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MAGNESIUM

Quantitative Determination of Magnesium.
Colorimetric Calmagite-EGTA Method.

For professional in vitro diagnostic use only.

INTENDED USE

Quantitative determination of Magnesium in Serum, Plasma or Urine. Colorimetric Calmagite-EGTA method.

GENERALITIES

Deficiency of magnesium is a quite common disorder which can be caused by malnutrition, malabsorption, renal loss and endocrinological disturbances. Complications associated with decreased magnesium concentrations are neuromuscular irritability (e.g. Tremor, seizures) and cardiac symptoms (e.g. tachycardia, arrhythmia). Decreased magnesium concentrations are often related to decreased calcium and potassium levels, taking into account that hypomagnesemia may be the primary cause of hypocalcemia. Elevated magnesium values can be observed in dehydration, renal disorders and after intake of excessive amounts of antacids and can be associated with weakness of reflexes and low blood pressure.

TEST PRINCIPLE

Magnesium ions react with Calmagite, a metallochromic indicator (1 - 1-hydroxy-4-methyl-2-phenylazo-2-naphtol-4-sulfonic acid), in alkaline medium to produce a red complex that is measured photometrically. EGTA reduces Calcium interference, reduces interference of heavy metals, and a surfactant reduces the interference of proteins and lipemia.

The intensity of color produced is directly proportional to magnesium concentration.

REAGENT COMPOSITION

R1: Buffer	
EGTA	0.8 mmol/L
KCl	1.34 mol/L
Triethanolamine	0.7 mmol/L
R2: Calmagite Solution	
Calmagite	0.33 mol/L
KCl	1.34 mol/L
Standard	
Magnesium	value on label

STORAGE, PREPARATION AND SHELFLIFE

Liquid and ready to use reagents, stable until the expiry date shown, if stored as indicated on the label and avoid contamination, evaporation and prolonged exposure to direct light. Do not freeze the reagents. Discard the reagent if signs of deterioration appear, such as the presence of particles and turbidity or failure to recover the values of certified control sera. After opening the bottles, it is advisable to withdraw the necessary volume, to immediately close the bottles and store them in the fridge to avoid contamination, degradation from direct light and evaporation.

Work Solution Preparation: mix 1 part of R1 and 1 part of R2 (E.g. 5 mL of R1 + 5 mL of R2). Stability: 24 hours at 15-25°C and 4 days at 2-8° C.

SAMPLE COLLECTION AND PREPARATION

Serum, heparinized plasma, cerebrospinal fluid (CSF) or 24 hours urine.

Do not use EDTA plasma. Avoid hemolysate or lipemic samples. Separate the serum from the clot quickly.

Collect 24-hours urine adding 10 mL of HCl at pH 3-4, then dilute the sample 1:5 (1+4) with distilled water.

Stability:

Serum/plasma: 7 days at 2- 8° C. One year at - 20°C Only freeze once.

Urine: 3 days at 2 - 8°C; 1 year at -20°C.

Discard contaminated specimens.

TEST PROCEDURE

Wavelength	: 510 nm (490 – 540)
Light path	: 1 cm
Temperature	: 37 °C
Measurement:	: against Reagent Blank
Assay type	: Endpoint

Assay:

	Blank	Assay
Working Solution	**1000 µL**	**1000 µL**
Sample/ Standard/ Cal	**/**	**10 µL**

- Mix and incubate for 3 min at 37 °C.
- Read the absorbance (A) of the samples and the standard against the reagent blank.

CALCULATION

Serum/ Plasma/CSF:

$$\text{Concentration} = \frac{\text{Abs Sample - Abs Blank}}{\text{Abs Std/Cal - Abs Blank}} \times \text{Std/ Cal.}$$

Urine:

Calculate as for the serum/plasma and multiply the result by 5 (initial sample dilution).

Magnesium (mg/24h) = Magnesium (mg/dL) x Urine Volume 24h (dL)

Conversion Factor: mg/dL x 0.4114 = µmol/L.

QUALITY CONTROL

Normal and abnormal control sera of known concentration should be analyzed routinely with each group of unknown samples.

EXPECTED VALUES

Serum/plasma:

- 1.6 - 2.5 mg/dL.

Urine:

- 24 - 244 mg/24h.

Each laboratory should establish a range of expected values based on its patient population and, if necessary, determine its own reference interval. For diagnostic purposes, results should always be assessed together with the patient's medical history, clinical examination and other results.

PERFORMANCE

PRECISION:

Low Level: Samples= 20; Average = 2.39; S.D. = 0.02; CV = 1.18%.
High Level: Samples = 20; Average = 4.01; S.D. = 0.07; CV = 1.73%.

ACCURACY:

A comparison between this method (x) and a certified method of trade (y) gave the following correlation:

y=0.971x + 0.145 r =0.9989

SENSITIVITY: 0.2 mg/dL.

LINEARITY: 5 mg/dL.

PRECAUTIONS

in case of contact of reagents with the operator, you must apply the following first aid:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of water. Wear suitable protective clothing, gloves and eye/face protection.

INTERFERENCES

No interference was observed by hemoglobin up to 300 mg/dL, Bilirubin up to 25 mg/dL, Lipides may interfere.

LITERATURE

- Tietz n.w. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.1034-1036 et 1408-1410.
- Young d.s., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-410 to 3-414.
- Gindler e.m., heth d.a., clin. chem. (1971), 17, p.662.
- H. Khayam-bashi, tsan z. liu, vern w. clin. chem. (1977), 23/2, p.289-291.

USED SYMBOLS

IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
REF	Catalogue Number
LOT	Batch Code
	Use by YYYY-MM (MM = end of month)
	Operator's Manual; Operating Instructions
	Keep away from Sunlight
	Keep away from Rain
	Temperature Limit
	Caution
	Do not use if Package is Damaged
	Do Not Re-Use
	Contains Sufficient for <N> Tests