respons®910

Triglycerides FS*

Order Information

Cat. No.	Kit size
1 5710 99 10 923	Σ 800 (4 x 200)

Intended Use

Diagnostic reagent for quantitative in vitro determination of triglycerides in human serum or heparin plasma on automated DiaSys respons®910.

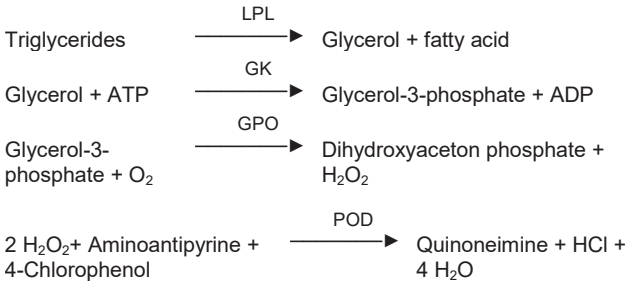
Summary

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. Measurement of triglycerides is used in screening of the lipid status to detect atherosclerotic risks and in monitoring of lipid lowering therapy. 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. [1,2]

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. Protect from light.

The in-use stability of the reagent is 18 months.

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. The bottles are placed directly into the reagent rotor.

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.

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). Use DiaSys TruLab N and P or TruLab L Level 1 and Level 2 for internal quality control. 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

Performance Characteristics

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 1000 mg/dL. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	4 mg/dL
Onboard stability	4 weeks
Calibration stability	7 days

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	9 mg/dL	225
Bilirubin (conjugated)	20 mg/dL	168
	30 mg/dL	485
Bilirubin (unconjugated)	10 mg/dL	163
	48 mg/dL	450
Hemoglobin	290 mg/dL	243
	300 mg/dL	534

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

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	65.7	148	231
CV [%]	1.98	1.12	1.58
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	75.4	165	246
CV [%]	4.74	2.40	3.43

Method comparison (n=146)	
Test x	DiaSys Triglycerides FS (Hitachi 917)
Test y	DiaSys Triglycerides FS (respons®910)
Slope	0.986
Intercept	1.51 mg/dL
Coefficient of correlation	0.999

** according to CLSI document EP17-A, Vol. 24, No. 34

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

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

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 [8].

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, 2000; 2nd edition, p. 207-19.
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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.
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7. 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.
8. 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.

Additions and/or changes in the document are highlighted in grey. For deletions, please refer to the customer information for the corresponding edition number of the package inserts.

IVD CE

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* Fluid Stable

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Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	TRIG
Shortcut:	
Reagent barcode reference:	052
Host reference:	

Technic	
Type:	End point
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	
Blank reagent	
Sensitive to light	
Main wavelength:[nm]	508
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance li	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	4
Concentration technical limits-Upper	1000
SERUM	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume[µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume[µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6

Results	
Decimals	0
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	All
Age	
SERUM	>= <=200
URINE	
PLASMA	>= <=200
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.004
Cal. 2	0.030
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X
Degree	1

* Enter calibrator value