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GAMMA-GT

CONCENTRATED LIQUID REAGENT

CE

Order information:

Catalogue number	Size
9481C	10 x 65 + 10 x 17 ml
9482C	4 x 65 + 4 x 17 ml

Reagent kit for quantitative in vitro determination of gamma-glutamyltransferase (γ-GT) in serum and plasma.

Summary

γ-GT plays an important role in amino acid transport in the course of glutathione metabolism. The enzyme present in the serum is mainly of hepato-biliary origin. Increased enzyme activities are found in association with chronic alcoholism, different toxic liver damages, intra- and extrahepatic cholestasis, acute viral hepatitis, pancreatitis, neoplastic diseases of the liver and pancreas, myocardial infarction as well as with diabetes mellitus.

Method

Optimized IFCC/Szasz method

L-γ-glutamyl-3-carboxy-4-nitroanilide+glycylglycine $\xleftrightarrow{\text{γ-GT}}$ L-γ-glutamyl-glycylglycine + 5-amino-2-nitrobenzoate

Reagents

Composition and concentrations

Reagent 1

Tris buffer, pH: 8.25	125 mmol/l
Glycylglycine	420 mmol/l

Reagent 2

L-γ-glutamyl-3-carboxy-4-nitroanilide	66 mmol/l

Storage and stability

The reagent is stable up to the end of the indicated month of expiry without opening, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze!
Onboard stability after opening and the frequeny of calibration is 72 days.
The absorbance at 410 nm should not be higher than 1,5

Warnings and precautions

Do not use reagents after the expiry date stated on each reagent container label.

Chemical safety

This product is not classified as dangerous. Safety data sheet is available upon request. The product contains sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. If disposal into a drain is in compliance with federal, state, and local requirements, flush reagents with a large amount of water to prevent the buildup of azides.

Preparation

The reagent is ready for use.

Sample

Serum, EDTA, heparin or citrate plasma.

Stability in serum	1 month at 2-8°C
	5 days at 15-25°C
	1 year at -20°C

Expected values and reference range

Szerum
Male: 12-52 U/l
Female: 8-34 U/l
It is recommended that each laboratory should assign its own normal range.

Assay procedure

Wavelength:	410 nm / 700 nm (primary/secondary)
Optical path:	1 cm
Temperature:	37°C
Measurement:	against water blank
Reaction:	kinetic, increasing

	blank	sample or standard
reagent 1	240 µl	240 µl
dist. water (diluent)	480 µl	480 µl
dist. water (blank)	90 µl	-
sample or standard	-	90 µl
Mix and incubate for 1 minute		
reagent 2	60 µl	60 µl
dist. water (diluent)	120 µl	120 µl
Mix and incubate for 1 minute then continuously read the absorbances for 3 minutes		

Calculation

γ-GT[U/l]=ΔA sample/ΔA standard × standard concentration[U/l]

Conversion factor

[U/l]=[µkat/l]×60

Calibration and quality control

S1: Distilled water
S2: Roche C.F.A.S. (Calibrator for automated system) or
Randox Calibration Serum Level I or
Randox Calibration Serum Level II
Calibration is recommended:

- after opening new reagent batch
- after system maitenance or troubleshooting

For internal quality control, two levels controls are recommended (normal and pathological) at least once a day. The measured values must in the range which was given by the control's manufacturer. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Preformance characteristics

Measuring range

The method is linear in the range 7 – 700 U/l

Interferences

No significant intereference was observed by bilirubin up to 1000 µmol/l bilirubin, triglycerides up to 12 mmol/l, hemoglobin up to 1 g/l and ascorbate up to 4 g/l. Significant interference: >10%.

Limit of detection

The limit of detection is 0,62 U/l

Precision

Repeatability	mean	SD	CV
n = 20	[U/l]	[U/l]	[%]
normal sample	53,1	0,91	1,72
pathological sample	171	2,1	1,23
Reproduceability	**mean**	**SD**	**CV**
n = 10	[U/l]	[U/l]	[%]
normal sample	52,9	1,73	3,27
pathological sample	170,9	2,95	1,73

Method comparison

Comparison with the non-concentrated reagent.
analyser: Advia 2400
number of samples: 150
range: 9 – 1681 U/l
correlation coefficient: 0,9997
regression line equation: y = 1,03x + 0,789
(x= normal reagent, y= concentrated reagent)

For in vitro diagnostic use only!

The following symbols can be used on the labels

IVD	In vitro diagnostic device
	Manufacturer
CE	CE-marking
	Temperature limitations
	Use by (year/month)
LOT	Batch code
REF	Catalogue number
	This way up
	Biological risk

Literature

Szasz G., Clin., Chem., 22.2051. 1976;
SFBC, Commission d'une méthode recommandée pour la détermination dans le sérum humain de la concentration catalytique de la gamma-glutamyl transférase a 30°CC. I.S.B, 12/5 (1986) 373
Tietz Clinical Guide To Laboratory Tests, 4th edition, Elsevier, 2006