respons®920

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®920.

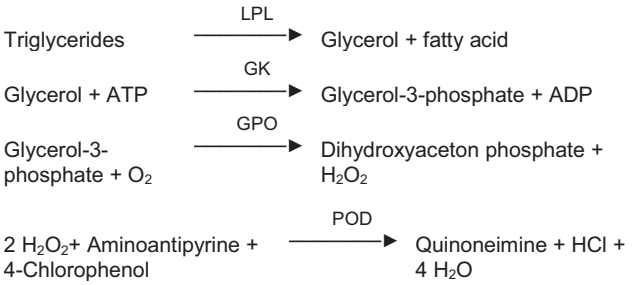
Summary

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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
6. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
7. 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.
8. 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.
9. 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**	2 mg/dL
Onboard stability	4 weeks
Calibration stability	2 weeks

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	9 mg/dL
Bilirubin (conjugated)	18 mg/dL
Bilirubin (unconjugated)	10 mg/dL
Hemoglobin	400 mg/dL

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]	106	163	241
CV [%]	1.83	2.12	0.97
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	111	169	247
CV [%]	1.14	1.09	2.47

Method comparison (n=97)	
Test x	DiaSys Triglycerides FS (Hitachi 917)
Test y	DiaSys Triglycerides FS (respons®920)
Slope	1.02
Intercept	–4.36 mg/dL
Coefficient of correlation	0.997

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

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.
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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

respons 920

Triglycerides FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	TRIG				Auto Rerun		☐
Report Name	:	Triglycerides				Online Calibration		☐
Unit	:	mg/dL	Decimal Places	:	0	Cuvette Wash		☐
Wavelength-Primary	:	505	Secondary	:	700	Total Reagents	:	1
Assay Type	:	1-Point	Curve Type	:	Linear	Reagent R1	:	TRIG R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	
M2 Start	:	33	M2 End	:	33			
Sample Replicates	:	1	Standard Replicates	:	3	Consumables/Calibrators:		
Control Replicates	:	1	Control Interval	:	0	Blank/Level 0	:	0
Reaction Direction	:	Increasing	React. Abs. Limit	:	0.00	Calibrators	:	*
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.00			
Technical Minimum	:	2.00	Technical Maximum	:	1000.00			
Y = aX + b a=	:	1.00	b=	:	0.00			

* Enter the calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	TRIG		
Sample Type	:	Serum		

Sample Volumes

Normal	:	2.00 µL	Dilution Ratio	:	1	X
Increase	:	4.00 µL	Dilution Ratio	:	1	X
Decrease	:	2.00 µL	Dilution Ratio	:	2	X
Standard Volume	:	2.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180 µL	R1 Stirrer Speed	:	High
RGT-2 Volume	:	µL	R2 Stirrer Speed	:	

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	TRIG		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	0.00	200.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other