

Ana-Chek® GAMMA GT

METHOD – GLUPA - C
PRODUCT CODE – LG01



INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of λ – GT activity in serum / plasma using Glupa-C method.

SUMMARY AND PRINCIPLE

Gamma glutamyl transferase (GGT) is clinically useful in detecting all forms of liver damages and diseases. Elevated levels are also associated with chronic alcoholism and drug abuse. Ana-Chek® Gamma GT is a reagent set for determination of Gamma GT in human serum / plasma based on Substrate gamma-glutamyl-3-carboxy-4-nitroanilide (Glupa-C), recommended by International Federation of Clinical Chemistry (IFCC). Ana-Chek® Gamma GT is a ready to use two liquid reagent system, using single step reconstitution.

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



L- λ -glutamyl-glycylglycine + 5-amino-2-nitrobenzoate

KIT COMPONENTS

Reagent 1 : Gamma GT Reagent 1
Reagent 2 : Gamma GT Reagent 2

REAGENT PREPARATION, STORAGE & STABILITY

Mix reagent R1 & R2 in ratio of 4:1 respectively to prepare desired volume of working reagent. Working reagent is stable for 21 days at 2-8 °C. The reagent kit should be stored at 2 - 8 °C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 1.000 O.D. against D/W at 405 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Gamma GT	Reagent Volume	1000 μ l
Reaction Type	Kinetic ($\uparrow$)	Sample Volume	50 μ l
Wavelength Primary	405 nm	Incubation Temperature	37 °C
Flow Cell Temp.	37 °C	Delay Time	60 sec
Instrument Blank setting	D.W.	Read Time	180 sec
Reagent Blank Abs Limit	<1.0	Factor	2201
Linearity	1000 IU/L	Std. Conc.	-

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum is preferred. Heparinized or EDTA plasma can be used. Gamma GT in Serum / Plasma is stable for 7 days at 2-8 °C and 6 months at -20 °C.

COMPONENTS OF REAGENT

Component	Concentration
MES Buffer	4 mmol/l
Glycylglycine	170 mmol/l
L-glutamyl-3-carboxy-4-nitroanilide	3 mmol/l
Stabilizers and inactive ingredients.	

ASSAY PROCEDURE

	Blank	Test
Reagent	1000 μ l	1000 μ l
Sample	-	50 μ l
Mix the reagent and sample in the above-mentioned ratio and start the stop watch.		
Aspirate reaction mixture into flow cell and record the absorbance at 60 th , 120 th , 180 th , 240 th sec.		

CALCULATION

$$\text{GGT (IU/L)} = \Delta \text{ Abs/min of sample} \times 2201$$

REFERENCE VALUES FOR NORMAL PEOPLE

Men - 8-61 IU/L.
Women - 8-35 IU/L.

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 11 - 1000 IU/L. If the Gamm GT value exceeds linearity limit (above 1000 IU/L), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct Gamma GT value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL and Ascorbic Acid upto 8 mg/dL.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (IU/L)	SD (IU/L)	CV %	Mean (IU/L)	SD (IU/L)	CV %
Low Value Serum	64.72	0.79	1.2	70.0	2.0	2.8
High Value Serum	170.1	1.2	0.7	163.7	1.77	1.1

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides

between run precision and accuracy data for Gamma GT. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. Discard the working reagent if its absorbance is more than 1.000 at 405 nm against distilled water.
2. If the Gamma GT activity exceeds 1000 IU/L then dilute the specimen suitably with normal saline and repeat the assay. In such case multiply the result obtained with the dilution factor to obtain correct Gamma GT value.

BIBLIOGRAPHY

1. Persijn JP, van der Silk W. A new method for the determination of -glutamyl transferase. J.Clin.Chem.Clin.Biochem.1976; 4:421.
2. Shaw LM, Stromme JH, London JL et al. Clin.Chem.Acta 1983; 135:315-338.
3. Shaw LM, Keeping pace with a popular enzyme GGT. Diagnostic Medicine 1982; May/June:1-8.
4. Tietz NW. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, Pa: WB Saunders Company, 1995-286.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry