Instructions for Use
For *in vitro* diagnostic use

MAGNÉSIO WS
Magnesium WS

Anvisa 80115310193

ORDER INFORMATION

Cat. No.	Kit size
3030250KWS	R: 1 x 250 mL
3030060MWS	R: 2 x 30 mL
3030094.8RWS	R: 4 x 23,7 mL
3030040MKWS	R: 2 x 20 mL

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Magnesium in serum, plasma, CSF or urine on photometric systems.

SUMMARY [1,2]

Magnesium deficiency is a common disorder that can be caused by malnutrition, malabsorption, kidney loss, and endocrine disorders. Complications associated with decreased magnesium concentration are neuromuscular irritability (e.g. tremor, seizure) and cardiac symptoms (e.g. tachycardia, arrhythmia). Decreases in magnesium concentrations are often related to decreases in calcium and potassium levels, taking into account that hypomagnesia may be the primary cause of hypocalcemia. High magnesium levels can be seen in dehydration and kidney disorders and after ingesting excessive amounts of antacids. It may also be associated with reduced reflexes and low blood pressure.

METHOD

Photometric test using xylidyl blue.

PRINCIPLE

Magnesium ions form a purple colored complex with xylidyl blue in alkaline solution. In presence of GEDTA, which complexes calcium ions, the reaction is specific. The intensity of the purple color is proportional to the magnesium concentration.

REAGENTS

Components and Concentrations

Ethanolamine	pH 11.0	<1 mol/L
GEDTA (Glycoletherdiamine-tetraacetic acid)		<100 μmol/L
Xylidyl blueil		<200 μmol/L

STORAGE AND STABILITY

Reagent is stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C, protected from light and if contamination is avoided. Do not freeze the reagent!

WARNINGS AND PRECAUTIONS

1. Danger! Causes skin irritation. Causes serious eye damage. Wear protective gloves/protective clothing/eye protection. IF IN SKIN: Wash thoroughly with soap and water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If exposed, seek medical advice.
2. In very rare cases, samples of patients with gammopathy might give falsified results [8].
3. Please refer to the safety data sheets 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.
4. 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, plasma, liquor (CSF) or urine
Do not use EDTA-plasma.

Stability [3]

In serum/plasma:	7 days	at	20 - 25 ºC
	7 days	at	4 - 8 ºC
	1 year	at	-20 ºC
In urine:	3 days	at	20 - 25 ºC
	3 days	at	4 - 8 ºC
	1 year	at	-20 ºC

Discard contaminated specimens.
Only freeze once!

Acidify urine with some drops of conc. HCl to pH 3 – 4, then dilute 1+4 with dist. water; multiply the result by 5.

ASSAY PROCEDURE

Applications for automatic systems are available upon request.

Wavelength	520 nm, Hg 546nm, 500 – 550 nm (↑ absorbance) 628 nm, Hg 623 nm, 570 – 650 nm (↓ absorbance)
Optical path	1 cm
Temperature	20 – 25 ºC / 37 ºC
Measurement	Against reagent blank

Note.: The standard contained in this Kit is water-based and this is not indicated for use in automation. Therefore, we recommend the use of a biological matrix calibrator such as TOPKAL U in automated equipment.

	Blank	Sample or standard
Sample or standard	-	10 μL
Distilled water	10 μL	-
Reagent	1000 μL	1000 μL
Mix and read the absorbance against the blank between 5 – 60 minutes at a temperature from 20 to 25 ºC / 37 ºC.		

CALCULATION

With Standard or Calibrator

$$\text{Magnesium (mg/dL)} = \frac{A_{Sample}}{A_{Standard/Cal.}} \times \text{Conc. Standard/Cal. (mg/dL)}$$

Conversion Factor

Magnesium [mg/dL] x 0.4114 = Magnesium [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. Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

Measuring range

The assay is designed to determine magnesium concentrations within a measurement range of 0.05 – 5 mg/dL (0.02 – 2.05 mmol/L). When the values exceed this range, the samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.

Specificity / Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, lipemia up to 2000 mg/dL of triglycerides and calcium up to 25 mg/dL. Hemoglobin interferes due to magnesium being released by

erythrocytes. For more information on interfering substances, see Young DS [7].

Sensitivity / Limit of Detection

The lowest detection limit is 0.05 mg/dL (0.02 mmol/L).

Precision

Intra-assay precision n = 10	Mean [mg/dL]	SD [mg/dL]	CV [%]
Normal control	1.92	0.07	3.69
Pathological control	4.372	0.03	0.70

Inter-assay precision n = 9	Mean [mg/dL]	SD [mg/dL]	CV [%]
Normal control	1.95	0.07	3.44
Pathological control	4.42	0.05	1.12

Method comparison

Method comparison between Kovalent Magnésio Colorimétrico (y) and a commercial test (x) using 30 samples demonstrated the following results: $y = 0.9609 x + 0.0703$; $R^2 = 0.9848$.

REFERENCE VALUES [1,6]

	mg/dL (mmol/L)
Serum/Plasma:	
Neonates	1.2 – 2.6 (0.48 – 1.05)
Children	1.5 – 2.3 (0.60 – 0.95)
Women	1.9 – 2.5 (0.77 – 1.03)
Men	1.8 – 2.6 (0.73 – 1.06)
Urine:	73 – 122 (3 – 5)
Liquor (CSF):	2.1 – 3.3 (0.85 – 1.35)

LITERATURE

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. P.231-41.
2. Endres DB, Rude RK. Mineral and bone metabolism. In. Burtis CA, Ashwood ER, editors. Tietz Textbook of Cinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. P. 1395-1457.
3. Guder WG, Zatwa B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: Git Verlag, 2001: 38-39, 50-51.
4. Mann CK, Yoe JH. Spectrophotometric determination of Magnesium with 1-Azo-2-hidroxy-3-(2,4-dimethyl-carboxanilido)-naphthalene-1'-(2-hydroxybenzene). Anal Chim Acta 1957; 16;155-60.
5. Bohoun C. Microdosage du magnesium dans divers mileux biologiques. Clin. Chim. Acta 1962; 7:811-7.
6. Sitzmann C. Normalwerte. Münchem: Hans Marseille Verlag GmbH: 1986.p.166.
7. 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.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

CONSUMER INFORMATION

Symbols used:

	Manufacturer
	Temperature limit
IVD	In vitro diagnostic device
	Caution
	Operating instructions
	Recycling material
	Do not discard directly into the environment
LOT	Batch code
	Date of manufacture
	Use by date
	Biological hazards
	Highly toxic
	Corrosive
	Harmful

Manufacturer:
Kovalent do Brasil Ltda.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro
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
80115310193	R: 2 x 50 mL
80115310193	R: 3 x 40 mL
80115310193	R: 5 x 40 mL

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

Expiration date and Lot no.: See label