Gamma-glutamyl transferase (Gamma-GT)

(IFCC Szasz Method)

In-vitro Diagnostic reagent/kit for quantitative determination of Gamma-glutamyl transferase in serum/plasma sample on Photometric System.

Reagent

Reagent 1: Buffer Solution
Reagent 2: Substrate Solution

Summary

Gamma-glutamyl transferase (Gamma-GT) is a cellular enzyme with wide tissue distribution in the body, primarily in the kidney, pancreas, liver and prostate. Measurements of gamma-glutamyl transferase (Gamma-GT) activity are used in the diagnosis and treatment of hepatobiliary diseases such biliary obstruction, cirrhosis or liver tumours. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method

Kinetic photometric test according to Szasz/Persijn. The test has also been standardized to the method according to IFCC (International Federation of Clinical Chemistry). Results according to IFCC are obtained using a special factor or, in case a calibrator 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 + Glycyl Glycine

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

Reagent Storage Instructions and Stability

Reagent 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!

Components and Concentrations

TRIS 100 mmol/L, Glycylglycine 100 mmol/L, L-Gamma-glutamyl-3-carboxy-4-nitroanilide 3 mmol/L

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Mix, 4 parts of reagent 1 and 1 part of reagent 2 = working reagent.
The stability of the working reagent is
21 days at 2° - 8°C.
Protect the reaction solution from light.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma Stability:
1 month at 2° – 8 °C,
3 months at -20 °C
Only freeze once!
Discard contaminated specimens.

Assay Procedure

Wavelength	405 nm
Light path	10 mm
Temperature	37°C

Measurement **against Water Blank**

	Sample
Working Reagent	1000 µL
Sample	20 µL
Mix, Incubate for 60sec. and read absorbance after every 60sec. for 180sec.	

Calculation:

ΔA/min x 7625 = U/L of Gamma-GT

Quality Control

For internal quality normal and abnormal controls should be assayed with each batch of samples.
Each laboratory should establish corrective action in case of deviations in control recovery.

Warnings and Precautions

1. **In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.**
2. **Wear suitable gloves and eye/face protection.**
3. **Always use safety pipettes to pull the reagents into a pipette.**
4. **Reagents may contain some non-reactive and preservative components. It is suggested to handle carefully, avoid direct contact with skin and do not swallow.**
5. **The reagents contain sodium azide (0.95g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.**
6. **For professional use only!**

Performance Characteristics

Measuring Range

Measuring range of the assay is 2 U/L to 500 U/L. When values exceed 500 U/L, the samples should be diluted 1+9 NaCl solution (9 g/L) and the result multiplied by 10.

Linearity/Limit of Maximum Detection

The higher limit of detection is 500 U/L.

Sensitivity/Limit of Detection

The lower limit of detection is 2 U/L.

Specificity/Interferences

No interference was observed by, Ascorbic acid up to 30 mg/dL, Bilirubin up to 40mg/dL and Triglycerides up to 2000 mg/dL.

Precision

Intra assay n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	48.25	0.05	1.19
Sample 2	77.12	0.48	0.62
Sample 3	197.89	1.06	0.53

Inter assay n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	47.25	0.47	0.99
Sample 2	78.53	0.54	0.69
Sample 3	205.52	1.77	0.86

Method Comparison

A comparison of Precision Biomed Gamma GT (y) with a commercially available test (x) using 15 samples gave following results:
$y = 1.001x - 0.985$; $r^2 = 0.998$.

Reference Range

Women 7-32 U/L
Men 11-50 U/L

Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Quick Reference

Parameter	Gamma GT
Mode	Kinetic
Reaction slope	Increasing
Wavelength	405 nm
Path length	10 mm
Temperature	37°C
Working Reagent	4 Part Reagent 1
	1 Part Reagent 2
Working reagent Volume	1000 µL
Sample volume	20 µL
Delay	60 sec.
Rate	60 sec.
No. of readings	3
Factor	7625
Normal range	Women 9-39 U/L
	Men 11 – 61 U/L
Linearity	500 U/L
Sensitivity	2 U/L

Pack Size

Cat No.	Configuration	Pack
GGT00025	Reagent R1 - 1 x 20mL Reagent R2 - 1 x 5mL	25mL
GGT00500	Reagent R1 -4 x 100mL Reagent R2 - 2 x 50mL	500mL

Literature

1. Tietz Textbook of Clinical Chemistry. 3rd edi. Philadelphia: W.B Saunders Company; 1999.p.809-61
2. Eur Heart J 1998: 19 1434-503.
3. Handbook of lipoprotein testing. Washington: ACC Press, 1997:99-114.
4. Handbook of lipoprotein testing. Washington: AACC Press, 1997:25 - 48.

Version : GGT/00

IVD In Vitro Diagnostic Use | See Pack Insert For Procedure | Single Use only | CE
Temperature Limit | Manufacturer's Address | Manufacturing Date | Expiry Date | LOT Lot Number

Manufactured in India by :
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