- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **TG0011**	R.1: 6 x 50 ml total 3·0 ml	2-8°C
Cat. No.: **TG0017**	R.1: 5 x 60 ml total 300 ml	2-8°C

- **Intended Use:**

In Vitro Diagnostic reagent pack for the quantitative determination of Triglycerides in human serum/plasma on automated and semi-automated photometric systems.
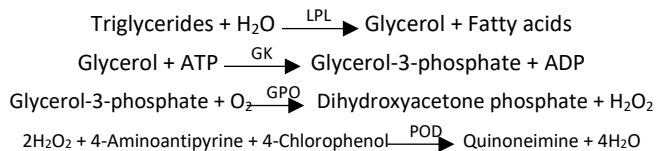
- **Summary and Explanation:**

Triglycerides is a complex which contain glycerol esters and three long chain fatty acids. In the plasma this molecule is going to be attached to the Apo lipoproteins in the form of VLDL and chylomicrons. Some part of triglycerides is synthesis on liver and the other part comes from diet. Measurement of triglycerides in diagnostic and monitoring of lipoprotein disorder, danger prediction in atherosclerosis, function of drugs in control of lipid in blood, lipid metabolism disorder analysis, analysis of lipid fraction in diabetes, nephritis, hepatic obstruction and pancreatic disorder is essential.

Meanwhile, studies shown that increase the level of triglycerides with LDL in plasma has a direct relation with high risk of heart coronary vascular disease.

Principle of the Method:

This method is based on triglycerides in the sample hydrolyzed with lipoprotein lipase enzyme which release fatty acids and glycerol. Then the hydrogen peroxide from glycerol with 4-aminoantipyrine and phenol in the presence of peroxidase the color complex termed quinoneimine appear. The intensity of the color will have measured on 500-550 (505)Nano meter wavelength which is correlate with the amount of Triglycerides on the sample.

$$\text{Triglycerides} + H_2O \xrightarrow{\text{LPL}} \text{Glycerol} + \text{Fatty acids}$$

$$\text{Glycerol} + ATP \xrightarrow{\text{GK}} \text{Glycerol-3-phosphate} + ADP$$

$$\text{Glycerol-3-phosphate} + O_2 \xrightarrow{\text{GPO}} \text{Dihydroxyacetone phosphate} + H_2O_2$$

$$2H_2O_2 + \text{4-Aminoantipyrine} + \text{4-Chlorophenol} \xrightarrow{\text{POD}} \text{Quinoneimine} + 4H_2O$$

- **Reagent Preparation and Stability:**

Reagent is ready for use.

Before use, mix reagent by gently inverting each bottle.

Reagent is stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.

Do not use reagents over the expiration date.

Do not freeze and protect from light.

The reagent is light beige color.

Waste Management:

Refer to local legal requirements for chemical disposal regulations.

Warning: Handle waste as potentially biohazardous material.

Dispose of waste according to accepted laboratory instructions and procedures.

- **Warnings and Precautions:**

For In Vitro Diagnostics Use Only.

For Professional Use Only.

Carefully read instructions for use.

In case of serious damage to the bottle or cap, resulting in product leakage or contamination, do not use the reagent pack and contact your distributor.

Take all necessary precautions required when handling laboratory reagents.

Do not use components past the expiry date stated on the Bottles.

Do not interchange caps among components as contamination may occur and compromise test results. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.

Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.

- **Type of Specimen:**

Use fresh serum and plasma heparinized or EDTA. The stability of Triglycerides in the samples at 2-8°C in 7 days and at -20°C in 3 months. The plasma /serum should be collected till 2 hours after blood collection.

General chemistry calibrator from TKS or other valid calibrators.
General chemistry control Level 1 & 2 from TKS or other valid controls.
Saline solution 0.9 % NaCl
General laboratory equipments

- **Notes:**

Carefully read instructions for use.

It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.

Use clean disposable pipette tips for its dispensation.

Disposable and glassware material used must be free of metals, ions and detergents.

Performance Characteristics:

Performance results can vary with the instrument used.

Data obtained in each individual laboratory may differ from these values.

Maximum determination in this 800 mg/dl

LOD: 5.3 mg/dl

For samples with a higher concentration (800 mg/dl), dilute 1:1 with 0.9 % NaCl and re-assay. Multiply result by 2.

Precision:

Intra Assay-Within run Triglycerides

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	75.27	1.11	1.47
2	20	133.96	1.65	1.23
3	20	258.89	2.72	1.05

Inter Assay-Between run Triglycerides

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	71.71	1.97	2.74
2	20	127.4	2.21	1.73
3	20	198.94	3.4	1.7

- **Accuracy:**

Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).

Correlation coefficient (r): 0.999

Regression equation: Y = 1.093 (X) - 0.083 mg/dl

The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**

Bilirubin (mixed isomer)	Less than 11% interference up to 150 µmol/L Bilirubin
Ascorbic Acid	6 mg/dl
Hemolysis	Less than 10% interference up to 5g/L Haemoglobin.

- **Reference Values:**

Serum/Plasma	
Optimal/Normal	**<160 mg/dl**

Each laboratory should establish its own expected values. The Triglycerides results should always be reviewed with the patient's medical examination and history.

- **Assay Procedure:**

Allow reagents to reach working temperature before using.

A proportional variation of the reaction volumes indicated does not change the result

- **Required but not Supplied:**

Triglycerides (TG)
(GPO/PAP Method)

Assay conditions:

505 (500-550) nm	Wavelengths
37 °C	Incubation Temperature
1 cm	Cuvette

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	Blank	
1000 µl	1000 µl	R
10 µl	-	Control/Sample/Calibrator
Gently mix and incubate for 10 minutes at 37°C. The absorbance of sample and calibrator against the blank.		

- **Calculations:**

Triglycerides(mg/dl) = $\underline{\text{Abs. Sample}}$ x Cal./STD. Conc. (mg/dl)
            Abs. STD/ Calibrator

Conversion Units:

Triglycerides (mg/dl) x 0.0113 = Triglycerides (mmol/L)

TOSE'E KIMIA SA'ADAT has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

- **References:**

1-Rifai N, Bachorik PS, Albers JJ. Lipids, lipoproteins and apolipoproteins. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Compony; 1999.p.809-61.
2-Cole TG, Klotzsch SG, McNamara J. Measurement of triglyceride concentration. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press, 1997.p.115-26.
3-Recommendation of the Second Joint Task Force of European and other Societies on Coronary Prevention. Prevention of coronary heart disease in clinical practice. Eur Heart J 1998; 19:1434-503.
4-Fossati P. Prencipe L., Clin.Chem., 28(1982)2077-80.
5-NCCLS documents M29-T2.2nd Ed. 1991.
6-Klotzsch, S.G.&MC Namara, R.j.clin.chem.1190;36:1605-13.

Symbols:

The following symbols are used in the labelling of TOSE'E KIMIA SA'ADAT systems:

IVD	In Vitro Diagnostics		Contains sufficient for <n> tests
LOT	Batch Code		Temperature limit
REF	Catalogue No.		Consult instruction for use
	Expiry Date		Caution
	Date of Manufacture		Keep dry
	Manufactured by		This way up
	Biological Risks		Keep away from sunlight

ISO 13485:2016
ISO 9001:2015

IVD

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