GAMMA GT Kit
CliniQuant – FSR
Glupa-C Method

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 GGT Reagent	R2 GGT Reagent
GGTFSR-01	1 x 8 / 1 x 2ml	1 x 8ml	1 x 2ml

INTENDED USE
This reagent is intended for quantitative analysis of GGT in human serum.

CLINICAL SIGNIFICANCE
Elevated GGT activity is found in all forms of liver disease, drug toxication, alcoholic cirrhosis.

PRINCIPLE OF THE METHOD
The enzyme GGT (γ-glutamyltransferase) catalyzes the GLUPA-C (L-glutamyl-3-carboxy-4-nitroanilide) to release 5-amino-2-nitrobenzoate. The 5-amino-2-nitrobenzoate is detected spectrophotometrically at 405 nm to give a measurement of GGT activity in the sample.

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

GGT ↓

L- γ- glutamylglyclyglycine +5-amino–2 - nitrobenzoate

KIT COMPONENTS
Composition :
R1 - GGT Reagent : Triton X-100 1.54 mmol/l, Glycyl Glycine 150 mmol/l, Tris Buffer 125 mmol/l
R2 - GGT Reagent : GPNA 22 mmol/l

MATERIALS REQUIRED BUT NOT PROVIDED
Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY
Mix reagent 1 & reagent 2 in ratio 4:1. Keep away from direct light sources.
Stability: up to expiration date on labels at 2-8 °C.
Stability of working reagent: 21 days at 2-8 °C.

REAGENT DETERIORATION
1. Discard the reagent if absorbance exceeds 0.7 against distilled water at 405 nm.

WARNINGS AND PRECAUTIONS
1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN
Use unhemolysed serum, plasma (EDTA or Heparin only). GGT is stable up to 7 days at 2-8°C and prolonged at -20°C.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	Rate
Factor	2210
Filter - 1 (nm)	405
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	60
Read Time (Sec)	120
Unit	U/l
Reaction Direction	Increase
Reference Low	0
Reference High	50
Linearity Limit	500

TEST PROCEDURE

Dispense working reagent in tube	1000 µl
Sample	50 µl
Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 2 readings at 60 seconds intervals. Calculate the ΔA/min.	

RESULT CALCULATION
Serum/plasma:
GGT U/l = ΔA/min x 2210

CE
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EXPECTED VALUES

Men: ≤ 50 U/l
Women: ≤ 30 U/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

When using the recommended Calibrator (BioCal), calibrate the assay:

a. When using a new reagent or lot
b. When QC values are out of range

TEST PERFORMANCE

1. Linearity

The linearity is up to 500 U/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 2 U/l.
The limit of quantification is 7 U/l

3. Interferences

No interference has been observed for the following
Hemoglobin up to 50 mg/dl
Bilirubin up to 25 mg/dl
Triglycerides up to 1000 mg/dl

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	58.94	0.96	1.64
sample 2	269.07	0.95	0.35

Inter-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	59.08	1.79	3.03
sample 2	269.73	2.98	1.10

5. Methods Comparison

Comparison was done between reference GGT Reagent and CliniQuant -FSR GGT Reagent (test)

N = 18 $y = 0.890x + 2.565$

$r^2 = 0.997$

LIMITATIONS

Samples with values above 500 U/l should be diluted with 0.9% saline, re-run and results multiplied by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 848 - 849.
2. Data on file: Meril Diagnostics.

IFU/GGTFSR01/00
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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged
EC REP	Authorized European Representative in the European Community		