MAGNESIUM $\quad$ CE

REF 1144005 2 x 50 mL **CONTENTS** R1. Reagent 2 x 50 mL CAL. Standard 1 x 3 mL	**MAGNESIUM MR** CALMAGITE *Colorimetric method* ENDPOINT
For *in vitro* diagnostic use only	

PRINCIPLE

The method[1] is based on the specific binding of calmagite, a metallochromic indicator[2], and magnesium at alkaline pH with the resulting shift in the absorbtion wavelength of the complex. The intensity of the cromophore formed is proportional to the concentration of magnesium in the sample.

$$\text{Calmagite + Magnesium} \xrightarrow{\text{pH 11.5}} \text{Calmagite-Magnesium complex}$$
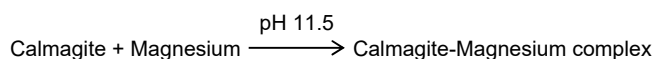
REAGENT COMPOSITION

R1 **Chromogen.** Calmagite 75 mmol/L, EGTA 60 mmol/L, amino-methyl-propanol 0.2 mol/L, KCl 0.2 mol/L, surfactant 0.05 % (w/v).

CAL **Calcium / Magnesium standard**. Calcium 10 mg/dL / Magnesium 2 mg/dL.
Organic matrix based primary standard. Concentration value is traceable to Standard Reference Material 909b.

STORAGE AND STABILITY

Store at 2-8ºC.
All the kit compounds are stable until the expiry date stated on the label. Do not use reagents over the expiration date.
Store the vials tightly closed, protected from light and prevented contaminations during the use.

Discard If appear signs of deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 520 nm > 0.600 in 1cm cuvette.

REAGENT PREPARATION

The Reagent and Standard are ready-to-use.

SAMPLES

Serum or heparinized plasma free of hemolysis. Other anticoagulants (EDTA, oxalate and citrate) must not be used.
Magnesium in serum or plasma is stable for 10 days at 2-8ºC. Freeze for longer storage.

INTERFERENCES

- Lipemia (intralipid) may affect the results.
- Bilirubin (< 10 mg/dL) does not interfere.
- Hemoglobin (> 1 g/L) may affect the results.
- Other drugs and substances may interfere[3].
- Many detergents and water supplies (see Notes).
- The interference by calcium is prevented by the use of EGTA into the buffer.

MATERIALS REQUIRED

- Photometer or colorimeter capable of measuring absorbance at 520 ± 20 nm.
- Pipettes with disposable plastic tips to measure reagents and samples.
- Disposable plastic tubes for the tests.

PROCEDURE

1. Bring reagents and samples to room temperature.
2. Pipette into labelled test tubes:

TUBES	Blank	Sample	CAL. Standard
R1.Reagent	1.0 mL	1.0 mL	1.0 mL
Sample	–	10 µL	–
CAL.Standard	–	–	10 µL

3. Mix and let the tubes stand 2 minutes at room temperature.
4. Read the absorbance (A) of the samples and the standard at 520 nm against the reagent blank.

The color is stable for at least 1 hour.

CALCULATIONS

Serum, plasma

$$\frac{A_{Sample}}{A_{Standard}} \times C_{Standard} = \text{mg/dL magnesium}$$

Samples with concentrations higher than 10 mg/dL should be diluted 1:2 with saline and assayed again. Multiply the results by 2.

If results are to be expressed as SI units apply:
mg/dL x 0.412 = mmol/L

REFERENCE VALUES[4]

Serum, plasma

Children (2-12 years)	1.7 - 2.3 mg/dL (0.70 - 0.94 mmol/L)
Adults (12-60 years)	1.6 - 3.0 mg/dL (0.66 - 1.23 mmol/L)

It is recommended that each laboratory establishes its own reference range.

QUALITY CONTROL

The use of a standard to calculate results allows to obtain an accuracy independent of the system or instrument used.
To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

REF   **1980005**   HUMAN MULTISERA NORMAL
Borderline level of magnesium. Assayed.

REF   **1985005** HUMAN MULTISERA ABNORMAL
Elevated level of magnesium. Assayed.

If the values are found outside of the defined range, check the instrument, reagents and procedure.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

CLINICAL SIGNIFICANCE

Magnesium is considered an essential nutrient and a major intracellular cation. More than 50% of the total magnesium found in the body is complexed with calcium in the skeleton; however, only 1% of total body magnesium is found in the circulation. Between 60% and 70% of serum magnesium is free; the remaining percentage is bound to albumin, phosphate, citrate, and other ions.

Magnesium is also used as an *activator* (inorganic ion that is needed as a cofactor for an enzyme reaction) for more 300 enzymes, especially those involved in oxidative phosphorylation, glycolysis, cell replication, and protein synthesis.

The absorption of magnesium in the intestinal tract and its reabsorption in the renal tubules are directly associated with the body´s need, balance and health.

Hypomagnesemia (an abnormal decrease in the level of serum magnesium) is usually associated with severe prolonged diarrea, impairment of neuromuscular function, gastrointestinal malabsorption and alcoholism.

Hypermagnesemia (an abnormal elevation in the level of serum magnesium) is usually associated with renal glomerular failure, dehydration; sever diabetic acidosis, and Addison´s disease.

NOTES

− Most of the detergents and water softening products used in the labs contain chelating agents. A defective rinsing will invalidate the procedure. Keep the glassware acid washed and thoroughly rinsed at all times.

− This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.

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

ANALYTICAL PERFORMANCE

- **Detection Limit :** 0.01 mg/dL

- **Linearity :** Up to 10 mg/dL

- **Precision:**

mg/dL	Within-run		Between-run	
Mean	2.16	4.54	2.16	4.54
SD	0.03	0.05	0.08	0.08
CV%	1.46	1.11	3.78	1.79
N	10	10	10	10

- **Sensitivity:** 0.0721 A / mg/dL magnesium.

- **Correlation.** This assay (y) was compared with a similar commercial method (x). The results were:

 N = 60   r = 0.99   y =1.09x - 0.214

The analytical performances have been generated using on automatic instrument. Results may vary depending on the instrument.

REFERENCES

1. Lindstrom, F., and Diehl. Anal. Chem. 32 : 1123 (1960).
2. Anderegg, G, Flashka, H., Sallmann, R. and Schwartzenbach, G. Metallindikatoren VII. Fasciculus: 37 : 113 (1954).
3. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
4. Tietz. N.W. Clinical Guide to Laboratory Tests, 3rd Edition. W.B. Saunders Co. Philadelphia, PA. (1995).
5. Chauhan, U.P.S., and Sarkar, B.C.R. Anal. Biochem. 32:70 (1969).