GAMMA GT (IFCC-Glupa c)

INDENDED USE

Bioline Gamma GT is intended for the quantitative *in vitro* diagnostic determination of Gamma-glutamyltransferase (GGT) in human serum.

CLINICAL SIGNIFICANCE

Gamma-glutamyltransferase (Y -GT) is a membrane bound enzyme mainly present in kidneys, pancreas, liver and prostate. This enzyme plays a significant role in glutathione metabolism and takes part in the transport of amino acids into the cells.

The rise of Y-GT activity, is more sensitive than Alkaline Phosphatase (ALP) during an infection of the liver or bile ducts. The highest increases are observed in cases of intrahepatic or posthepatic biliary obstructions (reaching levels from 5 to 30 times normal), primary or metastatic neoplasms of liver, pancreatic diseases (pancreatitis, cancer). Gamma-Glutamyltransferase (Y -GT) is useful as a marker for pancreatic cancer, prostatic cancer and hepatoma because levels reflect remission and recurrence. More moderate elevations are observed during infectious hepatitis, cirrhosis and hepatic steatosis. Alcohol in chronic ingestion, some drugs like antiepileptic (phenobarbital, phenytoine) can also increase Y-GT rate in the serum.

METHOD AND PRINCIPLE

GLUPA-C + Glycylglycine

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L-γ-Glutamyl-glycylglycine + 5-Amino-2-nitrobenzoic acid

REAGENT COMPOSITION

Glycylglycine, pH 7.70 (37 °C)	138 mmol/L
GLUPA-C	23 mmol/L

WARNINGS AND PRECAUTIONS

The reagents contain less than 0.1 % sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. If discharged in the plumbing system, rinse with plenty of water.

Use clean or single use laboratory equipment only to avoid contamination.

For more information, Material Safety Data Sheet (MSDS) is available on request for the professional users.

WORKING REAGENT PREPARATION

The working reagent is prepared by mixing 4 volumes of R1 with 1 volume of R2.

REAGENT STORAGE AND STABILITY

Store at 2-8 °C and protect from light.

The reagent is stable until the expiry date stated on the label.

REAGENT DETERIORATION

The reagent should be discarded if:

1. Turbidity has occurred; turbidity may be a sign of contamination.
2. The working reagent has an absorbance against water greater than 1.0 at 405 nm.

SPECIMEN COLLECTION AND STABILITY

-Serum or Lithium heparinized plasma.

-Do not use other specimens.

Samples are stable for 7 days at 2-8 °C and at least 2 months at -20 °C. For longer storage, freeze samples at -70 °C

- Samples must be free from haemolysis and lipemia.

INTERFERENCE

1. Most anticoagulants used in blood collection tubes inhibit GGT activity.
2. Anti-epileptic drugs (phenytoin and barbituates) may falsely elevate GGT levels.
3. Bilirubin to the level of 20 mg/dl has been found to exhibit negligible interference (< 5%) in this assay
4. Hemoglobin from 100-500 mg/dl has been found to show minimal depression (approximately 5-7%) of recovered GGT activities.

ASSAY PROCEDURE FOR SEMIAUTO ANALYZER.

Wavelength : 405 nm

Temperature : 37^{0}C

	Sample
Reagent R1	800 µL
Reagent R2	200 µL
Sample	50 µL

Mix and aspirate into the analyzer after a 1 minute of delay, measure the change of optical density per minute (ΔOD/min.) during next two minutes.

CALCULATION

Gamma GT Activity (IU/L) at 405 nm = ΔOD/min. X 2658

QUALITY CONTROL

To ensure adequate quality, control sera normal and abnormal control should be used. These controls must be performed & validated before the patient samples are assayed. The control frequency must be at least once a day, after each calibration and should be adapted to Quality Control procedures of each laboratory and the regulatory requirements. Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take corrective measures. Quality control material should be used in accordance with

local guidelines.

EXPECTED VALUES

Serum/plasma: Men : 8 –61 IU/L women : 5 – 36 IU/L

PERFORMANCE CHARACTERISTICS

1. Linearity: 0-800 IU/L. Samples that exceed 800 IU/L should be diluted with an equal volume of saline and re-assayed. Multiply the result by 2.

2. Comparison: Results obtained with this reagent in 102 samples ranging in GGT from 7 to 300 IU/L were compared with those obtained in the same samples using a dry powder based on the same methodology. The correlation coefficient was 0.999 and the regression equation was y=1.03x-1.24

3. Precision: Precision studies were performed following the modification of the guidelines contained in NCCLS document EP5-T2.

	N	Mean IU/L	Within run CV%	Between run CV%
Low Level	80	39.7	1.7	3.0
Medium Level	80	101.5	0.5	2.0
High Level	80	525.9	0.2	1.9

4. Sensitivity: The sensitivity for the GGT reagent was investigated by reading the change in absorbance for a saline sample. Ten replicates were performed. The results of this investigation indicated that, the GGT reagent showed little or no drift on a zero sample. Under the reaction conditions described, 1 IU/L gives an absorbance movement of 0.0003.

GENERAL TECHNICAL PARAMETER

Mode	Kinetic
Wavelength (Filter)	405 nm
Reaction Direction / Type	Increasing
Reagent Blank	No
Sample Vol.	50 µL
Reagent Vol.	1000 µL
Delay Time	60 Sec
Interval Time	60 Sec
No. of reading	2
Measuring Time	120 Sec
Factor	2658
Reagent Blank Abs.(Max)	NMT 1.0 Abs
Calibration Method	Fix factor
Linearity	800 IU/L
Decimal Places	1
Temp.	37^0C
Unit	IU/L
Ref. Low (Male / Female)	8/5 IU/L
Ref. High (Male / Female)	61/36 IU/L

REFERENCES

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