TRIGLYCERIDES (2-8°C)

GPO-PAP

CATALOGUE NUMBER	KIT SIZE (ML)
TRI1201	3 x 40ml
TRI2401	3 x 40ml
TRI4201	4 x 75ml

Intended Use:
For *In Vitro* diagnostic use by professionals only.
This reagent is intended for the quantitative determination of triglycerides in human serum and plasma.

Clinical Significance:
Triglycerides are a family of lipids absorbed from the diet and produced endogenously from carbohydrates. Measurement of triglycerides is important in the diagnosis and management of hyperlipidaemias. These diseases can be genetic or secondary to other disorders including nephrosis, diabetes mellitus, and endocrine disturbances. Elevation of triglycerides has been identified as a risk factor for atherosclerotic disease.

Test Principle:

Triglycerides + $3H_2O$ $\xrightarrow{LPL}$ Glycerol + 3RCOOH

glycerol + ATP $\xrightarrow{GK\ Mg^{2+}}$ G-3-P + ADP

G-3-P + O_2 $\xrightarrow{GPO}$ DAP + H_2O_2

H_2O_2 + 4–aminophenazone + p–chlorophenol $\xrightarrow{POD}$ Quininoneimine + $2H_2O$ +HCl

The formation of Quinoneimine dye can be measured spectrophotometrically and is proportional to the triglyceride concentration in the sample.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Triglycerides Reagent R1	GOODs Buffer pH 6.3	50 mmol/L
	p-Chlorophenol	2 mmol/L
	Lipoproteinlipase (LPL)	150000 U/L
	Glycerol kinase (GK)	500 U/L
	Glycerol-3-oxidase (GPO)	3500 U/L
	Peroxidase (POD)	440 U/L
	4 – Aminophenazone	0.1 mmol/L
	ATP	0.1 mmol/L
Triglycerides Standard	Triglycerides	200 mg/dl (2.26 mmol/l)

Reagent Preparation and Stability:
R1: Liquid, ready to Use
R2: Liquid, ready to Use
R1 and Standard are stable to the expiry date when stored unopened at 2 - 8°C. Once opened the reagents are stable for up to 30 days, when stored without contamination at 2 - 8°C.
Protect R1 from exposure to light.
Dispose of reagents carefully in line with local guidelines.

Sample / Sample Preparation / Sample Stability:
Collect serum and plasma by standard venepuncture technique.
Triglycerides are stable in samples for 5 days at 2 - 8°C and for 3 months stored frozen at -20°C.

Assay Procedure:

WAVELENGTH	505 nm (490 – 550 nm)
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Standard	Sample
Sample	-	-	10 µl
Standard	-	10 µl	-
Reagent	1000 µl	1000 µl	1000 µl
Mix and incubate for 5 minutes at assay temperature. Read the absorbance (Δ Abs) of Sample/Standard against the Reagent Blank within 30 minutes.			

Calculation:

$$\text{Concentration (mg/dl)} = \frac{\Delta\text{Abs Sample}}{\Delta\text{Abs Standard}} \times \text{Concentration of Standard}$$

Performance Characteristics:
Measuring range:
Up to 1200 mg/dl (13.6 mmol/l)

Dilute samples with higher concentrations with Normal saline 1+4 and rerun the assay. Multiply the result by the dilution factor (for 1+4 dilution, the dilution factor is 5)
Sensitivity (Analytical):
1 mg/dl = 0.013A

Imprecision
Intra-Assay Precision:

Sample	Mean (mg/dl)	SD (mg/dl)	CV %
Pool 1	109	0.64	0.58
Pool 2	224	1.01	0.45

Inter-Assay Precision:

Sample	Mean (mg/dl)	SD (mg/dl)	CV %
Pool 1	111	3.74	3.38
Pool 2	224	7.91	3.52

Method Comparison:
Prestige Diagnostics Triglycerides Reagent (y) was compared with another commercially available reagent (x) and gave the following results:
y = 0.9178 x - 0.5426, r = 0.9981

Interferences:
Criterion: Recovery within +/- 10%
Icterus: No significant interference up to 170 µmol/l of Bilirubin.
Haemolysis: No significant interference up to 10 g/l haemoglobin.

Reference Range:

Male	40-160 mg/dl (0.45-1.81 mmol/l)	No lipid metabolic disorders
Female	35-135 mg/dl (0.40-1.53 mmol/l)	
Cholesterol	200-300 mg/dl (2.25 – 3.39 mmol/l)	At risk if HDL Chol < 35 mg/dl (0.90 mmol/l)
Cholesterol Triglycerides	>300 mg/dl (3.39 mmol/l) > 200 mg/dl (2.25 mmol/l)	Indicates lipid metabolic disorder

Each laboratory should establish its own mean reference range according to the population.

Limitations:
The result from this test should not be used as the sole criteria for diagnosis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Automated systems:
Contact Prestige Diagnostics Technical Department for applications on a wide range of automated analysers.
For automation we recommend the use of a serum based calibrator.

Quality Control and Calibration Material:
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

References:

1. Buccolo G et al. Quantitative determination of serum triglycerides by use of enzymes. Clin Chem, 1973; 19: 476-482.
2. Fossati P et al. Clin Chem, 1982; 28: 2077-2080.
3. Kaplan A et al. Triglycerides. Clin Chem The CV. Mosby Co St Louis. Toronto Princeton, 1984; 437 and Lipids 1190-1206.
4. Young DS. Effects of drugs on Clinical Lab Tests. 4th ed AACC 2001.
5. Young DS. Effects of disease on Clinical Lab Tests. 4th ed AACC 1999.
6. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
7. Tietz NW et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		Keep away from sunlight

Prestige Diagnostics UK Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

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