Reactivos GPL

Barcelona, España

CE

- γ-GT LQ-

γ - GT LQ
Carboxy Substrate. Kinetic. Liquid

Store at: +2+8ºC.

Presentation:
Cod. EZ009LQ CONT: R1 1 x 100 + R2 1 x 25 mL.
EZ010LQ CONT: R1 2 x 100 + R2 2 x 25 mL.

Procedure

Quantitative determination of gamma-glutamyl transferase (γ– GT).

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY

γ - glutamyl transferase (γ-GT) catalyses the transfer of γ – glutamyl group from γ - glutamyl-p-nitroalidide to acceptor glycylglycine according to the following reaction:

γ-L-Glutamyl-3-carboxy-4-nitroanilide + Glycylglycine $\xrightarrow{\gamma-GT}$ γ-L-Glutamyl-glycylglycine + 2-Nitro-5-aminobenzoic acid

The rate of 2-Nitro-5-aminobenzoic acid formation, measured photometrically, is proportional to the catalytic concentration of γ – GT present in the sample[1,2].

REAGENTS COMPOSITION

R 1 **Buffer**	TRIS pH 8,6 Glycylglycine	100 mmol/L. 100 mmol/L.
R 2 **Substrate**	L-γ-glutamyl-3-carboxy-4-nitroanilide	3 mmol/L.

REAGENT PREPARATION AND STABILITY

Working reagent (WR):
Mix: 4 vol. (R1) Buffer + 1 vol. (R2) Substrate
Stability: 21 days at 2-8ºC or 5 days at room temperature (15-25ºC).
All the components of the kit are stable until the expiration date on the label when stored at 2-8ºC, protected from light and contamination prevented during their use.
Do not use reagents over the expiration date.
Signs of Reagent deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 405 nm. ≥ 1.20

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store at tightly closed at 2-8ºC. Do not use reagents over the expiration date.

SPECIMEN

Serum[1]. Gamma-GT Stability: 3 days at 2-8ºC. 8 hours at 15-25ºC and 1 month at – 20ºC.

MATERIAL REQUIRED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 405 nm.
- Thermostatic bath at 25ºC, 30ºC o 37ºC (± 0.1ºC).
- Matched cuvettes 1.0 cm. light path.

General laboratory equipment.

TEST PROCEDURE

1. Assay Conditions
   - Wavelenght : ..... 405 nm.
   - Cuvette: ..... 1 cm light path.
   - Constant temperature .....25ºC / 30ºC / 37ºC.
2. Adjust the instrument to zero with distilled water or air.
3. Pipette into a cuvette(note 1):

WR (mL.)	1.0
Sample (µL.)	100

4. Mix and incubate for 1 minute.
5. Read the absorbance (A) of the sample, start the stopwatch and read absorbance at 1 min. interval thereafter for 3 min.
6. Calculate the difference of absorbance and the average absorbance difference per minute (ΔA/min.)

CALCULATIONS

ΔA/min x 1190* = U/L de γ-GT(nota 2)

Unidades: La unidad internacional (UI) es la cantidad de enzima que convierte 1 µmol de substrato por minuto, en condiciones estándar. La concentración se expresa en unidades por litro (U/L).
Factores de conversión de temperaturas:
Para corregir los resultados a otras temperaturas multiplicar por:

Assay temperature	Conversion factor to		
	25ºC	30ºC	37ºC
25ºC	1.00	1.37	1.79
30ºC	0.73	1.00	1.30
37ºC	0.56	0.77	1.00

QUALITY CONTROL

Control sera are recommended to monitor the performance of the procedure, Control H Normal Ref. QC003 and Control H Pathological Ref. QC004. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions

REFERENCE VALUES[1]

	25ºC	30ºC	37ºC
Women	4 - 18 U/L.	5 - 25 U/L.	7 - 32 U/L.
Men	6 - 28 U/L.	8 - 38 U/L.	11 - 50 U/L.

(Estos valores son orientativos).

It is suggested that each laboratory establish its own reference range

CLINICAL SIGNIFICANCE

γ – GT is a cellular enzyme with wide tissue distribution in the body, primarily in the kidney, pancreas, liver and prostate.
Measurements of γ – GT, activity are used in the diagnosis and treatment of hepatobiliary diseases such biliary obstruction, cirrhosis or liver tumours[1,2,5,6].
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE

- *Measuring Range*:
  From detection limit of 2 U/L. to linearity limit of 300 U/L., under the described assay conditions.
  If results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L. and multiply result by 2.
- *Precisión*:

	Intra-assay n= 20		Inter-assay n= 20	
Mean (U/L)	38.3	190	40.1	198
SD	0.39	0.53	0.82	2.30
CV (%)	1.03	0.28	2.05	1.16

- Sensitivity: 1 U/L = 0.0008 ΔA/min
- Accuracy: Results obtained GPL reagents did not show systematic differences when compared with other commercial reagents.
  The results obtained using 100 samples were the following:
  Correlation coefficient (r): 0.99990
  Regression Equation: y= 1.334x – 1.493
  The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES

- Plasma should not be used, anticoagulants inhibit the enzyme. Hemolysis interferes with the assay[1]
- A list of drugs and other interfering substances with γ-GT determination has been reported[3,4].

NOTES

1. Use clean disposable pipette tips for its dispensation.
2. Formulation to reach constant:.

ΔA/min x 1190* = U/L of γ-GT

$$* \frac{Tv \times 1000}{\varepsilon \times LP \times Sv}$$

Tv= Total volume in mL
ε 2-nitro-5-aminobenzoic acid = 9.9 at 405 nm
LP= Light path
Sv= Sample volume in mL

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