TRIGLYCERIDES liquid

Trinder method - Endpoint

4 x 50 ml **CL53-200S**
4 x 100 ml **CL53-400S**

INTENDED USE

Kit for quantitative determination of Triglycerides in serum and plasma according to Trinder reaction.

CLINICAL MEANING

Triglycerides (TG) are the product of esterification of glycerol with fatty acids. After being ingested with food, they are hydrolyzed in the intestine by pancreatic and duodenal lipase in emulsion with biliar acids, absorbed as glycerol and fatty acids and then re-synthesized in TG and vehiculated as chylomicrons through intestinal lymph by which they get the typical chylous aspect. Through venous circle they reach the liver and the adipose tissue where they represent 95% of reserve deposits.
TG increase after meals, with stress, smoke and alcohol consumption. Pathological conditions that can be associated to hypertriglyceridemia are: hyperlipidemia, diabetes, renal insufficiency, obstructive jaundice, pancreatitis, metabolic syndrome and myocardial infarction.

PRINCIPLE

Glycerol, released by triglycerides after hydrolysis with lipoprotein-lipase (LPL), is transformed by glycerol-kinase (GK) into glycerol-3-phosphate which is oxidized by glycerol-phosphate-oxidase (GPO) into de-hydroxyacetone phosphate, with formation of hydrogen peroxide. In presence of peroxidase (POD), hydrogen peroxide reacts with ethyl-sulphopropyl-toluidine (ESPT) and 4-aminophenazone to form a colored complex, whose color intensity is directly proportional to triglycerides concentration in the sample.

SAMPLE

Serum, plasma. Separate blood cells by centrifuge, within 2 hours from the collection. Freeze the sample if it is not used within 24 hours.

REAGENTS

Only for in Vitro diagnostic use. Liquid monoreagent ready to use.

Package contents	**CL53-200**	**CL53-400**
REAGENT 1 Pipes buffer (pH 6,7) 20 mmol/L, ESPT 2 mmo/L, ATP 1 mmol/L, magnesium ions 0,6 mmol/L, 4-aminophenazone 0,8 mmol/L, LPL 350 KU/L, GK 40 U/L, GPO 4000 U/L, POD 800 U/L, sodium azide 15 mmol/L	**4 x 50 ml**	**4 x 100 ml**
STANDARD (Std) Glycerol, equivalent to 200 mg/dl (2,26 mmol/L) of triglycerides, detergent, sodium azide 15 mmol/L	**4 ml**	**4 ml**

Stability: reagents are ready to use. Store at 2-8°C and protect from light to keep the reagents stable up to the expiration date on the label. Do not freeze. Once opened the reagents are stable for 2 months at 2-8°C if contamination is avoided. Keep bottles closed when not in use. Do not use turbid reagents.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

MANUAL ASSAY PROCEDURE

Method:	increasing endpoint
Wavelength:	550 nm (540 - 560)
Optical path:	1 cm
Temperature:	37°C
Reaction Time:	10 minutes
Reading:	against blank reagent
Sample/Reagent:	1/100

Let the reagent reach the chosen temperature for the analysis.

Pipette in cuvette:

	Blank Reagent	Standard	Sample
Distilled water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl
Reagent 1	1,0 ml	1,0 ml	1,0 ml

Mix. Incubate for 10 minutes at 37°C. Then read the absorbance of the standard (AbsStd) and the sample (AbsS) against the blank reagent.

Reaction volumes can be proportionally varied without any change in calculation.

CALCULATION

Calculate the concentration in the sample using the following formula:

[mg/dl] triglycerides = AbsS / AbsStd x 200

[mmol/L] triglycerides = AbsS / AbsStd x 2,26

REFERENCE VALUES

Serum / plasma:

male	40 ÷ 240 mg/dl (0,45 ÷ 2,7 mmol/L)
female	30 ÷ 190 mg/dl (0,34 ÷ 2,15 mmol/L)

Each laboratory should define its own reference values for this method.

QUALITY CONTROL – CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:
PRE-NORM serums with normal values
PRE-PATH serums with pathological values
If the method requires it, a multi-parameter calibrator of human origin is available.

PERFORMANCE CHARACTERISTICS

Sensitivity
The sensitivity of the method is 3 mg/dl.

Linearity up to 1000 mg/dl.
For higher values, dilute the sample 1:10 with saline solution and multiply the result by 10.

Precision

Within run (n=10)	Average [mg/dl]	SD	CV %
Sample 1	125,6	3,6	2,9
Sample 2	199,2	6,1	3,1

Between run (n=20)	Average [mg/dl]	SD	CV %
Sample 1	121,1	4,5	3,7
Sample 2	199,9	7,0	3,5

Interferences: up to 30 mg/dl of bilirubin does not interfere. Up to 500 mg/dl of hemoglobin does not interfere.

Correlation against a reference method: the correlation of the method (Y) against a reference method (X) gives this equation:

Y = 1,0861X - 3,1742 r = 0,9996

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The reagents may contain non-reactive components and various preservatives. Contact with the skin and ingestion should be avoided. Use the normal precautions expected with correct behaviour in laboratory.

REFERENCES

1. Bucolo G., David M. “Clin Chem” 19, 476 (1973)
2. Werner M., Gabrielson D.G., Eastman G. “Clin Chem” 27.,268 (1981)
3. Kaplan LA, Pesce AJ: “Clinical Chemistry”, Mosby Ed. 1989
4. NCCLS Document, “Procedures for the collection of arterial blood specimens”, Approved Standard, 3rd Ed. (1999).
5. EU-Dir 1999/11 Commission Directive of 8 March 1999 adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC

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KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

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