Triglycerides FS

Triglycerides Reagent Test Kit

Intended to Use

Diagnostic reagent for quantitative determination of triglycerides in human serum or plasma on photometric analyzers.

Reagent Kits

Item Code	Pack Size
157109934840	R: 4 x 60 mL

Reagent Composition

Reagent	Good's buffer	pH7.2	50 mmol/L
	4- Chlorophenol		4 mmol/L
	ATP		2 mmol/L
	Mg^{2+}		15 mmol/L
	Glycerokinase (GK)		≥ 0.4 kU/L
	Peroxidase (POD)		≥ 2.0 kU/L
	Lipoprotein lipase (LPL)		≥ 2.0 kU/L
	4-Aminoantipyrine		0.5 mmol/L
	Glycerol-3-phosphate oxidase (GPO)		≥1.5 kU/L

Summary

Triglycerides are esters of glycerol with three fatty acids and the most abundant naturally occurring lipids. They are transported in plasma bound to Apo lipoproteins forming very low density lipoproteins (VLDL) and chylomicrons. Measurement of triglycerides is used in screening of the lipid status to detect atherosclerotic risks and in monitoring of lipid lowering measures. Studies have shown that elevated triglyceride concentrations combined with increased low density lipoprotein (LDL) concentrations constitute an especially high risk for coronary heart disease (CHD). High triglyceride levels also occur in various diseases of liver, kidneys and pancreas. Decreased levels are found in malnutrition and hyperthyroidism.

Method

Colorimetric enzymatic test using glycerol-3-phosphate-oxidase (GPO)

Principle

Determination of triglycerides involves enzymatic splitting with lipoprotein lipase. Indicator is quinoneimine, which is generated from 4-aminoantipyrine and 4-chlorophenol by hydrogen peroxide under the catalytic action of peroxides.

$$\text{Triglycerides} \xrightarrow{\text{Lipase}} \text{Glycerol} + \text{Fatty acids}$$

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

$$\text{Glycerol-3-phosphate} + O_2 \xrightarrow{\text{GPO}} \text{Dihydroxyaceton phosphate} + H_2O_2$$

$$2H_2O_2 + \text{Aminoantipyrine} + \text{4-Chlorophenol} \xrightarrow{\text{POD}} \text{Quinoneimine} + \text{HCl} + 4\,H_2O$$

Storage Instructions and Reagent Stability

The reagents are stable till the date of expiry, if stored at 2°C - 8°C , protected from light and contamination is avoided. Do not freeze the reagents.

Note: Measurement is not influenced by occasionally occurring color changes, as long as the absorbance of the reagent is < 0.3 at 505 nm.

Reagent Preparation

The reagent is ready to use.

Traceability

The assigned values of the calibrator and triglycerides standard have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (CG-IDMS).

Sample Material

Serum, Heparin plasma or EDTA plasma. Stability :

2 days	at	20°C - 25°C
7 days	at	4°C – 8°C
At least one year	at	-20°C

Discard contaminated specimens.

Assay Procedure

Wavelength	492/505 nm
Light path	10 mm
Temperature	37°C
Measurement	Against reagent blank

	Blank	Sample/Standard
Sample/Standard	-	10 µL
Distilled. water	10 µL	-
Reagent solution	1000 µL	1000 µL
Mix, incubate for 5 min. at 37°C. Read the absorbance against the reagent blank.		

Calculation

With Standard.

$$\text{Triglycerides mg/dL} = \frac{\Delta A\ \text{Sample}}{\Delta A\ \text{Std}} \times \text{conc.std mg/dL}$$

Calibrators and Controls

For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. For Semi-Auto Analyzers, given standard can be used for Triglycerides solution Calibration. The assigned values of TruCal U have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). For internal quality control DiaSys TruLab N or TruLab P controls should be assayed.

Reference Range

Desirable	< 200 mg/dL (2.3 mmol/L)
Borderline high	200-400 mg/dL (2.3 -4.5 mmol/L)
Elevated	> 400 mg/dL (4.5 mmol/L)

"Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary".

Clinical Interpretation

Epidemiological studies have observed that a combination of plasma triglycerides >180 mg/dL and HDL-Cholesterol < 40 mg/dL predict a high risk of CHD. Borderline levels (>200 mg/dL) should always be regarded in association with other risk factors.

Performance Characteristics

Measuring Range

The test has been developed to determine triglyceride concentrations within a measuring range from 1-1000 mg/dL (0.01 -11.3 mmol/L). When values exceed this range samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.

Interferences

No interference was observed by

Bilirubin	up to	40 mg/dL,
Ascorbic acid	up to	6 mg/dL,
Hemoglobin	up to	250 mg/dL.

Sensitivity/Limit of Detection

The lower limit of detection is 1 mg/dL.

Linearity

The linearity is 1000 mg/dL.

Precision

Intra-assay precision n=20	Mean mg/dL	SD mg/dL	CV (%)
Sample1	86.00	1.24	1.27
Sample2	87.00	2.04	2.18
Sample3	187.00	2.97	1.63
Sample 4	222.00	3.40	1.50
Inter-assay precision n=20	Mean mg/dL	SD mg/dL	CV (%)
Sample1	87.00	1.36	1.52
Sample2	195.00	3.18	1.81
Sample3	222.00	2.48	1.08

Method Comparison

A comparison of Triglycerides Test Kit (y) with a commercially available test (x) using 95 samples gave following results:
y = 0.958 x + 0.892 mg/dL; r = 0.9998

Warnings and Precautions

1. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Take off immediately all contaminated clothing.
3. Wear suitable gloves and eye/face protection.
4. Always use safety pipettes to pull the reagents into a pipette.
5. Reagents may contain some non-reactive and preservative components. It is suggested to handle carefully, avoid direct contact with skin and do not swallow.
6. Perform the test according to the Current Good Laboratory Practice" (GLP) guidelines.
7. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.

Quick References

Parameter	Triglycerides
Mode	End point
Wavelength	492/505 nm
Path length	10 mm
Temperature	37°C
Calibrator conc.	*
Reagent volume	1000 µL
Sample volume	10 µL
Incubation time	5 min at 37°C
Blanking	Reagent blank
Normal range	< 200 mg/dL
Linearity	1000 mg/dL

Limitations

Eventual Triglycerides GPO-PAP carry-over to reagents Magnesium (Xylidyl blue), Iron (Ferrene), Lipase (Enzymatic, colorimetric), Uric acid (AOX), Uric acid (TBHBA) and Phosphorous Inorganic (Molybdate). The actual carry-over depends on the analyzer.

Literature

1. Tietz textbook of clinical chemistry. 3rd ed. Philadephia: W.B. Sauderrs Company; 1999.p.809-61.
2. Handbook of lipoprotein testing. Washington : AACC Press, 1997.p . 115-26.
3. Prevention of coronary heart disease in clinical practice. Eur Heart J 1998:191434-503.

Notes on Symbols and Marks

	Consult instruction for use
	Use-by date
LOT	Batch code
REF	Catalogue number
	Caution
	Manufacturer
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CONT.	The pack contains
	Recycle
	Date of manufacture

ISO 9001, ISO 13485 and ICMED 13485 Certified Company

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