Cat. No 4-553

DIAGNOSTIC KIT FOR DETERMINATION OF TRIGLYCERIDES CONCENTRATION

HC – TG

INTRODUCTION

Triglycerides are built of glycerol molecule esterified with three fatty acids molecules. Triglycerides are delivered with food or are synthesized endogenously in liver. Triglycerides stored in adipose tissue constitute a reserve of energy. Elevated triglycerides serum level is a risk factor of atherosclerosis. Triglycerides measurement is useful for hyperlipidemia diagnosis and treatment or for estimation of atherosclerosis progression.

METHOD PRINCIPLE

Colorimetric, enzymatic method with glycerophosphate oxidase.

$$\text{triglycerides} + H_2O \xrightarrow{LPL} \text{glycerol} + \text{fatty acids}$$

$$\text{glycerol} + ATP \xrightarrow{GK} \text{glycerol-3-phosphate} + ADP$$

$$\text{glycerol-3-phosphate} + O_2 \xrightarrow{GPO} \text{dihydroxy-acetone-phosphate} + 2H_2O_2$$

$$2H_2O_2 + \text{4-AA} + ADPS \xrightarrow{POD} \text{quinoneimine dye} + 4H_2O$$

The colour intensity is proportional to the triglycerides concentration.

REAGENTS

Package

1-Reagent	6 x 74 ml
2-Reagent	6 x 19 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

buffer PIPES (pH 7.0)	40 mmol/l
4-aminoantipyrine (4-AA)	0.4 mmol/l
ATP	1.5 mmol/l
Mg^{2+}	1.6 mmol/l
ADPS	0.6 mmol/l
glycerol kinase (GK)	> 66.67 µkat/l
glycerol-3-phosphate oxidase (GPO)	> 60.00 µkat/l
peroxidase (POD)	> 20.00 µkat/l
lipoprotein lipase (LPL)	> 16.67 µkat/l

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum, EDTA or heparinized plasma (recommended: heparine lithium, sodium or ammonium salt) free from hemolysis.
Blood should be collected only if the patient has been fasting for minimum of 12 hours. Before blood collection patient should stay in rest position for about 30 minutes.
Plasma triglycerides values have been reported to be 2% to 4% lower than serum triglycerides values.
Serum and plasma can be stored up to 3 days at 2-8ºC or 3 months at -20ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagents are ready to use.
These reagents may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [7]

serum, plasma	< 150 mg/dl < 1.7 mmol/l

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.
The calibration curve should be prepared every 12 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 12.8 mg/dl (0.15 mmol/l).

- **Linearity:** up to 1600 mg/dl (18.08 mmol/l).
  For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 2.5 g/dl, bilirubin up to 20 mg/dl and ascorbate up to 62 mg/l do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	94.78	0.48	0.51
level 2	176.25	1.45	0.82

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	89.57	1.02	1.14
level 2	167.38	1.48	0.88

- **Method comparison**

A comparison between triglycerides values determined at Hitachi 912 (y) and at Cobas Integra 400 (x) using 133 samples gave following results:
y = 1.0186 x + 1.9792 mg/dl;
R = 0.9982 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Jacobs N.J., Van Denmark P.: J. Arch. Biochem. Biophys. 88, 250-255 (1960).
2. Kodischek L.K., Umbreit W.W.: J. Bacteriol. 98, 1063-1068 (1969).
3. Trinder P.: Ann. Clin. Biochem. 6, 24-27 (1969).
4. Schettler G., Nussel E.: Arb. Med. Soz. Med. Prav. Med. 10, 25 (1975).
5. Tietz N.W., ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders, 610, (1995).
6. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia, PA: WB Saunders, 2209, (1994).
7. Alan H.B. Wu. erditor. Tietz Clinical Guide to Laboratory Tests, 4th ed. St. Louis: W.B Saunders Company; 2006, p.1074.

Date of issue: 02. 2012.

MANUFACTURER

PZ CORMAY S.A.
ul. Wiosenna 22,
05-092 Łomianki, POLAND
tel.: +48 (0) 22 751 79 10
fax: +48 (0) 22 751 79 14
http://www.pzcormay.pl

02/12/02/12