γ- GLUTAMYLTRANSFERASE (9+1) (GGT)

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

REF: V/GT06.005	30 test	REF: V/GT06.010	60 test

CLINICAL SIGNIFICANCE

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 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 PRINCIPLE

Kinetic colorimetric according to Szasz method.
Determination of γ-Glutamyltransferase (γGT) 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.

REAGENT COMPOSITION

R1:(Buffer enzyme)	
Tris buffer PH 7.7	120 mmole/L
Glycylglycine	300 mmole/L
Sodium Azide	12 mmole/L
R2:(Coenzyme)	
L- γ -Glutamyl-3-carboxy-4-nitroanilide	1 mmole/L
Sodium Azide	8 mmole/L

PRECAUTIONS AND WARNING

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in

- Wearing personnel protective equipment (overall, gloves, glasses,..).
- Do not pipette by mouth.
- 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.
- Respect country requirement for 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.

For further information, refer to the **Lab.Vie** GGT reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

Lab.Vie GGT reagents (R1) and (R2) contain sodium azide which may react with copper or lead plumbing.
Preparing 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.
All reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2-8ºC.
Stability: 3 months at 2 - 8 ºC or 2 weeks at 15 -25 ºC when stored in a dark bottle.

Deterioration
The **Lab.Vie** GGT reagent normally clear. Do not use GGT reagent if it is turbid or if the absorbance is less than 1 at 405 nm.

SPECIMEN COLLECTION AND PRESERVATION

Serum or Plasma
Anticoagulants currently in use like EDTA, oxalate and fluoride do not affect the results. Hemolysis interferes with the assay.

SYSTEM PARAMETERS

Wavelength	405 nm (400 - 420 nm)
Optical path	1Cm
Assay type	Kinetic
Direction	decrease
Sample Reagent Ratio e.g: Reagent volume Sample volume	1:10 1 ml 100µl
Temperature	37º c to 30ºc
Equilibration time	30 Sec
Read time	1-3 mins
Zero adjustment	Against air
Reagent Blank Limits	Low 0.2 AU High 1.0 AU
Sensitivity	2.0 U/L
Linearity	600 U/L

ASSAY PROCEDURE

	Macro	*Semi-micro*
Working Reagent	1.0 ml	500µl
Specimen	100µl	50µl

Mix, read initial absorbance after 30 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 GGT activity uses the following formulae:
U/l = 1158 x ΔA 405 nm /min

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact **Lab.Vie** technical support

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	20	20	20	20
Mean U/l	44.75	120.2	45.1	121.3
SD.	2.07	2.2	2.19	2.29
CV. %	4.63	1.84	4.72	1.92

The results of the performance characteristics depend on the analyzer used.

Accuracy (Methods Comparison)
Result obtained from **Lab.Vie** GGT (9+1) reagent and a commercial reagent of the same methodology was performed on 20 human sera. 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 GGT 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

Hemolysis
No significant interference up to a hemoglobin level of 5 g/L.
Lipemia
Lipemic specimens may cause high absorbance flagging. Diluted sample is recommended.
Anticoagulants
Citrate, EDTA and fluoride inhibit the enzyme activity

Units: One international unit (IU) is the amount of enzyme that transforms 1 µmol of substrate per minute, in standard conditions. The concentration is expressed in units per liter of sample (U/L).

EXPECTED VALUES

	37ºC	**30ºC**	**25ºC**
Females	7-32 U/L	5-24 U/L	4-18 U/L
	0.12 -0.53 µkat/L	0.08 -0.4 µkat/L	0.07 -0.3 µkat/L
Males	11-50 U/L	8-37 U/L	6-28 U/L
	0.18 -0.82 µkat/L	0.1 -0.6 µkat/L	0.1 -0.5 µkat/L

DYNAMIC RANGE

2 – 600 U/L

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.

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		
	Expiration Date		
	Manufactured by		

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