TRIGLYCERIDES

COD 12528 10 x 50 mL
Only for *in vitro* use in the clinical laboratory

Automated Systems

BioSystems

TRIGLYCERIDES

GLYCEROL PHOSPHATE OXIDASE/PEROXIDASE

INTENDED USE

Reagent for the measurement of triglycerides concentration in human serum or plasma. The obtained values are useful as an aid in the diagnosis and classification and dyslipidemia.

This reagent is for use in the BioSystems A25 and A15 analyzers or in other analyzer with similar performance characteristics.

CLINICAL SIGNIFICANCE

Triglycerides are esters of glycerol and fatty acids coming from the diet or obtained by synthesis mainly in the liver. Triglycerides are transported in plasma by lipoproteins and used by adipose tissue, muscle and other. Their primary function is to provide energy to the cell.

Elevated serum triglycerides levels can be caused by liver disease, diabetes mellitus, nephrosis, hypothyroididsm, alcoholism, familial hyperlipoproteinemia IV and V, and other[1,2].

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Triglycerides in the sample originates, by means of the coupled reactions described below, a coloured complex that can be measured by spectrophotometry[3,4].

$$\text{Triglycerides} + H_2O \xrightarrow{\text{lipase}} \text{Glycerol} + \text{Fatty acids}$$

$$\text{Glycerol} + ATP \xrightarrow{\text{glycerol kinase}} \text{Glycerol} - 3 - P + ADP$$

$$\text{Glycerol} - 3 - P + O_2 \xrightarrow{\text{G-3-P-oxidase}} \text{Dihydroxyacetone} - P + H_2O_2$$

$$2\,H_2O_2 + 4 - \text{Aminoantipyrine} + 4 - \text{Chlorophenol} \xrightarrow{\text{peroxidase}} \text{Quinoneimine} + 4\,H_2O$$

CONTENTS AND COMPOSITION

A. Reagent: 10 x 50 mL. Pipes 45 mmol/L, magnesium acetate 5 mmol/L, 4-chlorophenol 6 mmol/L, lipase > 100 U/mL, glycerol kinase > 1.5 U/mL, glycerol-3-phosphate oxidase > 4 U/mL, peroxidase > 0.8 U/mL,4-aminoantipyrine 0.75 mmol/L, ATP 0.9 mmol/L, pH 7.0.

STORAGE AND STABILITY

Store at 2-8ºC.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

On board stability: Reagents open and kept in the refrigerated compartment of the analyzer are stable 2 months.

Indications of deterioration: Absorbance of the blank over the limit indicated in "Test Parameters".

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

REAGENT PREPARATION

Reagent is provided ready to use.

SAMPLES

Serum or plasma collected by standard procedures.

Triglycerides in serum or plasma are stable for 5 days at 2-8ºC. Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

CALIBRATION

A reagent blank should be done every day and a calibration at least every 2 months, after reagent lot change or as required by quality control procedures.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, 18009 and 18042) and II (cod. 18007. 18010 and 18043) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

REFERENCE VALUES

The following uniform cut-off points have been established by the US National Institutes of Health and have also been adopted in many other countries for the evaluation of risk[1].

Up to 150 mg/dL = 1.7 mmol/L	Normal
150-199 mg/dL = 1.70-2.25 mmol/L	Borderline-high
200-499 mg/dL = 2.26-5.64 mmol/L	High
> 500 mg/dL = > 5.65 mmol/L	Very high

METROLOGICAL CHARACTERISTICS

The metrological characteristics described below have been obtained using an A25 analyzer. Results are similar with A15.

- Detection limit: 4.4 mg/dL = 0.05 mmol/L.
- Linearity limit: 600 mg/dL = 6.78 mmol/L.
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
44 mg/dL = 0.50 mmol/L	2.8 %	2.9 %
207 mg/dL = 2.34 mmol/L	1.6 %	2.7 %

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

- Interferences: Hemolysis (hemoglobin up to 1000 mg/dL), bilirubin (up to 2.5 mg/dL) do not interfere. Ascorbic acid (up to 5 mg/dL) does not interfere. Other drugs and substances may interfere[5].

BIBLIOGRAPHY

1. National Cholesterol Educarion Program Expert Panel. 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. Bethesda: National Heart, Lung, and Blood Institute; 2001.
2. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.
3. Bucolo G and David H. Quantitative determination of serum triglycerides by use of enzymes. *Clin Chem* 1973; 19: 476-482.
4. Fossati P and Prencipe L. Serum triglycerides determined colorimetrically with an enzyme that produces hydrogen peroxide. *Clin Chem* 1982; 28: 2077-2080.
5. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

TEST PARAMETERS

These reagents may be used in several automatic analyzers. Specific instructions for application in many of them are available on request.

R1: use Reagent A.

	A25	A15
GENERAL		
Name	**TRIGLYCERIDES**	**TRIGLYCERIDES**
Sample type	SER	SER
Analysis mode	endpoint mon.	endpoint mon.
Units	mg/dL	mg/dL
Turbidimetry test	no	No
Decimals	0	0
Type of reaction	increasing	increasing
PROCEDURE		
Reading mode	bichrom.	bichrom.
Main filter	505	505
Reference filter	670	670
Sample	3	3
Vol. R1	300	300
Vol. R2	-	-
Washing	1.2	1.2
Reading 1 (cycle)	21	14
Reading 2 (cycle)	-	-
Reagent 2 (cycle)	-	-
Predilution factor	-	-
CALIBRATION AND BLANK		
Calibration type	multiple	multiple
Number of calibrators	-	-
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.150	0.150
Kinetic blank limit	-	-
Linearity limit	600	600
Substrate depletion	-	-

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