

Triglycerides FS*

Order Information

Cat. No.	Kit size	
1 5710 99 10 021	6 x	25 mL
1 5710 99 10 026	6 x	100 mL
1 5710 99 10 023	1 x	1000 mL
1 5710 99 10 704	8 x	50 mL
1 5710 99 10 717	6 x	100 mL
1 5710 99 10 917	10 x	60 mL

Kits for use in conjunction with DiaSys CE applications.

Intended Use

Diagnostic reagent for quantitative in vitro determination of triglycerides in human serum or heparin plasma on automated photometric systems.

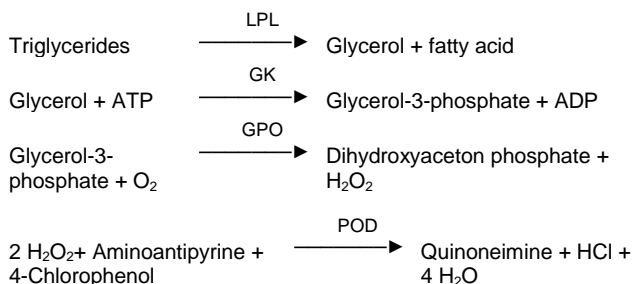
Summary

Triglycerides are esters of glycerol with three fatty acids. They represent the most abundant naturally occurring lipids. They are transported in plasma bound to apolipoproteins forming very low-density lipoproteins (VLDL) and chylomicrons [1]. With a prevalence of around 10 % in the adult population, hypertriglyceridemia (HTG) is a common problem [2]. Measurement of triglycerides is used for diagnosis of HTG that is directly associated with an increased risk of atherosclerotic cardiovascular disease (ASCVD). Furthermore, individuals with high triglyceride levels may develop type 2 diabetes mellitus. Very high triglyceride levels correlate with acute pancreatitis [2].

Method

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

Determination of triglycerides after enzymatic splitting with lipoprotein lipase. Quinoneimine is the indicator, generated from 4-aminoantipyrine and 4-chlorophenol by hydrogen peroxide under the catalytic action of peroxidase.



Reagent

Components and Concentrations

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)	≥ 2 kU/L
4-Aminoantipyrine		0.5 mmol/L
Glycerol-3-phosphate-oxidase	(GPO)	≥ 0.5 kU/L

Storage and Stability

Reagent is stable up to the date of expiry indicated on the kit, if stored at 2 - 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

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 material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
4. In very rare cases, samples of patients with gammopathy might give falsified results [3].
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
7. Please refer to the safety data sheets (SDS) 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.
8. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagent is ready to use.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [4]:

2 days	at	20 – 25°C
7 days	at	4 – 8°C
At least 1 year	at	-20°C

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	505/694 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	1.0 µL
Reagent	90 µL
Addition reagent	Cycle 19 (286 s)
Absorbance	Cycle 41/42 (586 s/600 s)
Calibration	Linear

Calculation

With Calibrator

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

To correct for free glycerol, subtract 10 mg/dL from the triglycerides value calculated above.

Conversion Factor

$$\text{Triglycerides [mg/dL]} \times 0.01126 = \text{Triglycerides [mmol/L]}$$

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). Triglycerides Standard FS may be used alternatively for calibration. Use DiaSys TruLab N and P or TruLab L Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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
Triglycerides Standard FS	1 5700 99 10 030	6 x 3 mL

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range up to 1000 mg/dL, linearity is given within $\pm 5\%$. When values exceed this range, samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.	
Limit of detection**	0.5 mg/dL

Interference by	Interferences $\leq 10\%$ up to	Analyte concentration [mg/dL]
Ascorbic acid	6 mg/dL	86.6
Bilirubin (conjugated)	30 mg/dL	86.6
Bilirubin (unconjugated)	12 mg/dL	87.0
Hemolysis	400 mg/dL	85.9

For further information on interfering substances, refer to the literature [5-7].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	63.7	138	231
CV [%]	0.936	0.742	0.823
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	76.5	114	177
CV [%]	1.71	1.08	0.995

Method comparison (n=100)	
Test x	Competitor Triglycerides (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Triglycerides FS (BioMajesty® JCA-BM6010/C)
Slope	1.00
Intercept	-0.888 mg/dL
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Reference Range [8]

	mg/dL	mmol/L
Normal	< 150	< 1.65
Borderline	150 – 199	1.69 – 2.25
High	200 – 399	2.26 – 4.51
Very high	≥ 400	≥ 4.52

Each laboratory should check if the 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 (> 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 [9].

Literature

- 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
- Ulrich Laufs, Klaus G Parhofer, Henry N Ginsberg, Robert A Hegele, Clinical review on triglycerides, European Heart Journal, Volume 41, Issue 1, 1 January 2020, Pages 99–109c.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240-1243.
- Guder WG, da Fonseca-Wollheim F, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B. Quality of Diagnostic Samples. 3rd edition; 2010. p. 62-3
- 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.
- Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinfx.wiley.com/aaccweb/aacc/>, accessed in July 2021. Published by AACC Press and John Wiley and Sons, Inc.
- Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.
- Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2023 [cited 2024 06 12]. Available from: <https://www.clinical-laboratory-diagnostics.com>
- 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.

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DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

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