BIOLABO

www.biolabo.fr

MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

GAMMA-GT carboxy GPNA

Reagent for quantitative determination of
Gamma Glutamyltransferase activity [EC 2.3.2.2] in human serum and plasma.

REF 81110	**R1** 8 x 30 mL	**R2** 8 x 30 mL
REF 81210	**R1** 1 x 105 mL	**R2** 10 x 10 mL
REF 81310	**R1** 10 x 100 mL	**R2** 10 x 100 mL

TECHNICAL SUPPORT AND ORDERS
Tel: (33) 03 23 25 15 50
Fax: (33) 03 23 256 256

CE

IVD IN VITRO DIAGNOSTIC USE

CLINICAL SIGNIFICANCE (1) (2)

Even though renal tissue has the highest level of γ-glutamyltransferase (GGT), the enzyme present in serum appears to originate primarily from the hepatobiliary system. GGT activity is elevated in any and all forms of liver disease. It is highest in cases of intrahepatic or posthepatic biliary obstruction. It is more sensitive than ALP and transaminases in detecting obstructive jaundice, cholangitis and cholecystitis. Only moderate elevation occurs in infectious hepatitis, chronic alcoholism or drugs use (sedatives, anticonvulsants,and tranquilisers). Decreased GGT activity is found in case of hypothyroidism.
In summary, GGT is the most sensitive enzymatic indicator of hepatobiliary disease available at present but doesn't allow discriminating between different kinds of liver disease.

PRINCIPLE (4) (5)

Szasz, Rosalki and Tarlow method. Reaction scheme is as follows:

L-G-Glutamyl-3-carboxy-4-nitroanilide + Glycylglycine **⟶ GGT ⟵** L-G-Glutamyl-glycylglycine + p-nitroaniline

The rate of formation of p-nitroaniline, directly proportional to GGT activity in the specimen, is measured at 405 nm.

REAGENTS COMPOSITION

Vial R1 **BUFFER**

Glycylglycine		100	mmol/L
TRIS	pH 8.25	95	mmol/L
Preservative			

Vial R2 **SUBSTRATE**

L-G-glutamyl-3-carboxy-4-nitroanilide (Carboxy-GPNA)	80	mmol/L

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Verify the integrity of the contents before use.
- Nitroaniline derivatives (product of the reaction) are toxic. Do not inhale, do not ingest.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagents contain sodium azide (concentration < 0,1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

REAGENT PREPARATION

Use a non-sharp instrument to remove aluminium cap.
REF 81210: Add promptly 10 mL of vial R1 (Buffer) into the contents of vial R2 (Substrate).
Others REF: Dilute the contents of vial R2 (Substrate) with approx. 10 mL of vial R1 (Buffer), transfer into vial R1 (buffer).
Mix gently and wait for complete dissolution before using reagent (approximately 2 minutes).

STABILITY AND STORAGE

Store away from light, well cap in the original vial at 2-8°C

- Unopened, reagents are stable until expiry date stated on the label of the kit when stored and used as described in the insert.
- Once reconstituted, working reagent is stable for 30 days when free from contamination.
- Discard any reagent if cloudy or if reagent blank at 405 nm > 1.000
- Don't use working reagent after expiry date stated on the label of the Kit.

SPECIMEN COLLECTION AND HANDLING (1) (2)

Unhemolysed serum or EDTA-plasma (up to 1 mg/ml of blood).
Heparin produces turbidity in the reaction mixture; citrate, oxalate and fluoride depress GGT activity by 10 to 15%.
GGT is stable in serum for:

- 1 month at 2-8°C
- 1 year at–20°C.

INTERFERENCES (1) (3)

Tests results on Kenza 240 TX:

Ascorbic Acid:	No interference up to 25 mg/dL.
Total Bilirubin:	Negative interference over 450 µmol/L.
Glucose:	No interference.
Haemolysis:	Negative interference over 225 µmol/L.
Turbidity:	No interference.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Medical analysis laboratory equipment.
2. Normal and pathological control sera.

CALIBRATION

Results will depend on the accuracy of the instrument calibration, the time counting, the respect of reagent/specimen ratio and the temperature control.

- Use the theoretical calibration factor (§ **CALCULATION**)
- Or REF 95015 BIOLABO Multicalibrator (calibration value determined with validated statistical techniques and metrologically controlled instrument)
- Or a multiparametric calibrator traceable to a reference method or material.

QUALITY CONTROL

- BIOLABO EXATROL-N Level I REF 95010
- BIOLABO EXATROL-P Level II REF 95011
- Other assayed control sera referring to the same method.
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Repeat the test with the same control.
2. If control is still out of range, prepare a fresh control serum and repeat the test.
3. If control is still out of range, verify analysis parameters: Wavelength, temperature, specimen/reagent ratio, time counting, calibration factor.
4. If control is still out of range, use a new vial of reagent and assay again
5. If control is still out of range, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (5)

Adult GGT activity, measured at 37°C

Men (IU/L)	11-50
Women (IU/L)	7-32

Each laboratory should establish its own normal ranges for the population it serves.

PERFORMANCE CHARACTERISTICS

Tests Results on Kenza 240 TX:

Within-run N = 30	*Normal level*	*Medium level*	*High level*
Mean UI/L	43	104	329
S.D. UI/L	0.9	0.7	3.6
C.V%	2.0	0.6	1.1
Criteria	< 4.5%	< 4.5%	< 4%

Run to run N = 30	*Normal level*	*Medium level*	*High level*
Mean UI/L	46	111	363
S.D.UI/L	1.3	2.5	10.8
C.V%	2.7	2.3	3
Criteria	< 6%	< 6%	< 5%

Detection limit: environ 4 UI/L

Sensitivity for 21 UI/L: environ 0,010 ΔAbs/min

Comparison studies with commercially available reagent:

y = 0.9387 x +2.214 r = 0,9985

LINEARITY

The assay is linear up to 320 IU/L (5.33 µkat/L).

Above, dilute specimen with saline solution and assay again taking into account the dilution factor. Linearity will depend on the specimen/reagent ratio.

MANUAL PROCEDURE

Let stand reagents and specimens at room temperature.

Pipette into 1 cm path length thermostated cuvette:	
Reagent	1 mL
Bring to 37°C (30°C) then add:	
Specimen or Calibrator	50 µL
Mix. Read initial absorbance after 30 seconds, record absorbance at 405 nm every minute during 3 minutes. Calculate absorbance change per minute (ΔAbs/min).	

Notes: Specific procedures are available upon request for automated instruments. Please contact BIOLABO technical support.

CALCULATION

Calculate the result as follows:

With theoretical factor:

IU/L = (ΔAbs./min.) x 2121

$$\mu kat/L = \frac{IU/L}{60}$$

With serous multicalibrator

$$GGT\ Activity = \frac{(\Delta Abs/min)\ Assay}{(\Delta Abs/min)\ Calibrator} \times Calibrator\ Concentration$$

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 686-689.*
(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 470-473..*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-296 à 3-300*
(4) *SZASZ G., Clin. Chem., (1969), 15, p.124*
(5) *SZASZ G., Bergmeyer H.U.,ed. Methods of Enzymatic analysis, (1974) Weinheim Verlag Chemie*

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | sufficient for | → dilute with