Spectrum For Diagnostic Industries

γ - Glutamyl transferase (γGT) (1+1)

IVD

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

Intended Use

γ-glutamyltransferase reagent is intended for the in-vitro quantitative and 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 (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 (γGT) according to the following reaction:

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 405nm.

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-γ-Glutamyl-3-carboxy-4-nitroanilide	4.0 mmol/L
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 γGT 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
Delay 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 (or add 0.5 ml R1 + 0.5 ml R2)
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.

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)

	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 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).

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.

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)

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. 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

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ISO 13485:2016