TECO DIAGNOSTICS
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γ – GLUTAMYL TRANSFERASE (GGT) KINETIC METHOD TC MATRIX

INTENDED USE
For the quantitative determination of γ-glutamyl transferase activity in serum or plasma on TC Matrix analyzer.

SUMMARY AND EXPLANATION OF THE TEST
γ-glutamyl transferase (γ-GT) is a membrane-localized enzymes that catalyzes the transfer of a γ-glutamyl group from a γ-glutamylpeptide to another peptide or an amino acid. Kidney, pancreas and liver are rich in γ-GT. Serum γ-GT is generally elevated as a result of liver disease. Cholestasis caused by alcohol or drug ingestion, mechanical or viral cholestasis, liver metastases all results in the increase of γ-GT activity. In bone disorders in which alkaline phosphatase is elevated but γ-GT is normal; and in skeletal muscle disorder in which the AST is elevated but γ-GT is normal.

γ-Glutamyl Transferase Reagent is used to measure the γ-glutamyl transferase activity by an enzymatic rate method. In the reaction, the γ-glutamyl transferase catalyzes the transfer of a gamma-glutamyl group from the colorless substrate, gamma-glutamyl-p-nitroaniline, to the acceptor, glycyclycine with production of the colored product, p-nitroaniline.

The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 410 nanometers. This change in absorbance is directly proportional to the activity of γ-glutamyl transferase in the sample and is used by the TC Matrix System to calculate and express γ-glutamyl transferase activity.

REAGENT CONTENTS:
Each kit contains: Four γ-glutamyl transferase reagent 1 (4 x 40 ml)
Four γ-glutamyl transferase reagent 2 (4 x 8 ml)
Instruction Insert.

REAGENT PREPARATION
No preparation is required.
γ-glutamyl transferase

REAGENT COMPOSITION
gamma-glutamyl-p-nitroaniline: 4.4 mmol/L
Glycyclycine: 150 mmol/L
Also non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
γ-Glutamyl Transferase Reagent stored unopened at 2°C to 8°C is stable until the expiration date showed on the bottle label. Once opened, γ-Glutamyl Transferase Reagent is stable for 14 days, unless the expiration date is exceeded.
DO NOT FREEZE.

SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum, plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and allow clotting. The serum is them separated from the clot. A maximum limit of two hours from the time of collection is recommended.
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum and plasma should be stored at 2°C to 8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.
3. For plasma, add whole blood directly into a tube containing anticoagulant. Acceptable anticoagulants are listed in the "LIMITATIONS" section.

CALIBRATION
Calibration is not required.

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
At least two levels of control material.

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, Ammonium Heparin were found to be compatible with this method.

INTERFERENCE
1. Samples showing evidence of hemolysis should not be used.
2. Lipemic samples >3+ should be ultra-centrifuged and the analysis performed on the infranate.
3. On this method, refer to the work of Young for a review of drug and comprehensive list of substances effect on γ-Glutamyl Transferase level.

EXPECTED VALUE
Male: 8-37 IU/L or 0.1 to 0.6 μkat/L
Female: 5-24 IU/L or 0.1 to 0.4 μkat/L

PRECAUTIONS:
1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.

PROCEDURES

TEST NAME:	GGT	R1:	200
TEST NO.		R2:	40
FULL NAME: γ-glutamyl transferase		SAMPLE VOLUME:	24
REFERENCE NO.:		R1 BLANK:	/
ANALY.TYPE:	Kinetic	MIX REAG. BLANK:	
PRI. WAVE :	405nm	CONCENTRATION:	/
SECON. WAVE:	670nm	LINEARITY LIMIT:	5-750
TREND:	Increase	SUBSTRATE LIMIT:	/
REACT. TIME:	0 - 10	FACTOR:	1158
INCUBATE TIME:	4	PROZONE CHECK:	/
UNIT:	U/L	Q1: / Q2: / Q3: / Q4: /	
PRECISION:	Integer	PC: / ABS.: /	

PERFORMANCE CHARACTERISTICS

Analytical Range: 5-750 IU/L

For γ-glutamyl transferase analyte by γ-Glutamyl Transferase Reagent on TC Matrix System, this method has been demonstrated to be linear from 5-750 IU/L

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter γ-Glutamyl Transferase Reagent was used to compare with γ-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 for γ-Glutamyl Transferase Reagent Set was determined following a modification of NCCLS EP5-A. Two commercial human serums were assayed on TC Matrix System for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (U/L)	40	156
Standard Deviation (U/L)	3.1	10.5
Coefficient of Variation (%)	7.5	8.1

Run-Day precision for γ-Glutamyl Transferase Reagent was determined following a modification of NCCLS EP5-A. Two commercial human serums were assayed on TC Matrix Systems five times per day for five days for the total of 25 values.

Sample	Sample 1	Sample 2
N	25	25
Mean (U/L)	40	157
Standard Deviation (U/L)	2.8	10.2
Coefficient of Variation (%)	7.4	8.7

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G572-780TM: 12/2015

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