# ISE S.r.l. Gamma GT – Instructions for use

CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

CE IVD

R1: 2x 18 mL R2: 2x4,5 mL **R3330000019** REF

Diagnostic reagent for quantitative in vitro determination of gamma-glutamyltransferase (gamma-GT) in human serum or plasma on photometric systems

## TEST PARAMETERS

| | |
|---|---|
| Method: | Colorimetric, kinetic, increasing reaction Szasz, standardized to IFCC |
| Wavelength: | 405 nm (400 – 420 nm) |
| Temperature: | 37 °C |
| Sample: | Serum, heparin plasma |
| Linearity: | up to 1200 U/L on automated systems |
| Sensitivity: | The lower limit of detection is 2 U/L |

## SUMMARY

Gamma-glutamyltransferase (gamma-GT / GGT), also called gamma-glutamyltranspeptidase, is an enzyme present in liver and bile duct which is the most sensitive indicator of hepatobiliary diseases. Because of a high negative predictive value for these diseases, the measurement of gamma-GT is widely used to rule out a hepatic or biliary origin. Together with other enzymes such as alanine aminotransferase (ALT), aspartate aminotransferase (AST) and cholinesterase gamma-GT is a valuable tool for the differential diagnosis in liver diseases. [1]

## TEST PRINCIPLE

Kinetic photometric test according to Szasz/Persjin [2]. The test has also been standardized to the method according to IFCC [4].
Gamma-GT catalyzes the transfer of glutamic acid to acceptors like glycylglycine. This process releases 5-amino-2-nitrobenzoate, which can be measured at 405 nm. The increase in absorbance at this wavelength is directly related to the activity of gamma-GT.

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

## REAGENT COMPOSITION

| COMPONENTS | CONCENTRATION |
|---|---|
| **Reagent 1:** | |
| TRIS, pH 8.28 | 135 mmol/L |
| Glycylglycine | 135 mmol/L |
| **Reagent 2:** | |
| L-Gamma-glutamyl-3-carboxy-4-nitroanilide, pH 6.00 | 22 mmol/L |

## REAGENT PREPARATION

**Substrate Start:**
The reagents are ready for use.
Sample Start:
Mix 4 parts of Reagent 1 + 1 part of Reagent 2
**(= working reagent).**

## REAGENT STABILITY AND STORAGE

| | | |
|---|---|---|
| Conditions: | Protect from light<br>Close immediately after use. Avoid contamination.<br>Do not freeze! | |
| Substrate Start: | | |
| Storage: | at 2 – 8 °C | |
| Stability: | up to the expiration date indicated on labels | |
| **Sample Start (working reagent):** | | |
| Storage: | at 2 – 8 °C | at 15 – 25 °C |
| Stability: | 4 weeks | 5 days |

The working reagent must be protected from light.

## SAMPLE STABILITY AND STORAGE

Serum, heparin plasma:
Stability [6]: at -20 to +25°C at least 1 week
Freeze only once!
Discard contaminated specimens.

## MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

## MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

**Substrate start** 37 °C

| Pipette into test tubes: | Blank | Sample |
|---|---|---|
| Reagent 1 | 1000 µL | 1000 µL |
| Distilled water | 100 µL | |
| Sample | | 100 µL |
| Mix. Incubate for approximately 1 minute. Then add: | | |
| Reagent 2 | 250 µL | 250 µL |
| Mix. Read initial absorbance after 1 minute and start a timer. Read absorbance again after exactly 1, 2 and 3 minutes. Determine ΔA/min. during the linear part of the assay. ΔA/min = [ΔA/min sample] – [ΔA/min blank] | | |

**Sample start** 37 °C

| Pipette into test tubes | Blank | Sample |
|---|---|---|
| Working reagent | 1000 µL | 1000 µL |
| Distilled water | 100 µL | |
| Sample | | 100 µL |
| Mix. Read initial absorbance after 1 minute and start a timer. Read absorbance again after exactly 1, 2 and 3 minutes. Determine ΔA/min. during the linear part of the assay. ΔA/min = [ΔA/min sample] – [ΔA/min blank] | | |

## CALCULATION

**With factor:** (light path 1 cm)
gamma-GT (U/L) = ΔA/min x factor

**Factors (37°C):**

| | Szasz | IFCC |
|---|---|---|
| **For Substrate start:** | 1421 | 1606 |
| For Sample start: | **1158** | **1309** |

**With calibrator:**

$$\text{GGT [U/L]} = \frac{\Delta A/\text{min Sample}}{\Delta A/\text{min Calibrator}} \times \text{activity calibrator [U/L]}$$

Results according to Szasz or IFCC resp. are obtained by use of the calibrator value given for the Szasz method, or for the IFCC method respectively.

## UNIT CONVERSION

U/L x 0.01667 = µkatal/L

**I.S.E S.r.l.**
Via Delle Driadi, 45 – 00133 Roma
Tel.+39 0774579365; FAX +39 0774579305
www.logotech-ise.com E-mail: info@logotech-ise.com

**RevisionA R3330000019 11-2018**

ISE S.r.l. **Gamma GT** – Instructions for use

CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

IVD

R1: 2x 18 mL R2: 2x4,5 mL **R3330000019** REF

## REFERENCE RANGE *

**According to Szasz [5]:**

| | U/L | µkat/L |
|---|---|---|
| **Women** | < 32 | 0.53 |
| **Men** | < 49 | 0.82 |

**According to IFCC:**

| | **Female [U/L]** | **Male [U/L]** |
|---|---|---|
| Adults [4] | < 38 | < 55 |
| Children/adolescents: [1] | | |
| 1 day – 6 months | 15 – 132 | 12 – 122 |
| 6 months – 1 year | 1 – 39 | 1 – 39 |
| 1 – 12 years | 4 – 22 | 3 – 22 |
| 13 – 18 years | 4 – 24 | 2 – 42 |

| | **Female [µkat/L]** | **Male [µkat/L]** |
|---|---|---|
| Adults [4] | < 0.63 | < 0.92 |
| Children/adolescents: [1] | | |
| 1 day – 6 months | 0.250 – 2.20 | 0.200 – 2.03 |
| 6 months – 1 year | 0.017 – 0.651 | 0.017 – 0.651 |
| 1 – 12 years | 0.067 – 0.367 | 0.050 – 0.367 |
| 13 – 18 years | 0.067 – 0.401 | 0.033 – 0.701 |

* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

## PERFORMANCE CHARACTERISTICS

### LINEARITY, MEASURING RANGE

On automated systems, the test is suitable for the determination of gamma-GT activities up to 1200 U/L.
In case of a manual procedure, the assay is suitable for gamma-GT activities which correspond to a maximum of ΔA/min = 0.20.
If such values are exceeded, the samples should be diluted 1+5 with NaCl solution (9 g/L) and the results multiplied by 6.

### SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 2 U/L

### PRECISION

| Intra-assay n = 20 | Mean [U/L] | SD [U/L] | CV [%] |
|---|---|---|---|
| Sample 1 | 39.9 | 0.99 | 2.48 |
| Sample 2 | 73.6 | 0.85 | 1.16 |
| Sample 3 | 206 | 1.32 | 0.64 |

| Inter-assay n = 20 | Mean [U/L] | SD [U/L] | CV [%] |
|---|---|---|---|
| Sample 1 | 41.5 | 0.62 | 1.49 |
| Sample 2 | 72.3 | 0.61 | 0.85 |
| Sample 3 | 204 | 0.74 | 0.36 |

### SPECIFICITY/INTERFERENCES

No interference up to:

| | |
|---|---|
| Ascorbic acid | 30 mg/dL |
| Bilirubin | 40 mg/dL |
| Hemoglobin | 400 mg/dL |
| Triglycerides | 2000 mg/dL |

For further information on interfering substances refer to Young DS [7].

### METHOD COMPARISON

A comparison of our gamma-GT, standardized to IFCC (y) with the IFCC reference reagent (x) using 51 samples gave following results:
y = 1.005 x – 0.741 U/L; r = 0.999
A comparison of our Gamma-GT, Szasz (y) with a commercially available test according to Szasz (x) using 51 samples gave following results: y = 0.996 x +1.354 U/l; r= 1.000.

## CALIBRATION

The use of a gamma-GT calibrator is optional.
We recommend the our multi calibration serum. In case this calibrator is used, use the according calibrator value for the Szasz method respectively for the IFCC method.

For calculation according to IFCC, standardization was performed against the original IFCC formulation.

## QUALITY CONTROL

Control sera with gamma-GT values determined by this method can be used.
We recommend the our serum controls (control serum with values in the normal and abnormal range)
Each laboratory should establish corrective action in case of deviations in control recovery.

## WARNINGS AND PRECAUTIONS

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. In very rare cases, samples of patients with gammopathy might give falsified results [8].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
4. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
5. For professional use only!

## WASTE MANAGEMENT

Please refer to local legal requirements.

## REFERENCES


1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft;1998.p.80-6.
2. Persijn JP, van der Silk W. A new method for the determination of gamma-glutamyltransferase in serum. J Clin Chem Clin Biochem 1976; 14:421-7.
3. Szasz G. Gamma-Glutamyltranspeptidase. In: Bergmeyer HU. Methoden der enzymatischen Analyse. Weinheim: Verlag Chemie, 1974. p. 757.
4. Schumann G, Bonora R, Ceriotti F, Férard G et al. IFCC primari reference procedure for the measurement of catalytic activity concentrations of enzymes at 37°C. Part 5: Reference procedure for the measurement of catalytic concentration of gamma-glutamyltransferase. Clin Chem Lab Med 2002; 40:734-8
5. Fischbach F, Zawta B. Age-dependent reference limits of several enzymes in plasma at different measuring temperatures. Klin Lab 1992;38:555-61.
6. Guder WG, Zawta B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 30-1.
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007; 45(9): 1240-1243.


### 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


**I.S.E S.r.l.**
Via Delle Driadi, 45 – 00133 Roma
Tel.+39 0774579365; FAX +39 0774579305
www.logotech-ise.com E-mail: info@logotech-ise.com



**RevisionA R3330000019 11-2018**