TECO DIAGNOSTICS
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γ-GT LIQUID REAGENT
TC MATRIX-240/480

INTENDED USE
For the Kinetic Quantitative Determination of γ-Glutamyl Transferase in Serum for Manual and/or Automated Procedures

SUMMARY AND PRINCIPLE
Gamma-glutamyl transferase (γ-GT) is one of a large group of enzymes known as peptidases. Although renal tissue has the highest level of γ-GT, the major source of the enzyme present in serum is of hepatic origin. Elevated levels of γ-GT are found in association with hepatobiliary and pancreatic disorders; alcoholics and heavy drinkers, in myocardial disorders and in diabetics[1].

Unlike alkaline phosphatase activity, the serum γ-GT activity remains normal in diseases affecting bone and during normal bone growth. Therefore, a rise in serum γ-GT activity may be considered as a sensitive and more specific indicator of liver disease than alkaline phosphatase activity.

The Teco γ-GT procedure has been optimized according to Szasz.

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

γ-GT catalyzes the transfer of a γ-Glutamyl group from L-γ-glutamyl-3-carboxy-4-nitroanilide. The rate of liberation of 5-amino-2 nitrobenzoate is directly related to the γ-GT activity in the sample and is quantitated by measuring the increase in absorbance at 405 nm.

REAGENTS
Each kit contains:

γ-GT Buffer (R1):	8 × 20 mL
γ-GT Substrate (R2):	8 × 4 mL

PRECAUTIONS
The reagents are for "In Vitro Diagnostic Use". Normal precautions exercised in handling laboratory reagents should be followed. The reagents contain sodium azide that may be toxic if ingested. Sodium azide may also react with lead and copper plumbing to form highly explosive metal azides. Refer to Material Safety Data Sheet for any updated risk, hazard or safety information.

REAGENT STORAGE AND STABILITY
Reagents are stable until the expiration date on their respective labels, when properly stored at 2-8°C and protected from light. R1 should appear clear/colorless while R2 should appear clear/yellow. Discard if either appears cloudy or contains particulate matter.

MATERIAL REQUIRED BUT NOT PROVIDED
1. At least two levels of control materials

SPECIMEN COLLECTION AND STORAGE
Serum or EDTA plasma, free of hemolysis, should be used. Complexing anticoagulants such as citrate, oxalate, fluoride and must be avoided since they inhibit γ-GT activity[2]. The loss of γ-GT activity is minimized by storing the samples refrigerated for up to 7 days or frozen up to 2 months[3]. Bilirubin levels up to 40 mg/dL and triglyceride levels up to 2000 mg/dL show no interference in this test.

INTERFERING SUBSTANCES
γ-GT is an inducible enzyme. Consequently patients who are receiving antiepileptic drugs or aminopyrine show elevated γ-GT activity. Chronic use of ethanol also increases serum γ-GT activity[4-5]. Certain drugs and other substances are also known to affect γ-GT values[6].

PROCEDURE

Test Name:	GGT	R1:	200
Full Name:	GGT	R2:	40
Pri. Wave:	405 nm	SAMPLE VOLUME:	24.0
Sec. Wave:	670 nm	Calibration Type:	1 point linear
Assay/ Point:	Kinetic	K Value:	1158
Start - End:	20 - 29	Point:	1
Decimal place:	2	Blank Type:	Reagent
Unit:	U/L	Point 0 (Blank) Con.:	0.0
Linearity Range:	5.0000 - 750.0000	Point 1 (STD) Con.:	/
Correlation Factor:	1.0000 - 0.0000		

QUALITY CONTROL
It is recommended that controls be included in each set of assays. Commercially available control material with established γ-GT values may be used for quality control. The assigned value of the control material must be confirmed by this methodology. Failure to obtain the proper range of values in the assay of control material may indicate reagent deterioration, instrument malfunction or procedural errors.

CALIBRATION
Calibration is not required.

LIMITATIONS
1. The anticoagulants EDTA, potassium oxalate, sodium fluoride and sodium citrate were found to be incompatible with this method.
2. The anticoagulants lithium heparin, sodium heparin and ammonium heparin were found to be compatible with this method.

EXPECTED VALUES[7]
Normal Range: Males: 8 – 37 U/L or 0.1-0.6 ukat/L
Females: 5 – 24 U/L or 0.1-0.4 ukat/L

This range should serve only as a guideline. It is recommended that each laboratory establish its own range of expected values, since differences exist between instruments, laboratories, and local populations.

PERFORMANCE CHARACTERISTICS

Comparison: Comparison study was performed on TC-Matrix system from 40 samples. Beckman Coulter Gamma-glutamyl transferase Reagent was used to compare with Teco Gamma-glutamyl transferase reagent. The results of this study in yield a correlation coefficient of 0.99 with a regression equation of y-0.99x+5.2.

Precision: Within-run precision was established by 25 assays on two different levels of commercial serum controls. Total Precision values were obtained by assaying the 2 commercial controls for 5 consecutive days.

	Within-Run	
	Serum 1	**Serum 2**
Mean γ-GT (U/L)	40	156
Std. Deviation (U/L)	3.1	10.5
C.V. (%)	7.5	8.1

	Total Precision	
	Serum 1	**Serum 2**
Mean γ-GT (U/L)	40	157
Std. Deviation (U/L)	2.8	10.2
C.V. (%)	7.4	8.7

Precision studies were performed according to NCCLS Tentative Guideline, EP5-A.

Linearity: Linear from 5 to 750 U/L. Performed according to NCCLS Guideline EP6-P.

REFERENCES

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