GAMMA GT (2-8°C)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRGGT1	1x60ml / 1x12ml
MPRGGT2	4x60ml / 2x24ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
This reagent is intended for the quantitative determination of Gamma Glutamyltransferase (γ-GT) in human serum and plasma.

Clinical Significance:
Elevated levels of γ-GT are found in many forms of liver disease including primary and secondary liver cancer.
Increased levels are also found in cases of alcohol abuse and liver cirrhosis. γ-GT is the most sensitive enzymatic marker of hepatobiliary disease.

Test Principle:
The substrate L- γ-glutamyl-3-carboxy-4-nitroanilide, in the presence of glycylglycine is converted to 5-amino-2-nitrobenzoate by γ-GT. The increase in absorbance due to the formation of 5-amino-2-nitrobenzoate can be measured photometrically at 405nm and is proportional to the γ-GT activity in the sample.

L- γ-glutamyl-3-carboxy-4-nitroanilide + glycylglycine γ-GT ⟶

L- γ -glutamylglycylglcine + 5-amino-2-nitrobenzoate

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Gamma GT R1	Tris Buffer	100 mmol/l
	Glycylglycine	150 mmol/l
	Preservative	0.09%
Gamma GT R2	L-Gamma Glutamyl 3 Carboxy 4 nitroanilide	2.9 mmol/l

Reagent Preparation and Stability:
R1: Liquid, ready to use
R2: Liquid, ready to use
R1 and R2 are stable to the stated expiry date when stored unopened at 2 - 8°C. Once mixed, the Working Reagent is stable up to 28 days stored at 2 - 8°C and 7 days at 20 – 25°C. Analyser onboard stability is up to 21 days when R1 and R2 are kept separate and up to 14 days as Working Reagent, with refrigeration (2 - 8°C) for each system.
Dispose of reagents carefully in line with local guidelines.

Sample / Sample Preparation / Sample Stability:
Collect serum and Li heparin or EDTA plasma by standard venepuncture technique. Gamma GT will be stable in serum for up to 7 days at 2 - 8°C and 20 - 25°C.
Centrifuge samples containing precipitate before performing the assay.

Assay Procedure: Sample Start
Prepare a Working Reagent by mixing R1 and R2 in the ratio 5 + 1 volumes.

WAVELENGTH	405nm (400 – 420nm)
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Air / Distilled water

Sample	250 µl	100 µl	50 µl
Working Reagent	2500 µl	1000 µl	500 µl
Mix, read initial absorbance and start a timer immediately. Read the absorbance again after exactly 1, 2 and 3 minutes then calculate the change in absorbance/min (ΔAbs)			

Calculation:
Concentration γ-GT (U/l) = ΔAbs x 1158

Assay Procedure: Substrate Start
R1 and R2 are ready to use.

WAVELENGTH	405nm (400 – 420nm)
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Air / Distilled water

R1	2500 µl	1000 µl	500 µl
Sample	250 µl	100 µl	50 µl
R2	500 µl	200 µl	100 µl
Mix, read initial absorbance and start a timer immediately. Read the absorbance again after exactly 1, 2 and 3 minutes then calculate the change in absorbance/min (ΔAbs)			

Calculation:
Concentration γ-GT (U/l) = ΔAbs x 1369
Calibration Frequency:
Two Point calibration is recommended on automated systems after reagent lot change or as required following quality control procedures.

Performance Characteristics:

Measuring range:
3 - 1200 U/l

Dilute samples with higher concentrations using Normal saline 1+9 and rerun the assay. Multiply the result by the dilution factor (for 1+9 dilution, the dilution factor is 10)
Analytical Sensitivity: (Lowest detection limit):
3 U/l

Imprecision:
Intra-Assay Precision

Sample	Mean (U/l)	SD (U/l)	CV %
Pool 1	41.6	0.60	1.44
Pool 2	105	0.65	0.62
Pool 3	169	0.62	0.37

Inter-Assay Precision

Sample	Mean (U/l)	SD (U/l)	CV %
Pool 1	39.5	0.66	1.67
Pool 2	87.1	1.42	1.63
Pool 3	215	2.91	1.35

Method Comparison:
AMS Gamma GT (γ) was compared with another available method (x) and the following results were obtained:
y = 0.993 x + 0.595, r = 0.999

Interferences:
Criterion: Recovery within +/- 10%
Icterus: No significant interference up 30 mg/dl of Bilirubin.
Haemolysis: No significant interference up to 150 mg/dl of Haemoglobin.
Lipaemia: No significant interference up to 2148 mg/dl of Triglycerides.

Reference Range:

	37°C (U/l)
Male	8 - 61
Female	5 - 36

Each laboratory should establish its own mean reference range according to the population.

Limitations of the Test:
On automated analysers use an acid wash facility when performing α-microglobulin and β-2 microglobulin assays to prevent carryover from the GGT assay.
The result from this test should not be used as the sole criteria for the diagnosis of liver disease, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Automated systems:
Contact AMS Diagnostics Technical Department for applications on a wide range of automated analysers.
For automation we recommend the use of a serum based calibrator.
Quality Control and Calibration Material:
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

References:

1. Glick M. R. Ryder K W, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. ClinChem 1986; 32:470-474
2. Bablok W. et al. A General Regression Procedure ofr Method Transformation. Clin Chem Clin Biochem 1988; 26: 783-790
3. Persijn JP, van der Silk W. A new method for the determination of gamma-glutamyltransferase. J Clin Chem Biochem 1976; 4:21#
4. Shaw L M. Keeping pace with a popular enzyme GGT. Diagnostic Medicine 1982; May/June 1-8.
5. Szasz G., Methods of Enzymatic Analysis 2nd English ed New York: Academic Press Inc 1974:717
6. Thomas K. Clinical Laboratory Diagnostics. 4 th ed. Marburg: Die Medizinsche Veriagsgesellschaft; 1992
7. Tietz NS. Clinical Guide to Laboratory tests 3rd ed. Philadelphia, Pa.W.B,Saunders Company. 1995:286

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

CE

AMS UK Ltd., 42 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL. Tel: +44(0)28 25656268
www.amslabs.co.uk info@amslabs.co.uk

V3: rev Dec 2018