Gamma GT – Instructions for use (IFU)

Distributed by: ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

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

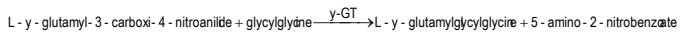
R1: 2 x 18,5 mL – R2: 1 x 18,5 mL • REF R3330000019

IVD CE

INTENDED USE
Product for use in the quantitative determination in vitro of the Creatinine concentration in human serum or urine. 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 (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.



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

REAGENTS
A-R0200000601 R1: 4 x 50 mL - R2: 4 x 20 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 18,5 mL - R2: 1 x 18,5 mL
Reagent 1: n°2 vials x 16,7 mL ready for use
Reagent 2: n°1 vial x 8,2 mL ready for use

Concentrations

Reagent 1:			
	Conc.	**U.M.**	
y-glutamyl-3-carboxi-4-nitroanilide	4.00	mM	
Reagent 2:			
Glycylglycine	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. y-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 y-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. R0400000006 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 R0300000006. For ISE srl instruments, the calibration is recommended every 10 days.

Traceability
The y-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)	µL	1000	1000
Calib. Serum	µL	100	-
Sample	µL	-	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 ΔO.D./min.
Reaction volumes may be varied proportionally without alteration of results.

Results
Calculation of γ-GT concentration

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

Materials included in the kit
Reagent described above.

Necessary materials not included in the kit
Controls and calibrators.

Sclavo Diagnostics International
Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
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NORMAL VALUE

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 titter 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 y-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° 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:
Sclavo Diagnostics International
Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
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Distributor:
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Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT 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.B	02/2023	Update of filling volumes