TRIGLYCERIDES SR KIT

(GPO / PAP Method)

(For veterinary invitro diagnostic use only)

INTENDED USE

QUADRAPED™ Triglycerides SR kit is used for the determination of Triglycerides in serum or plasma.

SUMMARY

Triglycerides are a form of fatty acid esters. They are produced in the liver by binding glycerol and other fatty acids. They are transported by VLDL and LDL and act as a storage source for energy. Increased levels are found in hyperlipidemias, diabetes, nephritic syndrome, hypothyroidism. Increased levels are risk factor for arteriosclerotic coronary disease and peripheral vascular disease. Decreased levels are found in malnutrition and hyperthyroidism.

PRINCIPLE

Lipoprotein lipase hydrolyses Triglycerides to glycerol and free fatty acids. The glycerol formed with ATP in the presence of glycerol kinase forms glycerol 3 phosphate which is oxidized by the enzyme glycerol phosphate oxidase to form hydrogen peroxide. The hydrogen peroxide further reacts with phenolic compound and 4-aminoantipyrine by the catalytic action of peroxidase to form a red coloured quinoneimine dye complex. Intensity of the colour formed is directly proportional to the amount of Triglycerides present in the sample.

Triglycerides $\xrightarrow{\text{Lipoprotein Lipase}}$ Glycerol + Free fatty acids

Glycerol + ATP $\xrightarrow{\text{Glycerol Kinase}}$ Glycerol 3 Phosphate + ADP

Glycerol 3 Phosphate + O_2 $\xrightarrow{\text{Glycerol 3 PO}}$ Dihydroxyacetone phos.+ H_2O_2

H_2O_2 + 4 Aminoantipyrine + Phenol $\xrightarrow{\text{Peroxidase}}$ Red Quinoneimine dye + H_2O

EXPECTED VALUES

Species	Triglycerides (mg/dl)
Dog	20-150
Cat	10-100
Cow	10- 30
Buffalo	18- 35
Horse	10- 85
Pig	10-200
Sheep	10- 30
Goat	6- 200
Rabbit	20-120

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

PRESENTATION

REF	1126210025
Pack Size	25 ml
L1 Triglycerides Reagent	25 ml
S Triglycerides Standard (200 mg/dl)	5 ml

COMPOSITION

Goods Buffer 50mmol; Phenol 5mmol; ATP 1.0mmol; Amino Antipyrine < 3.0mmol; Lipoprotein Lipase > 1.0KU; Glycerol Kinase > 1.0KU; Glycerol Phosphate Oxidase > 5.0KU; Peroxidase > 2.0KU; Non Reactive Stabilizers, Detergent and Preservatives.

STORAGE / STABILITY

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

REAGENT PREPARATION

Reagents are ready to use.

SAMPLE MATERIAL

Serum, plasma. Triglycerides is reported to be stable in the sample for 5 days when stored 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 : 505 nm (Hg 546 nm) / Green
Temperature : 37° C / R.T.
Light path : 1 cm

Pipette into clean dry test tubes labelled as Blank (B), Standard (S), and Test (T):

Addition Sequence	B (ml)	S (ml)	T (ml)
Triglycerides Reagent (L1)	1.0	1.0	1.0
Distilled Water	0.01	-	-
Triglycerides Standard (S)	-	0.01	-
Sample	-	-	0.01

Mix well and incubate at 37° C for 5 mins. or at R.T. (25° C) for 15 mins. Measure the absorbance of the Standard (Abs. S) and the Test Sample (Abs. T) against the Blank, within 60 mins.

CALCULATIONS

$$\text{Triglycerides in mg/dl} = \frac{\text{Abs. T}}{\text{Abs. S}} \times 200$$

QUALITY CONTROL

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

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

SPECIFIC PERFORMANCE CHARACTERISTICS

LOD : 1.0 mg/dl
LOQ : 5.0 mg/dl
Lower Limit : 1.0 mg/dl
Higher Limit : 1000 mg/dl
If the value exceeds this limit, dilute the sample with normal saline (NaCl 0.9%) and repeat the assay.

Interferences:

Sample when spiked with interferent such as upto 20 mg/dl Bilirubin and 1000 mg/dl haemoglobin does not affect the ability of the kit to determine the Triglycerides concentration.

Precision:

Within run

Within run	n	Mean	SD	% CV
Sample 1	10	95.7	0.84	0.88
Sample 2	10	265.6	1.16	0.44
Sample 3	10	121.2	0.85	0.70

Between run

Between run	n	Mean	SD	% CV
Sample 1	10	95.5	0.86	0.82
Sample 2	10	265.4	1.13	0.42
Sample 3	10	121.3	0.86	0.71

Method comparison:

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

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. Fasting samples of 12 to 14 hrs. are preferred. Fatty meals and alcohol may cause elevated results. Patient should not drink alcohol for 24 hrs. before the test. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. Trinder P., (1969) Ann. Clin. Biochem. 6 : 24.
2. Bucolo G., David H., (1973), Clin. Chem.. 19:476.
3. Fossati P., Prencipe L., (1982) Clin. Chem. 28: 2077.
4. Schettler G. E. Nussel (1975) Arbeitsmed Sozialmed Praventimed 0:25.
5. Duncan and Prasse's Veterinary Laboratory Medicine: Clinical Pathology, Kenneth S. Latimer, ISBN Jane Wardrop , 6th Edition – 2010.
6. Clinical Biochemistry of Domestic Animals, Sixth Edition, 2008 by Kaneko J.J., Harvey J.W. & Bruss M.L.
7. Data on file: Coral Clinical Systems.

System Parameters			
Reaction	: End Point	**Interval**	: ---
Wavelength	: 505 nm	**Sample Vol.**	: 0.01 ml
Zero Setting	: Reagent Blank	**Reagent Vol.**	: 1.00 ml
Incub. Temp.	: 37° C / R. T.	**Standard**	: 200 mg/dl
Incub. Time	: 5 min. / 15 min.	**Factor**	: ---
Delay Time	: ---	**React. Slope**	: Increasing
Read Time	: —	**Linearity**	: 1000 mg/dl
No. of read.	: ---	**Units**	: mg/dl

SYMBOL KEYS

8°C / 2°C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	GPO / PAP GPO / PAP Method
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	L1 Triglycerides Reagent
Date of Manufacture	REF Catalogue Number	This way up	S Triglycerides Standard (200 mg/dl)

Manufactured by:
Coral Clinical Systems
A Division of Tulip Diagnostics (P) Ltd.
BUILDING E, PLOT NO. M-46/47, PHASE III B, VERNA INDUSTRIAL ESTATE, VERNA, GOA-403 722, INDIA.
REGD. OFFICE : GITANJALI, TULIP BLOCK, DR. ANTONIO DO REGO BAGH, ALTO SANTACRUZ, BAMBOLIM COMPLEX P.O., GOA-403 202, INDIA.

QTGL1/0625/VER-01