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GAMMA-GT

STABLE LIQUID



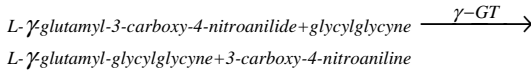
Cat. No.:	47261	47262	47263
	120 ml	600 ml	10x25 ml
	(1x100 ml+1x25ml)	(1x480 ml +1x125 ml)	(10x20 ml+ 10x5 ml)

Reagent kit for determination of γ -glutamyl-transferase (γ -GT) activity in serum. Modified kinetic colorimetric method of Szász.

γ -GT plays an important role in amino acid transport in the course of glutathione metabolism. The enzyme present in the serum is mainly of hepato-biliary origin. Increased enzyme activities are found in association with chronic alcoholism, different toxic liver damages, intra- and extrahepatic cholestasis, acute viral hepatitis, pancreatitis, neoplastic diseases of the liver and pancreas, myocardial infarction as well as with diabetes mellitus.

Principle

γ -GT catalyzes the transfer of the γ -glutamyl group from L- γ -glutamyl-3-carboxy-4-nitroanilide substrate to glycylglycine. The amount of released p-nitroaniline is proportional to the γ -GT activity of serum.



Reference values

Male: 11-50 U/l (0,18-0,83 μ kat/l)

Female: 7-32 U/l (0,12-0,53 μ kat/l)

It is recommended that each laboratory should assign its own normal range.

Reagents

1. Reagent (R1)

TRIS buffer pH= 8.25 125 mmol/l
Glycylglycine 140 mmol/l

2. Reagent (R2)

L- γ -glutamyl-3-carboxy-4-nitroanilide 22 mmol/l

Notes

These reagents contain 0.1 % sodium azide. To avoid the possible build-up of azide compounds, flush waste-pipes with water after the disposal of undiluted reagent. Avoid contamination by using clean laboratory materials (pipette, plastic vial for analyzers, ...).

Samples

Serum free of haemolysis.

PROCEDURE

Preparation and stability of working reagent

• One-reagent procedure:

Mix 4 volumes of reagent 1 with 1 volume of reagent 2.

Stability: at 20-25°C 5 days
at 2-8°C 3 weeks

• Two-reagent procedure:

The reagents are ready to use.

Do not use working reagent if its initial optical density measured against distilled water at 405 nm 1.0 exceeds.

Assay conditions

Wavelength: 405 nm
Temperature: 37°C
Cuvette: 1 cm light path
Method: kinetic (increasing)
Read against: distilled water

• One-reagent procedure

Working reagent	1 ml
Sample	100 μ l

Mix and after 1 minute incubation, measure the change of absorbance per minute (ΔA /min) for 3 minutes.

• Two-reagent procedure

Reagent 1	800 μ l
Sample	100 μ l

Mix and wait 1 minute.

Reagent 2	200 μ l
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Mix and after 1 minute incubation, measure the change of absorbance per minute (ΔA /min) for 3 minutes.

Calibration: (37°C, modified method of Szász)

S1: Distilled water

S2: Roche C.F.A.S. (Calibrator for automated system) or

Randox Calibration Serum Level I

Calibration frequency

Two-point calibration is recommended:

- after reagent lot change,

- as required following quality control procedures.

Calculation using calibration

$$\frac{\Delta A_{\text{sample}}}{\Delta A_{\text{standard}}} \times C_{\text{standard}} = C_{\text{sample}}$$

A = Absorbance, C = Concentration

Calculation using factor

One-reagent procedure:

activity (U/l) = ΔA /min x 1400 (405nm); (μ kat/l) = ΔA /min x 23,33

Two-reagent procedure:

activity (U/l) = ΔA /min x 1700 (405nm); (μ kat/l) = ΔA /min x 28,33

Quality control

A quality control program is recommended for all clinical laboratories. The analysis of control material in both the normal and abnormal ranges with each assay is recommended for monitoring the performance of the procedure. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

PERFORMANCES DATA

The following data were obtained using the Olympus 600 analyzer (37°C).

Linearity

The test is linear up to 700 U/l (11,67 μ kat/l)

Sensitivity

It is recommended that each laboratory establishes its own range of sensitivity as this is limited by the sensitivity of the spectrophotometer used. Under manual conditions however, a change of 0.001 Abs units/min is equivalent to 1.4 U/l (0,02 μ kat/l) γ -GT activity at 405 nm.

Precision

Sample	Reproducibility		
	Average activity (U/l)	SD	CV%
Sample I.	53.0	0.9	1.70
Sample II.	201	3.3	1.64

Sample	Repeatability		
	Average activity (U/l)	SD	CV%
Sample I.	22.2	0.42	1.89
Sample II.	157	1.30	0.83

Correlation

Comparative studies were done to compare our reagent with another commercial γ -GT assay on human samples.

The results from these studies are detailed below.

Correlation coefficient: r = 0.9996

Linear regression: y (U/l) = 1.019x + 2.212

(x = other commercial reagent, y = own reagent).

Specificity

Bilirubin 855 μ mol/l (50mg/dl), lipid 1000mg/dl, glucose 55.5 mmol/l (1000mg/dl) and ascorbic acid 2.84 mmol/l (50mg/dl) don't interfere with the assay up to the given levels.

Note

Do not use reagents after the expiry date stated on each reagent container label. Do not use products, test solutions and reagents described above for any purpose other than described herein.

For in vitro diagnostic use only!

The following symbols are used on labels

For in vitro diagnostic use

Use by (last day of the month)

Temperature limitation

Batch Code

Code

Bibliography

Szasz G., Clin., Chem., 22.2051. 1976;

SFBC, Commission d'une méthode recommandée pour la détermination dans le sérum humain de la concentration catalytique de la gamma-glutamyl transférase a 30°C. C.I.S.B, 12/5 (1986) 373