



Store at: +2+8°C.

Presentation:

Cod. SU025 CONT: R1 1 x 125 mL. + R2 1 x 125 mL. + Cal. 1 x 5 mL.

Procedure

Quantitative determination of magnesium.

Only for in vitro use in clinical laboratory (IVD)

TEST SUMMARY

Magnesium form a purple coloured complex when reacts with calmagite in alkaline solution^(Note 1).

The intensity of the color formed is proportional to the magnesium concentration in the sample¹.

REAGENTS COMPOSITION

| | | |
|----------------------|--------------------------------------|-------------------------|
| R.1 Buffer | Amino-methyl-propanol EGTA | 1 mmol/L 0.21 mmol/L |
| R.2 Chromogen | Calmagite | 0.30 mmol/L |
| Magnesium CAL | Magnesium aqueous primary calibrator | 10 mg/dL |

REAGENT PREPARATION AND STABILITY

Working reagent (WR):

Mix equal volumes of R 1 Buffer and R 2 Chromogen.

The working reagent is stable for 4 days at refrigerator (2-8°C) or 24 h at room temperature (15-25°C).

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.

Do not use reagents over the expiration date

Magnesium CAL: Once open is stable up to 1 month when stored tightly closed at 2-8°C, protected from light and contamination prevented during their use.

Signs of Reagent deterioration:

- Presence of particles and turbidity.
- Blank absorbance (A) at 520 nm ≥ 1.4

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store tightly closed at 2-8°C. Do not use reagents over the expiration date.

SPECIMEN

Serum, heparinized plasma¹:

Free of hemolysis and separated from cells as rapidly as possible.

Do not use oxalates or EDTA as anticoagulant.

Stability: 7 days at 2-8°C.

Urine¹:

Should be acidified to pH 1 with HCl.

If urine is cloudy; warm the specimen to 60°C for 10 min. to dissolve precipitates.

Dilute the sample 1/10 with distilled water and multiply the result by 10.

Stability: 3 days at 2-8°C.

MATERIAL REQUIRED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 520 nm.
- Matched cuvettes 1.0 cm. light path.

General laboratory equipment^(note 2).

TEST PROCEDURE

- Assay conditions:
Wavelength: 520 nm (500-550)
Cuvette: 1 cm light path
Temperature 37°C / 15-25°C
- Adjust the instrument to zero with distilled water.
- Pipette into a cuvette:

| | Blank | Standard | Sample |
|---------------------------------------|-------|----------|--------|
| WR (mL) | 1.0 | 1.0 | 1.0 |
| Calibrator ^(Note 3-4) (μL) | -- | 10 | -- |
| Sample (μL) | -- | -- | 10 |

- Mix and incubate for 5 min at room temperature or 3 min at 37°C.
- Read the absorbance (A) of the samples and calibrator, against the Blank. The colour is stable for at least 30 minutes.

CALCULATIONS

$$\text{Magnesium (mg/dl)} = \frac{(A) \text{ Sample}}{(A) \text{ Standard}} \times 2 (\text{Calibrator. conc.})$$

Conversion factors:

mg/dL x 0.412 = mmol/L or

0,5 mmol/L = 1.0 mEq/L = 1,22 mg/dL = 12,2 mg/L¹.

QUALITY CONTROL

Control sera are recommended to monitor the performance of the procedure, Normal and Pathological.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES¹

| | |
|------------------|--|
| Serum or plasma: | |
| | 1.6 – 2.5 mg/dL \cong 0.66 – 0.03 mmol/L |
| Urine: | |
| | 24 – 244 mg/24 h \cong 2 – 21 mEq/L/24 h |

(These values are for orientation purpose).

It is suggested that each laboratory establish its own reference range.

CLINICAL SIGNIFICANCE

Magnesium is the second more abundant intracellular cation of the human body after potassium, being essential in great number of enzymatic and metabolic processes.

Is a cofactor of all the enzymatic reactions that involve the ATP and comprises of the membrane that maintains the electrical excitability of the muscular and nervous cells.

A low magnesium level is found in malabsorption syndrome, diuretic or aminoglycoside therapy; hyperparathyroidism or diabetic acidosis.

Elevated concentration of magnesium is found in uremia, chronic renal failure, glomerulonephritis, Addison's disease or intensive anti acid therapy^{1,4,5}.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE

- Measuring Range:

From detection limit of 0.2 mg/dL. to linearity limit of 5 mg/dL., under the described assay conditions.

If results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L. and multiply result by 2.

- Precision:

| | Intra-assay n= 20 | | Inter-assay n= 20 | |
|--------------|-------------------|------|-------------------|------|
| Mean (mg/dL) | 2.39 | 4.01 | 2.27 | 4.14 |
| SD | 0.02 | 0.07 | 0.07 | 0.13 |
| CV % | 1.18 | 1.73 | 2.99 | 3.22 |

- Sensitivity: 1 mg/dL. = 0.055 A/min.

Accuracy: Results obtained GPL reagents did not show systematic differences when compared with other commercial reagents.

The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES

- Hemolysis and anticoagulants other than heparin¹.
- A list of drugs and other interfering substances with magnesium determination has been reported by Young et. al^{2,3}.

NOTES

- Interference by calcium is prevented by the use of EGTA¹.
- It is recommended to use disposable material. If glassware is used the material should be scrupulously clean with H₂SO₄ - K₂Cr₂O₇ and then thoroughly rinsed with distilled water and dried before use.
- Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
- Use clean disposable pipette tips for its dispensation.

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