LiquiCHEK™

AGAPPE

# 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:

$$\text{TGL} + H_2O \xrightarrow{\text{LPL}} \text{Glycerol} + \text{Fatty acid}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow[Mg^{++}]{\text{GK}} \text{Glycerol-3-phosphate} + \text{ADP}$$

$$\text{Glycerol-3-phospahte} + O2 \xrightarrow{\text{GPO}} \text{Dihydroxyacetone phosphate} + H_2O_2$$

$$2H_2O_2 + \text{4-Aminoantipyrine} + \text{TOPS} \xrightarrow{\text{POD}} \text{Violet coloured complex}$$

GPO = Glycereol-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 ferrocynate 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 Qualichek 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 ISO13485: 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 Qualicheck 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

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

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