INTENDED USE
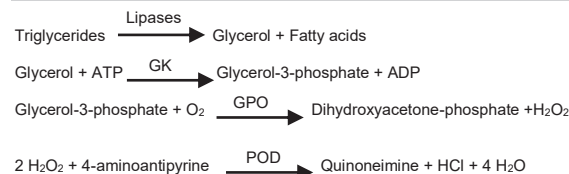
The TRUEchemie Triglycerides Test kit (GPO-POD) is used for the quantitative determination of Triglycerides in human serum or plasma.

INTRODUCTION

Triglycerides are esters of fatty acids and are hydrolyzed to glycerol and free fatty acids. Triglyceride determinations when performed in conjunction with other lipid assays are useful in the diagnosis of primary and secondary hyperlipoproteinemia. They are also of interest in following the course of diabetes mellitus, nephrosis, biliary obstruction and various metabolic abnormalities due to endocrine disturbances.

PRINCIPLE

$$\text{Triglycerides} \xrightarrow{\text{Lipases}} \text{Glycerol + Fatty acids}$$

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

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

$$2 H_2O_2 + \text{4-aminoantipyrine} \xrightarrow{\text{POD}} \text{Quinoneimine + HCl} + 4 H_2O$$

PACK SIZE

Kit size	2 x 50 ml	2 x 100 ml
Cat no.	ADX151	ADX152
Kit contents		
1) Triglycerides Reagent	2 x 50 ml	2 x 100 ml
2) Triglycerides Standard (200 mg/dL)	1 x 5 ml	1 x 5 ml

REAGENT COMPOSITION

1) Triglycerides Reagent

ATP	:	0.5 mmol/L
Magnesium acetate	:	12 mmol/L
4-Chlorophenol	:	3.5 mmol/L
4-Aminophenazone	:	0.3 mmol/L
Glycerol Phosphate Oxidase	:	> 4500 U/L
Lipase	:	>200,000 U/L
Glycerol kinase	:	>250 U/L
Peroxidase	:	>2,000 U/L
Buffer (pH 7.4)	:	50 mmol/L

Surfactants, stabilizers, and preservatives

2) Triglycerides Standard : 200 mg/dL

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. The disposal of the residues has to be done as per local legal regulations.

CALIBRATION

The procedures are calibrated with the standard solution which is included with each series of tests. Its absorbance is used to calculate the results.

REAGENT STORAGE & STABILITY

The components of the kit, stored at 2 - 8°C, will remain stable until the expiry date stated on the label.

SPECIMEN COLLECTION AND STORAGE

Test specimens should be serum free from hemolysis.
Triglycerides in serum is reported stable for 3 days at 2 - 8°C

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes
2. Test tubes/rack
3. Timer
4. 37°C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 505 nm

TEST PROCEDURE

Wavelength	:	505 nm
Temperature	:	37°C

Prewarm the reagent to reaction temperature.

	Blank (µL)	Standard (µL)	Sample (µL)
Triglycerides Reagent	1000	1000	1000
Triglycerides Standard	--	10	--
Sample	--	--	10

Incubate all tubes at 37°C for 5 minutes or 10 minutes at room temperature.
After incubation, zero the photometer with the reagent blank at 505 nm. Read and record the incubated standards and samples.

$$\text{Calculation} = \frac{\text{Sample OD}}{\text{Standard OD}} \times 200 \text{ mg Triglycerides/dL}$$

S.I. Units: (mg/dl) x 0.01143 = mmol/L

QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

EXPECTED VALUE

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)

It is strongly recommended that each laboratory establish its own normal range.

PERFORMANCE CHARACTERISTICS

Sensitivity: 0.218 mg/dL
Linearity: 1000 mg/dL under the described assay conditions. If the concentration is greater than linearity (1000 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision within run (n=10)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	184.2	0.6	0.7
Control Level - 2	74.5	1.4	0.5

Inter-assay precision run to run (n=12)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	184.8	0.7	0.9
Control Level - 2	75.5	0.6	0.4

The reagent was tested for 12 days, using two different Triglycerides concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie Triglycerides reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.996 and the regression equation is y=1.016x+1.626. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Hemoglobin concentration up to 150 mg/dL does not interfere.
Bilirubin concentration up to 20 mg/dL does not interfere.

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEM PARAMETERS

Mode	:	End point
Std. conc.	:	200
Wave length	:	505 nm
Units	:	mg/dL
Flow cell temp.	:	37°C
Blank	:	Reagent
Reagent volume	:	1000 µL
Sample volume	:	10 µL
Incubation	:	5 min at 37°C
Low normal	:	0.0
High normal	:	150
Sensitivity	:	0.218
Linearity	:	1000
Reaction Slope	:	Increasing

REFERENCES

1. Searcy, R.L.: Diagnostic Biochemistry, McGraw-Hill, New York (1969).
2. Fossati, P., Principle, L.: Clin. Chem. 28:2077 (1982).
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5. Young, D.S. Pestaner, L.C. and Gibberman, V.: Clin. Chem. 21:11 (1975).
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7. Tiffany, T. O., et. al. Clin. Chem., 20:476 (1974).
8. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

[i] Consult instructions for use	REF Catalogue number	⚠ Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
2°C—8°C Temperature limit 2-8 °C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
Do not use if package is damaged	Keep away from sunlight	

ATHENESE-Dx
Early diagnosis for better life
Athenese-Dx Pvt. Ltd.
Module No. 407 & 408, 4th Floor, TICEL Bio Park II, No. 5, CSIR Road. Taramani, Chennai-600113, India
Tel: +91-44-22541131
E-mail: info@athenesedx.com
Website: www.athenesedx.com

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