Triglyceride Assay Kit (TG)

Method: GPO-PAP

Cat .No.	Size	Instrument
GB110Z	5×100 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS111Z	6×70 ml	For Hitachi917 & OlympusAU640/400/600
GH111Z	6×50 ml	For Hitachi902
GT111Z	7×50 ml	For TOSHIBA
GX111Z	2×100 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800

INTENDED USE

For the *in vitro* quantitative determination of triglycerides in serum .

CLINICAL SIGNIFICANCE[1]

Triglycerides are a family of lipids absorbed from the diet and produced endogenously from carbohydrates. Measurement of triglycerides is important in the diagnosis and management of hyperlipidemias. These diseases can be genetic or secondary to other disorders including nephrosis, diabetes mellitus, and endocrine disturbances. Elevation of triglycerides has been identified as a risk factor for atherosclerotic disease.

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

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

$$\text{Glycerol-3-phosphate} + O_2 \xrightarrow{\text{Glycerolphosphate oxidase}} \text{DAP} + 2H_2O_2$$

$$H_2O_2 + \text{4-AAP} + \text{4-chloride phenol} \xrightarrow{\text{peroxidase}} \text{Quinoneiminedye} + 2H_2O$$

ASSAY PRINCIPLE[2,3]

Quinoneimine dye colored red is formed from 4-aminoantipyrine, 4-chloride phenol, and hydrogen peroxide. The absorption of the solution of this dye is proportional to the concentration of triglycerides in the sample.

SAMPLE COLLECTION AND PREPARATION

Serum samples or heparin, EDTA plasma samples.
Samples are stable for 3 days at 2-8°C.

REAGENT COMPOSITION

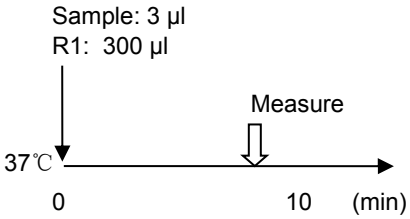
Contents	Concentration
Good's buffer, pH 7.2	50 mmol/L
4-chloride phenol	4 mmol/L
Mg2+	15 mmol/L
ATP	2 mmol/L
Glycerol kinase	≥0.4 KU/L
peroxidase	≥2 KU/L
lipase	≥2 KU/L
4-AAP	0.5 mmol/L
Glycerol phosphate oxidase	≥0.5 KU/L

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
The TG assay kit reagents are stable for 28 days on-board the analyser .

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 7170/917)
Assay Mode: end point, 34
Wave Length (main/sub): 505 nm/660 nm



1. Mix 3 µl sample with 300 µl R1 and incubate at 37℃ for 10 minutes.
2. Measure the absorbance of the sample (A_{sample}) and calibrator ($A_{calibrator}$) against reagent blank.

CALCULATION

$$\text{Concentration} = \frac{A_{sample} - A_{blank}}{A_{calibrator} - A_{blank}} \times \text{Calibrator value}$$

CALIBRATION

TG(Lipase/GPO-PAP no Correction).
Recommend that this assay should be calibrated using Gcell calibration serum, calibration trace to GBW09146. Randox calibration also can be used, Randox calibration choosing method: TG(Lipase/GPO-PAP no Correction)

QUALITY CONTROL

Use Gcell multi quality control serum calibration serum or Randox control serum, values obtained should fall within a specified range. If these values fall outside the range, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

Serum or plasma 0.7-1.7 mmol/L (60-150 mg/ml)

risk	1.82 -2.28 mmol/L	(160-200 mg/ml)
high risk	> 2.82 mmol/lL	(> 200 mg/ml)

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

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SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY
The assay is linear up to 11.4 mmol/L. Sample above this concentration should be diluted 1+1 with 0.9% NaCl and reassay. Multiply the result by 2.

PRECISION
The CV of the test should be less than 5%.

Intra assay precision		
N=20	Level1	Level 2
Mean (mmol/L)	1.128	2.962
SD	0.015	0.044
CV	1.34%	1.49%
Inter assay precision		
N=5	Level1	Level 2
Mean (mmol/L)	1.082	2.931
SD	0.008	0.033
CV	0.72%	1.14%

SENSITIVITY
The minimum detectable concentration of TG with an acceptable level of precision was determined as 0.01mmol/L.

INTERFERENCE
The following analytes were tested up to the levels indicated and found not to interfere:
Hemoglobin: 200 mg/dl
Direct bilirubin: 15mg/dl

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=0.977X+0.032, R^2=0.999; 70 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS
1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES
1. Stein E.A. and Myers G.L. " Lipids, Lipoproteins and Apolipoproteins" in Tietz Textbook of Clinical Chemistry. Burtis C.A. and Ashwood E.R. (Ed). WB Saunders Company, Second Edition. 1994; 23: 1002-93.
2. McGowan MW, et al. Clin Chem 1983; 29: 538.
3. Fossati P, Prencipe L. Clin Chem 1982; 28: 2077-80.

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

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