respons®910

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

Diagnostic reagent for quantitative in vitro determination of gamma-glutamyltransferase (gamma-GT) in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 2801 99 10 920
4 twin containers for 200 tests each

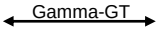
Method

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 at 405 nm. The increase in absorbance at this wavelength is directly related to the activity of gamma-GT.

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



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 and contamination is avoided. Do not freeze the reagents! Reagents must be protected from light. DiaSys respons containers provide protection from light.

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 patient's 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 rotor.

Specimen

Serum or heparin plasma

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

Calibrators and Controls

For calibration, the 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 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**	2 U/L gamma-GT
On-board stability	4 weeks
Calibration stability	7 days

Interfering substance	**Interferences < 10%**	**GGT [U/L]**
Ascorbate	up to 30 mg/dL	43.8
Hemoglobin	up to 150 mg/dL	42.0
	up to 600 mg/dL	87.9
Bilirubin, conjugated	up to 40 mg/dL	43.9
	up to 40 mg/dL	124
Bilirubin, unconjugated	up to 40 mg/dL	44.7
	up to 40 mg/dL	120
Lipemia (triglycerides)	up to 2000 mg/dL	41.9
	up to 2000 mg/dL	116
For further information on interfering substances refer to Young DS [6].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	29.3	89.4	178
Coefficient of variation [%]	1.77	1.92	1.64
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	28.8	89.6	198
Coefficient of variation [%]	1.70	1.48	1.89

Method comparison (n=110)	
Test x	DiaSys Gamma-GT FS (Hitachi 911)
Test y	DiaSys Gamma-GT FS (respons®910)
Slope	1.015
Intercept	1.12 U/L
Coefficient of correlation	0.9999

** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor:

GGT [U/L] x 0.0167 = GGT [µkat/L]

Reference Range

According to Szasz [4]

Women	< 32 U/L	< 0.53 µkat/L
Men	< 49 U/L	< 0.83 µkat/L

According to IFCC

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

According to IFCC [µkat/L]

	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.

* fluid stable

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. 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.
7. Szasz G. Gamma-Glutamyltranspeptidase. In: Bergmeyer HU. Methoden der enzymatischen Analyse. Weinheim: Verlag Chemie, 1974. p. 757.
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.)

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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	GGT
Shortcut:	
Reagent barcode reference:	034
Host reference:	034

Technic	
Type:	Linear kinetic
First reagent:[µL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	405
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	07:24
Last reading time [min:sec]	10:36
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	1.3000
Linearity: Maximum deviation [%]	100.0000
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	2.0000
Concentration technical limits-Upper	1200.0000
SERUM	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	6.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	6.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	6.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	6.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	6.0
Above normal dilution (factor)	6

Results	
Decimals	1
Units	U/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	Male
Age	
SERUM	>= <=55.0
URINE	
PLASMA	>= <=55.0
CSF	
Whole blood	
Gender	Female
Age	
SERUM	>= <=38.0
URINE	
PLASMA	>= <=38.0
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.002
Cal. 2	0.004
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value