


R1: 4 x 42 mL – R2: 4 x 11 mL •  A-R0200000601R1: 2 x 16,7 mL – R2: 1 x 8,5 mL •  R333000019**INTENDED USE**

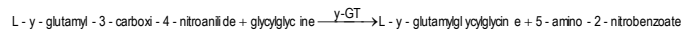
Product for use in the quantitative determination in vitro of the γ -GT concentration in human serum and plasma. The results of the test must always be interpreted in conjunction with the clinical context. For professional use only.

CLINICAL SIGNIFICANCE

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).

PRINCIPLE

Gamma glutamyl transpeptidase (γ -GT) catalyzes the transfer of the γ -glutamyl group from the substrate γ -glutamyl-3-carboxy-4-nitroanilide to glycyglycine releasing L-glutamyl-glycyglycine and 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

A-R0200000601 R1: 4 x 42 mL - R2: 4 x 11 mL

Reagent 1: n°4 vials x 42,0 mL ready for use**Reagent 2:** n°4 vials x 11,0 mL ready for use

R333000019 - R1: 2 x 16,7 mL - R2: 1 x 8,5 mL

Reagent 1: n°2 vials x 16,7 mL ready for use**Reagent 2:** n°1 vial x 8,5 mL ready for use**Concentrations**

Reagent 1:			
	Conc.	U.M.	
γ -glutamyl-3-carboxy-4-nitroanilide	4.00	mM	
Reagent 2:			
Glycyglycine	750	mM	 *GHS07

GHS07** Signal word: **Warning*H315** Causes skin irritation.**H319** Causes serious eye irritation.**P264** Wash thoroughly after handling.**P280** Wear eye protection / face protection.**P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P332+P313 If skin irritation occurs: Get medical advice/attention.**P362+P364** Take off contaminated clothing and wash it before reuse.**P337+P313** If eye irritation persists**Precautions for use**

Kit for professional laboratory use, used only by qualified and properly trained technical personnel, under the supervision of a doctor in charge of the laboratory. In addition to any risk statements relating to active components, reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in EC 1272/2008 Regulation and subsequent amendments and additions. However, it is recommended to handle the reagents according to the rules of good laboratory practice.

Reports of serious incidents

In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

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. Use serum free of hemolysis. γ -GT is stable in serum for at least a week if stored at - 4°C to + 20°C and 3 months at - 20°C.

Precautions

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

Procedure**Quality control**

Control sera with a known titer γ -GT of are commercially available for quality control, including certificates of analysis showing values and confidence limits. Normal and pathological control sera are available as "Normal control serum" cod. R040000006 and "Pathological control serum" code R0400000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:

- Cleaning of the glassware.
- Wavelength.
- Expiration date of reagents.

Automation

Although this device has been developed and manufactured to be used with manual methods and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique".

All applications that are not explicitly approved cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user.

Calibration

For calibration use the kit "Multicalibrator" code R030000006. For ISE srl instruments, the calibration is recommended every 10 days.

Traceability

The γ -GT concentration is reported in the package insert supplied with the Calibrator Serum.

Reaction conditions

Wavelength: 405 nm

Temperature: 37°C

Technique - Procedure with Serum as starter

Bring the reagents to the reaction temperature.
Add 1 volume of Reagent B to 4 volumes of Reagent A and mix gently.

	U.M.	Calibrator Serum	Sample
Reagent (A+B)	μ L	1000	1000
Calib. Serum	μ L	100	-
Sample	μ L	-	100

Mix gently and incubate at reaction temperature (37°C) for 60 sec.

After the incubation, read the absorbance at 405 nm. Repeat readings at 1-minute intervals. Recording a minimum of 3 absorbance changes is recommended. Determine the mean Δ O.D./min.

Reaction volumes may be varied proportionally without alteration of results.

Results

Calculation of γ -GT concentration

$$\frac{\Delta \text{O.D. sample}}{\Delta \text{O.D. Calib. serum}} \times \text{Calib. serum conc. (U/L)} = \text{U/L of } \gamma\text{-GT}$$


Materials included in the kit

Reagent described above.

Necessary materials not included in the kit

Controls and calibrators.



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Serum:

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

Each laboratory should calculate its own normal values based on 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 multiplying for the dilution factor.

Specificity

This method is specific for GT-γ, the substrate concentration is optimized for the isoenzymes normally present in serum. Any non-specific reaction wears off during the delay time before reading.

Accuracy-Recovery

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

Precision of the method

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	36,53	1,311	3,59%	18
High	mg/dL	152,7	3,774	2,47%	18
Between-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	36,53	0,756	2,07%	18
High	mg/dL	152,7	1,317	0,86%	18

Sensitivity

The sensitivity of method at λ 405 nm is 9,00 U/L.








Comparative method

The γ-GT test method was compared with a method in use. It was determined:

A regression curve was determined: $y = 1,017x + 5,09$;Coefficient of Correlation $r = 1,000$;Samples analysed $n^{\circ} 48$.**Disposal of reagents**

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

Manufacturer:**Scavo Diagnostics International**Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
Phone +39 0577 39041 - Fax +39 0577 390 444**Distributor:****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**Symbols used in IFU and Packaging**

 In vitro diagnostic medical device vitro	 Manufacturer
 Catalogue Number	 Instruction for use
 Lot Number	 Temperature limitation
 Expiration date	

Reference

1. Jaffe M. Z Physiol Chem 1886; 10: 391-400.
2. Henry RJ. Clinical Chemistry: Principles and Technics. Harper & Row Publishers, New York 1968; 287-292.
3. Teger-Nilsson AC. Scand J Clin Lab Invest 1961; 13: 326-331.

REVISION	DATE	CHANGE
Rev.D	01/2024	Edit header and "Reagents" paragraph.

