GAMA GT

Gamma GT

Anvisa 80115310254

ORDER INFORMATION

Cat. No.	Kit size
2160075M	R1: 3 x 20 mL + R2: 1 x 15 mL
2160250K	R1: 5 x 40 mL + R2: 1 x 50 mL
2160179.2R	R1: 4 x 34,5 mL + R2: 4 x 10,3 mL
2160075K	R1: 3 x 20 mL + R2: 1 x 15 mL
2160050MK	R1: 1 x 40 mL + R2: 1 x 10 mL

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Gamma-glutamyltransferase (Gamma-GT) in serum or plasma on photometric systems.

SUMMARY

Gamma-glutamyltransferase (gamma-GT/GGT), also called gamma-glutamyltranspeptidase, is an enzyme present in the liver and bile ducts, and is the most sensitive indicator of hepatobiliary diseases. Due to a high negative predictive value for these diseases, gamma-GT measurement is widely used to exclude a biliary or hepatic origin. Together with other enzymes such as alanine aminotransferase (ALAT), aspartate aminotransferase (ASAT) and cholinesterase, gamma-GT is a tool of great value for the differential diagnosis of liver diseases [1].

METHOD

Kinetic colorimetric test according to SZASZ/PERSIJN [2]. The test has also been standardized to the method according to IFCC (International Federation of Clinical Chemistry) [4]. The results according to IFCC are obtained using a special factor or, in case a calibrator is used (TopKal U), the calibration values provided for the IFCC method.

PRINCIPLE

Gamma-GT catalyzes the transfer of glutamic acid to the acceptor glycylglycine. With this process, 5-amino-2-nitrobenzoate is released, which can be measured photometrically at 405 nm. The increase of absorbance is proportional to the catalytic gamma-GT concentration in the sample.

L-Gamma-glutamyl-3-carboxy-4-nitroanilide + Glycylglycine

$$\xrightarrow{\text{Gamma-GT}}$$

Gamma-glutamyl-glycylglycine + 5-Amino-2-nitrobenzoate

REAGENTS

Components and Concentrations

R1	Tris	137 mmol/L
	Glycylglycine	< 200 mmol/L
R2	Glupa-Carboxylate	< 50 mmol/L

STORAGE AND STABILITY

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents!
Reagent 2 must be protected from light.

WARNINGS AND PRECAUTIONS

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. In very rare cases, samples of patients with gammopathy might give falsified results [8].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
4. For professional use only.

WASTE MANAGEMENT

Follow the requirements of the current guidelines about technical regulation for the management of healthcare service waste, as well as other equivalent biosafety practices.

REAGENT PREPARATION

Starting with Substrate
The reagents are ready to use.

Starting with Sample
Mix 4 parts of R1 with 1 part of R2
(e.g. 20 mL R1 + 5 mL R2) = monoreagent

Stability:	5 days	at	15 - 25 ºC
	4 weeks	at	2 - 8 ºC

Protect the monoreagent from light!

MATERIALS REQUIRED, BUT NOT PROVIDED

1. NaCl solution 9 g/L.
2. General laboratory equipment.

SPECIMEN

Human serum or heparin plasma.
Stability [6]: 1 week between -20 °C and 25 °C

Only freeze once!
Discard contaminated specimens.

ASSAY PROCEDURE

Applications for automatic systems are available upon request or on our website: www.kovalent.com.br

Wavelength	405 nm (400 – 420nm)
Optical path	1 cm
Temperature	37 °C
Measurement	Against reagent blank

Starting with Substrate

	Blank	Sample
Sample or calibrator	-	100 µL
Distilled water	100 µL	-
Reagent 1	1000 µL	1000 µL
Mix, incubate for approximately 1 min, then add:		
Reagent 2	250 µL	250 µL
Mix, read the absorbance after 1 min and start the stopwatch. Read the absorbance again after 1, 2 and 3 min.		

Starting with Sample

	Blank	Sample
Sample or calibrator	-	100 µL
Distilled water	100 µL	-
Monoreagent	1000 µL	1000 µL
Mix, read the absorbance after 1 min and start the stopwatch. Read the absorbance again after 1, 2 and 3 min.		

CALCULATION

With factor
From the absorbance readings, calculate the ΔA/min and multiply by the corresponding factor from the table below:

ΔA/min x factor = Gama-GT activity [U/L]

		Szasz	IFCC
Starting with substrate	405 nm	1421	1606
Starting with sample	405 nm	1158	1309

With Calibrator

$$\gamma\text{ - GT [U/L]} = \frac{\Delta A/min_{Sample}}{\Delta A/min_{Cal.}} \times \text{Conc. Cal. [U/L]}$$

Conversion Factor
GGT [U/L] x 0.0167 = GGT [µkat/L]

CALIBRATORS AND CONTROLS

For calibration in automated photometric systems, Kovalent Topkal U calibrator is recommended. Use Kovalent Topkon N and P for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

WARRANTY
These instructions for use should be read carefully before using the product and the information contained therein should be strictly adhered to. The reliability of the test results cannot be guaranteed if the instructions are not followed.

PERFORMANCE CHARACTERISTICS
Measuring range
In automated systems the test is suitable for the determination of Gamma-GT activity within a range of 2 - 1200 U/L.
In the case of manual procedure, the test is suitable for the determination of Gamma-GT activity, which correspond to a maximum ΔA/min of 0.20.
If these values are exceeded, the samples should be diluted 1 + 5 with NaCl solution (9 g/L) and the results multiplied by 6.

Specificity / Interferences
No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 400 mg/dL, and lipemia up to 2000 mg/dL of triglycerides. For more information on interfering substances, see Young DS [7].

Sensitivity / Limit of Detection
The lowest detection limit is 2 U/L.

Precision (at 37°C)

Within run n = 10	Mean [mg/dL]	SD [mg/dL]	CV [%]
Normal Control	22.22	0.28	1.27
Pathological Control	66.2	0.75	1.13

Between day n = 9	Mean [mg/dL]	SD [mg/dL]	CV [%]
Normal Control	22.42	0.24	1.09
Pathological Control	66.91	1.45	2.17

Method comparison
Method comparison between Kovalent Gama GT (IFCC) (y) and IFCC reference reagent (x) using 30 samples demonstrated the following results:
y = 1.012x - 0.1609 U/L; r =0.9993

REFERENCE VALUES

According to Szasz [5]	**[U/L]**	**[µkat/L]**
Women	< 32	< 0.53
Men	< 49	< 0.82
According to IFCC	**[U/L]**	**[µkat/L]**
Women		
Adults [4]	< 38	< 0.63
Children or teenagers [1]		
1 day - 6 months	15 - 132	0.250 - 2.20
6 months – 1 year	1 - 39	0.017 - 0.651
1 - 12 years	4 - 22	0.067 - 0.367
13 - 18 years	4 - 24	0.067 - 0.401
Homens		
Adults [4]	< 55	0.92
Children or teenagers [1]		
1 day - 6 months	12 - 122	0.200 - 2.03
6 months – 1 year	1 - 39	0.017 - 0.651
1 - 12 years	3 - 22	0.050 - 0.367
13 - 18 years	2 - 42	0.033 - 0.701

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

LITERATURE

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998.p80-6.
2. Persijn JP, van der Silk W. A new method for the determination og gamma-glutamyltransferase in serum. J. Clin Chem Clin Biochem 1976; 14:421-7.
3. Szasz G. Gamma-Glutamyltranspeptidase. In: Bergmeyer HU. Methoden der enzymatischen Analyse. Weiheim: Verlag Chemie, 1974. p. 757.
4. Schumann G, Bonora R, Ceriotti F, Férard G et al. IFCC primary reference procedure for the measurement of catalytic activity concentration of enzymes at 37 °C. Part 5: Reference procedure for the measurement of catalytic concentration of γ-glutamyltransferase. Clin Chem Lab Med 2002; 40:734-8.
5. Fischbach F, Zawta B. Age-dependent reference limits of several enzymes in plasma at different measuring temperatures. Klin Lab 1992;38:555-61.
6. Guder WG, Zawta B et al. The Quality of Diagnostic Samples.1st ed. Darmstadt: GIT Verlag; 2001; p. 30-1.
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

CONSUMER INFORMATION

Symbols used:

	Manufacturer
	Temperature limit
	In vitro diagnostic device
	Caution
	Operating instructions
	Recycling material
	Do not discard directly into the environment
	Batch code
	Date of manufacture
	Use by date
	Biological hazards
	Highly toxic
	Corrosive
	Harmful

Manufacturer:

Kovalent do Brasil Ltda.
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São Gonçalo – RJ – CEP 24722-414 - Brasil
www.kovalent.com.br
CNPJ: 04.842.199/0001-56

Kit sizes variations on demand:

Anvisa No.	Kit size
80115310254	R1: 2 x 50 mL + R2: 2 x 12,5 mL
80115310254	R1: 2 x 40 mL + R2: 2 x 10 mL
80115310254	R1: 3 x 40 mL + R2: 3 x 10 mL
80115310254	R1: 4 x 40 mL + R2: 4 x 10 mL

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Expiration date and Lot no.: See label