

Triglycerides (Glycerol-3-Phosphate-Oxidase)

In-vitro Diagnostic reagent/kit for quantitative determination of Triglyceride in serum/plasma sample on Photometric System.

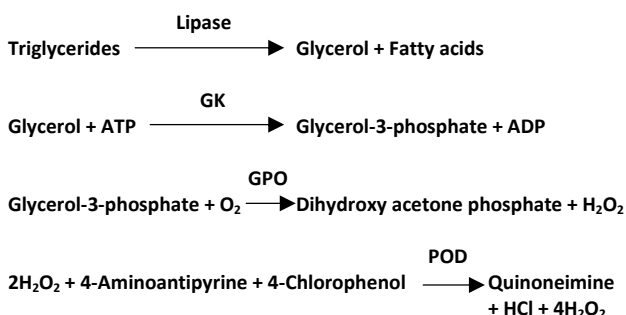
Reagent :

Reagent – Triglyceride Reagent

Standard – 200mg/dL

Principle

Determination of triglycerides involves enzymatic splitting with lipoprotein lipase. Indicator is quinoneimine, which is generated from 4-aminoantipyrine and 4-chlorophenol by hydrogen peroxide under the catalytic action of peroxidases.



Summary

Triglycerides are the fatty acid esters of glycerol formed by the liver cells. They are the energy source of the body and are transported by Low and Very Low Density Lipoproteins. Their abnormal level increased concentrations are found in diabetes, liver disease, hypothyroidism, nephritic syndrome. Increased concentrations of Triglycerides are also a risk factor in Coronary artery disease and Peripheral vascular disease. Decreased concentrations of Triglycerides are found in malnutrition and hyperthyroidism

Storage Instructions and Reagent Stability

The reagents and standard are stable till the date of expiry, if stored at 2°C-8°C, protected from light and contamination is avoided.

Do not freeze the reagents.

Components and Concentrations

Reagent - Good's buffer (pH 7.2) 50 mmol/L, 4- Chlorophenol 4 mmol/L, ATP 2 mmol/L, Mg²⁺ 15 mmol/L, Glycerokinase (GK) ≥ 0.4 kU/L, Peroxidase (POD) ≥ 2.0 kU/L, Lipoprotein lipase (LPL) ≥ 2.0 kU/L, 4-Aminoantipyrine 0.5 mmol/L, Glycerol-3-phosphateoxidase (GPO) ≥ 1.5 kU/L

Standard: Triglycerides - 200 mg/dL

Waste Management

Please refer to local regulatory requirements.

Reagent Preparation

The reagent and standard are ready to use.

Materials required but not provided

NaCl solution 9 g/L

General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma Stability:

1 months at 2° – 8 °C,

3 months at -20 °C

Only freeze once!

Discard contaminated specimens.

Assay Procedure

Wavelength	505nm
Light path	10mm
Temperature	37°C
Measurement	Against reagent Blank

	Blank	Sample/Standard/Calibrator
Sample/Standard/Calibrator	-	10 µL
Distilled water	10 µL	-
Reagent	1000 µL	1000 µL
Mix, incubate for 5 min. at 37°C. Read absorbance against the reagent blank		

Calculation:

With Standard or Calibrator

$$\text{Triglyceride (mg/dL)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std. /Cal}} \times \text{Conc. of Std. /Cal (mg/dL)}$$

Quality Control

For internal quality normal and abnormal controls should be assayed with each batch of samples.

Each laboratory should establish corrective action in case of deviations in control recovery.

Warnings and Precautions

- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- Wear suitable gloves and eye/face protection.
- Always use safety pipettes to pull the reagents into a pipette.
- Reagents may contain some non-reactive and preservative components. It is suggested to handle carefully, avoid direct contact with skin and do not swallow.
- The reagents contain sodium azide (0.95g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For professional use only!

Performance Characteristics Measuring Range

Measuring range of the assay is 5 to 1000 mg/dL. When values exceed 1000 mg/dL, the samples should be diluted 1+4 NaCl solution (9g/L) and the result is multiplied by 5.

Linearity/Limit of Maximum Detection

The maximum limit of detection is 1000 mg/dL.

Sensitivity/Limit of Detection

The lower limit of detection is 5 mg/dL.

Specificity/Interferences

No interference was observed by Ascorbic acid up to 6 mg/dL and Bilirubin up to 40 mg/dL.

Precision

Intra-assay n=20	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	55.57	0.48	0.87
Sample 2	203.41	1.58	0.77
Sample 3	426.78	2.04	0.48

Inter-assay n=20	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	55.20	0.56	1.01
Sample 2	195.40	1.15	0.59
Sample 3	423.65	1.86	0.44

Method Comparison

A comparison of Precision Biomed Triglyceride (y) with a commercially available test (x) using 15 samples gave following results:
 $y = 1.062x - 19.33; r^2 = 0.927$.

Reference Range

Desirable	< 200 mg/dL (2.3 mmol/L)
Borderline high	200-400 mg/dL (2.3 -4.5 mmol/L)
Elevated	> 400 mg/dL (4.5 mmol/L)

Note: It is recommended that each laboratory should establish its own reference range based on the patient population.

Quick Reference

Parameter	Triglycerides
Mode	End point
Wavelength	505 nm(505-550)
Path length	10 mm
Temperature	37°C
Standard conc.	200 mg/dL
Reagent volume	1000 µL
Sample volume	10 µL
Incubation time	5 min
Blanking	Reagent blank
Normal range	< 200 mg/dL
Linearity	1000 mg/dL
Sensitivity	5 mg/dL









Pack Size :

Cat No.	Configuration	Pack
TRI00100	Reagent - 2 x 50mL Standard – 1 x 2mL	100mL
TRI01000	Reagent - 2 x 500mL Standard – 1 x 4mL	1000mL

Literature

1. Tietz textbook of clinical chemistry. 3rd ed. Philadelphia: W.B. Saunders Company; 1999.p.809-61.
2. Handbook of lipoprotein testing. Washington: AACC Press, 1997.p.115-26.
3. Prevention of coronary heart disease in clinical practice. Eur Heart J1998:191434-503.

Version : TRI/00

IVD In Vitro Diagnostic Use	 See Pack Insert For Procedure	 Single Use only	
 Temperature Limit	 Manufacturer's Address	 Manufacturing Date	 Expiry Date
		 LOT Lot Number	



Manufactured in India by :

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