Pariksha Biotech
A game changer in IVD

Gamma-GT Estimation kit

High-Q Gamma - GT

(IFCC Method)

HIGH®
Command on Quality

Intended Use: Kit for the quantitative determination of Gamma-Glutamyltransferase (GGT) in human serum.

Summary & Clinical Significance:
Gamma-glutamyltransferase is used in the diagnosis and monitoring of hepatobiliary diseases, Enzymatic activity of GGT is often the only parameter with increased values when testing for such diseases, and is one of the sensitive indicators known. Gamma-glutamyltransferase is also a sensitive screening test for occult alcoholism. Elevated GGT activities are found in the serum of patients requiring long-term medication with phenobarbital and phenytoin. IFCC, the kinetic procedure was published for GGT estimation in serum using γ-glutamyl-p-nitroanilide as substrate and glycylglycine as acceptor. In order to circumvent the poor solubility of γ-glutamyl-pnitroanilide, Persijn and van der Slik investigated various derivatives of the compound with respect to solubility. The substrate L-γ-glutamyl-3- carboxy-4-nitroanilide is superior in terms of stability and solubility. The assay described below uses the water-soluble substrate L-γ-glutamyl-3-carboxy-4-nitroanilide . The results correlate with those derived using the original substrate.

Test Principle:

L-γ-Glutamyl–3–carboxy–4–nitroanilide + Glycylglycine $\xrightarrow{\gamma\text{-GT}}$ L-γ-glutamyl-glycylglycine + 5-amino–2-nitrobenzoate

Gamma-glutamyltransferase transfers the γ-glutamyl group of L-γ-glutamyl-3-carboxy-4-nitroanilide to glycylglycine. The amount of 5-amino-2-nitrobenzoate liberated is proportional to the GGT activity and can be determined photometrically.

Reagent Composition:

	Active Ingredients	Concentrations
Reagent 1	Glycylglycine	180 mM
Reagent 2	L-Gamma-glutamyl-3-carboxy-4-nitroanilide	6.8 mM

Concentrations are those in the working reagent.

Reagent Preparation:
All the reagents are Liquid Stable and ready to use reagents. They are stable till the expiry date mentioned on the labels

Specimen
Un hemolyzed Serum is the specimen of Choice
Specimen Stability : at least 1 week at - 20°C
Discard the contaminated specimen.

Expected Values:

Adults: Male up to 55 U/L
Female up to 36 U/L

Assay Procedure:
Pipette the reagents as follows.

R1	400 µl
Serum	25 µl
R2	100 µl

Mix well and immediately aspirate in to the analyzer. After 60 Seconds incubation (Delay), measure the change of optical density per 60 seconds during 180 seconds (Measuring) against distilled water at 405 nm as follows:

Aº	Exactily after 60 Seconds
A1, A2, A3	Exactily after every 60 seconds for 180 seconds.

Calculation:
From the absorbance reading calculate ΔA/min and multiply by the corresponding factor

Δ A/ min x 3450 = Gamma-GT activity [U/L]

System Parameters:

Reaction Type (Mode)	:	**Kinetic**
Reaction Direction	:	**Increasing**
Wave Length	:	**405nm**
Flow Cell Temp.	:	**37°C**
Zero Setting with	:	**Distilled Water**
Delay time	:	**60 seconds**
Measuring Time	:	**180 Seconds**
Reagent Volume	:	**(R1 400 µl + R2 100 µl)**
Sample Volume	:	**25 µl**
Factor	:	**3450**
Linearity	:	**500 U/L**
High Normal	**Male :**	**55 U/L**
	Female :	**36 U/L**

Performance Characterestics:
Measuring Range:
The test has been developed to determine Gamma-GT activities which correspond to maximal ΔA /min of 0.145. If such values exceeds the sample should be diluted 1+5 with Normal saline and result should be multiplied by 6.

Specificity / Interference:
No significant interference was observed from Bilirubin up to 20 mg/dl (Both conjugated and unconjugated Bilirubin) Hemoglobin up to 50 mg/dl,Lipemia as Triglycerides up to 2000 mg/dl, Ascorbic acid up to 50 mg/dl.

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Sensitivity / Linearity:

The lower limit of detection is 2 U/L
Linearity is 500 U/L

Precision:

Intra-assay precision	Mean	SD	CV (%)
N=20	(U/l)	(U/l)	(U/l)
sample1	40	0.99	2.48
sample 2	74	0.88	1.18
sample 3	206	1.32	0.640

Inter-assay precision	Mean	SD	CV (%)
N=20	(U/l)	(U/l)	(U/l)
sample1	42	0.63	1.5
sample 2	73	0.62	0.84
sample 3	202	0.75	0.37

Method Comparison:

A comparison between **High-Q Gamma GT** (Standardized to IFCC) (y) and IFCC reference reagent (x) using 40 samples gave following result: y = 1.005 x - 0.74U/L ; r = 0.999

Notes :

1. The reagents contain sodium azide (0.95 gm/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
2. Take the necessary precautions for the use of laboratory reagents.

References:

1. Bablock W. et al A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26:783-790
2. Glick M.R.. Ryder K.W.. Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation, Clin Chem1986;32:470-474
3. Passing H., Bablock W., A New Biometrical Procedure for Testing the Equality of Measurements from two Different Analytical Methods. J Clin Chem Clin Biochem 1983;21:709-720
4. Persijn JP, van der Silk W. A mew method for the determination of gamma-glutamyltransferase J Clin Chem Biochem 1976;4:421

Ordering Information

Ref./Cat. No.	Pack Size	Presentation
P-GGT -10	10 ml	Two Liquid Reagents
P-GGT -20	20 ml	

Product Features

- **Liquid Stable, Ready to use Two Reagents (4 parts R1 + 1 part R2).**
- **4 Minutes increasing Kinetic Reaction (60 Sec Delay+ 180 Sec Measuring)**
- **Linearity : 500 IU/L**
- **Measuring Wavelength 405 nm**
- **Results by Kinetic Factor : 3450**
- **Serum is the specimen**
- **Available as multipurpose reagents and dedicated system packs**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

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Pariksha Biotech Pvt Ltd,
Plot no.1/B-14, SVICE,
Balanagar,
Hyderabad-500037
Telangana State

+91 7075706709
info@parikshabio.com
www.parikshabio.com

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