γ - Glutamyl transferase (γ GT) (1+1)

REF.	Pack size		
171 04 025	(4 x 25 ml) 100	tests	

IVD

Intended Use

 $\gamma\text{-glutamyltransferase}$ reagent is intended for the in-vitro quantitative and diagnostic determination of $\gamma\text{-glutamyltransferase}$ in human serum and plasma on both automated and manual systems.

Introduction

 $\gamma\text{-}Glutamyltransferase~(\gamma GT)$ is usually most significantly elevated by obstructive disease and has good specificity for the liver. It is not elevated in bone diseases or pregnancy (as in ALP) or in skeletal muscle diseases (as AST). γGT can also help to differentiate between mechanical and viral cholestasis and drug induced cholestasis. The highest concentration of γGT is found in the luminal membrane of the proximal tubules of the kidney. Other sources are the pancreas, prostate, and liver. High γGT activity is found in prostate tissue, which may account for the increased γGT activity seen in some sera from men compared with sera from women.

Method

Kinetic colorimetric according to Szasz method.

Principle

Determination of γ -Glutamyltransferase (γ GT) according to the following reaction:

L-g-Glutamyl-3-carboxy-4-nitroanilide + Glycylglycine

L-g-Glutamyl- glycylglycine + 5-amino-2-nitrobenzoate

The rate of liberation of yellow-coloured indicator 5-amino-2-nitrobenzoate is directly proportional to γ -GT activity in the sample and is quantitated by measuring the increase in absorbance at 405nm

Reagents

Reagent 1 (Buffer) Tris buffer pH 8.2 Glycylglycine Sodium Azide

80 mmol/L 130 mmol/L 8.0 mmol/L

Reagent 2 (Starter)

Modified L-γ-Glutamyl-3-carboxy-4-nitroanilide mmol/L

4.0

Sodium Azide

8.0 mmol/L

Reagents preparation, storage and stability

All reagents are stable till the expiration date stated on label when stored refrigerated at 2 - 8 °C.the open vaials are stable for 2 months at the specified temperature.

Working solution can be prepared by adding equall volumes from R1 and R2; Stability: 4 weeks at 2 - 8 °C or 1 week at 15 -25 °C when stored in a dark bottle.

Deterioration

Do not use liquizyme γGT reagent if it is turbid or if the absorbance of the working reagent is greater than 1.0 at 405 nm. Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Both reagents (R1) and (R2) contain sodium azide which may react with copper or lead plumbing.

Specimen Collection and Preservation

Use serum and plasma, free from hemolysis. Heparin is the only acceptable anticoagulant. The biological half-life of γ GT in serum is 3 – 4 days.

Stability: 7 days at 4-8 °C ; 7 days at 20-25 °C ; 1 year at -20 °C

Procedure

Wavelength 405 nm
Optical path 1 cm
Assay type Kinetic
Direction Increase
Sample : Reagent Ratio
e.g.: Reagent volume
Sample volume Sample volume

Sample volume
Temperature
Delay time
Read time
Zero adjustment
Reagent Blank Limits

100 μl
37 °C or 30 °C
60 seconds.
1 to 3 minutes
Against air
Low 0.2 AU
High 1.0 AU

Working 1.0 ml (or add 0.5 ml R1 + 0.5 ml R2)

Solution

Specimen 100 µl

Mix, read initial absorbance after 60 seconds and start timer simultaneously. Read again after 1, 2 and 3 minutes. Determine the mean absorbance change per minute ($\Delta A/min$).

Calculation

 γ -GT activity (U/L) = 1450 × Δ A 405 nm/min

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Performance Characteristics

A comparison between Spectrum Diagnostics γ –GT reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.969 was obtained.

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (U/L)	44.75	120.2
SD	2.07	2.2
CV%	4.63	1.84

Run to run (Reproducibility)

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	Level 1	Level 2
n	20	20
Mean (U/L)	45.1	121.3
SD	2.19	2.29
CV%	4.72	1.92

Sensitivity

When run as recommended, the minimum detection limit of this assav is 2.0 U/L.

Linearity

The reaction is linear up to γ -Glutamyltransferase concentration of 600 U/L; specimens showing higher concentration should be diluted 1+5 with physiological saline and repeat the assay (result×6).

Interference

HaemolysisNo significant interference up to a haemoglobin level of 5 g/L.

No significant interference.

Lipemia

Lipemic specimens may cause high absorbance flagging. Diluted sample treatment may be recommended.

Anticoagulants

Citrate, EDTA and fluoride inhibit the enzyme activity.

Expected Values

37 ^O C Females	7 -32 U/L	(0.12 -0.53 μkat/L)
Males	11-50 U/L	(0.18 -0. 82 μkat/L)
30 ^O C Females	5-24 U/L	(0.08-0. 4 μkat/L)
Males	8-37 U/L	(0.1 -0. 6 μkat/L)
25 ^O C Females	4-18 U/L	(0.07-0. 3 μkat/L)
Males	6-28 U/L	(0. 1-0. 5 μkat/L)

Analytical Range

2 - 600 U/L.

Waste Disposal

This product is made to be used in professional laboratories Please consult local regulations for a correct waste disposal. S56: dispose of this material and its container at hazardous or special waste collection point.

\$57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. refer to special instructions/safety data sheets.

References

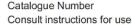
- 1. Moss DW, Henderson AR, Kachmar IF. Enzymes In: Tietz NW, ed.
- Fundamentals of clinical chemistry. 3 rd ed.

 2. Persjn JP, van der slike W. A new method for the determination of g-glutamyl transferase in serum. J Clin Chem Clin Biochem.
- 3. Szasz, G., Persijn JP. Clin. Chem. Clin. Biochem.

SYMBOLS IN PRODUCT LABELLING



For in-vitro diagnostic use Batch Code/Lot number







CAUTION. Consult instructions for use



Manufactured by

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