

DIAGNOSTIC KIT FOR DETERMINATION OF TRIGLYCERIDES CONCENTRATION



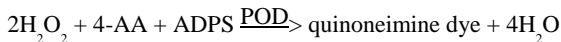
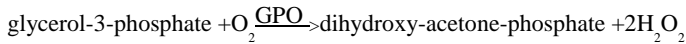
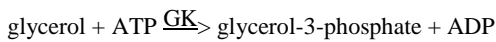
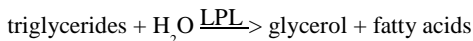
OS – TG

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.



The colour intensity is proportional to the triglycerides concentration.

REAGENTS

Package

1-Reagent	2 x 56 ml
2-Reagent	2 x 21 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 < 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 should be separated from red blood cells as soon as possible after blood collection.

Serum and plasma can be stored up to 3 days at 2-8°C or 3 months at -20°C. Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analysers Olympus AU400/AU640.

1-Reagent and 2-Reagent are ready to use.

For reagent blank 0.9% NaCl is recommended.

APPLICATION

Reagent ID: 018

Specific Test Parameters									
General		LIH	ISE	Range					
Test name: TG						Type: Serum	Operation: Yes		
Sample: Volume	2 µL	Dilution	0 µL	Pre-Dilution Rate:	1	Min OD		Max OD	
Reagents: R1 Volume	100 µL	Dilution	50 µL			L	-2.0000	H	2.5000
R2 Volume	30 µL	Dilution	0 µL			L	-2.0000	H	2.5000
Wavelength: Pri. 540 Sec. 800						Reagent OD Limit:			
Method: END						First L	-2.0000	First H	2.5000
Reaction Slope: +						Last L	-2.0000	Last H	2.5000
Measuring Point 1: First 0 Last 27						Dynamic Range:			
Measuring Point 2: First 0 Last 7						L	3	H	2000
Linearity: %						Correlation Factor:			
No-Lag-Time: %						A	1.000	B	0.000
						On-board Stability Period:		84	

Specific Test Parameters									
General		LIH	ISE	Range					
Test name: TG						Type: Serum			
Value/Flag: #		Level L: #		Level H: #					
Normal Ranges:									
	Sex	Age L	Age H		L	H			
		Year	Month	Year	Month				
1.	#	#	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#	#	#
7. None Selected						#	#	#	#
8. Out of Range						#	#	#	#
Panic Value:		L	#	H	#	Unit: mg/dl		Decimal Places: 1	

Calibration Specific					
General		ISE			
Test name: TG					Type: Serum
Calibration Type: 2AB		Formula: Polygonal	Counts: 3	Process: CONC	
	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		*	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:					
Point 4:					
Point 5:					
Point 6:					
Point 7:					
1-Point Cal.Point: <input type="checkbox"/>		with CONC=0		Slope Check: None	Advanced Calibration: #
MB Type Factor:				Calibration Stability Period: 84	

- # User defined
- * Calibrator value

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) and LEVEL 2 (Cat. No 5-175; 5-177) is recommended.

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 Olympus AU400. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 3 mg/dl (0.034 mmol/l).
- **Linearity:** up to 2000 mg/dl (22.6 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 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	92.51	1.09	1.17
level 2	189.88	1.59	0.82

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	168.59	2.97	1.76
level 2	92.04	2.08	2.26

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 100 samples gave following results:

$$y = 0.976x - 0.0707 \text{ mmol/l};$$

$$R = 0.9996 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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