BioMajesty®

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

Order Information

Cat. No.	Kit size
1 2801 99 10 963	2280 (R1: 4 x 570, R2: 3 x 760)
1 2801 99 10 962	2280 (R1: 6 x 380, R2: 6 x 380)

Intended Use

Diagnostic reagent for quantitative in vitro determination of gamma-glutamyltransferase (gamma-GT/GGT) activity in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

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. The bottles are placed directly into the reagent rotor.

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.

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

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Performance Characteristics

Results according to original IFCC formulation

Measuring range up to 1200 U/L, linearity is given within ± 5%. In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	1.2 U/L
Onboard stability	6 weeks
Calibration stability	6 weeks

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.

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

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

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* Fluid Stable

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Chemistry code 10 280

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	3
Sample vol (U)	3
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	GGT
Digits	2
M-wave L.	410
S-wave.L	694
Analy.mthd.	RRA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	3	3
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	21
M-DET.P.m	25
M-DET.P.n	40
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	21
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	1.4
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999