



Instructions For Use

GENESIS

Triglycerides (GPO/PAP Method)

Cat no.	Size
1108 101	4*25
1108 102	2*50
1108 103	4*50
1108 104	2*25

INTENDED USE

The Triglycerides Reagent is intended for in vitro Quantitative diagnostic determination of triglycerides in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

Triglycerides are a form of fatty 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, nephrotic syndrome, and hypothyroidism. Increased levels are risk factor for arteriosclerotic coronary disease and peripheral vascular disease. Decreased levels are found in malnutrition and hyperthyroidism. Triglycerides kit uses GPO / PAP method to determine triglycerides in serum or plasma

PRINCIPLE OF THE METHOD

Serum triglycerides are hydrolyzed to glycerol and free fatty acids by lipoprotein lipase. In the presence of ATP and glycerol kinase (GK), the glycerol is converted to glycerol-3-phosphate, which then is oxidized by glycerol phosphate oxidase (GPO) to yield hydrogen peroxide. The oxidative condensation of 4-Chlorophenol and (4-AAP) 4-aminophenazone in the presence of Peroxidase (POD) and hydrogen peroxide produces a rose colored dye which is measured at 550 nm. The intensity of the color formed is directly proportional to the triglycerides concentration in the sample.

COMPOSITION

REAGENT(R)	
Good's Buffer (pH 7.2)	50 mmol/L
4-Chlorophenol	4 mmol/L
ATP	2 mmol/L
Mg ²⁺	15 mmol/L
Glycerokinase (GK)	≥ 0.4 kU/L
Peroxidase (POD)	≥ 2 kU/L
Lipoproteinlipase (LPL)	≥ 4 kU/L
4-Aminoantipyrine	0.5 mmol/L
Glycerin-3-phosphatoxidase	≥ 1.5 kU/L
STANDARD (S)	
	200 mg/dL

STORAGE

Store at 2-8°C.

Reagent and Standard are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION

Reagent and Standard are provided ready to use.

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37°C
- Analyzer, spectrophotometer able to read at 546 nm

SAMPLES

1. Serum or plasma collected by standard procedures.
2. Triglycerides is stable for 7 days at 2-8°C.
3. Heparin, EDTA, oxalate and fluoride may be used as anticoagulants

Precautions and Warnings

Do not ingest or inhale. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Symbols in Product Labeling			
	Authorized Representative		Expiration date
	For in-vitro diagnostic use		CAUTION, consult instructions for use
	Catalogue number		Manufactured by
	Lot number		

PROCEDURE

1. Bring the Reagent to room temperature.
2. Pipette into labeled test tubes:

	Blank	Standard	Sample
Reagent (R)	1.0 mL	1.0 mL	1.0 mL
Standard (S)	-	10 µL	-
Sample	-	-	10 µL

3. Mix thoroughly and incubate the tubes for **10 minutes** at room temperature (16-25°C) or for **5 minutes** at 37°C.
4. Measure the absorbance (A) of the Standard and Sample at 546 nm against the Blank. The color is stable for at least 1 hour.

CALCULATIONS

The Triglycerides concentration in the sample is calculated using the following general formula:

$$\frac{A \text{ Sample}}{A \text{ Standard}} \times \frac{200}{0.0114} = \text{mg/dL Triglycerides}$$

REFERENCE VALUES

Normal	Up to 150 mg/dL = 1.7 mmol/L
Borderline High	150-199 mg/dL = 1.70-2.25 mmol/L
High	200-499 mg/dL = 2.26-5.64 mmol/L
Very High	> 500 mg/dL => 5.65 mmol/L

QUALITY CONTROL

It is recommended to use the Control Serum level I and II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

METROLOGICAL CHARACTERISTICS

- Detection limit: 4.4 mg/dL = 0.05 mmol/L.

- Linearity limit: 600 mg/dL = 6.78 mmol/L.

For higher values dilute sample 1/2 with physiological Saline and repeat measurement.

- Repeatability (within run):

Mean Concentration	CV	n
44 mg/dL = 0.50 mmol/L	2.8 %	20
207 mg/dL = 2.34 mmol/L	1.6 %	20

- Reproducibility (run to run):

Mean Concentration	CV	n
44 mg/dL = 0.50 mmol/L	2.9 %	25
207 mg/dL = 2.34 mmol/L	2.7 %	25

-INTERFERENCES:

Hemoglobin (10 g/L) does not interfere

Bilirubin (2.5 mg/dL) may interfere

Other drugs and substances may interfere

BIBLIOGRAPHY

1. Bucolo G and David H. Quantitative determination of serum triglycerides by use of enzymes. Clin Chem 1973; 19: 476-482.
2. Fossati P and Prencipe L. Serum triglycerides determined colorimetrically with an enzyme that produces hydrogen peroxide. Clin Chem 1982; 28: 2077-2080.
3. National Cholesterol Education Program Expert Panel. Third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III). NIH Publication. Bethesda: National Heart, Lung, and Blood Institute; 2001.