

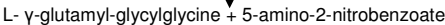
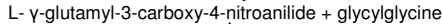
GAMMA - GT
(IFCC Method)

Intended Use

Gamma GT is a reagent set for determination of gamma glutamyltrasferase (GGT) in serum and plasma based on IFCC method.

Principle

Gamma-glutamyltrasferase(GGT) transfers the γ -glutamyl group of L- γ -glutamyl-3-carboxy-4-nitroanilide to glycylglycine. The amount of 5-amino-2-nitrobenzoate liberated at 405 nm is proportional to the activity of GGT in serum/plasma and is measured kinetically.



Reagents provided

- 1. Reagent R1
- 2. Reagent R2

Working reagent preparation

Prepare working solution by mixing Reagent R1 and Reagent R2 in the ratio 4:1 as per requirement.

Reagent storage and stability

The reagent kit should be stored at 2 - 8°C and is stable till the expiry date indicated on the label.

R₁ and R₂ reagents are stable till expiry at 2 - 8°C.

The working solution (4R₁ + 1R₂) is stable for 21 days at 2 - 8°C.

Specimen collection and preservation

Blood should be collected in a clean dry container. Although serum is preferred, plasma with heparin or EDTA can be used. GGT in serum/plasma is stable for 7 days at 2 - 8°C and 6 months at -20°C. Centrifuge samples containing precipitate before performing the assay. The samples should be brought to room temperature prior to use.

Assay guidelines for Analyzer

Reaction type	Kinetic
Reaction slope	Increasing
Wavelength	405 nm
Flowcell temperature	37°C
Zero setting with	Working solution
Delay time	60 seconds
Measuring time	120 seconds
Sample Volume	50 μ l (0.05ml)
Reagent Volume	1000 μ l (1.0ml)
Factor	2121

Assay guidelines for Manual procedure

Prewarm at 37°C the required amount of working solution before use.

Reagent	Blank	Test
Working reagent	1000 μ l (1.0 ml)	1000 μ l (1.0 ml)
Sample	-	50 μ l (0.05ml)

Mix thoroughly and transfer the assay mixture immediately to the thermostated cuvette and start the stop watch simultaneously. Record the first reading at 60th second and subsequently two more readings with 60 seconds interval at 405 nm.

Calculation

Activity of GGT in IU/L = $\Delta\text{Abs}/\text{min.} \times 2121$

Normal Range

Men : 8 – 61 IU/L

Women : 5 – 36 IU/L

Note: Expected range varies from population to population. It is therefore recommended that each laboratory should establish its own normal range.

Limitations

- If the GGT activity exceeds 1000 IU/L, dilute the specimen with normal saline and repeat the assay. In such cases the results obtained should be multiplied with the dilution factor to obtain correct GGT activity.
- The working solution is considered unsatisfactory and should not be used if the absorbance exceeds 1.000 at 405 nm against distilled water.

Quality Control

To ensure adequate quality control, it is recommended that each batch should include normal and abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, and accuracy of pipetting.

References

1. Persijn JP, van der slik W.A new method for the determination of γ -glutamyltransferase. *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.

Symbols

IVD	In Vitro Diagnostics.		Caution.		Keep away from sun light.		Date of Manufacture.
LOT	Batch No.		Read Instructions.		Fragile.		Product Expiry Date.
CONT	Content.		Storage Temperature.		Keep Dry.		Manufactured By.
REF	Catalogue No.						



KEE DIAGNOSTICS PVT LTD.

CIN: U24231DL2004PTC:128343 .

A subsidiary of KEE PHARMA LTD

A-8 . 3RD FLOOR. NARAINA INDUSTRIAL AREA, PHASE 2.

NEW DELHI-110028.

W. www.keediagnostics.com.

E. info@keediagnostics.com, T. 011 43136000.

 ISO 9001 : 2015 & ISO 13485 : 2016 Certified Company