MAGNESIUM CALMAGITE

In vitro diagnostic reagent, for professional use only

CLINICAL SIGNIFICANCE (1,2)
Approximately, 55% of the total body magnesium is in the skeleton; the remainder is intracellular. Magnesium and potassium are the two most important cations. Mg²⁺ is the cofactor of a lot of enzymatic systems including ATP-dependant enzymes. Only 1% of the total body magnesium content is carried by blood; in serum, about 55% of magnesium is free, 30% is associated with proteins (primarily albumin), and 15% forms complexes with phosphate, citrate, and other anions. A severe magnesium deficiency is not common since the body has great abilities keeping magnesium. Hypomagnesemia can be due to renal losses, gastrointestinal disorders and some therapeutic treatments. A magnesium deficiency induces neuromuscular hyperirritability and can lead to hypocalcemia contributing to neurological symptoms. Hypermagnesemia is caused almost always by excessive intake (parenteral therapy, inappropriate dosage of therapeutic substances (magnesium sulfate)). The decrease of magnesium excretion can happen in case of severe renal troubles, and the use of treatments containing magnesium (pumping out of the stomach, anti acids) can then lead to hypermagnesia. Neuromuscular system depression is the main show of a magnesium poisoning.

METHOD (2,3)
Colorimetric-Calmagite.

End Point.

PRINCIPLE (2,3)
Magnesium forms a coloured complex with calmagite in alkaline solution. EGTA eliminates the calcium interference.

REAGENTS COMPOSITION
Reagent 1: R1
2-Methyl-2-Amino-1-Propanol 1 mol/L
EGTA 215 µmol/L
Reagent 2: R2
Calmagite 300 µmol/L
Standard: Std
Magnesium sulfate 2 mg/dL
20 mg/L
824 µmol/L

► MATERIAL REQUIRED BUT NOT PROVIDED
CONT- 0060 ELITROL I 10 × 5 ML
CONT- 0160 ELITROL II 10 × 5 ML

► PRECAUTIONS
- Use clean or single use laboratory equipment to avoid contamination.
- The standard should be immediately and tightly capped to prevent contamination and evaporation.

► WASTE MANAGEMENT
Disposal of all waste material should be in accordance with local and legal requirements.

STABILITY OF REAGENTS
To store at 2-8°C and protected from light.
The reagents and the standard are stable until the expiry date stated on the label.

PREPARATION AND STABILITY OF WORKING REAGENTS
- Preparation
Mix 1 volume of reagent R1 with 1 volume of reagent R2.
- Stability
24 hours at 20 - 25 °C
4 days at 2 - 8 °C

On board stability:
The stability is specific for each analyser (for Selectra refer to § PERFORMANCE DATA).

SAMPLES (1, 2, 4)
- Specimen
Serum free of hemolysis.
Heparin plasma. Do not use EDTA or chelating agents, oxalate, citrate.
Urine collected on 24 hours diluted 1/5 with distilled water, acidified with HCl (about pH 1, 0).

Note: Collect specimen in metal-free container.

- Storage
Serum and heparin plasma are stable 7 days if refrigerated at 2-8°C. For a longer storage, freeze samples.
Store urine at 2-8°C. Do not use preservatives.

REFERENCE VALUES (1,4)
Serum, plasma: 1.7 - 2.4 mg/dL
17 - 24 mg/L
0.70 - 0.99 mmol/L
Urine: 73 - 122 mg/24h
3.0 - 5.0 mmol/24h

Urinary excretion of magnesium is diet dependant.

Note: It is recommended for each laboratory to establish and maintain its own reference values. The data given here are only an indication.

PROCEDURE
This reagent can be used on most analysers, semi automated analysers and manual methods.
The applications are available on request.
Wavelength: 500 nm
Temperature: 37°C
Read against reagent blank

<table>
<thead>
<tr>
<th>BLANK</th>
<th>CALIBRATION</th>
<th>TEST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working Reagent</td>
<td>300 µL</td>
<td>300 µL</td>
</tr>
<tr>
<td>Distilled water</td>
<td>3 µL</td>
<td>-</td>
</tr>
<tr>
<td>Standard</td>
<td>-</td>
<td>3 µL</td>
</tr>
<tr>
<td>Sample</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Mix and read the absorbance (A) after 75 second incubation.

Note: Procedure sheet for erythrocytes is available on request.

CALCULATION
\[
A_{\text{Sample}} \times n = \text{standard concentration}
\]
\[
A_{\text{Standard}}
\]
Take dilution factor into account for the calculation of magnesium concentration in urine.

► CALIBRATION
Concentration value for Magnesium Standard is traceable to the Standard Reference Material SRM 909b (of the National Institute of Standards and Technology).
The calibration frequency is specific for each analyser (for Selectra refer to § PERFORMANCE DATA).

QUALITY CONTROL
To ensure adequate quality, control sera such as ELITROL I (normal control) and ELITROL II (abnormal control) are recommended.
In vitro diagnostic reagent, for professional use

### PERFORMANCE DATA at 37°C on Selectra

#### - Analytical range
The reagent is linear from 0.34 to 5 mg/dL (3.40 to 50 mg/L, 0.14 to 2.03 mmol/L).

#### - Detection limit
Determined according to SFBC protocol, the detection limit is equal to 0.12 mg/dL (1.2 mg/L, 45.8 µmol/L).

#### - Analytical sensitivity
The average variation of the analytical sensitivity is 50 mA per mg/dL of magnesium (5.0 mA per mg/L; 0.120 Å per mmol/L) for a light path of 1 cm.

#### - Precision

<table>
<thead>
<tr>
<th></th>
<th>Medium level</th>
<th>High level</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>m</td>
<td>2.37 mg/dL</td>
<td>4.64 mg/dL</td>
</tr>
<tr>
<td>CV</td>
<td>2.5%</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

#### Between-run reproducibility on sera

<table>
<thead>
<tr>
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<th>High level</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>m</td>
<td>2.64 mg/dL</td>
<td>4.74 mg/dL</td>
</tr>
<tr>
<td>CV</td>
<td>3.3%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

#### - Correlation

A comparative study was performed between ELTech method and another commercial reagent (colorimetric method-Calmagite) on 63 serum samples. The sample concentrations range from 0.6 to 5.3 mg/dL.

The linear regression parameters are as follows:

- Correlation coefficient: \( r = 0.9963 \)
- Linear regression: \( y = 1.1457x + 0.16 \) mg/dL

#### - Interferences

According to SFBC recommendations, studies were performed to determine the interference level of different compounds:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Level</th>
<th>Interference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>Normal</td>
<td>Positive bias from 5 mg/dL (90 µmol/L) on normal serum and 14.5 mg/dL (250 µmol/L) on pathological serum.</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>Normal</td>
<td>No significant interference up to 1200 mg/dL (12 g/L)</td>
</tr>
<tr>
<td>Glucose</td>
<td>Normal</td>
<td>No significant interference up to 600 mg/dL (6 g/L; 34 mmol/L)</td>
</tr>
</tbody>
</table>

Other compounds may interfere. \(^{(6-8)}\)

**Note:** Do not use hemolysed samples

#### - On board stability/calibration frequency on Selectra (no refrigerated)

On board stability: 3 hours
Calibration frequency: 3 hours

Make a new calibration when reagent lots change, when quality control results fall outside the established range, and after the maintenance operation.

### BIBLIOGRAPHY


### SYMBOLS USED ON LABELS

- IVD : In vitro diagnostic medical device
- : Consult Instruction for use
- : Manufacturer’s address
- : Catalogue number
- : Temperature limitation
- : LOT number
- : Expiration date

Revised Version: PIT-MAGN-9 03/2010