SPECTRUM

The Creative Approach to Bioscience

γ - Glutamyltransferase-(γGT)-Liquizyme (9+1) E.C.2.3.2.2.

REF: 246 001 (4 x 20 ml) 80 test
REF: 246 002 (10 x 10 ml) 100 test
REF: 246 003 (9 x 20 ml) 180 test
REF: 246 004 (4 x 60 ml) 240 test
REF: 246 005 (5 x 20 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 and plasma on both automated and manual systems.

Background

γ- Glutamyltransferase (γGT) 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 ALP) or in skeletal muscle diseases (as AST). γGT can also help to differentiate between mechanical and viral from 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[5] method.

Assay Principle

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

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

↓ γ-GT

L-γ-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 (R1 Buffer)

Tris buffer pH 8.2	80 mmol/L
Glycylglycine	130 mmol/L
Sodium Azide	8.0 mmol/L

Reagent 2 (R2 Starter)

Modified L-γ-Glutamyl-3-carboxy-4-nitroanilide	4.0 mmol/L
Sodium Azide	8.0 mmol/L

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

Reagent Preparation

Prepare working solution as following:

REF: 246 001: add 2 ml from R2 to one bottle of R; mix gently.
REF: 246 002: add 1 ml from R2 to one bottle of R; mix gently.
REF: 246 003: add 2 ml from R2 to one bottle of R; mix gently.
REF: 246 004: add 6 ml from R2 to one bottle of R; mix gently.
REF: 246 005: add 2 ml from R2 to one bottle of R; mix gently.

Or prepare the working solution according to the number of tests required by mixing 9 volumes of reagent 1 (R1) and 1 volume of reagent 2 (R2) ,e.g. 900 µl R1 +100 µl R2.

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

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.

Reagent Storage and Stability

All reagents are stable until expiration date stated on label when stored refrigerated at 2 - 8 °C.Once opened, the reagent is stable for 2 months at the specified temperature.
Working solution is stable for 4 weeks at 2 – 8 °C or 1 weeks at 15 to 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.

Specimen Collection and Preservation

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

Stability: 7 days at 4 – 8 °C ; 2 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
Temperature	37 °C or 30 °C
Equilibration time	60 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:	Macro	Semi-Micro
Working Solution	1.0 ml	500 µl
Specimen	100 µl	50 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 (ΔA/min).

Calculation

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

U/L = 1450 × ΔA 405 nm/min

Quality Control

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

Performance Characterstics

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	1.83

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (U/L)	45.1	121.3
SD	2.19	2.29
CV%	4.86	2.92

Methods Comparison

A comparison between Spectrum Diagnostics γ-GT and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.979 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×6).

Interfering Substances

Haemolysis
No significant interference up to a haemoglobin 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 μkat/L)
Males	11-50 U/L	(0.18 -0. 82 μkat/L)
30 °C Females	5-24 U/L	(0.08-0. 4 μkat/L)
Males	8-37 U/L	(0.1 -0. 6 μkat/L)
25 °C Females	4-18 U/L	(0.07-0. 3 μkat/L)
Males	6-28 U/L	(0. 1-0. 5 μkat/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**
246 001	4 x 20 ml
246 002	10 x 10 ml
246 003	9 x 20 ml
246 004	4 x 60 ml
246 005	5 x 20 ml

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