

6 x 50 mL •  A-R0100000901

 3 x 18,5 mL •  R3330000025

INTENDED USE

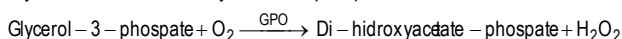
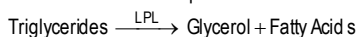
Product for use in the quantitative determination in vitro of the Triglycerides concentration in human serum or plasma. The results of the test must always be interpreted in conjunction with the clinical context. For professional use only.

INTRODUCTION

Triglycerides constitute 95% of the lipids reserve in the human organism and the predominant form of glycerol esters present in the plasma. Thanks to the action of lipases and biliary salts, triglycerides are hydrolyzed into glycerol and fatty acids, and transported in the plasma by the apolipoproteins. The lipoproteins with the highest percentage of triglycerides are the chylomicrons and the very low-density lipoproteins (VLDL). The combination of an increase in LDL Cholesterol and triglycerides is an aggravating factor in the risk of coronary disease. Hypertriglyceridemia is a common disease in adults and is associated with diseases such as diabetes mellitus, insulin-resistance or obesity. Secondary hypertriglyceridemia on the other hand is associated with much more serious conditions such as liver and renal disease, hyperthyroidism and pancreatitis.

PRINCIPLE (1,2)

Glycerol released by the hydrolysis of triglycerides with lipoprotein-lipase (LPL), is transformed by glycerol-chinase (GK) to glycerol-3-phosphate which in turn is oxidised by glycerol-phosphate-oxidase (GPO) to di-hydroxyacetone-phosphate with the formation of hydrogen peroxide; this, in turn, in the presence of peroxidase (POD), reacts with ethyl-sulfo-propyl-toluidine (ESPT) and 4-aminophenazone, giving rise to a coloured compound, the intensity of which is directly proportional to the triglyceride concentration in the sample.



REAGENTS

A-R0100000901 - 6 x 50 mL

Reagent: n° 6 vials x 50,0 mL ready to use

R3330000025 - 3 x 18,5 mL

Reagent: n° 3 vials x 14,0 mL ready to use

Concentrations

| Reagent: | Conc. | U.M. |
|-------------------------------------|-------|------|
| PIPES buffer (pH 6.7) | 20.0 | mM |
| Adenosine-triphosphate (ATP) | 1.00 | mM |
| Lipoprotein-lipase (LPL) | 350 | KU/L |
| Magnesium ions | 0.60 | mM |
| Glycerol-chinase (GK) | 40.0 | U/L |
| Glycerol-3-phosphate-oxidase (GPO) | 4000 | U/L |
| Sodium Azide (NaN ₃) | 14.6 | mM |
| Ethyl-sulfo-propyl-toluidine (ESPT) | 2.00 | mM |
| 4-Aminophenazone | 0.80 | mM |
| Peroxidase (POD) | 800 | U/L |

Precautions

Kit for professional laboratory use, used only by qualified and properly trained technical personnel, under the supervision of a doctor in charge of the laboratory. In addition to risk indications related to the active components, reagents may contain inactive components such as preservatives and detergents. The total concentration of these components is lower than the limits reported in the EC 1272/2008 Regulation and subsequent amendments and additions. However, it is recommended to handle reagents according to the standards of good laboratory practice

Reports of serious incidents

In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

Storage and stability

Store at 2 - 8°C and protect from direct light. When correctly stored, the reagents are stable up to the expiry date reported on the label. A slight variation in the composition of

the reagents may occur between batches, but this has no effect on the test results. After opening, the vials are stable 30 days if recapped immediately and protected from contamination, evaporation, direct light and stored at correct temperature.

Reagent Preparation

Store at 2 - 8 ° C and protect from direct light. If properly stored, the reagents are stable until the expiry date indicated on the label. A slight variation in the composition of the reagents may occur between batches, but this has no effect on the test results.

SAMPLE COLLECTION

Type of sample and storage

Serum or plasma samples collected with EDTA or heparin should be used. Samples can be stored for 7 days at 4 - 8°C or 3 months at - 20°C.

Precautions

All human samples must be handled and disposed of as potentially infectious materials.

Procedure

Quality control

Human control sera with known levels of Triglycerides are commercially available for quality control, including certificates of analysis showing the values and limits of confidence. Normal and pathological control sera "Normal control serum" cod. R040000006 and "Pathological control serum" code R040000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:

- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation

Although this device has been developed and manufactured to be used by manual method and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique".

All applications that are not explicitly approved cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user.

Calibration

For calibration use the "Multicalibrator" code R030000006. For the use on ISE srl Instruments, the calibration is recommended to be done every 10 days.

Traceability:

The Triglycerides traceability is reported on the package insert supplied with the "Multicalibrator".

Reaction conditions

Wavelength (primary): 550 nm
Temperature: 37°C

Technique

Bring the reagents to the reaction temperature and operate away from direct light

| Reagent | U.M. | Calib. Serum | Sample | Blanck |
|--------------|------|--------------|--------|--------|
| | µL | 1000 | 1000 | 1000 |
| Calib. Serum | µL | 10 | - | - |
| Sample | µL | - | 10 | - |
| Blanck | µL | - | - | 10 |

Mix gently then incubate at 37°C for 10 minutes. Read the absorbances of the sample and the calibrator, subtracting the absorbance of the reagent blank.

The reaction volumes can be varied proportionally while the calculation remains unchanged.

Results:

Manual Method

Calculation of Triglycerides concentration:

$$\frac{\text{O.D. Sample}}{\text{O.D. Calibrator Serum}} \times \text{Concentr. Calibrator serum} = \text{Triglycerides mg/dL}$$

NORMAL VALUES

Serum or plasma.

Male and Female:

- Normal values: < 150 mg/dL (< 1.7 mmol/L)
- Borderline values: 150 - 199 mg/dL (1.7 - 2.25 mmol/L)
- High values: 200 - 499 mg/dL (2.26 - 5.64 mmol/L)



Triglycerides – Instructions for use (IFU)

Distributed by:



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Each laboratory must establish its own normal values on the basis of its local population.

Reagents included in the kit

The reagent is described above.

Materials required but not supplied in the kit

Controls and calibrators.

ANALYTICAL CHARACTERISTICS/PERFORMANCE

Linearity

The reaction is linear up to 1200 mg/dL.

Specificity

The method is specific for the determination of Triglycerides, in the test conditions reported.

Accuracy – Recovery

The recovery from normal samples to which known Triglycerides concentrations had been added, showed an accuracy of 97.5%.

Interferences

The high dilution of the sample with the reagent reduces to a minimum possible interference by lipids. Bilirubin below 30 mg/dL does not interfere in the reaction. Hemoglobin influences the reaction at concentrations over 500 mg/dL. For other interfering substances, make reference to the bibliography reported below.

Precision of the method

| Within-run precision | | | | | |
|-----------------------|-------|-------|-------|----------|-----|
| Range | U.M. | Mean | S.D. | C.V. (%) | No. |
| Low | mg/dL | 94.55 | 4.615 | 4.88% | 20 |
| High | mg/dL | 204.7 | 6.648 | 3.25% | 20 |
| Between-run precision | | | | | |
| Range | U.M. | Mean | S.D. | C.V. (%) | No. |
| Low | mg/dL | 94.55 | 2.537 | 2.68% | 20 |
| High | mg/dL | 204.7 | 6.524 | 3.19% | 20 |

Sensitivity

At λ 546 nm, a concentration of about 4.25 mg/dL of Triglycerides in the conditions established for this test.

Comparative method

The Triglycerides method was compared with a similar commercial method. Samples tested = No.71; $Y = 1.0653x - 5.76$; Correlation Coefficient $r = 0.9902$.

Disposal of reagents

Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

Manufacturer:

Sclavo Diagnostics International

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Distributor:

I.S.E S.r.l.

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Symbols used in IFU and Packaging

| | |
|--|------------------------|
| In vitro diagnostic medical device vitro | Manufacturer |
| Catalogue Number | Instruction for use |
| Lot Number | Temperature limitation |
| Expiration date | |

Reference

1. Butris CA and Ashwood ER (Ed.), Tietz Fundamentals of Clinical Chemistry, 5th Edition, W.B. Saunders Company, Philadelphia, 2001, p. 473 - 474.
2. Thomas L. (ed.), Clinical laboratory Results, 1st Edition, TH-Books Verlag Gesellschaft mBH, Frankfurt/Main, Germany, 1998, pp. 169 - 170.
3. Guder WG, Narayanan S., Wisser H., Zavata B. List of analytes; preanalytical variables. Brochure in: Samples: from patient to the laboratory. Git Verlag GmbH, Darmstad, 1996.
4. Young D, Effects of drugs on clinical laboratory tests. 5th Edition, AACC Press, Washington, DC, 3-781 – 3-801.
5. Third Report of the National Cholesterol education Program (NCEP) Expert Panel on Detection, Evaluation and treatment of high blood cholesterol in adults (ATP III). NIH Publication no. 02 - 5215, 2002.

| REVISION | DATE | CHANGE |
|----------|---------|--|
| Rev.A | 12/2022 | New Issue for IVDR Regulation (UE) 2017/746 compliance |

