BioMed-Triglycerides L.S

Enzymatic, Colorimetric GPO-PAP

REF:

TG117090 (3×30 ml)	TG117040 (2 × 20 ml)
TG117120 (2×60 ml)	TG117200 (10×20 ml)
TG117100 (2×50 ml)	TG117240 (2×120 ml)

INTENDED FOR USE:

For the quantitative determination of Triglycerides in serum and plasma

PRINCIPLE :

For the enzymatic determination of Triglycerides according to the following reaction:

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

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

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

$$2\,H_2O_2 + \text{4-AAP} + \text{4-CHLOROPHENIL} \xrightarrow{\text{POD}} \text{colored compound} + H_2O$$

The intensity of the red colour produced is directly proportional to Triglycerides in the sample

SPECIMEN COLLECTION :

Fresh serum or plasma (heparin or EDTA) obtained from fasting individuals.
Do not use grossly hemolized or highly icteric specimens.
Triglycerides in serum or plasma is stable for 2 days when stored in the refrigerator at 2-8°C.
Do not store samples at room temperature as phospholipids may hydrolyze, releasing free glycerol and falsely elevating Triglycerides value.
Shake and bring the samples at room temperature (+15-25°C) before using.

REAGENTS COMPOSITION:

R1 Standard	Triglycerides Standard	200mg/dl (2.28mmol/l)
R2	Good's Buffer	100mmol/L
	Magnesium Chloride	15mmol/L
	ATP (Adenosina-5-Triphosphate)	4mmol/L
	4-AAP (4-Aminoantipyrine)	1mmol/L
	4-CHLOROPHENOL	0.1mmol/L
	LPL (Lipoprotein Lipase)	2500U/L
	GK (Glycerol Chinasi)	1000U/L
	GPO (Glycerol-3-phosphate oxidase)	5500U/L
	POD (Peroxidase)	1800U/L

PACKAGE : Collection & Storage .

Store at +2-8°C.
Stable until the expiration date reported upon the package.

After the unsealing and the taking of the reagent , it is advised to close up the bottle immediately in order to avoid evaporation , direct light exposure and bacterial contamination .

PRECAUTION & WARNINGS

Avoid pipette by mouth **.**
The preparation , according to current regulation . is classified as not dangerous.
The total concentration of non active components (preservatives , detergents ,stabilizers) is below the minimum required for citation .
Anyway handle with care , avoid ingestion , avoid contact with eyes , skin and mucous membranes
The samples must be handle as potentially infected from HIV or Hepatitis .

REAGENT PREPATION & STABILITY :

Before using reagents must be at room temperature.(+15-25°C.)
The reagent is limpid and rose-coloured.
A light reagent coloration (less than 0.050 O.D.) due to air or direct light exposure, will not impair its functioning.
Stable until the date indicated on the label.

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instrumentations.

PROCEDURE :

Wavelength	500-550 nm
Optical path :	1 cm light path
Temperature :	+20-25/37°C
Reading :	Against blank reagent
Assay tipe :	Endpoint

Procedure : Pipetting in tubes :

	BLANK	STANDARD	SAMPLE
Reagent (R2)	1000 µL	1000 µL	1000 µL
Distilled Water	10 µL		
Standard (R1)		10 µL	
Sample			10 µL

Mix, incubate for 5 min at 37°C or 10 min at room temperature (+15-25°C) and read sample and standard extinction.
Color is stable for 60 min at room temperature.
Volumes can be proportionally modified.
This methodology describes the manual procedure to use the kit. For automated procedure, ask for specific application.

CALCULATION :

$$\textbf{Triglycerides mg/dl} = \frac{\text{(A) sample}}{\text{(A) Standard}} \times 200$$

Unit conversion:
mg/dl x 0.0114 = mmol/l

EXPECTED VALUES :

Men	40 – 160 mg/dl	0.45 – 1.82 mmol/l
Women	35 – 135 mg/dl	0.4 - 1.54 mmol/l

The above mentioned values are to be considered as a reference. It is strongly recommended that each laboratory establish its own normal range according to its geographic area , according to IFCC protocol .

WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal .

QUALITY CONTROL :

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

PERFORMANCE :

MEASURE INTERVAL L INEARITY :	4.78 - 900 mg/dl
DETECTION LIMIT :	4.78 mg/dl
SENSITIVITY:	3 mg/dl=0.00173A at 546 nm

INTER-ASSAY PRECISION: n=20

LOW LEVEL	M = 59.98 mg/dl	C.V.=2.85%
MEDIUM LEVEL	M = 120.64 mg/dl	C.V.=2.08%
HIGH LEVEL	M = 687.40 mg/dl	C.V.=2.43%

INTRA-ASSAY PRECISION: n=20

LOW LEVEL	M = 57.03 mg/dl	C.V.2.3%
MEDIUM LEVEL	M = 123.08 mg/dl	C.V.1.2%
HIGH LEVEL	M = 686.23 mg/dl	C.V.2.4%
ANALIZED INTERVAL	42.5 – 383.9 mg/dl	
CORRELATION	r = 0.99811	n=53
LIN. REGRESSION	y = 1.054× +0.50915	n=53

INTERFERENCE:

Interferences are negligible up to :			
Glucose	500 mg/dl	Bilirubin	10 mg/dl
Ascorbic Acid	3.0 mg/dl	Hemoglobin	0.5 g/l
Uric Acid	20 mg/dl		

METHOD LIMITATIONS:

Glycerol (free glycerol and glycerol release upon hydrolysis of Triglicerides) is measured by this procedure.

Free glycerol levels in serum are generally low in fresh samples (< 9,6 mg/dl), but elevation may be caused by improper storage or sample

contamination.For a thorough evaluation of the interfering substances , consult : Young, D.S.,et al.,Clin.Chem. 21:1D (1975).

REFERENCES :

Fossati,P.,Principe, et al.Clin.Chem.28,2077-80(1982).
Vassault,A. et al. Ann.Biol.Clin.,44,686,(1986).

	Consult Instructions for Use
	Caution, Consult accompanying
IVD	In Vitro Diagnostic Medical
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

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