

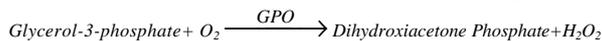
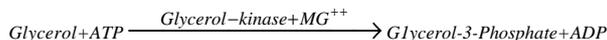
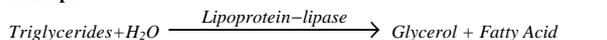
Cat. No.:	46561,46561S	46562,46562S	46563
	120 ml	600 ml	10x30 ml
	(1x80 ml+1x40 ml)	(1x400 ml+1x200 ml)	(10x20 ml+ 10x10 ml)

Reagent kit for the quantitative determination of triglycerides concentration in serum.

Enzymatic colorimetric method (ADPS).

Triglycerides are esters formed from Glycerol and Fatty acids, the latter being synthesized in the liver or extracted from blood. Determining the level of Triglyceride concentration is part of the evaluation of lipid metabolism and plays a major role in identification of the various hyperlipoproteinemia. The level is increased in certain liver and renal diseases in diabetes mellitus and coronary artery disease.

Principle



ADPS= N-Ethyl-N-sulfopropyl-n-anisidine

GPO= Glycerol-3-phosphate oxidase

Reference values

Male: 0.68-1.88 mmol/l (60-165 mg/dl)

Female: 0.46-1.60 mmol/l (40-140 mg/dl)

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

Reagents

1.Reagent (R1):

Pipes buffer, pH=7.00	50 mmol/l
Mg ⁺⁺	15 mmol/l
ADPS	1 mmol/l
ATP	1.5 mmol/l
Lipoprotein lipase	1800 U/l
Glycerol kinase	450 U/l
Glycerol-3-phosphate-Oxidase	1500 U/l
Ascorbate oxidase	≥3000 U/l

2.Reagent (R2)

4-Aminoantipyrine	0.9 mmol/l
Peroxidase	500 U/l

3. Triglycerides standard

Ready for use. For details please check the insert.

Available only in Cat. No.: 46561S and 46562S

Precautions

Discard cloudy reagent. Avoid contamination by using clean laboratory material (pipettes, plastic vials for analyzers, ...).

The reagents contain 0.1 % sodium azide. To avoid the possible build-up of azide compounds, flush waste-pipes with water after the disposal of undiluted reagent.

Sample

Serum free of haemolysis.

PROCEDURE

Preparation and stability of working reagent

•One-reagent procedure

Mix 2 volumes of R1 with 1 volume of R2.
Stability: at 20- 25 °C: 2 weeks
at 2-8 °C: 1 month

•Two-reagent procedure

The reagents are ready for use.

If the absorbance of working reagent is higher than 0.1 at 546 nm the reagent can not be used.

Assay conditions

Wavelength:	546 (520-570) nm
Temperature:	37 °C
Cuvette:	1 cm light path
Read against:	reagent blank
Method:	endpoint (increasing)

•One-reagent procedure

	Blank	Standard	Sample
Working Reagent	1 ml	1 ml	1 ml
Distilled water	10 µl		
Standard		10 µl	
Sample			10 µl

Mix and read the absorbance (A) after a 5-minute incubation.

•Two-reagent procedure

	Blank	Standard	Sample
R1	1 ml	1 ml	1 ml
Distilled water	15 µl		
Standard		15 µl	
Sample			15 µl

Mix and wait 1 minute and add:

R2	500 µl	500 µl	500 µl
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Mix and read the absorbance (A) after a 5-minute incubation.

Calibration (37°C, ADPS/ASOD method)

S1: Distilled water
S2: Triglycerides standard Cat. No.: 51011 or Roche C.F.A.S. (Calibrator for automated system)
Randox Calibration Serum Level I or Randox Calibration Serum Level II

Calibration frequency

Two-point calibration is recommended:

- after reagent lot change,
- as required following quality control procedures.

Calculation using factor

$$\frac{A_{\text{sample}}}{A_{\text{standard}}} \times C_{\text{standard}} = C_{\text{sample}}$$

A = Absorbance, C = Concentration

Quality control

A quality control program is recommended for all clinical laboratories. The analysis of control material in both the normal and abnormal ranges with each assay is recommended for monitoring the performance of the procedure. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

PERFORMANCES DATA

The following data were obtained using the Olympus 600 analyzers (37°C).

Linearity

The test is linear up to 11.4 mmol/l (1000mg/dl) triglycerides concentration.

Sensitivity

It is recommended that each laboratory establishes its own range of sensitivity as this is limited by the sensitivity of the spectrophotometer used. Under manual conditions however, a change of 0.001 Abs is equivalent to 0.009 mmol/l (0,8 mg/dl) triglycerides concentration at 546 nm.

Precision

	Reproducibility		
	Average conc. (mmol/l)	SD	CV%
Sample I.	1.49	0.038	2.52
Sample II.	2.34	0.053	2.28

	Repeatability		
	Average conc. (mmol/l)	SD	CV%
Sample I.	1.17	0.01	0.97
Sample II.	7.61	0.06	0.84

Correlation

Comparative studies were done to compare our reagent with our Triglycerides PAP assay.

The results from these studies are detailed below.

Correlation coefficient: r=0.9994

Linear regression: y (mmol/l)= 0.952x+0.124

(x=Triglycerides PAP assay y= Triglycerides ADPS assay).

Specificity

Bilirubin 855 µmol/l (50 mg/dl), glucose 55.5 mmol/l (1000 mg/dl), and ascorbic acid 0.6 mmol/l (10 mg/dl) don't interfere with the assay up to the given levels.

NOTE

Do not use reagents after the expiry date stated on each reagent container label. Do not use products, test solutions and reagents described above for any purpose other than described herein.

For in vitro diagnostic use only.

The following symbols are used on labels

 For in vitro diagnostic use

 Use by (last day of the month)

 Temperature limitation

 Batch Code

 Code

Bibliography

- Buccolo G., David M., Clin. Chem., 19,476 1973;
- Werner M., Gabrielson D.G., Eastman G., Clin. Chem, 21, 268,1981;
- Annoni G., Bottasso B.M., Ciaci D., Donato M.F., Tripoli A., Iab JJ. Res. Lab. Med. 9 115, 1982;