


## Triglycerides FS\*

### Order Information

#### Cat. No.

1 5710 99 10 923

#### Kit size

 800 (4 x 200)

### Intended Use

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

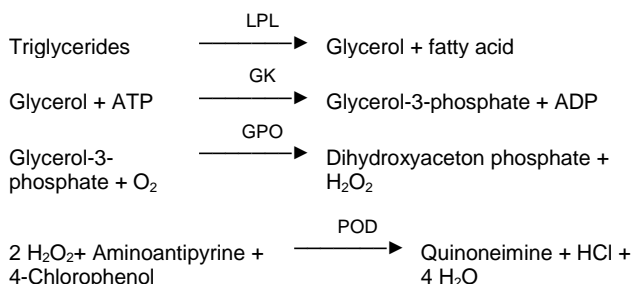
### Summary

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 [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 <sup>2+</sup>		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. 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. 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
	5 9030 99 10 065	3 x 3 mL

## Performance Characteristics

Measuring range from 3.08 mg/dL up to 1300 mg/dL, linearity is given within ± 5%.  
In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	3.08 mg/dL
Limit of quantitation**	3.08 mg/dL
Onboard stability	4 weeks
Calibration stability	7 days

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
<b>Ascorbic acid</b>	9 mg/dL	225
<b>Bilirubin (conjugated)</b>	20 mg/dL	168
	30 mg/dL	485
<b>Bilirubin (unconjugated)</b>	10 mg/dL	163
	48 mg/dL	450
<b>Hemolysis</b>	290 mg/dL	243
	300 mg/dL	534

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]	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 911)
Test y	DiaSys Triglycerides FS (respons <sup>®</sup> 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 [8]

	mg/dL	mmol/L
<b>Normal</b>	< 150	< 1.65
<b>Borderline</b>	150 – 199	1.69 – 2.25
<b>High</b>	200 – 399	2.26 – 4.51
<b>Very high</b>	≥ 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
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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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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:	052

Technic	
Type:	End point
First reagent:[ $\mu$ L]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[ $\mu$ L]	
Blank reagent	
Sensitive to light	
Main wavelength:[nm]	508
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(-00:12)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics	
Substrate depletion: Absorbance limit	
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 [ $\mu$ L]	0 (no hemolysis)
Cleaner	
Sample [ $\mu$ L]	0
Technical limits	
Concentration technical limits-Lower	3.0800
Concentration technical limits-Upper	1300.0000
SERUM	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6

Results	
Decimals	0
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	#
URINE	
PLASMA	#
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	
	<b>Max delta abs.</b>
Cal. 1	0.004
Cal. 2	0.030
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

\* Enter calibrator value

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