Gamma-GT FS* (Szasz mod./IFCC stand.)

Order Information

Cat. No.	Kit size				
1 2801 99 10 021	R1	5 x 20 mL	+	R2	1 x 25 mL
1 2801 99 10 026	R1	5 x 80 mL	+	R2	1 x 100 mL
1 2801 99 10 023	R1	1 x 800 mL	+	R2	1 x 200 mL
1 2801 99 10 704	R1	8 x 50 mL	+	R2	8 x 12.5 mL
1 2801 99 10 917	R1	8 x 60 mL	+	R2	8 x 15 mL
1 2801 99 10 930	R1	4 x 20 mL	+	R2	2 x 10 mL

Kits for use in conjunction with DiaSys CE applications.

Intended Use

Diagnostic reagent for quantitative in vitro determination of gamma-glutamyltransferase (gamma-GT/GGT) activity in human serum or heparin plasma on automated photometric systems.

Summary

Gamma-GT is a peptidase, which catalyzes the transfer of amino acids from one peptide to another. The main portion of gamma-GT measurable in blood originates from the hepatobiliary system. For this reason, elevated gamma-GT activity values are a very sensitive and accurate indicator of hepatobiliary diseases and chronic alcohol consumption [1,2]. However elevated gamma-GT activity is also associated with vascular diseases such as heart attack and stroke [1,2] or metabolic syndrome [1]. Together with other enzymes such as alanine aminotransferase (ALAT), aspartate aminotransferase (ASAT) and cholinesterase, gamma-GT is a valuable tool for the differential diagnosis in liver diseases.

Method

Kinetic photometric test according to Szasz/Persijn [3]. The test has also been standardized to the method according to IFCC (International Federation of Clinical Chemistry) [4].

Gamma-GT catalyzes the transfer of glutamic acid to the acceptor glycylglycine. With this process, 5-amino-2-nitrobenzoate is released, which can be measured photometrically at 405 nm. The increase of absorbance is proportional to the catalytic gamma-GT concentration in the sample.

L-Gamma-glutamyl-3-carboxy-4-nitroanilide + Glycylglycine

gamma-GT

Gamma-glutamyl-glycylglycine + 5-Amino-2-nitrobenzoate

One unit of gamma-GT is the amount of enzyme that will convert 1.0 µmol of L-gamma-glutamyl-3-carboxy-4-nitroanilide and glycylglycine to gamma-glutamyl-glycylglycine and 5-amino-2-nitrobenzoate per minute at the enzyme specific conditions.

Reagents

Components and Concentrations

R1:	TRIS	pH 8.28	135 mmol/L
	Glycylglycine		135 mmol/L
R2:	L-Gamma-glutamyl-3-carboxy-4-nitroanilide	pH 6.00	22 mmol/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 12 months until expiry date.

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 [5].
3. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
4. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
5. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [6]:

7 days	at	20 – 25°C
7 days	at	4 – 8°C
1 year	at	-20°C

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	410/694 nm
Temperature	37°C
Measurement	Kinetic
Sample/Calibrator	3.0 µL
Reagent 1	80 µL
Reagent 2	20 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance	Cycle 25/40 (367 s/573 s)
Calibration	Linear

Calculation

With Calibrator

$$\text{gamma-GT [U/L]} = \frac{\Delta A/\text{min Sample}}{\Delta A/\text{min Cal.}} \times \text{Conc. Cal. [U/L]}$$

Conversion Factor

gamma-GT [U/L] x 0.0167 = gamma-GT [µkat/L]

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Use calibrator value for the Szasz method respectively for the IFCC method. Calibrator values for IFCC have been made traceable against the original IFCC formulation. Use DiaSys TruLab N and P for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

Results according to original IFCC formulation

Measuring range up to 1200 U/L, linearity is given within ± 5%. When values exceed this range, samples should be diluted 1 + 5 with NaCl solution (9 g/L) and the result multiplied by 6.

Limit of detection**	1.2 U/L

Interference by	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	33.5
Bilirubin (conjugated)	36 mg/dL	33.8
Bilirubin (unconjugated)	48 mg/dL	34.1
Hemolysis	100 mg/dL	35.5
Lipemia (triglycerides)	2000 mg/dL	33.8

For further information on interfering substances, refer to the literature [7,8].

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	57.2	113	213
CV [%]	1.79	1.34	1.22
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	30.6	82.5	132
CV [%]	3.18	2.91	2.06

Method comparison (n=100)	
Test x	Competitor Gamma-GT (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Gamma-GT FS (Szasz mod./IFCC stand.) (BioMajesty® JCA-BM6010/C)
Slope	1.04
Intercept	1.02 U/L
Coefficient of correlation	0.999

** lowest measurable activity which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Reference Range

According to Szasz [9]

	Female		Male	
	U/L	**µkat/L**	**U/L**	**µkat/L**
Adults	< 32	< 0.53	< 49	< 0.82

According to IFCC [1]

	Female		Male	
	U/L	**µkat/L**	**U/L**	**µkat/L**
Children				
1 – 7 days	18 – 148	0.30 – 2.47	25 – 168	0.42 – 2.80
8 – 30 days	16 – 140	0.27 – 2.33	23 – 174	0.38 – 2.90
1 – 3 months	16 – 140	0.27 – 2.33	16 – 147	0.27 – 2.45
4 – 6 months	13 – 123	0.22 – 2.05	5 – 93	0.08 – 1.55
7 – 12 months	8 – 59	0.13 – 0.98	8 – 38	0.13 – 0.63
1 – 3 years	2 – 15	0.03 – 0.25	2 – 15	0.03 – 0.25
4 – 6 years	5 – 17	0.08 – 0.28	5 – 17	0.08 – 0.28
7 – 9 years	9 – 20	0.15 – 0.33	9 – 20	0.15 – 0.33
10 – 11 years	12 – 23	0.20 – 0.38	12 – 25	0.20 – 0.42
12 – 13 years	10 – 20	0.17 – 0.33	12 – 39	0.20 – 0.65
14 – 19 years	6 – 23	0.10 – 0.38	6 – 30	0.10 – 0.50
Adults	< 40	< 0.65	< 60	<1.00

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

Literature

1. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2023 [cited 2024 Mar 06]. Available from: https://www.clinical-laboratory-diagnostics.com/
2. Emdin M, Pompella A, Paolicchi A. Gamma-glutamyltransferase, atherosclerosis, and cardiovascular disease: triggering oxidative stress within the plaque. Circulation. 2005 Oct 4;112(14):2078-80.
3. 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.
4. Schumann G, Bonora R, Ceriotti F, Férard G et al. IFCC primary 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 γ-glutamyltransferase. Clin Chem Lab Med 2002; 40: 734-8.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
6. Guder WG et al. Die Qualität diagnostischer Proben – Empfehlung der Arbeitsgruppe Präanalytik der Deutschen Vereinten Gesellschaft für Klinische Chemie und Laboratoriumsmedizin. 3rd ed. Heidelberg: BD Diagnostics Preanalytical Systems; 2010. p. 46-47
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 15th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
8. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in February 2024. Published by AACC Press and John Wiley and Sons, Inc.
9. Thomas L, Müller M, Schumann G, Weidemann G, Klein G, Lunau S, Pick KH, Sonntag O. Consensus of DGKL and VDGH for interim reference intervals on enzymes in serum Konsensus von DGKL und VDGH zu vorläufigen Referenzbereichen für Serumenzyme. J Lab Med 2005;29(5):301-305.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Fluid Stable