Spectrum For Diagnostic Industries

γ - Glutamyl transferase (γGT) (4+1)

IVD

REF.	Pack size
170 02 020	(2 x 20 ml) 40 tests
170 01 050	(1 x 50 ml) 50 tests
170 10 010	(10 x10 ml) 100 tests
170 04 050	(4 x 50 ml) 200 tests

Intended Use

SDI 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.

Introduction

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 or in skeletal muscle diseases. γGT can also help to differentiate between mechanical and viral from drug induced cholestasis.

Method

Kinetic colorimetric according to Szasz method.

Principle

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

γ-GT ↓

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 405 nm.

Reagents

Reagent 1 (Buffer)

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

Reagent 2 (Starter)

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

Reagents preparation, storage and stability

Prepare working solution by adding 4 volumes from R1 and 1 volume of R2,Working solution is stable for 4 weeks at 2 - 8 °C .
All reagents are stable till the expiration date stated on label when stored refrigerated at 2 - 8 °C.Once Opened , the reagent is stable for 2 months at specified temperature.

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.

Specimen collection and preservation

Use serum and plasma, free from haemolysis. 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	1 : 10
e.g.: Reagent volume	1 ml
Sample volume	100 µl
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

Working Solution	1.0 ml
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 (ΔA/min).

Calculation

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

Quality control

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

Sensitivity

2.0 U/L.

Linearity

600 U/L

Interference

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.

Analytical Range

2 – 600 U/L.

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)

Performance Characteristics

A study using 20 human specimens between this γ–GT reagent and reference method yielded a correlation coefficient of 0.993 and a linear regression equation of y= 1.021x + 0.072

Precision
Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (U/L)	44.7	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

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. 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

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

Spectrum For Diagnostics Industries - Free Zone
Ismailia Free Zone Industrial Area, Block 5 .
Cairo- Port said Avenue.
Ismailia,Egypt
Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015
www.sdi-fz.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany