

#### Order information:

Catalogue number	Size
9821C	10 x 65 ml
9822C	4 x 65 ml

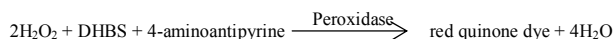
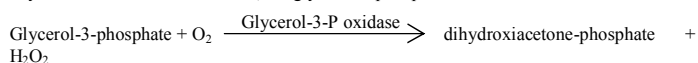
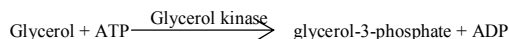
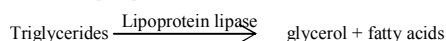
#### Reagent kit for quantitative in vitro determination of triglycerides in serum and plasma.

#### Summary

Triglycerides are esters formed from glycerol and fatty acids, the latter being synthesized in the liver or extracted from blood. Determining the level of triglyceride concentration is part of the evaluation of lipid metabolism and plays a major role in identification of the various hyperlipoproteinemia. The level is increased in certain liver and renal diseases in diabetes mellitus and coronary artery disease.

#### Method

Glycerol-3-phosphate oxidase/PAP method



#### Reagents

##### Composition and concentrations

PIPES buffer pH=6,70	50 mmol/l
DHBS	4 mmol/l
ATP	10,0 mmol/l
Lipoprotein lipase	10000 U/l
Glycerol kinase	2000 U/l
Glycerin-3-phosphate oxidase (GPO)	8000 U/l
Peroxidase	10000 U/l
4-aminoantipyrine	5 mmol/l

#### Storage and stability

The reagent is stable up to the end of the indicated month of expiry without opening, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze! Onboard stability after opening and the frequency of calibration is 21 days.

#### Warnings and precautions

Do not use reagents after the expiry date stated on each reagent container label.

#### Chemical safety

This product is not classified as dangerous. Safety data sheet is available upon request. The product contains sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. If disposal into a drain is in compliance with federal, state, and local requirements, flush reagents with a large amount of water to prevent the buildup of azides.

#### Preparation

The reagent is ready for use.

#### Sample

Serum, heparin, citrate or EDTA plasma.	
Stability in serum:	7 days at 4 – 8°C
	2 days at 20 – 25 °C
	1 year at -20°C

#### Expected values and reference range

Serum, male:	0,99 – 2,10 mmol/l
female:	0,9 – 1,87 mmol/l

It is recommended that each laboratory should assign its own normal range.

#### Assay procedure

Wavelength:	505 nm / 700 nm (primary/secondary)
Optical path:	1 cm
Temperature:	37°C
Measurement:	against reagent blank
Reaction:	endpoint, increasing

	blank	sample or standard
reagent	200 µl	200 µl
dist. water (diluent)	800 µl	800 µl
dist. water (blank)	10 µl	-
sample or standard	-	10 µl
Mix and incubate for 5 minutes and read the absorbance against reagent blank		

#### Calculation

Triglycerides[mmol/l]=ΔA sample/ΔA standard × standard concentration[mmol/l]

#### Conversion factor

[mmol/l]×88,69=[mg/dl]

#### Calibration and quality control

S1: Distilled water

S2: Triglycerides standard Cat.: 51011 or

Roche C.F.A.S. (Calibrator for automated system) or

Randox Calibration Serum Level I or

Randox Calibration Serum Level II

Calibration is recommended:

- after opening new reagent batch
- after system maintenance or troubleshooting

For internal quality control, two levels controls are recommended (normal and pathological) at least once a day. The measured values must in the range which was given by the control's manufacturer. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

#### Performance characteristics

##### Measuring range

The method is linear in the range 0,13 – 17,3 mmol/l

##### Interferences

No significant interference was observed by bilirubin up to 200 µmol/l bilirubin, hemoglobin up to 1,0 g/l and ascorbate up to 0,01 g/l. Significant interference: >10%.

##### Limit of detection

The limit of detection is 0,0001 mmol/l

##### Precision

Repeatability n = 20	mean	SD	CV
	[mmol/l]	[mmol/l]	[%]
normal sample	1,30	0,01	1,07
pathological sample	3,20	0,02	0,49
Reproduceability n = 10	mean	SD	CV
	[mmol/l]	[mmol/l]	[%]
normal sample	1,26	0,03	2,34
pathological sample	3,15	0,05	1,48

#### Method comparison

Comparison with the non-concentrated reagent.

analyser: Advia 1650

number of samples: 179

range: 0,32 – 15,93 mmol/l










correlation coefficient: 0,997

regression line equation:  $y = 0,927x + 0,389$

(x= normal reagent, y= concentrated reagent)

#### For in vitro diagnostic use only!

#### The following symbols can be used on the labels

	In vitro diagnostic device
	Manufacturer
	CE-marking
	Temperature limitations
	Use by (year/month)
	Batch code
	Catalogue number
	This way up
	Biological risk

#### Literature

Piero F. Lorenzo Prencipe, *Clin. Chem.* 28/10, 2077-2080 (1982)

Werner M., Gabrielson D.G., Eastman G., *Clin. Chem.*, 21, 268, 1981

Annoni G., Bottasso B.M., Ciaci D., Donato M.F., Tripoli A., *Lab J.J. Res. Lab. Med.*, 9,115,1982

Tietz *Clinical Guide To Laboratory Tests*, 4<sup>th</sup> edition, Elsevier, 2006