Gamma-GT (Szasz mod/IFCC Standard)

DiaSystem Scandinavia AB

Diagnostic reagent for quantitative in vitro determination of gamma-glutamyltransferase (gamma-GT) in serum or plasma on photometric systems

Order Information

Cat. No.	Kit size						
01 00022 70 04 0125	R1	5 x	20 mL	+	R2	1 x	25 mL
01 00022 70 04 0500	R1	5 x	80 mL	+	R2	1 x	100 mL
01 00022 70 10 0180	R1	4 x	36 mL	+	R2	4 x	9 mL
CDT-GGT	R1	3 X	30 mL	+	R2	2 x	11.3 mL

Summary

Gamma-glutamyltransferase (gamma-GT/GGT), also called gamma-glutamyltranspeptidase, is an enzyme present in liver and bile duct which is the most sensitive indicator of hepatobiliary diseases. Because of a high negative predictive value for these diseases the measurement of gamma-GT is widely used to rule out a hepatic or biliary origin. 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. [1]

Method

Kinetic photometric test according to Szasz/Persijn [2]. The test has also been standardized to the method according to IFCC (International Federation of Clinical Chemistry) [4]. Results according to IFCC are obtained using a special factor or, in case a calibrator (DiaSystem UniCal) is used, by use of 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

<u>Gamma-GT</u>

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! Reagent 2 must be protected 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. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
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

Substrate Start

The reagents are ready to use.

Sample Start

Mix 4 parts of R1 + 1 part of R2
(e. g. 20 mL R1 + 5 mL R2) = mono reagent

Stability :	4 weeks	at	2 - 8 °C
	5 days	at	15 – 25 °C

The mono reagent must be protected from light.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma
Stability [6]:
at least 1 week between - 20 °C and + 25 °C
Discard contaminated specimens.

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	405 nm (400 – 420 nm)
Optical path	1 cm
Temperature	37 °C
Measurement	Against reagent blank

Substrate start

	Blank	Sample
Sample/Calibrator	-	100 µL
Dist. Water	100 µL	-
Reagent 1	1000 µL	1000 µL
Mix, incubate for approx. 1 min, then add:		
Reagent 2	250 µL	250 µL
Mix, read absorbance after 1 min and start stopwatch.		
Read absorbance again after 1, 2 and 3 min.		

Sample start

	Blank	Sample
Sample/Calibrator		100 µL
Dist. Water	100 µL	
Monoreagent	1000 µL	1000 µL
Mix, read absorbance after 1 min and start stopwatch.		
Read absorbance again after 1, 2 and 3 min.		

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Calculation

With factor

From absorbance readings calculate ΔA/min and multiply by the corresponding factor from table below:

ΔA/min x factor = Gamma-GT activity [U/L]

	According to Szasz	According to IFCC
Substrate start 405 nm	1421	1606
Sample start 405 nm	1158	1309

With calibrator

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

Calibrators and Controls

In case UniCal CC 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 DiaSystem UniLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
UniCal CC	06 00122 70 04 0018	6 x 3 mL
UniLab N	07 00123 70 05 0030	6 x 5 mL
UniLab P	07 00124 70 05 0030	6 x 5 mL

Performance Characteristics

Measuring range

On automated systems the test is suitable for the determination of gamma-GT activities up to 1200 U/L.
In case of a manual procedure, the test is suitable for gamma-GT activities which correspond to a maximum of ΔA/min of 0.20.
If such values are exceeded the samples should be diluted 1 + 5 with NaCl solution (9 g/L) and results multiplied by 6.

Specificity/Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 400 mg/dL and lipemia up to 2000 mg/dL triglycerides. For further information on interfering substances refer to Young DS [7].

Sensitivity/Limit of Detection

The lower limit of detection is 2 U/L.

Precision

Intra-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	39.9	0.99	2.48
Sample 2	73.6	0.85	1.16
Sample 3	206	1.32	0.64

Inter-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	41.5	0.62	1.49
Sample 2	72.3	0.61	0.85
Sample 3	204	0.74	0.36

Method Comparison

A comparison of DiaSystem GGT (standardized to IFCC) (y) with the IFCC reference reagent (x) using 51 samples gave following results:
y = 1.005 x – 0.741 U/L; r= 0.999.

A comparison of DiaSystem GGT (according to Szasz) (y) with a commercially available test according to Szasz (x) using 51 samples gave following results:
y = 0.996 x +1.354 U/L; r= 1.000

Reference Range

According to Szasz [5]

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

According to IFCC

	Female	Male
Adults[4]	< 38 U/L	< 55 U/L
Children / adolescents [1]		
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

	Female µkat/L	Male µkat/L
Adults[4]	< 38 U/L	< 55 U/L
Children / adolescents [1]		
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

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8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

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