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

Diagnostic reagent for quantitative in vitro determination of gamma-glutamyltransferase (gamma-GT) in serum or plasma on BioMajesty JCA-BM6010/C

Order information

Cat. No.	Tests		
1 2801 99 10 963	R1	4 x	570 tests
	R2	3 x	760 tests
1 2801 99 10 962	R1	6 x	380 tests
	R2	6 x	380 tests

Method

Kinetic photometric test according to Szasz/Persijn [1]. The test has also been standardized to the method according to IFCC (International Federation of Clinical Chemistry) [2]. Results according to IFCC are obtained using the calibrator value given for the IFCC method.

Principle

Gamma-GT catalyzes the transfer of glutamic acid to acceptors like glycylglycine in this case. This process releases 5-amino-2-nitrobenzoate, which can be measured photometrically. The increase in absorbance is directly related to the activity of gamma-GT.

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

Gamma-GT

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

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 Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

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. For diagnostic purposes, the results should always be assessed with the patients' medical history, clinical examinations and other findings.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

Specimen

Serum or heparin plasma

Stability [3]:
at least 1 week between –20°C and +25°C
Only freeze once. Discard contaminated specimens.

Calibrators and Controls

For calibration DiaSys TruCal U calibrator is recommended. In case TruCal U is used as a calibrator, 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. For internal quality control DiaSys TruLab N and P controls should be assayed. 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

Measuring range up to 1200 U/L (20 µkat/L) gamma-GT (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 (0.02 µkat/L) gamma-GT
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 100 mg/dL
Conjugated bilirubin up to 36 mg/dL
Unconjugated bilirubin up to 48 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
For further information on interfering substances refer to Young DS [7].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	57.2	113	213
Mean [µkat/L]	0.953	1.88	3.55
Coefficient of variation [%]	1.79	1.34	1.22
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	30.6	82.5	132
Mean [µkat/L]	0.510	1.38	2.20
Coefficient of variation [%]	3.18	2.91	2.06

Method comparison (n=100)	
Test x	Competitor Gamma-GT
Test y	DiaSys Gamma-GT FS
Slope	1.036
Intercept	1.02 U/L (0.017 µkat/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]

BioMajesty

Reference Range

According to Szasz [4]

Women	< 32 U/L	< 0.53 µkat/L
Men	< 49 U/L	< 0.82 µkat/L

According to IFCC

	Female U/L	**Male** U/L
Adults [2]	< 38	< 55
Children/adolescents [5]		
1 day – 6 months	15 – 132	12 – 122
6 months – 1 year	1 – 39	1 – 39
1 – 2 year(s)	4 – 22	3 – 22
13 – 18 years	4 – 24	2 – 42

	Female µkat/L	**Male** µkat/L
Adults [2]	< 0.63	< 0.92
Children/adolescents [5]		
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 year(s)	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.

Literature

1. 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.
2. 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.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 30-1.
4. Fischbach F, Zawta B. Age-dependent reference limits of several enzymes in plasma at different measuring temperatures. Klin Lab 1992; 38: 555-61.
5. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft;1998. p. 80-6.
6. Szasz G. Gamma-Glutamyltranspeptidase. In: Bergmeyer HU. Methoden der enzymatischen Analyse. Weinheim: Verlag Chemie, 1974. p. 757.
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. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer

IVD CE

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

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