

Magnesium

INTENDED USE

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



METHOD

Arsenazo dye - EGTA. Colorimetric

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.

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		2 mg/dL
R 2 Color Reagent	Tris buffer	100 mmol/L
	Chelating agent	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 plasma: 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.
Urine:

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
Cuvette	1 cm light path
Temperature	37 °C
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=

$$\frac{\text{Absorbance of Specimen}}{\text{Absorbance of Standard}} \times \text{Standard value}$$

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 magnesium 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.

INTERFERING SUBSTANCES

Hemolysis and anticoagulants other than heparin. A list of drugs and other interfering substances with magnesium determination has been reported by Young et. al2

PERFORMANCE CHARACTERISTICS

Measuring range: From detection limit of 0,026 mg/dL to linearity limit of 32 mg/dL. If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.

Precision

	Intra-assay (n=20)		Inter-assay (n=20)	
	Mean (mg/dl)	SD	CV (%)	
Mean (mg/dl)	1.99	3.55	1.98	3.41
SD	0.03	0.04	0.09	0.15
CV (%)	1.68	1.14	4.55	4.42

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 0.026 mg/dl.

Accuracy

Results obtained using Vitro Scient reagents (y) did not show systematic differences when compared with other commercial reagents (x). The results obtained were the following: Correlation coefficient (r)² : 0,92276 Regression equation: $y=1,027x + 0,102$ The results of the performance characteristics depend on the analyzer used.

Linearity

When run as recommended, the assay is linear up to 32 mg/dl

If result exceeds 32 mg/dl, specimen should be diluted with 0.9% NaCl solution and reassayed. Multiply the result by the dilution factor.

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.

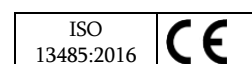
SYMBOL DECLARATION

	Manufacturer
	Consult instructions for use
	Batch code (Lot #)
	Catalog number
	Temperature limitation
	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

ORDERING INFORMATION

REF	SIZE
16201	2 X 25 ml
16202	2 X 50 ml
16203	2 X 100 ml

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BIBLIOGRAPHY