BIOLABO
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MANUFACTURER:
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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
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CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantitative determination of Gamma Glutamyltransferase to evaluate its activity in human serum and plasma.

I GENERALITIES (1) (2)

GGT activity measured in serum is principally increased in case of hepatobiliary disorders.
In summary, elevated GGT results associated with other liver tests indicate liver or biliary ducts disorders, 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 $\xrightleftharpoons{\text{GGT}}$ 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.

I REAGENTS

R1	**GAMMA GT**		Buffer
Glycylglycine		100	mmol/L
TRIS	pH 8.25	95	mmol/L
Preservative			

EUH210 : Safety data sheet available on request

R2	**GAMMA GT**	Substrate
L-G-glutamyl-3-carboxy-4-nitroanilide (Carboxy-GPNA)	80	mmol/L

According to CLP regulation n°1272/2008 (EC), these reagents are not classified as dangerous

Once reconstituted: Working Reagent is not classified as dangerous.

I LIMITS (1) (3)

Alcohol and some drugs (i.e. some anticonvilusant, warfarin) may induce microsomal hepatic enzymes (cytochrome P-450) , which may increased GGT levels and so limits its specificity.
For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

I REAGENTS PREPARATION

REF 81110, REF 81310:

Measure 10 mL of buffer R1 and transfer promptly into R2, then transfer the mixture into vial R1.

REF 81210 :

Measure 10 mL of R1 and transfer promptly into R2.

Recap and mix gently until complete dissolution.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, when stored and used as described, reagents are stable:

Unopened:

- Until expiry date stated on the label of the kit.

Once opened:

- Reconstitute immediately the reagent R2.
- The reagent R1 is stable eat least 6 months.

Once reconstituted:

- Transfer requested quantity and store in the original vial at 2-8°C.
- Working reagent is stable at least for 30 days.
- Discard reagent if cloudy or if absorbance at 405 nm is > 1.000.
- Don't use working reagent after expiry date.

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.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer
3. Saline solution

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with

I CALIBRATION

- REF 95015 Multicalibrator traceable to *an Internal Masterlot traceable to* ERM® - AD452/IFCC

The calibration frequency depends on proper instrument functions and on the preservation of reagent

REFERENCE INTERVAL (5)

Adult GGT activity,	at 37°C
Men (IU/L)	11-50
Women (IU/L)	7-32

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

I PERFORMANCES

On KENZA 240TX analyzer, 405 nm, 37°C

Detection limit: approx. 1 IU/L

Linearity Range: between 25 (LOQ) and 470 IU/L

Above, dilute specimen with saline solution and assay again taking into account the dilution factor.

Precision:

Within-run N = 30	*Low level*	*Normal level*	*High level*
Mean (IU/L)	19	63	404
S.D. (IU/L)	0,6	1,2	7,2
C.V. %	3,3	1,9	1,8
Criteria	< 4.5%	< 4.5%	< 4%

Between run N = 30	*Low level*	*Normal level*	*High level*
Mean (IU/L)	19	60	405
S.D. IU/L	1,0	2,3	12,6
C.V. %	5,1	3,9	3,1
	< 6%	< 6%	< 5%

Analytical Sensitivity: approx. 0.010 abs/min for 10 IU/L

Interferences:

Turbidity	No interference up to 0.349 abs
Ascorbic acid	No interference up to 2500 mg/dL
Total bilirubin	Negative interference from 294.5 µmol/L
Direct bilirubin	Positive interference from 351.5 µmol/L
Hemoglobin	Negative interference from 119 µmol/L
Glucose	No interference up to 994 mg/dL

Other substances may interfere (see § Limits)

Comparison studies with commercially available reagent:

y = 0.9387 x +2.214 r = 0,9985

On the board stability: 12 days

Calibration Stability: 12 days

Make a new calibration when changing reagent batch, if quality control results are found out of the range and after maintenance operations.

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- 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. Prepare a fresh control serum and repeat the test.
2. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat the tests with a new vial of reagent.

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Manual Method

Let stand reagent and specimens at room temperature.

Pipette into 1 cm path length thermostated cuvette (37°C):	
Reagent	1000 µL
Standard / Control or Specimen	50 µL
Mix. After 30 second at 405 nm, record the absorbance each minute during 3 minutes.	
Calculate absorbance change per minute (ΔAbs/min).	

1- Performances with manual procedure should be validated by user.

2- KENZA applications and other applications proposal are available on request.

I CALCULATION

With serum Multicalibrator:

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

With theoretical factor:

Activity (IU/L) = ΔAbs/min x Factor

$$\text{Factor} = \frac{\text{VR} \times 1000}{9{,}5 \times \text{VE} \times \text{P}}$$

With:
VR = Total reactional volume (mL)
VE = Specimen volume (mL)
9,5 = Molar extinction coefficient for PNPP at 405 nm
P = Path length (cm).

Example, with manual Procedure,
(Path length 1 cm, 37°C, 405 nm):

IU/L = (ΔAbs/min) x 2121

$$\text{µkat/L} = \frac{\text{IU/L}}{60}$$

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), 22, p.124-136*
(5) *SZASZ G., Bergmeyer H.U.,ed. Methods of Enzymatic analysis, (1974) Weinheim Verlag Chemie*