ROBONIK®

CE

prietest™ ...Clinical Chemistry Reagents

GAMMA-GT

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative in vitro determination of activity of gamma-glutamyltransferase (Gamma-GT) in serum on photometric systems.

ORDERING INFORMATION

Pack Size	Cat No.
1 X 10 ml	GGT 01 10
1 X 25 ml	GGT 01 25
2 X 50 ml	GGT 02 50
4 X 50 ml	GGT 04 50

CLINICAL SIGNIFICANCE : Gamma-glutamyltransferase (GGT) is a membrane-localized peptidase mainly present in kidneys, pancreas, liver and prostate. This enzyme plays a significant role in glutathione metabolism and takes part in the transport of amino acids into the cells. The rise of GGT activity, often isolated (earlier and longer increase compared to other enzymes), is one of the most sensitive indicators of an affection of the liver or bile ducts. The strongest increases are observed in cases of intra hepatic or posthepatic biliary obstructions (reaching levels from 5 to 30 times normal), primary or secondary neoplasms, acute or chronic pancreatitis, and other pancreatic malignancies (especially those associated with hepatobiliary obstruction). More moderate elevations are observed during infectious hepatitis, cirrhosis and hepatic steatosis. Alcohol in chronic ingestion, some drugs like phenobarbital and phenytoine or contraceptives can also increase GGT rate in the serum.

METHOD :
Modified IFCC method. Enzymatic. Kinetic, UV.

PRINCIPLE :
Optimized kinetic determination of γ-glutamyltransferase (γ-GT) activity :

GLUPA-C + Glycylglycine $\xrightarrow{\gamma\text{-GT}}$ L-γ-Glutamyl-glycylglycine + 5-Amino-2-nitrobenzoic acid

GLUPA-C : L-γ-Glutamyl-3-carboxy-*p*-nitroanilide

The increase of absorbance at 405 nm due to the formation of 5-amino-2-nitrobenzoic acid is proportional to γ-GT activity.

REAGENTS :

COMPONENTS AND CONCENTRATIONS:
N.B: Concentrations are those in the final test mixture.

R1 :

Tris Base	100 mmol/l
Glycyl Glycine	100 mmol/l

R2 :

L-Gamma-glutamyl-3-carboxy-4-nitroanilide	4 mmol/l
Preservative & Stabilizer	

STORAGE INSTRUCTIONS AND REAGENT STABILITY :
The reagents are stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C, protected from light and contamination is avoided. Do not freeze the reagent ! Discard the Reagent if found turbid or in case the Absorbance of Working Reagent exceeds 0.8 AU at 405 nm against distilled water.

WARNINGS AND PRECAUTIONS :
Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT :
Please refer to local regulation requirements.

REAGENT PREPARATION :
1) Two Reagent procedure : The reagents are ready-to-use.
2) One Reagent Procedure : Mix four volumes of reagent R1 with one volume of reagent R2.
Stability of working reagent solution : Three weeks at 2 to 8°C

MATERIAL REQUIRED BUT NOT PROVIDED :
NaCl solution 9 g/l, General laboratory equipment, Analyser / Photometer, pipettes etc.

SPECIMEN :
Serum free from hemolysis.
Stability in serum : Sera are stable 7 days at 2 to 8°C, Two months at – 20°C.
Discard contaminated specimens.

ASSAY PROCEDURE 1: Two Reagent procedure
Application sheets for automated systems are available on request.

Wavelength	:	Hg 405 nm
Optical path	:	1 cm
Temperature	:	37°C
Mode	:	Kinetic

Bring all the contents of the kit to Room Temperature prior to use.
Read rate of change of absorbance of sample against distilled water or air.
Label the test tube as sample, control and pipette into respective test tube the reagent, sample, control sample as per the table given below :

	Sample / Control
Reagent R1	800 µl
Reagent R2	200 µl

Mix and pre warm the working reagent at 37°C for 2 minutes then add

Sample / Control	50 µl

Mix and after a 60 seconds incubation at 37°C measure the change of absorbance per minute (ΔA/minute) during 180 seconds.

ASSAY PROCEDURE 2: One Reagent procedure
Label the test tube as sample, control and pipette into respective test tube the reagent, sample, control sample as per the table given below :
Prewarm working reagent at 37°C for two minutes prior to addition of sample.

	Sample / Control
Working Reagent	1000 µl
Sample / Control	50 µl

Mix and after a 60 seconds incubation at 37°C measure the change of absorbance per minute (ΔA/minute) during 180 seconds.

CALCULATION :
At 405 nm with one reagent procedure and two reagent procedure for 1 cm path light cuvette
Activity of Sample (U/L) = (Δ A/Min) X 2211

TEMPERATURE CONVERSION FACTORS :
To correct result to other temperatures multiply by factor shown in table

Assay Temperature	Conversion Factor to		
	25°C	30°C	37°C
25°C	1.00	1.37	1.79
30°C	0.73	1.00	1.30
37°C	0.56	0.77	1.00

CALIBRATION :
For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL :
To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :

MEASURING RANGE :
The test has been developed to determine Gamma GT activity within a measuring range from 5 to 1000 U/L. When values exceed higher limit of the range, such samples should be diluted 1 + 1 with NaCl solution (9 g/l) and the result multiplied by 2.

SPECIFICITY / INTERFERENCE :
No interference was observed by Ascorbic Acid up to 20 mg/dl, Bilirubin up to 20 mg/dl, Glucose up to 500 mg/dl and lipemia up to 600 mg/dl Triglycerides. A list of drugs and other interfering substances with Gamma-GT determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION :
The lower limit of detection is 5 U/L.

PRECISION :

Intra-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	25	0.2	0.80
Sample 2	60	0.5	0.83
Sample 3	336	3.0	0.89

Inter-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	28	0.2	0.71
Sample 2	63	0.5	0.79
Sample 3	344	3.0	0.87

METHOD COMPARISON :
A comparison between Robonik Prietest Gamma GT (y) and a commercially available test (x) using 20 samples gave following results:
Linear Regression : y = 0.9956 x - 3.0 U/L
Correlation Coefficient : r = 0.9990
REFERENCE RANGE :
Men : 0 to 55 U/L **Women** : 0 to 38 U/L
It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Scherwin, J.E, *Liver function.* Clinical Chemistry: Theory, Analysis, Correlation, 4th Ed., Kaplan, L.A, Pesce, A.J., Kazmierczak, S.C., (Mosby Inc. eds St Louis USA), (2003), 492 and appendix.
2. Henderson, A.R., Moss, D.W., *Enzymes*, Tietz Fundamentals of Clinical Chemistry, 5th Ed., Burtis, C.A. & Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA), 2001, 352.
3. Young, D.S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press,1995

INSTRUMENT APPLICATION
prietest TOUCH

Name : GAMMAGT , Mod : KIN
Pri.: 405 , Sec.: 0
Temp: 37C , KF : 1.000
Vol : 500ul , Unit : U/L
Lag : 60 , Read : 180
Blk : N, QC : Y, Norm : Y
Std : N , Factor : 2211
Normal HI = 55
Normal LO = 0
QCNH : *
QCNL : *
QCABH = *
QCABL = *
Init. OD : = 0.8 H
Max Delta/Min : = 0.452
Rgnt. Linearity : 1000
NOTE :
* Indicates user definable parameter.
NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING

TEST NAME	GAMMA GT
Reaction	Kinetic
Reaction Slope	Increasing
Wavelength 1	405 nm
Temperature	37°C
Zero Setting	Distilled Water
Factor	2211
Units	U/L
Sample Volume	50 µl
Reagent Volume	1000 µl
Lag Time	60 Seconds
Read Time	180 Seconds
Reference Range	0 to 55
Reagent Linearity	1000
Max Delta/Min	0.452
Initial OD	< 0.8

ROBONIK®
An ISO 9001 : 2008 Certified Company
An ISO 13485 : 2012 Certified Company

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Ver.: PGGT/1009/00