ROBONIK®

CE

prietest™...Clinical Chemistry Reagents

TRIGLYCERIDES TEST KIT

INTENDED USE:
- Quantitative in vitro determination of Triglycerides in serum or plasma on photometric systems.
- In vitro diagnostic test kit, for laboratory and professional use.
- This manual contains instructions for operation by qualified personnel only.

ORDERING INFORMATION	**Pack Size**	**Cat No.**
	2 X 10 ml	TRIG 02 10
	5 X 10 ml	TRIG 05 10
	4 X 50 ml	TRIG 04 50
	5 X 100 ml	TRIG 05 100

CLINICAL SIGNIFICANCE: Triglycerides are esters of glycerol with three fatty acids and are the most abundant naturally occurring lipids. They are transported in plasma bound to apo lipoproteins forming very low density lipoproteins (VLDL) and chylomicrons. Measurement of triglycerides is used in screening of the lipid status to detect atherosclerotic risks and in monitoring of lipid lowering measures. Recent studies have shown that elevated triglyceride concentrations combined with increased low density lipoprotein (LDL) concentrations constitute an especially high risk for coronary heart disease (CHD). High serum triglyceride levels are associated with important risks of atherosclerosis, lipid metabolism disorder, diabetes, renal or endocrine disorders

METHOD : Photometric test according to enzymatic GPO, Trinder, End-point

PRINCIPLE : Determination of Triglycerides after 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 Peroxidase.

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

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

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

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

REAGENTS:
COMPONENTS AND CONCENTRATIONS:

Buffer	:	100 mmol/l	
Lipoprotein Lipase	:	>2000U/l	
Glycerol-3-P-Oxidase	:	>1000U/l	
Glycerol Kinase	:	>300U/l	
Peroxidase	:	>500 U/l	
Preservative & Stabilizer			
Standard	:	200 mg/dl	(2.28 mmol/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY : Reagent and standard are stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C, protected from light and contamination is avoided. Do not freeze the reagent!
NOTE: It has to be mentioned, that the measurement is not influenced by occasionally occurring color changes, as long as the absorbance of the reagent is < 0.3 at 510 nm.

WARNINGS AND PRECAUTIONS :
1. The reagent contains Sodium Azide (0.95 g/l) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT : For disposal of these biomedical waste refer local biosafety regulations.

REAGENT PREPARATION : The reagent and the standard are ready-to-use.

MATERIALS REQUIRED BUT NOT PROVIDED : NaCl solution 9 g/l, General laboratory equipment, Analyser / Photometer, Pipettes etc.

SPECIMEN :
Serum, heparin plasma or EDTA plasma from fasting patients.
Stability: 5 to 7 days if stored at 2 to 8°C, 3 months at – 20°C.
Discard contaminated specimens.

ASSAY PROCEDURE :
Application sheets for automated systems are available on request.

Wavelength	:	Hg 510 nm, 546 nm, 505 nm
Optical Path	:	1 cm
Temperature	:	37°C
Mode	:	End Point

Bring all the contents of the kit to Room Temperature prior to use.
Read absorbance of sample against reagent blank.
Label the test tube as blank, standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below :

	Blank	Standard	Sample / Control
Reagent	1000 µl	1000 µl	1000 µl
Distilled Water	10 µl	—	—
Standard	—	10 µl	—
Sample / Control	—	—	10 µl

Mix and read the absorbance (A) after a 10 minutes incubation but within 30 minutes.

CALCULATION : With standard or calibrator.

$$\text{Conc. in unknown Sample} = \frac{\text{Concentration of Standard}}{\text{Abs. Standard - Abs. of Reagent Blank}} \times \text{Abs. of unknown Sample} - \text{Abs. of Reagent Blank}$$

CONVERSION FACTOR : Triglycerides [mg / dl] x 0.0114 = Triglycerides [mmol/l]

CALIBRATION : For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL : To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS:
MEASURING RANGE : The test has been developed to determine Triglyceride concentrations within a measuring range from 1 to 1000 mg/dl (0.0114 to 11.4 mmol/L). When values exceed higher limit of the range, it is advisable to dilute high triglyceride / lipaeric sample with another known low value / normal serum sample (Diluent). Test result to be corrected with dilution ratio. Then subtract the value of normal serum sample to obtain correct value of triglyceride in the lipaemic sample.

SPECIFICITY / INTERFERENCES : No interference was observed by Bilirubin up to 25 mg/dl (427.6 µmol/L), Ascorbic Acid 2 mg/dl (113.56 µmol/L), Hemoglobin 250 mg/dl (2.5 g/L). A list of drugs and other interfering substances with Triglyceride determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION : The lower limit of detection is 1 mg/dl (0.0114 mmol/L).

PRECISION :

Intra-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	197.46	1.70	0.86
Sample 2	177.7	1.64	0.92
Sample 3	162.2	0.93	0.57

Inter-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	88.6	1.69	1.90
Sample 2	80.03	1.39	1.74
Sample 3	194.2	3.46	1.78

METHOD COMPARISON :
A comparison between Robonik Prietest Triglycerides (y) and a commercially available test (x) using 20 samples gave following results :

Linear Regression	:	y = 1.0371 x + 10.623 mg/dl
Correlation Coefficient	:	r = 0.9978

REFERENCE RANGE :

Normal	:	< 150 mg/dl	(< 1.71 mmol/L)
Borderline High	:	150 to 199 mg/dl	(1.71 to 2.27 mmol/L)
High	:	200 to 499 mg/dl	(2.28 to 5.69 mmol/L)
Very High	:	>500 mg/dl	(>5.70 mmol/L)

It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Naito, H.K., *Coronary Artery Disease and Disorders of Lipid Metabolism.* Clinical Chemistry: Theory, Analysis, Correlation, 4th Ed., Kaplan, L.A., Pesce, A.J., Kazmierczak, S.C. (Mosby, Inc. eds. St Louis USA), (2003), 603.
2. Tietz, N.W., Clinical guide to laboratory tests, 3rd Ed. (W.B. Saunders eds. Philadelphia USA), (1995), 610.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed. AACC Press, 1995

INSTRUMENT APPLICATION *prietest* INSTRUMENTS	
Name : TRIG,	Mod : END-P
Pri.: 510,	Sec.: 0
Temp: 37C,	KF : 1.000
Vol : 500ul,	Unit : mg/dl
Lag : 5,	Read : NA
Blk : Y, QC : Y,	Norm : Y
Std : 1, Concen :	
Std.: 1 = 200	
Normal HI = 200	
Normal LO = 150	
QCNH : *	
QCNL : *	
QCABH = *	
QCABL = *	
Rgnt. Linearity : 1000	
NOTE :	
* Indicates user definable parameter.	
NA Implies Not Applicable	

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	TRIGLYCERIDES
Reaction	End Point
Reaction Slope	Increasing
Wavelength 1	510 nm
Temperature	37°C
Zero Setting	Reagent Blank
Units	mg/dl
Standard Conc.	200
Sample Volume	10 µl
Reagent Volume	1000 µl
Incubation Time	10 minutes
Reference Range	150 to 200
Reagent Linearity	1000

ROBONIK®

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