MAGNESIUM

COD 12797 5 x 20 mL

Only for *in vitro* use in the clinical laboratory

BioSystems

MAGNESIUM
XYLIDYL BLUE

INTENDED USE

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

This reagent is for use in the BioSystems A25 and A15 analyzers.

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 aminoglucoside therapy. It also may be due to hypoparathyroidsm 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. 5 x 16 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. 2 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.

STORAGE AND STABILITY

Store at 2-8ºC.

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.

On board stability: Reagents open and kept in the refrigerated compartment of the analyzer are stable 7 days.

Indications of deterioration: Absorbance of the blank over the limit indicated in "Test Parameters".

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)

Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

REAGENT PREPARATION

Working Reagent: Add 4.0 mL of 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 2-8ºC.

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 - 8ºC. Use heparin as anticoagulant[5].

Collect 24-hour urine in a bottle containing 10 mL of 10% (v/v) hydrochloric acid. Stable for 1 week at 2-8ºC. Centrifuge or filter the sample before measurement.

CALIBRATION

A reagent blank should be done every day and a calibration at least every 3 days, after reagent lot change or as required by quality control procedures.

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.

REFERENCE VALUES

Serum and plasma[1]: 1.7 - 2.4 mg/dL = 0.66 - 1.07 mmol/L.

Urine[1]: 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.

METROLOGICAL CHARACTERISTICS

The metrological characteristics described below have been obtained using an A25 analyzer. Results are similar with A15.

- Detection limit: 0.21 mg/dL = 0.08 mmol/L. Quantification limit: 0.99 mg/dL = 0.40 mmol/L.
- Linearity limit: 4 mg/dL = 1.64 mmol/L. Measuring range: 0.99 mg/dL - 4 mg/dL. For samples with higher values, dilute manually or refer to the Test Parameterization for Automatic dilution (note that all these samples will be diluted with the same dilution ratio).
- Precision:

Serum. Mean concentration	Repeatability (CV)	Within-laboratory (CV)
1.41 mg/dL = 0.58 mmol/L	3.6 %	4.9 %
3.01 mg/dL = 1.23 mmol/L	1.7 %	4.4 %
3.40 mg/dL = 1.39 mmol/L	1.6 %	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 223 mg/dL) do not interfere. Other drugs and substances may interfere[6].

BIBLIOGRAPHY

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 6th ed. Rifai N, Horvath AR, Wittwer CT. WB Saunders Co, 2018.
2. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.
3. Barbour HM and Davisdon W. Studies on measurement of plasma magnesium: application of the Magon dye method to the "Monarch" centrifugal analyzer. Clin Chem 1988; 34/10: 2103-2105.
4. 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.
5. Word Health Organization (WHO). Use of anticoagulants in diagnostic laboratory investigations. Document WHO/DIL/LAB/99.1, Rev.2; 2002.
6. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

TEST PARAMETERS

R1: Use Reagent A, R2: se Reagent B.

	A25	A15
GENERAL		
Name	**MAGNESIUM Xylidyl**	**MAGNESIUM Xylidyl**
Sample type	SER / URI	SER / URI
Analysis mode	endpoint mon.	endpoint mon.
Units	mg/dL	mg/dL
Turbidimetry test	no	no
Decimals	2	2
Type of reaction	increasing	increasing
PROCEDURE		
Reading mode	monoch.	monoch.
Main filter	505	505
Reference filter	-	-
Sample	3	3
Vol. R1	300	300
Vol. R2	-	-
Washing	1.2	1.2
Reading 1 (cycle)	21	14
Reading 2 (cycle)	-	-
Reagent 2 (cycle)	-	-
Predilution factor	- / 5*	- / 5*
Predilution reduced factor	2	2
CALIBRATION AND BLANK		
Calibration type	multiple	multiple
Number of calibrators	-	-
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.650	0.650
Kinetic blank limit	-	-
Linearity limit	4 / 20	4 / 20
Substrate depletion	-	-

* Distilled water is required for the dilution of the sample.

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