respons®920

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®920

Order Information

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

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-nitroanilide + 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		22 mmol/L
		pH 6.00	

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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
3. In very rare cases, samples of patients with gammopathy might give falsified results [8].
4. 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.
5. 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

DiaSys TruCal U calibrator is recommended for calibration. 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**	3 U/L gamma-GT
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 50 mg/dL
Bilirubin up to 60 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
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]	27.5	85.2	156
Coefficient of variation [%]	1.31	0.75	0.65
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	27.5	83.6	158
Coefficient of variation [%]	2.99	1.68	1.08

Method comparison (n=110)	
Test x	DiaSys Gamma-GT FS (Hitachi 917)
Test y	DiaSys Gamma-GT FS (respons®920)
Slope	1.00
Intercept	–0.608 U/L
Coefficient of correlation	1.00

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

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	< 0.82 µkat/L

According to IFCC [U/L]

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

* fluid stable

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.

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

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IVD CE

respons®920

Gamma-GT FS Szasz mod./IFCC stand.

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	GGT				Auto Rerun		☐
Report Name	:	Gamma-GT				Online Calibration		☐
Unit	:	U/L	Decimal Places	:	1	Cuvette Wash		☐
Wavelength-Primary	:	405	Secondary	:	700	Total Reagents	:	2
Assay Type	:	RATE - A	Curve Type	:	Linear	Reagent R1	:	GGT R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	GGT R2
M2 Start	:	21	M2 End	:	32			
Sample Replicates	:	1	Standard Replicates	:	3	**Consumables/Calibrators:**		
Control Replicates	:	1	Control Interval	:	0	Blank/Level 0		0
Reaction Direction	:	Increasing	React. Abs. Limit	:	2.20	Calibrator		*
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.00			
Technical Minimum	:	3.00	Technical Maximum	:	1200.00			
Y = aX + b a=	:	1.00	b=	:	0.00			

* Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	GGT		
Sample Type	:	Serum		

Sample Volumes

Normal	:	6.00 µL	Dilution Ratio	:	1	X
Increase	:	12.00 µL	Dilution Ratio	:	1	X
Decrease	:	3.00 µL	Dilution Ratio	:	1	X
Standard Volume	:	6.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	160 µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	40 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	GGT		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (U/L)	Upper Limit (U/L)
Normal	:	0.00	55.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other