Triglycerides – Instructions for use (IFU)

Manufactured exclusively for: ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

6 x 50 mL • REF A-R0100000901

3 x 14 mL • REF R3330000025

IVD CE

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 chilomicrons 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

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 oxidased 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-sulfopropyl-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.

$$\text{Triglycerides} \xrightarrow{\text{LPL}} \text{Glycerol} + \text{Fatty Acid s}$$

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

$$\text{Glycerol} - 3 - \text{phospate} + O_2 \xrightarrow{\text{GPO}} \text{Di} - \text{hidroxyacetate} - \text{phospate} + H_2O_2$$

$$2H_2O_2 + 4 - \text{aminophenazone} + \text{ESPT} \xrightarrow{\text{POD}} \text{Coloured compound}$$

REAGENTS

A-R0100000901 - 6 x 50 mL

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

R3330000025 - 3 x 14 mL

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

Concentrations

Reagent:		
	Conc.	**U.M.**
PIPES buffer (pH 6.7)	20.0	mM
Adenosine-triphosfate (ATP)	1.00	mM
Lipoprotein-lipase (LPL)	350	KU/L
Magnesium ions	0.60	mM
Glicerol-chinase (GK)	40.0	U/L
Glycerol-3 phosphate-oxidase (GPO)	4000	U/L
Sodium Azide (NaN3)	14.6	mM
Ethyl-sulfopropyl-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. R0400000006 and "Pathological control serum" code R0400000106. 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 R0300000006. 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

	U.M.	**Calib. Serum**	**Sample**	**Blanck**
Reagent	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)

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

Sclavo Diagnostics International S.p.A
Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
Phone +39 0577 39041 - Fax +39 0577 390 444

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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
Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
Phone +39 0577 39041 - Fax +39 0577 390 444

Distributor:
I.S.E S.r.l.
Via Delle Driadi, 45 – 00133 Roma
Tel.+39 077 4579365; FAX +39 077 4579305
E-mail: info@logotech-ise.com
www.logotech-ise.com

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT 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 Gesellaschaft 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.C	01/2024	Edit header and “Reagents” paragraph.