# SBio TRIGLYCERIDES KIT

**(GPO / PAP Method)**

(For invitro diagnostic use only)

| REF | 90810075 |
|---|---|
| Pack Size | 75 ml |

CE

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|---|---|---|---|---|
| 8°C 2°C Store at 2-8°C | Manufacturer | IVD *In vitro* Diagnostic Medical Device | L1 Enzyme Reagent 1 | GPO / PAP GPO / PAP Method |
| Use by (Last day of stated month) | Consult Instructions for use | | L2 Enzyme Reagent 2 | This way up |
| Date of Manufacture | REF Catalogue Number | LOT Batch Number | S Triglycerides Standard (200 mg/dl) | EC REP Authorised Representative in the European Community |

## INTENDED USE

Triglycerides Kit is used for the determination of Triglycerides in serum or plasma.

## PRINCIPLE OF THE TEST

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 oxidised 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 —*Lipoprotein Lipase*→ Glycerol + Free Fatty Acids

Glycerol + ATP —*Glycerol Kinase*→ Glycerol 3 Phosphate + ADP

Glycerol 3 Phosphate + $O_2$ —*Glycerol 3 PO*→ Dihydroxyacetone phos. + $H_2O_2$

$H_2O_2$ + 4 Aminoantipyrine + Phenol —*Peroxidase*→ Red Quinoneimine dye + $H_2O$

## CLINICAL SIGNIFICANCE

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, 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.

| PRESENTATION | 75 ml |
|---|---|
| L1 : Enzyme Reagent 1 | 60 ml |
| L2 : Enzyme Reagent 2 | 15 ml |
| S : Triglycerides Standard (200 mg/dl) | 5 ml |

## COMPOSITION

Goods buffer 50 mM; pH 7.0; LPL ≥ 1000 U/L; GK ≥ 1000 U/L; GPO ≥ 5000 U/L; POD ≥ 1000 U/L; 4-AAP 0.3 mM; Chlorophenol 3.0 mM; ATP 1.0 mM; Non-Reactive Stabilizers, Detergents 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.

**Working reagent:** Pour the contents of 1 bottle of L2 (Enzyme Reagent 2) into 1 bottle of L1 (Enzyme Reagent 1). This working reagent is stable for at least 8 weeks when stored at 2-8°C. Upon storage the working reagent may develop a slight pink colour however this does not affect the performance of the reagent.

Alternatively for flexibility as much of working reagent may be made as and when desired by mixing together 4 parts of L1 (Enzyme Reagent 1) & 1 part L2 (Enzyme Reagent 2). Alternatively 0.8 ml of L1and 0.2 ml of L2 may also be used instead of 1 ml of the working reagent directly during the assay.

## SAMPLE MATERIAL

Serum, plasma. Triglycerides are reported to be stable in 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.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

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

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

## PROCEDURE

| | | |
|---|---|---|
| Wavelength/filter | : | 505 nm (Hg 546 nm) / Green |
| Temperature | : | 37° C / R.T. |
| Light path | : | 1 cm |

## MATERIALS REQUIRED BUT NOT PROVIDED

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

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

| Addition Sequence | B (ml) | S (ml) | T (ml) |
|---|---|---|---|
| Working Reagent | 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 minutes or at R.T. (25° C) for 15 minutes. Measure the absorbance of the Standard (Abs. S) and Test Sample (Abs. T) against the Blank within 60 minutes.

## 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. *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

**Linearity:**

The procedure is linear upto 1000 mg/dl. If the value exceeds this limit, dilute the serum with normal saline (NaCl 0.9%) and repeat the assay.

**Limit of detection:**

The limit of detection for Triglycerides is 1 mg/dl.

**Interferences:**

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

**Precision:**

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

| Sample | Within-run | | Between-run | | Total | |
|---|---|---|---|---|---|---|
| | Mean | CV% | Mean | CV% | Mean | CV% |
| Control 1 | 123.11 | 1.25 | 115.9 | 2.85 | 239.01 | 4.1 |
| Control 2 | 203.43 | 1.40 | 204.24 | 1.54 | 407.67 | 2.94 |

**Method comparison:**

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

## REFERENCE RANGE

Serum / Plasma (Suspicious) : 150 mg/dl and above

(Elevated) : 200 mg/dl and above

It is recommended that each laboratory establish its own normal range representing its patient population*.

## NOTE

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. The reagent may be used in several automated analyzers. Instructions are available on request.

Standard is traceable to standard reference material (SRM) 909b. 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 10:25.



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EC REP

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