BioMed - ¥ - Gamma GT

Kinetic

REF:

GGT124030 (5x 6 ml)
GGT12460 (10 x 6 ml)

INTENDED FOR USE:

For the quantitative determination of γ-glutamyl transferase in serum .

PRINCIPLE :

Kinetic determination of γ-glutamyl transferase in human serum according to the following reaction :

L - γ-glutamyl - 3-carboxy-4-nitroanilide + glycylglycine

$$\xrightarrow{\gamma\text{-GT}}$$

L - γ - glycylglycine + 5-amino-2-nitrobezoate .

The amount of 5-amino-2- nitrobezoate formed is proportional to γ-GT activity in the sample .

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

SPECIMEN COLLECTION:

Serum :

Notes :

γ-GT activity is inhibited by most anticoagulants.

γ-GT in serum is stable7 days at +2-8°C and up to 2 months frozen at -20°C and protected from evaporation .

REAGENT COMPOSITION:

R1	*Buffer reagent (Liquid)* Tris buffer pH 8.2 Glycylglycine Sodium Azide	 120 mmol/l 300 mmol/l 12 mmol
R2	*Substrate reagent (Lyophilized)* L-γ-glutamyl-3-carboxy-4-nitroanilide Sodium Azide	 1.0 mmol/l 8 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 .

Add 5 volume of R1 to ONE volume of R2

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 µL
Sample	100 µL

Adjust the instrumen zero with distiledwater.

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 ΔA/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 γ-GT (U/L) = ΔE/min × 1500

EXPECTED VALUES :

	Women	**Men**
37°C :	8-36 U/L	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.

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 .

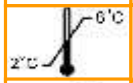
γ-GT activity is inhibited by most anticoagulants used in blood collection .

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) .

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

	Consult Instructions for Use
	Caution, Consult accompanying
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

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