γ-Glutamyl transferase Assay Kit (γ-GT/GGT)

Method: GPNA Substrate

Cat .No.	Size	Instrument
GB9050G	R1:2×90 ml R2:2×30 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS9051G	R1:3×60 ml R2:3×20 ml	For Hitachi 917 & OlympusAU640/400/600
GH9051G	R1:2×48 ml R2:2×16 ml	For Hitachi 902
GT9051G	R1:5×42ml R2:2×35ml	For TOSHIBA
GX9051G	R1:2×60 ml R2:2×20 ml	For SYNCHRON CX4-5-7-9 /LX20/DXC600-800

INTENDED USE

For the *in vitro* quanti-tative determination of γ - glutamyl transferase in human serum or plasma. This product is suitable for manual use, and is also suitable for all automatic analyzer.

CLINICAL SIGNIFICANCE[1]

γ-GT plays an important role in amino acid transport in the course of glutathione metabolism. The enzyme present in the serum is mainly of hepato-biliary origin. Increased enzyme activities are found in association with chronic alcoholism, different toxic liver damages, intra- and extrahepatic cholestasis, acute viral hepatitis, pancreatitis, neoplastic diseases of the liver and pancreas myocardial infarction as well as with diabetes mellitus.

ASSAY PRINCIPLE[2,3,4]

γ -GT catalyzes the transfer of glutamic acid to acceptors like glycylglycine. This process releases 5-amino-2-nitrobenzoate, which can be measured at 405nm. The increase in absorbance at this wavelength is directly related to the activity of γ -GT.

L-γ-glutamyl-3-carboxy-4 nitroanilide+glycylglycine

$$\xrightarrow{\gamma\text{-GT}}$$

L-γ-glutamyl-glycylglycine+5-amino-2nitrobenzoate

SAMPLE COLLECTION AND PREPARATION

Serum or plasma samples are stable for a week at 2-8℃.

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
glycylglycine	150 mmol/L
stabilizer	
Reagent 2 (R2)	
L-γ-glutamyl-3-carboxy-4 nitroanilide	4.5 mmol/L
stabilizer	

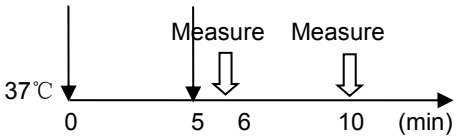
STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
The reagent is stable for 28 days on-board the analyser at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers
Assay Mode: RATE
Wave Length (main/sub): 405 nm / 505 nm

Sample: 10 µl
R1: 240 µl R2: 80 µl



1. Mix 10 µl sample with 240 µl R1 and incubate at 37℃ for 5 minutes.
2. Add 80 µl R2 into cuvette, mix and incubate at 37℃ for 1 minute.
3. Read initial absorbance and start timer simultaneously, read again after 1 and 5 minutes.
4. Calculate absorbance change per minute (ΔA/min)

CALCULATION

1. Using calibrator
Recommend that this assay should be calibrated using Gcell Calibration Serum.

$$\text{Concentration} = \frac{A_{sample}/\text{min}}{A_{calibrator}/\text{min}} \times \text{Calibrator value}$$

2. Using K facter (ε=9.5)

$$\text{GGT (U/L)} = \frac{\Delta A/\text{min} \times V_t}{\varepsilon \times V_s \times L} \times 1000 = \Delta A/\text{min} \times K$$

K = 5368

QUALITY CONTROL

For quality control, use Control as daily quality control sera and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.
4. Check the quality of the water used for reagents reconstitution.

NORMAL VALUE

10~47 U/L
Each laboratory should establish an expected range with a set of standards.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 2000 U/L. If the sample above this concentration should be diluted with 0.9% NaCl and repeat assay. Multiply the result by dilution factor.

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CE Revised 01DEC11 version 0801

PRECISION

The CV of the test should be less than 5%

Intra assay precision		
N=15	Level1	Level 2
Mean	56.7	192.8
SD	0.82	1.08
CV	1.44%	0.56%
Inter assay precision		
N=5	Level1	Level 2
Mean	58.0	191.7
SD	0.76	1.40
CV	1.30%	0.73%

SENSITIVITY

The minimum detectable level that can be distinguished fr zero has been determined as 4.0 U/L.

INTERFERENCE

The following analyze were tested up to the levels indicated and found not to interfere:

Hemoglobin: 200 mg/dl
Intralipid: 500 mg/dl
Bilirubin: 40 mg/dl
Ascorbic Acid: 50 mg/dl

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y=0.982X+0.797, R^2=0.999; 87 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Solution R1 contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed.Frankfurt:THBooksVerlagsgesellschaft;1998.p. 80-6.
2. 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.
3. Szasz G. Gamma-Glutamyltranspeptidase. In: Bergmeyer HU. Methoden der enzymatischen Analyse. Weinheim: Verlag Chemie, 1974. p. 757.
4. Schumann G, Bonora R, Ceriotti F, Férard G et al. IFCC primariy 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 gamma-glutamyltransferase. Clin Chem Lab Med 2002; 40:734-8.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
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