

QUADRAPED™

γ GLUTAMYL TRANSFERASE KIT

(Carboxy Substrate Method)

(For veterinary invitro diagnostic use only)

INTENDED USE

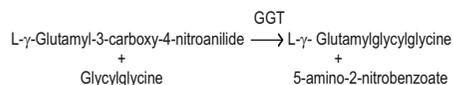
QUADRAPED™ γ Glutamyl Transferase kit is used for the determination of γ Glutamyl Transferase Activity in serum.

SUMMARY

γ Glutamyl Transferase (GGT) is an enzyme found mainly in serum from hepatic origin, though the highest levels are in kidneys. Elevated levels are found in hepatobiliary and pancreatic diseases, chronic alcoholism, myocardial infarction with secondary liver damage and diabetics.

PRINCIPLE

GGT catalyzes the transfer of amino group between L-γ-Glutamyl-3-carboxy-4-nitroanilide and Glycylglycine to form L-γ-Glutamylglycylglycine and 5-amino-2-nitrobenzoate. The rate of formation of 5-amino-2-nitrobenzoate is measured as an increase in absorbance which is proportional to the GGT activity in the sample.



EXPECTED VALUES

Species	GGT (U/L)
Dog	6 - 17
Cat	1 - 15
Cow	6 - 17.4
Horse	6 - 32
Pig	10 - 60
Sheep	20 - 52
Goat	20 - 56
Rabbit	0 - 7
Buffalo	2 - 8

It is recommended that each laboratory establish its own range as reference ranges may vary between laboratories.

PRESENTATION

REF	1126110102
Pack Size	10 x 2 ml
L1 Buffer Reagent	25 ml
T1 Substrate Tablets	10 Nos.

COMPOSITION

Tris Buffer 110 mM; pH 8.5; Glycylglycine 110 mM; Carboxy Substrate (Glupa) 4 mM.

STORAGE / STABILITY

Contents are stable at 2-8°C till the expiry mentioned on the labels.

REAGENT PREPARATION

Working reagent: Dissolve 1 Substrate Tablet in 2.2 ml of Buffer Reagent. This working reagent is stable for at least 15 days when stored at 2-8°C.

SAMPLE MATERIAL

Serum free from hemolysis. GGT is reported to be stable in serum for 4 days at 2-8°C.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimens, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

MATERIALS REQUIRED BUT NOT PROVIDED

Photometer analyzer with standard thermostatic cuvette holder, micropipette and appropriate laboratory equipment.

PROCEDURE

Wavelength / filter : 405 nm
 Temperature : 37°C / 30°C / 25°C
 Light path : 1 cm

Pipette into a clean dry test tube labelled as Test (T):

Addition Sequence	(T) (ml)
Working Reagent	1.0
Incubate at the assay temperature for 1 minute and add	
Sample	0.1

Mix well and read the initial absorbance A_0 after 30 secs. and repeat the absorbance reading after every 1 & 2 mins. Calculate the mean absorbance change per min. ($\Delta A / \text{min}$).

CALCULATIONS

GGT Activity in U/L = $\Delta A / \text{min} \times 1158$

QUALITY CONTROL

The following process is recommended for QC during the assay of GGT. *Define and establish acceptable range for your laboratory.

- Two levels of control (Normal and Abnormal) are to be run on a daily basis.
- If QC results fall outside acceptance criteria, recalibration may be necessary.
- Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

LOD: 2 U/L

LOQ: 4 U/L

Lower Limit: 2 U/L

Higher Limit: 700 U/L

If the absorbance change ($\Delta A / \text{min}$) exceeds 0.250, use only the value of the first 2 mins. to calculate the result, or dilute the sample 1 + 9 with normal saline (NaCl 0.9%) and repeat the assay (Results x 10).

Interferences:

Sample when spiked with interferent such as upto 20 mg/dl Bilirubin, 1000 mg/dl intralipid and 140 mg/dl haemoglobin does not affect the ability of the kit to determine γ Glutamyl Transferase concentration.

Precision:

Within run

Within run	n	Mean	SD	% CV
Sample 1	10	48	1.34	2.79
Sample 2	10	179	1.54	0.86
Sample 3	10	497	1.41	0.28

Between run

Between run	n	Mean	SD	% CV
Sample 1	10	49	1.54	3.16
Sample 2	10	179	1.51	0.84
Sample 3	10	496	1.41	0.28

Method comparison:

Comparative studies were done to compare our reagent with another commercial γ Glutamyl Transferase Assay. No significant differences were observed. Details of the comparative studies are available on request.

TEMPERATURE CONVERSION FACTORS

Assay Temperature	Desired Reporting Temperature		
	25°C	30°C	37°C
25°C	1.00	1.37	1.79
30°C	0.73	1.00	1.30
37°C	0.56	0.77	1.00

NOTE

In vitro diagnostic reagent for laboratory and professional use only Not for medicinal use. The reagent contain sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water. Only clean and dry glassware must be used. Samples having a very high activity show a very high initial absorbance. If this is suspected then dilute the sample and repeat the assay. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

- IFCC methods for the measurement of catalytic concentrations of enzymes, J. Clin. Chem. Clin Biochem. (1986) 24:497.
- Clinical Chemistry, Principles, Procedures, Correlations, Michael L. Bishop, et. al., 5th Edition.
- Duncan and Prasse's Veterinary Laboratory Medicine: Clinical Pathology, Kenneth S. Latimer, ISBN Jane Wardrop, 6th Edition - 2010.
- Clinical Biochemistry of Domestic Animals, Sixth Edition, 2008 by Kaneko J.J., Harvey J.W. & Bruss M.L.
- Data on file: Coral Clinical Systems.

System Parameters

Reaction	: Kinetic	Interval	: 30 Sec.
Wavelength	: 405 nm	Sample Vol.	: 0.10 ml
Zero Setting	: Distilled Water	Reagent Vol.	: 1.00 ml
Incub. Temp.	: 37°C	Standard	: —
Incub. Time	: —	Factor	: 1158
Delay Time	: 30 Sec.	React. Slope	: Increasing
Read Time	: 120 Sec.	Linearity	: 700 U/L
No. of read.	: 4	Units	: U/L

SYMBOL KEYS

Store at 2-8°C	Manufacturer	In vitro Diagnostic Medical Device	Buffer Reagent	Carboxy Substrate Method
Use by (Last day of stated month)	Consult Instructions for use	Batch Number	Substrate Tablets	This way up
Date of Manufacture	Catalogue Number			



Manufactured by:

Coral Clinical Systems

A Division of Tulip Diagnostics (P) Ltd.

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