ISE S.r.l.
CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

Gamma -GT – Instructions for use

IVD CE

R1: 3 x 20 mL • REF A-R0000000013 R1: 4 x 50 mL • REF A-R0200000601
R2: 3 x 20 mL R2: 4 x 20 mL

INTENDED USE
Product for use in the quantitative determination in vitro of the γ-GT activity in human serum. The results of the test must always be interpreted in conjunction with the clinical picture.

INTRODUCTION
Although γ-GT IFCC is present in a large number of tissues, the enzyme which we wish to detect in the serum is principally part of the hepato-biliary system. Consequently raised levels of γ-GT are seen in all forms of disease or damage to the hepatic system. From the clinical viewpoint, the enzyme is useful for the diagnosis of obstructive jaundice, cholangitis and cholecystitis. High γ-GT levels are also seen during the assumption of alcohol or pharmaceutical products (sedatives, anticonvulsants and tranquillizers) (1).

PRINCIPLE
Gamma glutamyl transpeptidase (y-GT) catalyzes the transfer of the g-glutamyl group from the substrate g-glutamyl-3-carboxy-4-nitroanilide to glycylglycine releasing L-glutamyl-glycylglycine and 5-amino-2-nitrobenzoato.

L - γ - glutamyl - 3 - carboxi - 4 - nitroanilide + glycylglycine $\xrightarrow{\text{γ-GT}}$ L - γ - glutamylglycylglycine + 5 - amino - 2 - nitrobenzoate

The rate of formation of 5-amino-2-nitrobenzoate, determined kinetically at 405 nm, is proportional to γ-GT activity.

REAGENTS
Kit R1: 3 x 20 mL R2: 3 x 20 mL code A-R0000000013
Reagent 1: no. 3 vials x 19.5 mL code 184025
Reagent 2: no. 3 vials x 5.0 mL code 184026
Kit R1: 4 x 50 mL R2: 4 x 20 mL code A-R0200000601
Reagent 1 : no. 4 vials x 40.5 mL code 184052
Reagent 2 : no. 4 vials x 10.5 mL code 184053

Concentrations

Reagent 1:			
	Conc.	**U.M.**	
γ-glutamyl-3-carboxi-4-nitroanilide	4.00	mM	
Reagent 2:			
Glycylglycine	750	mM	!

Precautions
Reagent B is harmful and must be used with caution. Refer to the appropriate Material Safety Data Sheet for the risk phrases and safety measures (**Identification of Risks**: **GHS07 - H315, H319).** In addition to any risk indications related to the active components, reagents may contain inactive components such as preservatives and detergents. The total concentrations of these components are lower than the limit reported in the EC directive 1272/2008 and subsequent amendments and additions. However, It is recommended to handle reagents according to the standards of good laboratory practice and adopt all adequate protective measures.

Storage and stability
Store at 2 - 8°C and protect from direct light. When correctly stored, the reagents are stable up the expiry date reported on the label. After opening, the vial R1 and R2 are stable 30 days if recapped immediately and protected from contamination, evaporation, direct light and stored at correct temperature.

SAMPLE COLLECTION
Type of sample and storage
Use serum or plasma with EDTA, heparin, citrate or oxalate/fluoride (5). Use serum free of hemolysis. γ-GT is stable in serum for at least a week if stored at - 4°C to + 20°C (6) and 3 months at - 20°C (5).

Precaution
All human samples must be handled and disposed of as potentially infectious materials.

Procedure
Quality control
Human control serum with known levels of γ-GT is commercially available for quality control purposes. Data sheets are included, listing the values and the confidence limits. Normal and abnormal control sera are available from I.S.E. S.r.l. "Normal control serum" code R0400000006 and "Pathological control serum" code R0400000106. Obtained values must be within the range of acceptability. If erratic results occur, the following points should be checked:
- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation
This kit, though developed and manufactured to be used as manual assay and with I.S.E. S.r.l. 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 I.S.E. S.r.l. cannot be guaranteed in terms of performance, and must therefore be established by the operator.

Calibration
For calibration use the "Multicalibrator" I.S.E. S.r.l. code R0300000006.
Traceability:
The γ-GT concentration is reported in the package insert supplied with the Calibrator Serum.

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

Method for automated instrumentation

Analyzer:	**I.S.E. Miura**		
Analyte Name :	**Gamma GT**	Ref.:	A-R0000000013 A-R0200000601
Analyte Code:	**γGT**		
Method:	**Kinetic**		
Unit:	**U/L**		
Filter F1:	**405 nm**		
Blank in:	**Not Used**		

Step	**Reaction volume**	**U.M.**
Volume reagent R1:	**160**	µL
Volume reagent R2:	**40**	µL
Sample volume:	**20**	µL
Final Incubation:	**60**	Sec.
Kinetic reading time	**240**	Sec.

Materials included in the kit
The reagents are described above.

Materials required but not supplied in the kit
Calibrators and controls.

NORMAL VALUE
Serum:
- Male: 11 – 51 U/L
- Female: 7 – 33 U/L

Each laboratory should calculate its own normal values on the basis of its local population

ANALYTICAL CHARACTERISTICS / PERFORMANCE
Linearity
If concentration at 405 nm is greater than > 500 IU/L, repeat the test using serum diluted 1:10 with isotonic saline. Multiply by 10.

I.S.E S.r.l.
Via Delle Driadi, 45 – 00133 Roma
Tel.+39 077 4579365; FAX +39 077 4579305
E-mail: info@logotech-ise.com
www.logotech-ise.com

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Specificity
Under the conditions of the assay system this method is specific for y-glutamyl transpeptidase.

Accuracy-Recovery
The recovery of pure γ-GT added to normal sample at known titter was 101.7%.

Precision of the method

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	U/L	36.53	1.311	3.59%	18
High	U/L	152.7	3.774	2.47%	18
Between-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	U/L	36.53	0.756	2.07%	18
High	U/L	152.7	1.317	0.86%	18

Sensitivity
At λ 405 nm a concentration of about 9,00 U/L of y-GT in the conditions established for this test.

Comparative method
The I.S.E. S.r.l. method was compared to a method in use.
A linear regression slope Y = 1.017x + 5.09 was determined. A Correlation coefficient r = 1.000 was calculated. Sample tested No.= 48.

Disposal of reagent
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

The product is in conformity with D.L: 8 September 2000, no. 332 "Actuation of the directive 98/79/EC regarding in vitro medical diagnostic devices".

Symbols on labels and packaging

IVD = In vitro diagnostic medical device
REF = Catalog Number
LOT = Lot Number
= Manufacturer
= Expiration date
= Temperature limitation
= Instruction for use

References

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3. IFCC 2002/7: IFCC Primary Reference Procedures for the Measurement of Catalytic Activity Concentrations of Enzymes at 37°C. Part. 6. Reference Procedure for the Measurement of Catalytic Concentration of γ-Glutamyltransferase, Clin. Chem. Lab. Med. 2002, 40(7): 734-738.
4. Nielsen L.G. et al. Amer J Med Technol; 44: 279,1978

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