

# TRIGLICERÍDEOS WS

## Triglycerides WS

Anvisa 80115310207

### ORDER INFORMATION

Artigo nº	Apresentação
1060500KWS	2 x 250mL
1060180MWS	6 x 30mL
1060174.4RWS	4 x 43,6mL
1060250KWS	1 x 250mL
1060120MKWS	3 x 40mL

### INTENDED USE

Reagent for quantitative determination of Triglycerides in serum or plasma on photometric systems.

### SUMMARY [1,2]

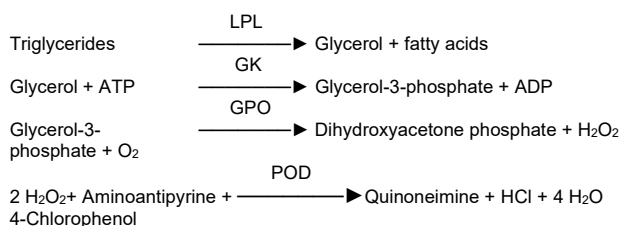
Triglycerides are esters of glycerol with three fatty acids. They represent the most abundant naturally occurring lipids. They are transported in plasma bound to apolipoproteins forming very low-density lipoproteins (VLDL) and chylomicrons. Triglyceride measurement is used as a screening for lipid level assessment in determining atherosclerosis risks and monitoring lipid level decreases. Recent studies have shown that an increase in triglyceride concentration combined with an increase in low-density lipoprotein (LDL) constitutes a high risk for coronary heart disease (CHD). High triglyceride levels also occur in various diseases of the liver, kidneys, and pancreas.

### METHOD

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

### PRINCIPLE

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

##### Monoreagent

Good's buffer	pH 7,2	< 100 mmol/L
4-Chlorophenol		< 5 mmol/L
ATP		2 mmol/L
Mg <sup>2+</sup>		15 mmol/L
Glycerokinase	GK	< 1 KU/L
Peroxidase	POD	< 10 KU/L
Lipoprotein lipase	LPL	< 10 KU/L
4-Aminoantipyrine		< 1 mmol/L
Glycerol-3-phosphate oxidase	GPO	< 5 KU/L

### STORAGE AND STABILITY

The reagent is ready for use and stable until the expiration date if stored at 2 to 8 °C, protected from light and contamination is avoided. Do not freeze the reagent!

**Note:** The measurement is not influenced by an occasional color change if the absorbance of the reagent is < 0.3 at 546 nm.

### 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 biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.

3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
5. 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.
6. For professional use only.

### WASTE MANAGEMENT

Follow the requirements of the current guidelines about technical regulation for the management of healthcare service waste, as well as other equivalent biosafety practices.

### REAGENT PREPARATION

The reagent is ready to use.

### MATERIALS REQUIRED BUT NOT PROVIDED

1. NaCl solution 9 g/L.
2. General laboratory equipment.

### SPECIMEN

Serum, heparin plasma or EDTA-plasma

Stability [4]:	2 days	at	20 – 25 °C
	7 weeks	at	4 - 8 °C
	At least 1 year	at	- 20 °C

Discard contaminated specimens. Only freeze once!

### ASSAY PROCEDURE

Applications for automatic systems are available upon request or on our website: [www.kovalent.com.br](http://www.kovalent.com.br)

Wavelength	500 nm, Hg 546nm
Optical path	1 cm
Temperature	20 - 25 °C / 37 °C
Measurement	Against reagent blank

	Blank	Sample or calibrator
Sample or calibrator	-	10 µL
Distilled water	10 µL	-
Reagent	1000 µL	1000 µL
Mix, incubate for 5 minutes at 37 °C or 10 minutes at 20 - 25 °C. Read absorbance against reagent blank within 60 minutes.		

### CALCULATION

#### With calibrator

$$\text{Triglycerides [mg/dL]} = \frac{A_{\text{sample}}}{A_{\text{cal}}} \times \text{Conc. Cal [mg/dL]}$$

To correct for free glycerol, subtract 10 mg/dL (0.11 mmol/L) from the triglycerides value calculated above.

#### Conversion Factor

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

### WARRANTY

These instructions for use should be read carefully before using the product and the information contained therein should be strictly adhered to. The reliability of the test results cannot be guaranteed if the instructions are not followed.

### CALIBRATORS AND CONTROLS

For calibration in automated photometric systems, Kovalent Topkal U calibrator is recommended. Use Kovalent Topkon N and P for internal quality control. The Kovalent Topkon L control can also be used. Each laboratory should establish corrective action in case of deviations in control recovery.

### PERFORMANCE CHARACTERISTICS

#### Measuring range

The test is designed to determine triglyceride concentrations within a measurement range of 1 to 1000 mg/dL (0.01 - 11.3 mmol/L). When the

## Instructions for Use

For *in vitro* diagnostic use

values exceed this range, the samples should be diluted 1 + 4 with NaCl solution (9g/L) and the results multiplied by 5.

### Specificity / Interferences

No interference was observed by ascorbic acid up to 3 mg/dL, bilirubin up to 40 mg/dL, bilirubin (unconjugated) up to 9 mg/dL and hemoglobin up to 500 mg/dL. For more information on interfering substances, see Young DS [5].

### Sensitivity / Limit of Detection

The lowest detection limit is 1 mg/dL.

### Precision

Intra-assay precision n = 10	Mean [mg/dL]	SD [mg/dL]	CV [%]
Normal control	89.80	1.69	1.88
Pathological control	170.8	3.46	2.02

Inter-assay precision n = 9	Mean [mg/dL]	SD [mg/dL]	CV [%]
Normal control	87.46	1.96	2.24
Pathological control	169.34	5.41	3.19

### Method comparison

Method comparison between Kovalent Triglicerídeos WS (y) and a commercial test (x) using 30 samples demonstrated the following results:  
 $y = 1.0148x - 0.7381$ ;  $R^2 = 0.9997$ .

### REFERENCE VALUES [2]

	[mg/dL]	[mmol/L]
Desirable	< 200	2.3
High Risk Threshold	200 – 400	2.3 – 4.5
High risk	> 400	4.5

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

### CLINICAL INTERPRETATION [3]







Epidemiological studies have observed that a combination of plasma triglycerides > 180 mg/dL (> 2 mmol/L) and HDL-cholesterol < 40 mg/dL (1 mmol/L) predict a high risk of CHD (coronary heart disease). Borderline levels (> 200 mg/dL) should always be regarded in association with other risk factors for coronary diseases.









### 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, 1997.p.115-26.
3. 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.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1<sup>a</sup> ed. Darmstadt: GIT Verlag; 2001; p. 46-7.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5<sup>th</sup> ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Bakker AJ, Mucke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240-1243.

### CONSUMER INFORMATION

Symbols used:

	Manufacturer
	Temperature limit
	In vitro diagnostic device
	Caution
	Operating instructions
	Recycling material

	Do not discard directly into the environment
	Batch code
	Date of manufacture
	Use by date
	Biological hazards
	Highly toxic
	Corrosive
	Harmful

### Manufacturer:

#### Kovalent do Brasil Ltda.

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 São Gonçalo – RJ – CEP 24722-414 - Brasil  
 www.kovalent.com.br  
 CNPJ: 04.842.199/0001-56

Kit sizes variations on demand:

Anvisa No.	Kit size
80115310207	R 4x50mL
80115310207	R 2x20mL
80115310207	R 5 x40mL

Customer service: sac@kovalent.com.br - (21) 3907-2534 / 0800 015 1414

Expiration date and Lot no.: See label