Quantitative determination of Gamma GT in serum/plasma
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
GGT 10	1 X 10 mL
GGT 25	1 X 25 mL
GGT 50	2 X 25 mL

CLINICAL SIGNIFICANCE

Gamma-glutamyl transferase (γ-GT) is a cellular enzyme with wide tissue distribution in the body, primarily in the kidney, pancreas, liver and prostate. Measurements of gamma-glutamyl transferase (γ-GT) activity are used in the diagnosis and treatment of hepatobiliary diseases such biliary obstruction, cirrhosis or liver Tumours.
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method

Kinetic photometric test according to Szasz/Persijn. The test has also been standardized to the method according to IFCC (International Federation of Clinical Chemistry)

PRINCIPLE

Gamma-glutamyl is transferred from gamma-glutamyl-p-nitroanilide to glycylglycine by Gamma-GT (Gamma-Glutamyl-Transferase). The p-nitroaniline formed absorbs at 405nm. The amount of pnitroaniline formed is directly proportional to Gamma-GT activity.

REAGENT

Reagent I : Buffer reagent
Reagent II : Substrate reagent

REAGENT PREPARATION

Mix 4 ml (4 parts) of Buffer Reagent with 1 ml (1 part) of Substrate Reagent.

REAGENT STORAGE AND STABILITY

Prior to use:
When stored between 2-8°C the reagent is stable until the expiration date stated on the bottle and kit box label.

Reconstituted Reagent:
When stored capped at 2-8°C, the reagent is stable for at least 3 days.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum or heparin plasma
It is very important to store the sample protected from light!
Stability: at least 1 week between -20 °C and 4 °C in case of immediate freezing.
Freeze only once! Discard contaminated specimens!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28°C, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	405 nm
Cuvette	1 cm light path
Reaction Temperature	37°C
Measurement	Against distilled water
Reaction Type	Kinetic test
Reaction Direction	Increasing
Sample Volume	100 µl
Reagent Volume	1000 µl
Delay/Lag/time	60 Secs
Interval time	60 Secs
No: of Readings	03
Blank Absorbance limit	< 0.85
Factor	1640
Low Normal at 37°C	7 IU/L
High Normal at 37°C	50 IU/L
Linearity at 37°C	200 IU/L

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

SAMPLE	100 µl
WORKING REAGENT	1000 µl

Mix well and Incubate for 1 min at 37°C. Read initial absorbance and start timer simultaneously; read again after 1, 2 and 3 min. calculate (Δ Abs/min.)

SAMPLE DILUTIONS

- This method is linear upto a concentration of 200 IU/L.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION

Results are calculated, usually automatically by the instrument, as follows:

Gamma GT IU/L = Δ Abs/min. x 1640

CALIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

For calculation according to IFCC, standardization was performed against the original IFCC formulation.

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Norm	47.58	1.46	3.07%
Path	140.04	3.79	2.71%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Norm	47.99	1.54	3.21%
Path	141.55	3.61	2.55%

LINEARITY

The method is linear upto a concentration of 200U/L. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Gamma GT is 2 IU/L.

METHOD COMPARISON

A comparison of Accucare Gamma GT with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9900$

REFERENCE VALUES

Serum at 37°C	
Male	10-50 IU/L
Female	7-35 IU/L

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Hemoglobin: No interference found upto 200 mg/dL.
- Bilirubin: No interference found upto 25mg /dL.
- Lipemia: No interference found upto 500 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

1. Szasz G.,Clin. Chem., (1969), 15:24,

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No.: 3225, Chemical Zone,
GIDC Sarigam – 396155, Dist. Valsad, Gujarat, India.
Tel.: +91 22 2554 2109 /1558
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