LiquiMAX GAMMA - GT-SLR (OPTIMIZED) IFCC METHOD

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVGGT - 10	10 ml	1 x 8 ml/1 x 2 ml
AVGGT - 20	20 ml	2 x 8 ml/2 x 2 ml

INTENDED USE:

LiquiMAX GAMMA-GT is an in-vitro diagnostic kit is use for the quantitative determination of Gamma-Glutamyl Transferase (GGT) in human serum and plasma.

PRODUCT FEATURES :

1. Two Liquid Reagent (4 part R1 + 1Part R2).
2. Linearity 500 IU/L.
3. Measuring wavelength 405 nm.
4. Kinetic reaction time 4 minutes.
5. Kinetic factor 3450 at 405 nm at 37 degrees.
6. Can be used on any discrete semi automated and automated analyzers.

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.

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 STORAGE AND STABILITY

1. Substrate Reagent is ready to use and it does not need reconstitution. When the reagent is stored properly at 2-8°C and the contamination is avoided, it is stable up to the expiry date mentioned on the labels and kit box.
2. It is recommended that when the reagent is not in use, it should be strictly kept at 2-8°C for better performance and stability.
3. Substrate Reagent must be protected from direct sun light.
4. Do not expose the reagent to high temperatures above 10°C.

KIT COMPONENTS

1. Reagent R1
2. Reagent R2

COMPOSITION

TRIS	PH 8.25	100 mmol/l
	Glycyglycine	180 mmol/l
	L-Gamma-Glutamyl-3 carboxy 4-nitroanilide	6.8 mmol/l

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent if blank reagent absorbance exceeds 0.8 at 340 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN & COLLECTION STORAGE

- Serum
- Specimen Stability : at least 1 week at - 20°C
- Discard the contaminated specimen.

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
Kinetic Interval	:	60 seconds
Number of readings	:	4
Reagent Volume	:	R1 - 400 µl + R2 - 100 µl
Sample Volume	:	25 µl
Factor	:	3450
Linearity	:	500 U/L
Units	:	U/L

TEST PROCEDURE:

Reagent	Test
Reagent - 1	400 µl
Serum	25 µl
Reagent - 2	100 µl

Mix well and after 1 minute incubation, measure the change of optical density during the next 180 seconds against distilled water at 405nm as follows.

Ao-Exactly after 60 seconds

A1, A2, A3 - Exactly after every 60 seconds for 180 seconds after Ao

CALCULATION

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

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

EXPECTED VALUES

Adult

Male upto 55 U/L

Female upto 36 U/L

QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result. Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:

a) When using a new reagent or lot.

b) When QC values are out of range.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 500 U/l

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 2 U/L

3. Interferences

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.

4. Precision:

Intra-assay (N = 20) Sample	Mean (U/l)	SD (U/l)	CV (%) (U/l)
sample 1	40	0.99	2.48
sample 2	74	0.88	1.18
sample 3	206	1.32	0.640

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

5. Method Comparison:

A comparison between LiquiMAX 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

LIMITATIONS

The test has been developed to determine Gamma-GT activities which correspond to maximal ΔA /min of 2.

If such values exceeds the sample should be diluted 1+5 with Normal saline and result should be multiplied by 6.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

Notes :

1. The reagents contain sodium azide (0.95G/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

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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