

γ - Glutamyltransferase- (γ GT)-Liquizyme (1+1) E.C.2.3.2.2.

REF: 247 001 (2 x 25 ml) 50 test
REF: 247 002 (4 x 25 ml) 100 test

Intended Use

Spectrum Diagnostics liquizyme γ -glutamyltransferase reagent is intended for the in-vitro quantitative, diagnostic determination of γ -glutamyltransferase in human serum on both automated and manual systems.

Background

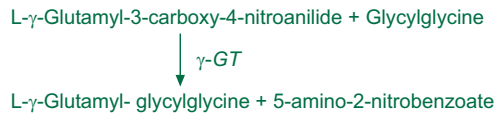
γ -Glutamyltransferase (γ GT) is usually most significantly elevated by obstructive disease and has good specificity for the liver. It is not elevated in bone diseases or pregnancy (as in ALP) or in skeletal muscle diseases (as AST). γ GT can also help to differentiate between mechanical and viral from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

Method

Kinetic colorimetric according to Szasz⁽⁵⁾ method.

Assay Principle

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



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 (R1 Buffer)

Tris buffer pH 8.2 120 mmol/L
Glycylglycine 300 mmol/L
Sodium Azide 12 mmol/L

Reagent 2 (R2 Starter)

L- γ -Glutamyl-3-carboxy-4-nitroanilide 1.0 mmol/L
Sodium Azide 8 mmol/L

For further information, refer to the γ -Glutamyltransferase reagent material safety data sheet.

Precautions and Warnings










Do not ingest or inhale. 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.

Reagent Preparation, Storage and Stability

All reagents are stable until expiration date stated on label when stored refrigerated at 2 - 8 °C.
Working solution can be prepared by adding equal volumes from R1 and R2 ; Stability : 3 months at 2 - 8 °C or 2 weeks at 15 -25°C when stored in a dark bottle.

SYMBOLS IN PRODUCT LABELLING

	Authorised Representative		Temperature Limitation
	For in-vitro diagnostic use		Use by/Expiration Date
	Batch Code/Lot number		CAUTION. Consult instructions for use
	Catalogue Number		Manufactured by
	Consult instructions for use		

Deterioration

Do not use liquizyme γ GT 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.

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

System Parameters

Wavelength	405 nm (400 – 420 nm)
Optical path	1 cm
Assay type	Kinetic
Direction	Increase
Sample : Reagent Ratio	1 : 10
e.g.: Reagent volume	1 ml
Sample volume	100 μ l
Temperature	37 °C or 30 °C
Equilibration time	30 seconds.
Read time	1 to 3 minutes
Zero adjustment	Against air
Reagent Blank Limits	Low 0.2 AU High 1.0 AU
Sensitivity	2.0 U/L
Linearity	600 U/L

Procedure

Pipette in a test tube:

working solution	1.0 ml (or add 0.5 ml R1 + 0.5 ml R2)
Specimen	100 μ l

Mix, read initial absorbance after 30 sec. and start timer simultaneously. Read again after 1, 2 and 3 minutes. Determine the mean absorbance change per minute (ΔA /min).

Calculation

To calculate the γ -glutamyl transferase (γ GT) activity, use the following formula:

$$U/L = 1158 \times \Delta A \text{ 405 nm /min}$$

Quality Control

Normal & abnormal control serum of known concentrations should be analyzed with each run.

Performance Characteristics

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)

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

Methods Comparison

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.

Sensitivity

When run as recommended, the minimum detection limit of this assay 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 \times 6).

Interfering Substances

Serum, plasma

Hemolysis

No significant interference up to a hemoglobin level of 5 g/L.

Icterus

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

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

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.

S57: use appropriate container to avoid environmental contamination.

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

References

1. Heersink W, Hafkenscheid JCM, Siepel H, van der venjongekryg J, Dijt CCM. Temperature – converting factors for enzymes: comparison of methods. Enzyme. 1980;25: 333-341.
2. Moss DW, Henderson AR, Kachmar IF. Enzymes In :Tietz NW, ed. Fundamentals of clinical chemistry. 3 rd ed.
3. Persjn JP, van der slike W. A new method for the determination of g-glutamyl transferase in serum. J Clin Chem Clin Biochem. 1976;14421-427.
4. Saw M, Stromme JH, london JL, Theodorsen L. IFCC method for g-glutamyl transferase[(g-glutamyl) – peptide:ammino acid g-glutamyl transferase, EC 2.3.2.2]. Clin Chem Acta. 1983; 135:315F-338F.
5. Szasz, G., Persijn JP. Clin. Chem. Clin. Biochem. 1974;12:228.

ORDERING INFORMATION

CATALOG NO.	QUANTITY
247 001	2 x 25 ml
247 002	4 x 25 ml



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