Triglycerides FS*

Diagnostic reagent for quantitative in vitro determination of triglycerides in serum or plasma on photometric systems

Order Information

Cat. No.	Kit size		
1 5760 99 10 021	R	5 x 25 mL	+ 1 x 3 mL Standard
1 5760 99 10 026	R	6 x 100 mL	
1 5760 99 10 023	R	1 x 1000 mL	
1 5760 99 90 314	R	12 x 25 mL	
1 5700 99 10 030		6 x 3 mL	Standard

Summary [1,2]

Triglycerides are esters of glycerol with three fatty acids and the most abundant naturally occurring lipids. They are transported in plasma bound to apolipoproteins 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.

Method

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

Principle

Determination of triglycerides after 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 peroxidase.

$$\text{Triglycerides} \xrightarrow{\text{LPL}} \text{Glycerol} + \text{fatty acid}$$

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

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

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

Reagents

Components and Concentrations

Reagent:		
Good's buffer	pH 7.2	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 kU/L
Lipoprotein lipase	(LPL)	≥ 4 kU/L
4-Aminoantipyrine		0.5 mmol/L
Glycerol-3-phosphate-oxidase	(GPO)	≥ 1.5 kU/L
Standard:		200 mg/dL (2.3 mmol/L)

Storage Instructions and Reagent Stability

Reagent and standard are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagent!
Note: It has to be mentioned, that the measurement is not influenced by occasionally occurring color changes, as long as the absorbance of the reagent is < 0.3 at 546 nm.

Warnings and Precautions

1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. The reagent contains biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagent and the standard are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma

Stability [4]:			
	2 days	at	20 – 25°C
	7 days	at	4 – 8°C
	at least one year	at	–20°C

Discard contaminated specimens. Freeze only once!

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	500 nm, Hg 546 nm
Optical path	1 cm
Temperature	20 – 25°C/37°C
Measurement	Against reagent blank

	Blank	Sample or standard
Sample or standard	-	10 µL
Dist. water	10 µL	-
Reagent	1000 µL	1000 µL

Mix, incubate 10 min. at 20 – 25°C or 5 min. at 37° C.
Read absorbance against the blank within 60 min

Calculation

With standard or calibrator

$$\text{Triglycerides [mg/dL]} = \frac{\text{A Sample}}{\text{A Std/Cal}} \times \text{Conc. Std/Cal [mg/dL]}$$

To correct for free glycerol, subtract 10 mg/dL (0.11 mmol/L) from the triglycerides value calculated above.

Conversion factor

Triglycerides [mg/dL] x 0.01126 = Triglycerides [mmol/L]

* fluid stable

Calibrators and Controls

For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. 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 and P or TruLab L controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab L Level 1	5 9020 99 10 065	3 x 3 mL
TruLab L Level 2	5 9030 99 10 065	3 x 3 mL

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.

Specificity/Interferences

No interferences were observed by ascorbic acid up to 3 mg/dL, conjugated bilirubin up to 40 mg/dL, by unconjugated bilirubin up to 9 mg/dL and hemoglobin up to 500 mg/dL. For further information on interfering substances refer to Young DS [5].

Sensitivity/Limit of Detection

The lower limit of detection is 1 mg/dL.

Precision (at 37℃)

Intra-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	55.0	0.319	0.58
Sample 2	210	1.51	0.72
Sample 3	448	3.56	0.80

Inter-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	90.3	0.857	0.95
Sample 2	238	3.52	1.48

Method Comparison

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

Reference Range [2]

Desirable: < 200 mg/dL (fasting) (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 the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Clinical Interpretation [3]

Epidemiological studies have observed that a combination of plasma triglycerides > 180 mg/dL (> 2.0 mmol/L) and HDL-cholesterol < 40 mg/dL (1.0 mmol/L) predict a high risk of CHD. Borderline levels (> 200 mg/dL) should always be regarded in association with other risk factors for CHD.

Literature

1. Rifai N, Bachorik PS, Albers JJ. Lipids, lipoproteins and apolipoproteins. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 809-61.
2. Cole TG, Klotzsch SG, McNamara J. Measurement of triglyceride concentration. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press, 1997.p.115-26.
3. Recommendation of the Second Joint Task Force of European and other Societies on Coronary Prevention. Prevention of coronary heart disease in clinical practice. Eur Heart J 1998;19: 1434-503.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 46-7.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240–1243.

Manufacturer

IVD CE
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany