

TRIGLYCERIDES

Enzymatic and colorimetric determination of Triglycerides in serum and plasma

TEST SUMMARY

are hydrolized presence lipoproteinlipase, into fatty acids and glycerol. Glycerol is being phosphorated to glycerol -3phosphate by means of glycerol kinase and ATP and the product of phosphorated, again transformed in didroxyacetonphosphate and peroxide of hydrogen from glycerol-3-phosphate oxidase. Peroxide of hydrogen, in presence of preoxidase, reacts with 4aminoantipyrine and p-chlorophenol, to form a red compound which intensity is proportional to the triglycerides concentration present in the sample.

SAMPLES

Samples should be obtained from patients keep in fast at least from 10-14 hours.

Use in serum or plasma.

With EDTA plasma, the obtained value has to be converted multiplying this value by 1.03, find for serum the equivalent value.

Stability: 3 days at 4°C or 2 weeks at -20°C.

Lipemic samples may require after defrost, warming at 37°C, and then a vigorous mixing.

REAGENTS

Sole reagent: Good's buffer pH 7.20 50 mM, ATP 2 mM, GK > 1000 U/L, POD > 1000 U/L, LPL > 2000 U/L, GPO > 5000 U/L, 4-clorophenol 2.7 mM, 4-AAP 0.3 mM, tensioattivi.

Standard: Triglycerides 200 mg/dl.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solutions.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow. Perform the test according to the general "Good Laboratory Practice" (GPL) guidelines.

REAGENTS PREPARATION

Reagents are supplied in liquid form ready to use. Stability: until expiration date on label, stored at 2-8°C avoiding exposure to strong light sources. Stability after first opening: ≥ 60 days at 2-8°C.

Reagent is slightly photosensitive.

Avoid prolungate exposure to strong light source.

PROCEDURE

Kind of analysis: Final point Reading time: 5 minutes 510 nm (480 - 520) Wavelenght: Temperature: 37°C

Lightpath 1 cm Zero: Blank Reagent

Reagents	Blank	Standard	Sample
Distilled water	10 μl		
Standard		10 μl	
Sample			10 μl
Sole reagent	1 ml	1 ml	1 ml

CALCULATION

Serum/Plasma Triglycerides (mg/dl)

(A sample/A standard) x 200

EXPECTED VALUES

Desirable < 200 mg/dl (2.26 mmol/l)

Each laboratory should establish appropriate reference intervals related to its population.

NOTE

- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.
- Only for IVD use.

CALIBRATION/QUALITY CONTROL

It is suggested to perform an internal quality control. For this purpose the following control sera on human base are available on request:

QN 0050 CH 10 x 5 ml

Control Sera normal values

QP 0050 CH 10 x 5 ml

Control Sera pathological values

TEST PERFORMANCE

Precision

Intra-assay (n = 30)	Mean (mg/dl)	SD (mg/dl)	CV%
Sample 1	188.3	0.7022	0.37
Sample 2	63.26	0.6396	1.01

Inter-assay (n = 30)	Mean (mg/dl)	SD (mg/dl)	CV%
Sample 1	188.4	0.9684	0.51
Sample 2	63.23	0.7279	1.15

Sensibility/limit of detection

The method is able to discriminate until 1 mg/dl.

The method is linear up to 1000 mg/dl.

If the values is exceeded, it is suggested to dilute the sample 1+9 with saline and to repeat the test, multiplying the results by 10.

Method comparison

A comparison with a commercial available product gave the following results in a comparison on 31

Triglycerides LTA = x Triglycerides competitor = y n = 31

y = 0.99598x - 098743r = 0.9988

Interferences

No interference was observed by the presence of: hemoglobin ≤ 500 mg/dl bilirubin ≤ 18 mg/dl

WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE CC02200 (400 TESTS) Sole reagent 4 x 100 ml (liquid) Standard 1 x 5 ml (liquid)

REFERENCES

Trinder P. - J. Clin. Path. 22, 158 (1969) Brucolo G., David M. - Clin. Chem. 19,476 (1973). McGowan M.W., Artiss J.D., Standbergh D.R., Zak B. Clin.Chem. 29, 538 (1983).

Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).

MANUFACTURER

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SYMBOLS

IVD Only for IVD use

LOT Lot of manufacturing

REF Code number

X Storage temperature interval

Expiration date (year, month)

 \triangle Warning, read enclosed documents

 $|\mathbf{i}|$ Read the directions

Biological risk

Mod. 01.06 (ver. 4.6 - 12/02/2009)

