BIOLABO
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MANUFACTURER:
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GAMMA-GT Carboxy GPNA

Reagent for quantitative determination of Gamma Glutamyl transferase activity [EC 2.3.2.2] in human serum.

I REF K1110	**R1** 2 x 16 mL	**R2** 1 x 8 mL
I REF K2110	**R1** 2 x 32 mL	**R2** 2 x 8 mL
I REF K4110	**R1** 2 x 40 mL	**R2** 1 x 20 mL

TECHNICAL SUPPORT AND ORDERS
Tel: (33) 03 23 25 15 50
support@biolabo.fr
Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantification of global activity of the γ-glutamyl transferase (GGT) enzyme in human serum.

GENERALITIES (1) (2)

Even though renal tissue has the highest level of 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. 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 $\xrightleftharpoons{\text{GGT}}$ 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.

REAGENTS

R1 **GGT** Buffer

Glycylglycine		100 mmol/L
TRIS	pH 8.6	100 mmol/L
Preservative		

EUH210: Safety Data Sheet available on request

R2 **GGT** Substrate

TRIS	pH 8.6	100 mmol/L
L-G-glutamyl-3-carboxy-4-nitroanilide (Carboxy-GPNA)		3 mmol/L
Preservative		

According to 1272/2008/EC Regulation, these reagents are not classified as dangerous

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.

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.

REAGENT PREPARATION

Ready for use

STABILITY AND STORAGE

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

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened:
- 2 separated reagents are stable at least 2 months.
- Discard any reagent if cloudy or if reagent blank at 405 nm > 1.800

SPECIMEN COLLECTION AND HANDLING (1) (2)

Unhemolysed serum.

GGT is stable in serum for:
- 1 month at 2-8°C
- 1 year at –20°C.

LIMITS (3) (6) (7)

Heparin produces turbidity in the reaction mixture.
Citrate, oxalate and fluoride depress GGT activity by 10 to 15%.
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. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

REFERENCE INTERVALS (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.

PERFORMANCES at 37°C on KENZA ONE

Refer to the application of analyzer used.

Linearity Range: between 23 and 286 IU/L

Detection limit: approx. 0.1U/L

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/L)	16	63	269
S.D. (IU/L)	0.4	0.8	4.7
C.V. %	2.5	1.3	1.7

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/L)	18	61	263
S.D. IU/L	0.7	1.9	9.7
C.V. %	3.9	3.1	3.7

Comparison studies on spectrophotometer with commercially available reagent:

Realized on serum specimens (n=50) from 10 IU/L to 400 IU/L

y = 1.334 x + 1.493 r = 0.9999

Analytical Sensitivity: approx. 0.037 abs/min for 10 IU/L

Interferences:
Do not use plasma. Anticoagulants inhibit the enzyme.

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration Stability: 30 days

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

Stability and performances data on Kenza 240TX/ISE and Kenza 450TX/ISE are available on request.

CALIBRATION

- REF 95015 Multicalibrator traceable to *ERM-AD454*

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

Make a new calibration when changing reagent batch, if quality control results are found out of the established 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. If control is still out of range, prepare a fresh control serum and repeat the test.
2. If control is still out of range, verify analysis parameters: Wavelength, temperature, specimen/reagent ratio, time counting, calibration factor.
3. If control is still out of range, use a new vial of reagent and assay again

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

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly final result in IU/L.

Refer to the instruction of use of Kenza analyzer.

REFERENCES

(1) *TIETZ N.W. Textbook 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*

(6) *Gender S.γ-GT. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1120-1123.*

(7) *Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001*

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