GAMMA GLUTAMYL TRANSFERASE (GGT)

Gamma-gutamyl transferase determination in serum and plasma

TEST SUMMARY

The enzyme γ-GT hydrolyses GLUPA-C to release p-nitroanaline, which formation could be measured spectrophotometrically at 405 nm to give a measurement of GGT activity in the sample.

SAMPLES

Serum, plasma EDTA. Avoid hemolysis.
Stability: 7 days at 2-8°C or at –20°C for longer periods.

REAGENTS

Reagent A: Tris buffer 100 mM pH 8.25, glycilglycine 00 mM; preservatives and stabilizers.

Reagent B: L-γ-glutamyl-3-carboxy-4-nitroanilide 4 mM.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Physiological solution.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general "Good Laboratory Practice" (GPL) guidelines.

SAMPLES PREPARATION

Add 10 ml of Regent B to a vial of reagent A.
Work reagent is stable 30 days at 2-8°C away from light sources.
Reagents are stored at 2-8°C until expirtion date away from light source.

PROCEDURE

Kind of analysis:	kinetics (increasing)
Reading time:	1,2,3 minutes
Delay:	60 sec.
Wavelength:	405 nm
Temperature:	37°C
Lightpath:	1 cm
Zero:	Distilled water

REAGENTS	CUVETTE
Work reagent	1 ml
Preincubate at 37 °C at least for 5 minutes.	
Sample	100 µl

CALCULATION

Activity in U/l: ΔA/min x 1111

Activity in µkat/l: U/l x 0.0167

EXPECTED VALUES

Men	<50 U/l	(<0.83 µkat/l)
Women	<30 U/l	(<0.50 µkat/l)

Each laboratory should establish appropriate reference intervals related to its population.

NOTES

- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.
- Only for IVD use.

CALIBRATION/QUALITY CONTROL

It is suggested to perform an internal quality control. For this purpose the following control sera on human base are available on request:

QN 0050 CH **10 x 5 ml**
Control Sera normal values

QP 0050 CH **10 x 5 ml**
Control Sera pathological values

TEST PERFORMANCE

Precision

Intra-assay (n = 25)	Mean (U/l)	SD (U/l)	CV%
Sample 1	15.852	0.1084	0.68
Sample 2	168.12	0.8326	0.5

Inter-assay (n = 25)	Mean (U/l)	SD (U/l)	CV%
Sample 1	15.84	0.1	0.63
Sample 2	168.4	0.913	0.54

Sensivity/limit of detection
The method is able to discriminate until 1 U/l.

Linearity
The method is linear up to 300 U/l.
If value is exceeded at 300 U/l, is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the results by 10.

Methods comparison
A comparison with a commercial available product gave the following results in a comparison on 28 sample:

GGT LTA = x
GGT competitor = y
n = 28

y = 1,0448x - 0,26324 r = 0,99179

Interferences
No interference was observed by the presence of:

hemoglobin	≤ 500 mg/dl
bilirubin	≤ 28 mg/dl
lipids	≤ 600 mg/dl

WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE CC01800	(200 TESTS)	
Reagent A	4 x 40 ml	(liquid)
Reagent B	1 x 40 ml	(liquid)

REFERENCES

SZASZ G. – Clin. Chem. 22, 2051 (1976).
TIETZ Texbook of Clinical Chemistry, Second Editino, Burtis-Ashwood (1994).
BERGMEYER HU Method of enzymatic analysis (1987).

MANUFACTURER

LTA s.r.l.
Via Milano 15/F
20060 Bussero (Milan) ITALY
Tel: ++39 02 95409034
Fax: ++39 02 95334185
e-mail: info@ltaonline.it
Website: http://www.ltaonline.it

SYMBOLS

IVD Only for IVD use
LOT Lot of manufacturing
REF Code number
Storage temperature interval
Expiration date (year, month)
Warning, read enclosed documents
Read the directions
Biological risk

Mod. 01.06 (ver. 4.6 – 12/02/2009)

CE