ARENA BioScien

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MAGNESIUM – Single Reagent

Diagnostic reagent for the in-vitro quantitative determination of Magnesium in human serum and plasma and urine on manual systems.

REF: BS.1/MG02.025.0050	50 test	REF: BS.1/ MG02.050.0100	100 test
REF: BS.1/ MG04.025.0100	100 test	REF: BS.1/ MG02.100.0200	200 test

CLINICAL SIGNIFICANCE

Magnesium is an activator for various physiochemical processes, including phosphorylation, protein synthesis, and DNA metabolism. It is also involved in neuromuscular conduction and excitability of skeletal and cardiac muscle.
Ingested magnesium is absorbed in the intestine and the amount absorbed is inversely related to the total magnesium intake. The kidneys effectively control magnesium homeostasis through tubular reabsorption, which conserves magnesium when intake is low and excretes excess when intake is high.
Increased serum magnesium concentrations occur in renal failure, acute diabetic acidosis, dehydration, or Addison's disease.
Hypermagnesemia has a depressing effect on the central nervous system, causing general anesthesia and respiratory failure. It alters the conduction mechanism of the heart, causing cardiac arrest.
Hypomagnesiumia may be observed in chronic alcoholism, malabsorption, severe diarrhea, acute pancreatitis, diuretic therapy, prolonged parenteral fluid therapy without magnesium supplementation, and the kidney disorders such as glomerulonephritis and tubular reabsorption defects.

METHOD PRINCIPLE

Xylidyl Blue, Colorimetric Endpoint.
Magnesium ions form a colored chelate complex when reacting with xylidyl blue in alkaline solution, the intensity of the color is proportional to the magnesium concentration. Calcium ions are masked by GEDTA.

REAGENT COMPOSITION

R1: Standard	2.5 mg/dl (1.0 mmol/L)
R2: Reagent	
Ethanolamine pH 11.0	1 mol/L
GEDTA (Glycoletherdiamin-tetraacetic acid)	60 µmol/L
Xylidylblue	100 µmol/L

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.
Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the magnesium reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien magnesium reagents are supplied ready-to-use. All reagents are stable until expiration date stated on label when stored at 2-8°C.

Deterioration
The ***BioScien*** magnesium reagent is normally clear, do not use reagent if it is turbid.

SPECIMEN COLLECTION AND PRESERVATION

Use serum or Heparinized plasma or urine.
Serum with any visible hemolysis cannot be used because of the large amount of magnesium released from the erythrocytes. The specimen should be separated from the clot as soon as possible to prevent falsely elevated magnesium due to passage of magnesium from the erythrocytes into the serum.
EDTA, Sodium fluoride and oxalate should be avoided because they interfere with the results.

SYSTEM PARAMETERS

Wavelength	630 nm
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample Reagent Ratio	1:100
e.g.: Reagent volume	1 ml
Sample volume	10 µl
Temperature	15-25˚C
Incubation time	10 min at 15-25˚C
Zero adjustment	Reagent blank
Sensitivity	0.2 mg/dl
Linearity	5.0 mg/dl

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes, automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Blank	*Standard*	*Specimen*
Reagent	1.0 ml	1.0 ml	1.0 ml
Standard		10 µl	
Specimen			10 µl

Mix, incubate for 10 minutes at room temp. Measure absorbance of specimen and standard against reagent blank. The color is stable for at least 1 hour.

CALCULATION

$$\text{magnesium concentration (mg/dl)} = \frac{\text{Abs. specimen}}{\text{Abs. standard}} \times 2.5$$

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	20	20	20	20
Mean mg/dl	1.98	3.99	1.88	4.04
SD.	0.02	0.03	0.02	0.06
CV. %	1.01	0.80	1.06	1.36

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

Accuracy (Methods Comparison)
Result obtained from ***BioScien*** magnesium reagent compared with commercial reagent of the same methodology performed on 20 human sera give a correlation of 0.995.

Sensitivity
When run as recommended, the minimum detection limit of the assay is 0.2 mg/dl.

Linearity
The reaction is linear up to concentration of 5.0 mg/dl. Specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result×2).

INTERFERING SUBSTANCES

Haemoglobin
It interferes because magnesium is released by erythrocytes.
Icterus
No significant interference up to a bilirubin level of 40 mg/dl.
lipemia
No significant interference up to 2000 mg/dl.
Calcium
No significant interference up to 25mg/dl.
Drugs
No interference was observed by ascorbic acid up to 30 mg/dl.
Others
Other drugs and substances may interfere.

EXPECTED VALUES

	mg/dl	***mmol/l***
Serum / Plasma		
Newborns	1.2 – 2.6	0.48 – 1.05
Children	1.5 – 2.3	0.60 – 0.95
Women	1.9 – 2.5	0.77 – 1.03
Men	1.8 – 2.6	0.73 – 1.06
Urine	1.0 – 10.0	3.0 – 5.0 mmol/24h
	73 – 122 mg/24h	
C.S.F	2.4 – 3.5	

DYNAMIC RANGE

0.2– 5.0 mg/dl.

REFERENCES

1. Thomas L. Clinical Laboratory Diagnostics 1st ed Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 231-41.
2. Mann ck,yoe JH. Spectrophotometric determination of Mg Anal. chem Acta 1957; 16: 155 – 60.

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

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CE