



COD 11797 4 x 50 mL

Only for *in vitro* use in the clinical laboratory**INTENDED USE**

Reagent for the measurement of magnesium concentration in human serum, plasma or urine for the assessment of its imbalance.

CLINICAL BENEFIT

Increased serum magnesium concentrations have been observed in dehydration, severe diabetic acidosis, Addison's disease, and conditions that interfere with glomerular filtration^{1,2}.

Low magnesium concentration in plasma is found as a result of gastrointestinal malabsorption, fluid losses, renal losses caused by diuretic therapy and aminoglycoside therapy. It also may be due to hypoparathyroidism and alcoholism^{1,2}.

Based on clinical guidelines and textbooks, and when used in conjunction with other diagnostic technologies and options, this medical information is useful for the assessment of Magnesium imbalance.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Magnesium in the sample reacts with xylidyl blue in alkaline medium forming a coloured complex that can be measured by spectrophotometry. EGTA is included in the reagent to remove calcium interference^{3,4}.

CONTENTS AND COMPOSITION

A. Reagent. 4 x 40 mL. Sodium carbonate 0.1 mol/L EGTA 0.1 mmol/L, triethanolamine 0.1 mol/L, potassium cyanide 7.7 mmol/L, sodium azide 0.95 g/L.

DANGER: H314: Causes severe skin burns and eye damage. P280: Wear protective gloves/protective clothing/eye protection/face protection. P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

B. Reagent. 4 x 10 mL. Glycine 25 mmol/L, xylidyl blue 0.5 mmol/L, chloroacetamide 2.6 g/L.

WARNING: H317: May cause an allergic skin reaction. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

S. Calcium/Magnesium Standard. 1 x 5 mL. Calcium 10 mg/dL, magnesium 2 mg/dL (0.82 mmol/L). Aqueous primary standard.

STORAGE AND STABILITY

Store at 2-8°C.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

Indications of deterioration:

- Reagents: Presence of particulate material, turbidity, absorbance over 0.900 at 520 nm (1 cm cuvette).
- Standard: Presence of particulate material, turbidity.

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents. Safety data sheet available for professional user on request. Disposal of all waste material should be in accordance with local guidelines. Any serious incident that might occur in relation to the device shall be reported to BioSystems S.A.

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

- Analyzer, spectrophotometer or photometer with cell holder able to read at 520 ± 20 nm.
- Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

REAGENT PREPARATION

Working Reagent: pour the contents of the Reagent B into the Reagent A bottle. Mix gently. Other volumes can be prepared in the proportion: 4 mL Reagent A + 1 mL Reagent B. Stable for 15 days at 2-8°C.

Standard is provided ready to use.

SAMPLES

Serum, plasma or urine collected by standard procedures. Hemolysed and lipemic samples are not suitable for testing.

Magnesium in serum or plasma is stable for 7 days at 4-8°C. Use heparin as anticoagulant⁵.

Collect 24-hour urine in a bottle containing 10 mL of 10% (v/v) hydrochloric acid. Stable for 1 week at 2-8°C. Centrifuge or filter the sample and dilute 1/5 with distilled water before measurement.

PROCEDURE

- Bring the Working reagent to room temperature.
- Pipette into labelled test tubes: (Notes 1, 2)

	Blank	Standard	Sample
Magnesium Standard (S)	—	10 µL	—
Sample	—	—	10 µL
Working reagent	1.0 mL	1.0 mL	1.0 mL

- Mix thoroughly and let stand the tubes for 2 minutes at room temperature.
- Read the absorbance (A) of the Standard and the Sample at 520 nm against the Blank. The colour is stable for at least 1 hour.

CALCULATIONS

The magnesium concentration in the sample is calculated using the following general formula:

$$\frac{A_{\text{Sample}}}{A_{\text{Standard}}} \times C_{\text{Standard}} = C_{\text{Sample}}$$

If the Magnesium Standard provided has been used to calibrate (Note 2):

$\frac{A_{\text{Sample}}}{A_{\text{Standard}}}$	x 2 = mg/dL magnesium x 0.82 = mmol/L magnesium
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REFERENCE VALUES

Serum and plasma¹: 1.7 - 2.4 mg/dL = 0.66 - 1.07 mmol/L.

Urine¹: 12 - 291 mg/24-h = 0.5 - 12.0 mmol/24-h.

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, cod. 18009 and cod. 18042) and II (cod. 18007, cod. 18010 and cod. 18043) and the Biochemistry Control Urine (cod. 18054 and cod. 18066) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

METROLOGICAL CHARACTERISTICS

- Detection limit: 0.16 mg/dL = 0.06 mmol/L. Quantification limit: 0.45 mg/dL = 0.18 mmol/L.
- Linearity limit: 4 mg/dL = 1.64 mmol/L. For higher values dilute sample 1/2 with distilled water and repeat measurement.
- Precision:

Serum. Mean concentration	Repeatability (CV)	Within-laboratory (CV)
1.53 mg/dL = 0.63 mmol/L	1.6 %	2.9 %
2.88 mg/dL = 1.18 mmol/L	0.9 %	3.1 %
3.43 mg/dL = 1.41 mmol/L	0.9 %	1.9 %

Urine. Mean concentration	Repeatability (CV)	Within-laboratory (CV)
3.22 mg/dL = 1.32 mmol/L	3.8 %	8.6 %
7.10 mg/dL = 2.91 mmol/L	4.1 %	5.3 %
13.4 mg/dL = 5.50 mmol/L	2.0 %	3.9 %

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

- Interferences: Bilirubin (up to 6 mg/dL), hemolysis (hemoglobin up to 300 mg/dL) and lipemia (triglycerides up to 158 mg/dL) do not interfere. Other drugs and substances may interfere⁵.

NOTES

- Contamination of glassware with magnesium will affect the test. Use acid-washed glassware or plastic tubes.
- The reagent may be used in several automated analyzers. Instructions for many of them are available on request.
- Calibration with the provided aqueous standard may cause a matrix related bias, specially in some analyzers. In these cases, it is recommended to calibrate using a serum based standard (Biochemistry Calibrator, cod. 18011 and 18044).

BIBLIOGRAPHY

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- Chromýa V, Svoboda V, and Štěpánová I. Spectrophotometric determination of magnesium in biological fluids with xylidyl blue II. Biochem Med 1973; 7/2: 208-217.
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