GAMMAGLUTAMYLTRANSFERASE

Cat. No.	Pack Name	Packaging (Content)
BLT00023	GGT 100	R1: 4 x 20 ml, R2: 1 x 20 ml
BLT00024	GGT 250	R1: 4 x 50 ml, R2: 1 x 50 ml

EN

CE IVD

INTENDED USE
Diagnostic reagent for quantitative *in vitro* determination of GGT in human serum and plasma.

CLINICAL SIGNIFICANCE
Although GGT is present in a variety of tissues, the serum enzyme appears to be primarily from the hepato-biliary system. Consequently, GGT is elevated in all forms of liver disease or damage. It is clinically useful in detecting obstructive jaundice, cholangitis and cholecystitis. Elevated levels are also observed with drug use (alcohol, sedatives, anticonvulsants and tranquilizers).

PRINCIPLE
Kinetic colorimetric method according to Persijn & van der Slik. Standardized against recommended IFCC method.
GGT present in the sample catalyzes the transfer of the glutamyl group from the substrate γ-glutamyl-3-carboxy-4-nitroanilide to glycylglycine forming glutamyl glycylglycine and 5-amino-2-nitrobenzoate.

L-γ-glutamyl-3-carboxy-4-nitroanilide + glycylglycine
↓ GGT
L-γ-glutamylglycylglycine + 5-amino-2nitrobenzoate

The rate of formation of 5-amino-2-nitrobenzoate is proportional to the activity of GGT present in the sample and can be measured kinetically at (400-420) nm.

REAGENT COMPOSITION
R1

Tris buffer (pH 8.25)	125 mmol/l
Glycyl Glycine	125 mmol/l

R2

L-γ-Glutamyl-3-carboxy-4-nitroanilide	20 mmol/l

REAGENT PREPARATION
Reagent is liquid, ready to use.

STABILITY AND STORAGE
The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

Two reagents method – substrate start
Reagents are ready to use.
After opening, reagents are stable until expiry date at 2–8°C if stored at appropriate conditions, closed carefully and without any contamination.

Monoreagent method – sample start
Mix 4 portion of reagent R1 with 1 portion of reagent R2.
Stability: 14 days at 22–28°C in the dark
6 weeks at 2–8°C in the dark

SPECIMEN COLLECTION AND HANDLING
Use serum, plasma (EDTA).
It is recommended to follow NCCLS procedures (or similar standardized conditions).
Stability

in serum / plasma:	3 days	at 20–25°C
	7 days	at 4–8 °C
	1 year	at -20°C

Discard contaminated specimens.

12000046
12000047

CALIBRATION
Calibration with calibrator XL MULTICAL, Cat. No. XSYS0034 is recommended.

QUALITY CONTROL
For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT00081 are recommended.

UNIT CONVERSION
U/l x 0.017 = mmol/l

EXPECTED VALUES [3]
At 37°C
Male: < 55 U/l
Female: < 38 U/l
It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA
Data contained within this section is representative of performance on ERBA XL systems. Data obtained in your laboratory may differ from these values.
Limit of quantification: 1.68 U/l
Linearity: 500 U/l
Measuring range: 1.68 – 500 U/l

PRECISION

Intra-assay precision Within run (n=20)	Mean (U/l)	SD (U/l)	CV (%)
Sample 1	91.5	0.84	0.89
Sample 2	186.66	1.44	0.90

Inter-assay precision Run to run (n=20)	Mean (U/l)	SD (U/l)	CV (%)
Sample 1	45.6	0.72	1.61
Sample 2	216.5	4.14	1.91

COMPARISON
A comparison between XL-Systems GGT (y) and a commercially available test (x) using 40 samples gave following results:
y = 1.078 x + 4.50 U/l
r = 0.994

INTERFERENCES
Following substances do not interfere:
haemoglobin up to 5 g/l, bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl.

WARNING AND PRECAUTIONS
For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.
Reagents of the kit are not classified like dangerous but contain less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment.

WASTE MANAGEMENT
Please refer to local legal requirements.

ASSAY PROCEDURE
Wavelength: 405 (400 - 420 nm)
Cuvette: 1 cm
Two reagents method – substrate start

	Reagent blank	Calibrator	Sample
Reagent 1	1.000 ml	1.000 ml	1.000 ml
Sample	-	-	0.100 ml
Calibrator	-	0.100 ml	-
Distilled water	0.100 ml	-	-

Mix and after 1 min. incubation (at 37°C) add:

Reagent 2	0.250 ml	0.250 ml	0.250 ml

Mix, incubate 1 min. at 37°C and then measure the initial absorbance of calibrator and sample against reagent blank. Measure the absorbance change exactly after 1, 2 and 3 min. Calculate 1 minute absorbance change (ΔA/min).

Monoreagent method – sample start

	Reagent blank	Calibrator	Sample
Working reagent	1.000 ml	1.000 ml	1.000 ml
Sample	-	-	0.100 ml
Calibrator	-	0.100 ml	-
Distilled water	0.100 ml	-	-

Mix, incubate 1 min. at 37°C and then measure the initial absorbance of calibrator and sample against reagent blank. Measure the absorbance change exactly after 1, 2 and 3 min. Calculate 1 minute absorbance change (ΔA/min).

CALCULATION
1. GGT (U/l) = $\frac{\Delta A_{sam}/min.}{\Delta A_{cal}/min.}$ x C_{cal} C_{cal} = calibrator concentration
2. Using factor: GGT (U/l) = f x ΔA/min f = factor

Substrate Start:

	Szasz	IFCC
standardized against factors at 405 nm and 37°C	1421	1606

Sample Start:

	Szasz	IFCC
standardized against factors at 405 nm and 37°C	1158	1309

Applications for automatic analysers are available on request.

ASSAY PARAMETERS FOR PHOTOMETERS

Mode	Kinetic
Wavelength 1 (nm)	405
Sample Volume (µl)	50/100
Working Reagent Volume (µl)	500/1000
Lag time (sec.)	60
Kinetic interval (sec.)	60
No. of readings	3
Kinetic factor	1158
Reaction temperature (°C)	37
Reaction direction	Increasing
Normal Low (U/l)	0
Normal High (U/l)	38
Linearity Low (U/l)	1.68
Linearity High (U/l)	500
Blank with	Water
Absorbance limit (max.)	1.5
Units	U/l

Erba Lachema s.r.o., Karásek 1d, 621 00 Brno, CZ
e-mail: diagnostics@erbalachema.com, www.erbamannheim.com

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REFERENCES

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2. Persijn J. P., Vander Silk W. : J. Clin. Chem. Clin. Biochem. 14, 421 - 427 (1976).

3. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Burtis, C.A., Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Comp., 2012.

SYMBOLS USED ON LABELS

REF Catalogue Number	Manufacturer	See Instruction for Use
LOT Lot Number	CE Mark - Device comply with the Directive 98/79/EC	Storage Temperature
Expiry Date	IVD In Vitro Diagnostics	CONT Content

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

Erba Lachema s.r.o., Karásek 1d, 621 00 Brno, CZ
e-mail: diagnostics@erbalachema.com, www.erbamannheim.com