

DIAGNOSTIC KIT FOR DETERMINATION OF TRIGLYCERIDES CONCENTRATION

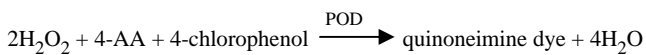
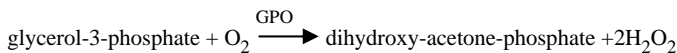
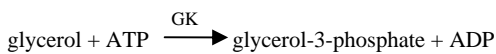
HC – TG mono

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.



The colour intensity is proportional to the triglycerides concentration.

REAGENTS

Package

1-Reagent 6 x 91 ml

The reagent when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 11 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

buffer TRIS (PH 8.0)	200 mmol/l
4-aminopyridine (4-AA)	< 0.4 mmol/l
ATP	< 1.5 mmol/l
Mg ²⁺	< 1.6 mmol/l
4-chlorophenol	< 2.5 mmol/l
chlorophenicol	1.6 mmol/l
potassium hexacyanoferrate (II)	< 1 mmol/l
FAD-2Na	< 1 mmol/l
glycerol kinase (GK)	~ 2500 U/l
glycerol phosphate oxidase (GPO)	~ 2500 U/l
peroxidase (POD)	~ 1900 U/l
lipoprotein lipase (LPL)	~ 2000 U/l
detergents, preservatives	

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents should be used by suitably qualified laboratory personnel only in accordance with intended purpose.
- The reagents contain < 0.1% sodium azide 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. Venous blood is recommended for triglycerides measurement.

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 2-8°C or up to 3 months at -20°C.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagent is ready to use.

This reagent 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) is recommended.

Calibrator and 0.9% NaCl should be used for calibration.

The calibration curve should be prepared every 11 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 an automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 6.46 mg/dl (0.073 mmol/l).
- **Linearity:** up to 1750 mg/dl (19.78 mmol/l).
For higher triglycerides concentrations dilute the sample with 0.9% NaCl in the ratio of 1 to 4 and repeat the assay. Multiply the result by 5.
- **Specificity / Interferences**
Haemoglobin up to 0.31 g/dl, bilirubin up to 8.6 mg/dl and ascorbate up to 31 mg/l do not interfere with the test.

▪ **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	84.81	0.63	0.74
level 2	180.78	0.92	0.51

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	92.90	1.53	1.65
level 2	171.35	2.40	1.40

▪ **Method comparison**

A comparison between triglycerides values determined on Hitachi 912 (y) and on COBAS INTEGRA 400 (x) using 85 samples gave following results:

$$y = 1.0177 x + 1.2443 \text{ mg/dl};$$

$$R = 0.9992 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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