ANA BIO ISP GAMMA - GT

(IFCC Method)

For Miura Instruments

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.

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

↓ GGT

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

Components & Concentration of Reagents

Reagent	Component	Concentration
Reagent 1	Glupa C	4 mmol/L
	Stabilizers, excipients & surface active agents	
Reagent 2	Glycylglycine	750 mmol/L
	Stabilizers, excipients & surface active agents	

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.
A slight variation in the composition of the components may occur between batches, but this has no effect on the test results.
After opening, the vial R1 and R2 are stable 30 days if recapped immediately and protect from contamination, evaporation, direct light and stored at correct temperature.

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.

Automation
This kit, though developed and manufactured to be used as manual assay and with I.S.E. Miura Analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions – Test procedure" Application sheets are available for automatic instruments.
All applications not explicitly approved by KDPL. Cannot be guaranteed in terms of performance, and must there be established by the operator.

Calibration
For Calibration use the "Multicalibrator"

Calibration Stability
For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

Materials required but not supplied in the kit
Calibrators and controls

Assay guidelines for Analyzer I.S.E. Miura

Analyte Name	GGT	
Method Code	GGT	
Type	Kinetic-Substrate Start	
Unit	IU/L	
Filter F1	405 nm	
Blank in	Not Use	
Step	Reaction Volume	U.M.
Volume reagent R1	200	µl
Sample volume	12	µl
Incubation R1, S → R2	60	Sec
Volume reagent R2	50	µl
Final Incubation	60	Sec
Kinetic Reading	120	Sec.

Normal Range
Men : 8 – 61 IU/L
Women : 5 – 36 IU/L
Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitations
This method is linear up to 1000 IU / L. If the activity exceeds 800 IU/L, dilute the sample suitably with normal saline and repeat the assay. Apply proper dilution factor to calculate the final results.

Quality Control
To ensure adequate quality control measures, it is recommended that each batch should include a normal and an 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, Wavelength setting, Expiration date of reagents and accuracy of prob aspiration.

Accuracy-Recovery
GGT added to a serum matrix containing known amounts of GGT gave an average recovery of 99.5%.

Precision of the Method

Within-run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	IU/L	36.53	1.311	3.59	20
High	IU/L	152.7	3.774	2.47	20
Between run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	IU/L	36.53	0.756	2.07	60
High	IU/L	152.7	1.317	0.86	60

Sensitivity
At 405 nm, the activity of GGT of 5.95 IU/L can estimate.

References

1. Persijn JP, van der slik W.A new method for the determination of γ-glutamyltrasferase. 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
LOT	Batch No.		Product Expiry Date
CONT	Content		Manufactured By
	Read Instructions		Date of Manufacture
	Storage Temperature		Keep Dry
REF	Catalogue No.		Fragile
			Keep away from sun light

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