MAGNESIUM Single Reagent

INTENDED USE

METHOD

Vitro Magnesium reagent is intended for the determination of Magnesium in human serum and plasma on both automated and manual systems



Arsenazo dye - EGTA. Colorimetric

BACKGROUND

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 malabsortion syndrome, diuretic or aminoglucoside therapy; hyperparathyroidism or diabetic acidosis. Elevated concentration of magnesium is found in uremia, chronic renal failure, glomerulonephritis, Addisons's disease or intensive anti acid therapy1,4,5. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data..

ASSAY PRINCIPLE

Arsenazo dye which binds preferentially with magnesium. The absorbance of the Arsenazo Magnesium complex is measured at 620 nm and is proportional to the concentration of magnesium present in the sample. Calcium interference is prevented by incorporation of an unconventional calcium chelating agent.

EXPECTED VALUES

Serum or plasma:

1.6 - 2.5 mg/dL 0.66 - 0.03 mmol/L

Urine:

24 - 244 mg/24 h 2 - 21 mEq/L/24 h

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range.

REAGENTS

R1 Standard R 2 Color Reagent 2 mg/dL

Tris buffer Chelating agent 100 mmol/L 0.21 mmol/L

Arsenazo dye

· Reagent Preparation & Stability

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.

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 2-8ºC.

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

PROCEDURE

Manual Procedure

Wavelength 620 nm 1 cm light path Cuvette Temperature

Zero adjustment against reagent blank Specimen Serum or plasma

	Blank	Standard	Specimen
R ₂	1.0 ml	1.0 ml	1.0 ml
Standard		25 μl	
Specimen			25 μl

Mix, and Incubate for 5 minutes at 37 °C . Measure the absorbance of specimen (A_{specimen}) and standard (A_{standard}) against reagent blank.

The color is stable for 60 minutes.

Automated Procedure

User defined parameters for different auto analyzers are available upon request.

CALCULATION

Calculate the magnesium concentration in serum by using the following formulae

Serum magnesium Concentration=

Absorbance of Specimen X Standard value

Absorbance of Standard

QUALITY CONTROL

It is recommended that controls (normal and abnormal) be included in:

- Each set of assays, or
- At least once a shift, or
- When a new bottle of reagent is used, or
- After preventive maintenance is performed or a clinical component is replaced.

Commercially available control material with established potassium values may be routinely used for quality control.

Failure to obtain the proper range of values in the assay of control material may indicate:

- Reagent deterioration,
- Instrument malfunction, or
- Procedure errors.

The following corrective actions are recommended in such situations:

- Repeat the same controls.
- · If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results on fresh control material still remain outside the limits, then repeat the test with fresh reagent.
- If results are still out of control, contact Vitro Technical Services.

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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. al₂

PERFORMANCE CHARACTERISTICS

Sensitivity

The sensitivity is defined as the change of analytical response per unit change in analyte concentration at a pathlength of 1 cm.

When run as recommended the sensitivity of this assay is 0.2 $\,$ mg/dll.

LINEARITY

When run as recommended, the assay is linear up to 5 mg/dl If result exceeds 5 mg/dl, specimen should be diluted with 0.9% NaCl solution and reassayed. Multiply the result by the dilution factor.

BIBLIOGRAPHY

- 1. Farrell E C. Magnesium. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1065-1069.
- 2. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
- 3. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
- 4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
- 5. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

SYMBOL DECLARATION

**	Manufacturer	
\bigcap_i	Consult instructions for use	
LOT	Batch code (Lot #)	
REF	Catalog number	
1	Temperature limitation	
IVD	In vitro diagnostic medical device	
\square	Use by	
<u> </u>	Caution. Consult instructions	
(S)	Keep away from light	

ORDERING INFORMATION

REF SIZE

1491 2 X 25 ml

1492 2 X 50 ml

Manufactured in Egypt by: Vitro Scient

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