
	Detergent	3.0 g/l
<b>R2</b>	<i>Substrate reagent (Lyophilized)</i>	
	L- $\gamma$ -glutamyl-3-carboxy-4-nitroanilide	2.9 mmol/l

### PACKAGE : Collection & Storage

Store at +2-8°C.

Stable until the expiration date reported upon the package.

After the unsealing and the taking of the reagent , it is advised to close up the bottle immediately in order to avoid evaporation , direct light exposure and bacteric contamination .

### PRECAUTIONS & WARNING:

Avoid pipette with mouth .

The preparation , according to current regulation . Pipette is classified as not dangerous.

The total concentration of non active components (preservatives, detergents, stabilizers ) is below the minimum required for citation .

Anyway handle with care , avoid ingestion , avoid contact with eyes , skin and mucous membranes

The samples must be handle as potentially infected from HIV or Hepatitis .

### REAGENT PREPARATION & STABILITY :

Reagents must be at room temperature ( +15-25°C ) before using .

Reconstitute one vial of R2 (enzyme reagent) with 3 ml R1 (buffer reagent). Mix well do not shake.

Reconstituted reagent is limp and pale yellow

### REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instrumentations .

### PROCEDURE :

Wavelength 405 nm ( 400-420)  
Optical path : 1 cm light path  
Temperature : +25/30/37°C  
Reading : Against distilled water  
Assay type : Increasing Kinetic  
Sample/Reagent ratio : 1\10

#### Pipetting in tubes :

	SAMPLE	
Reagent(R1+R2)	1000	$\mu$ L
Sample	100	$\mu$ L

Adjust the instrumen zero with distilledwater.

Mix , transfer in cuvette and incubate for 60 sec at 37°C ( T , 0 sec ) ; read sample increase and extinction at time after 60\120\180'' .

Calculate  $\Delta A/\text{min}$  . at 405 nm .

Volumes can be proportionally modified .

This methodology describes the manual procedure to use the kit .

For automated procedure, ask for specific application .

### Calculation :

405 nm  $\gamma$ -GT ( U/L ) =  $\Delta E/\text{min} \times 1158$

### EXPECTED VALUES :

**Women** 8-36 U/L  
**Men** 12-55 U/L

The above mentioned values are to be considered as a reference.

It is strongly recommended that each laboratory establish its own normal range according

### WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal .

## QUALITY CONTROL :

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

## REFERENCES:

1. Tietz, N.W. Fundamentals of Clinical Chemistry 2nd Ed., W.B. Saunders, Philadelphia, PA., 1976.
2. Szasz, G., Clin. Chem. 15(24), 1969.
3. Rosalki, S.B., et al., Ann. Clin. Biochem. 7(143), 1970.
4. Young, D.S., et al., Clin. Chem. 20(10), 1975

## PERFORMANCE :

MEASURE INTERVAL :	0-300 U/L
DETECTION LIMIT :	2 U/L
SENSITIVITY :	1 U/L= 0.009 ΔE/min.

### INTRA-ASSAY PRECISION : n=20

LOW LEVEL	M = 22 U/L	C.V = 1.5%
HIGH LEVEL	M = 335 U/L	C.V = 0.3%

### INTER-ASSAY PRECISION : n=20

LOW LEVEL	M = 21 U/L	C.V = 3.0%
HIGH LEVEL	M = 333U/L	C.V = 1.8%

CORRELATION	r = 0.999	n=50
LIN. REGRESSION	y= 1.04 x -2.7	n=50

## INTERFERENCE:

Interferences are negligible up to :			
Bilirubin	30 mg/dL	Triglycerides	500 mg/dL
Hemoglobin	100 mg/dL	Glucose	500 mg/dL






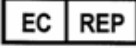



## METHOD LIMITATIONS:

For concentration higher than 300 U/L repeat the measure on a sample diluted 1:10 with physiological saline and multiply the results by 10 .

γ-GT activity is inhibited by most anticoagulants used in blood collection .

anti-epileptic drugs ( phenytoin and barbiturates ) may falsely elevate γ-GT levels .

For through evaluation of the interfering substances ,consult : Young , D. S ,et al , Clin , Chem , 21:1 D ( 1975 ) .

	Consult Instructions for Use
	Caution, consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

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