

TRIGLYCERIDES (S.L)

4x10 mL, 5x25 mL, 6x50 mL, 5x100 mL
11410007, 11410002, 11410008, 11410004

Intended Use

This reagent is intended for *in vitro* quantitative determination of triglycerides in serum or plasma.

- GPO-TOPS methodology
- Linear up to 1000 mg/dL
- Contains LCF (Lipaemic clearing factor) which minimizes rerun.

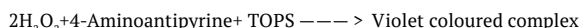
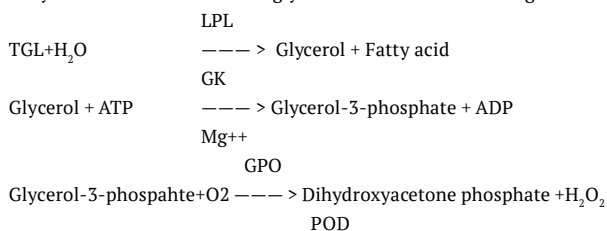
Clinical Significance

Triglycerides are simple lipids, formed in the liver by glycerol & fatty acids. They are transported by VLDL, LDL & constitute about 95% of fat, stored as source of energy in the tissue & plasma.

Increased levels are found in hyperlipidemias, diabetes, nephrotic syndrome & hypothyroidism. Increased levels are risk factor for arteriosclerotic coronary disease, peripheral vascular disease, acute pancreatitis & hyperlipoproteinaemia. Decreased levels are found in malnutrition & hyperthyroidism.

Principle

Enzymatic determination of triglyceride is based on following reactions:



GPO = Glycerol-3-phosphate Oxidase.

LPL = Lipoprotein Lipase

GK = Glycerol Kinase

Kit Components

Reagent/Component	Product code: 11410007	Product code: 11410002	Product code: 11410008	Product code: 11410004	Description
Triglycerides	4x10mL	5x25mL	6x50mL	5x100mL	Pipes-buffer (pH7.00) 5 mmol/L TOPS 5.3 mmol/L Potassium ferrocyanate 10 mmol/L Magnesium Salt 17 mmol/L 4-Aminoantipyrine 0.9 mmol/L ATP 3.15mmol/L Lipoprotein Lipase > 1800 U/L Glycerol Kinase > 450 U/L Glycerol-3-phosphate oxidase > 3500 U/L Peroxidase > 450
Triglycerides Standard	1 x 4 mL	1 x 4 mL	1 x 4 mL	1 x 4 mL	Triglycerides standard concentration 200 mg/dL

Risk & safety

Material Safety data sheets (MSDS) will be provided on request.

Reagent Preparation

Triglycerides Reagent & Standard are ready to use.

Reagent Storage

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2- 8°C and protected from light.

Open Vial Stability

Once opened, the reagent is stable up to 4 weeks at 2- 8°C if contamination is avoided.

On-board Calibration Stability

On-board Calibration stability is 20 days

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualichex Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using a fresh vial of reagent.

Precaution

To avoid contamination, use clean laboratory wares. Use clean, dry disposable pipette tips for dispensing. Close reagent bottles immediately after use.

Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management

Reagents must be disposed off in accordance with local regulations.

Sample

Serum / plasma (free of haemolysis).

Interferences

No interference for

Bilirubin up to 20 mg/dL

Haemoglobin up to 1000 mg/dL

Materials Provided

Triglycerides Reagent & Standard.

Materials required but not provided

- Pipettes & Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Parameters

Mode of Reaction	End Point
Slope of reaction	Increasing
Wavelength I	546 nm (540-560 nm)
Wavelength II	630 nm
Temperature	37°C
Standard Concentration	200 mg/dL
Linearity	1000 mg/dL
Blank	Reagent
Incubation time	5 min
Sample volume	10 µL
Reagent volume	1000 µL
Cuvette	1 cm light path

Application parameters for various instrument are available. Please contact customer support department for specific information.

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
mg/dL	mmol/L	x 0.0114

Calibration

Agappe multicalibrator is recommended for Calibration of this assay on fully auto analyzers.

Use provided Triglycerides standard for calibration of this assay on Semi auto analyzer.

Procedure notes

Laboratory procedure for Semi Auto Analyzer.			
	Blank	Standard	Sample
Reagent	1000 µL	1000 µL	1000 µL
Standard	-	10 µL	-
Sample	-	-	10 µL
Mix and incubate for 5 minutes at 37°C. Measure the change in absorbance of standard and sample against reagent blank.			

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE SEE PACKAGE INSERT FOR PROCEDURE LOT LOT NUMBER MANUFACTURER'S ADDRESS MANUFACTURING DATE EXPIRY DATE TEMPERATURE LIMIT



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REV.NO.: ADL/IFU/TGL/LIQ/R02

CE ISO 9001 : 2015
EN ISO 13485: 2016

Calculation

$$\text{Triglycerides Con. (mg/dL)} = \frac{\text{Absorbance of Sample}}{\text{Absorbance of Standard}} \times 200$$

Quality control

It is recommended to use Agappe Qualichek Norm & Path (11601001) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range

It is recommended that each laboratory establish its own reference values.

The following value may be used as guide line.

Male : 60 - 165 mg/dL

Female : 40 - 140 mg/dL

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance**1. Linearity**

This reagent is linear up to 1000 mg/dL.

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.

2. Comparison

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of $r^2 = 0.9932$ and a regression equation of $y = 0.965x$.

3. Precision

Intra Run		
	Control Level 1	Control Level 2
n	20	20
Mean (mg/dL)	184.8	85.1
SD	4.03	2.19
CV(%)	2.18	2.57

Inter Run		
	Control Level 1	Control Level 2
n	20	20
Mean (mg/dL)	184.65	84.56
SD	3.48	2.10
CV(%)	1.89	2.48

Accuracy (mg/dL)		
Control	Expected Value	Measured Value
Control Level 1	185 ± 42	189.5
Control Level 2	75 ± 10	79.2
Qualichek Norm	110 ± 12	109.6
Qualichek Path	210 ± 35	209.4

4. Sensitivity

Lower detection Limit is 2 mg/dL.

Bibliography

- Schettler, G., Nussel, E.; Arav. Med 10, 25 (1975)
- Jacobs, N.J., VanDemark, P.J.; Arch. Biochem, Biophy. 88, 250 – 255 (1960)

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