

Magnesium

1.0 INTENDED USE

This reagent is intended for the quantitative determination of Magnesium in serum.

2.0 BACKGROUND

2.1 METHOD AND HISTORY

This method is based on the xylidyl blue reaction which was first described by C.K. Mann and J.H. Yoe. (10.1,10.2) The reagent was modified to eliminate the use of organic solvents so that it can be used on discrete analyzers. (10.3,10.9)

This method provides rapid, precise, and accurate results that correlate with those obtained by atomic absorption.

2.2 TEST PRINCIPLE

Magnesium forms a red chelate with xylidyl blue in an alkaline medium which results in a spectral shift. The change in absorbance at 500 nm is directly proportional to the magnesium concentration and can be quantitated by an endpoint measurement after two minutes.

2.3 CLINICAL SIGNIFICANCE

Magnesium levels in serum are normally quite stable. The body content of magnesium in the adult is 0.36gm per kg and 0.27gm per kg in the newborn. The storage of magnesium in the body and its clinical significance is described by Alfrey and Miller. (10.4)

Decreased serum magnesium levels have been observed in cases of diabetes, alcoholism, excessive use of diuretics, hyperthyroidism, hypoparathyroidism, malabsorption, hyperalimentation, myocardial infarction, congestive heart failure and liver cirrhosis. Increased serum magnesium levels have been found in cases of renal failure, severe diabetic acidosis, and Addison's disease. (10.7,10.9)

3.0 SPECIMEN COLLECTION AND HANDLING

3.1 PATIENT PREPARATION

No special patient preparation is required.

3.2 SPECIMEN COLLECTION.

Fresh, clear unhemolyzed serum is the preferred specimen.

Since magnesium levels in erythrocytes are substantially greater than serum, hemolyzed samples should not be used for analysis.

Use a standard venipuncture tube to draw patient sample.

The amount of sample required will depend on the analyzer used. The amount of serum required is in the range of 5-25 µl. Call Biotron's technical service department at 1-800-595-8766 for the recommended sample volume for your analyzer.

Record the patient's name, date and time of sample collection and preparation.

3.3 SPECIMEN STORAGE

The blood specimens should be centrifuged within 30 minutes after collection and the serum separated from the cells. It is recommended that testing be done as soon as possible after sample collection and preparation.

4.0 MATERIALS

(2 X 125 ml)

(1 X 500 ml)

Reagents necessary for the determination of magnesium are included in the kit.

4.1 REAGENT

Magnesium Reagent contains:

Xylidyl blue-1	0.39 mmol/L
EGTA (Ethylene-bis tetraacetic acid)	0.09 mmol/L
potassium carbonate buffer and surfactant	153 mmol/L

4.2 WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use. Not for Internal use in Humans or Animals. In Vitro Diagnostics reagents may be hazardous. Avoid ingestion and skin or eye contact.

4.3 REAGENT PREPARATION

The reagent is ready to use as is.

4.4 REAGENT STORAGE AND STABILITY

When stored at 18°-26°C unopened reagents are stable until the expiration date printed on the label.

4.5 ADDITIONAL MATERIALS REQUIRED

- 4.5.1 Spectrophotometer or colorimeter capable of reading absorbance at 500 nm.
- 4.5.2 1 cm cuvettes or a flow cell capable of transmitting light at 500 nm.
- 4.5.3 Test tubes capable of holding 3 ml.
- 4.5.4 Pipettes capable of delivering 2 ml and 20 µl.
- 4.5.5 Deionized or distilled water.
- 4.5.6 Timer for a 2 minute incubation.
- 4.5.7 Constant temperature source which can be adjusted to 18-26° C or 37° C.
- 4.5.8 Calibrator
- 4.5.9 Normal and abnormal control for quality control.

5.0 TEST PROCEDURE

The following is a general procedure for use on a manual instrument.

5.1 PROCEDURE CONDITIONS

Wavelength	500 nm
Temperature	37° C, or 18-26° C
Pathlength	1.0 cm
Mode	endpoint
Reaction time	2 min
Sample volume	20 µl
Reagent volume	2 ml
Total volume	2.02 ml
Sample to reagent ratio	1/100

5.2 INSTRUMENT

Any instrument capable of reading absorbance accurately with a sensitivity of 0.001 absorbance at 500 nm may be used. The band width should be 10 nm or less, stray light 0.5% or less, and the wavelength accuracy within 2 nm.

5.3 CALIBRATION

The magnesium assay is calibrated by referencing the absorbance of the unknown sample to the absorbance of the calibrator.

5.4 PROCEDURE

The following is a general procedure for use on a manual instrument.

- 5.4.1 Prepare the required volume of Magnesium reagent.
- 5.4.2 Adjust the absorbance reading at 500 nm on the spectrophotometer to 0.000 using distilled water as the blank.
- 5.4.3 Determine the absorbance (Ar) of the magnesium reagent at 500 nm.
- 5.4.4 Into separate test tubes pipette 20 µl of calibrator or serum to be assayed.
- 5.4.5 Add 2.0 ml of reagent and mix.
- 5.4.6 Incubate for 2 minutes at 37° C or 18-26° C and determine the absorbance of the calibrator (As) and of each serum (A) at 500 nm using distilled water as the blank.

5.5 CALCULATION AND RESULTS

A - Ar

Magnesium = ----- X concentration of calibrator

As - Ar

Ar = initial absorbance of the reagent

A = absorbance of the unknown

As = absorbance of the calibrator

Example:

$$1.376 - 1.138$$

$$\text{Magnesium} = \frac{1.376 - 1.138}{1.508 - 1.138} \times 3.6 \text{ mEq/L} = 2.3 \text{ mEq/L}$$

$$1.508 - 1.138$$

with Ar = 1.138, A = 1.376, As = 1.508, concentration of calibrator = 3.6 mEq/L.

Note: 1 mEq/L = 0.500 mmol/L.

- 10.5 Martin, E.W., Hazard of Medication, Philadelphia, PA and Toronto, Canada, J.B. Lippencott Company (1971) pp 169-189
- 10.6 Contantino, N.V. and Kabat H.F., Drug-induced modifications of laboratory test values, revised 1973, Am J Hosp Pharm 30:21-71 (1973)
- 10.7 Tietz, N.W., (Editor), Clinical Guide to Laboratory Tests, W.V. Saunders Co., Philadelphia (1983) p. 338.
- 10.8 A.C. Alfrey, N.L. Miller and D. Butkus, J. Lab & Clin. Med. 84, 153 (1974).
- 10.9 Faulkner, W.R., AACC Press, Washington D.C. 1982 pp 277-280.
- 10.10 G.J. Kost, "Critical Limits for Urgent Clinician Notification at U.S. Medical Centers"; JAMA, Feb. 2, 1990; Vol 263, No.5, p.704

6.0 INTERPRETATION OF RESULTS

6.1 EXPECTED VALUES (10.8)

The range of expected values is: 1.8-2.4 mEq/L (0.90-1.20 mmol/L)

These values are suggested guidelines. It is recommended that each laboratory establish the normal range for the area in which it is located.

6.2 MEDICAL ALERT VALUES (10.10)

Each laboratory should establish low and high values beyond which the patient would require immediate attention by a physician. If a "medical alert value" is reached, always repeat the test to confirm the result and notify a physician if the result is confirmed.

6.3 LIMITATIONS OF PROCEDURE

A number of substances have been reported to cause physiological changes in serum Magnesium concentrations. See Young (10.4), Martin (10.5), and Contantino (10.6).

As with any chemical reaction, users should be alert to the possible effect on results caused by unknown interferences from medications or endogenous substances. All patient results should be evaluated in light of the total clinical status of the patient.

7.0 QUALITY CONTROL

Standard practice for quality control should be applied to this system. Commercially available lyophilized controls can be used to monitor the daily acceptable variations. Normal and abnormal controls should be assayed at the beginning of each run of patient samples, whenever a new reagent or a different lot number is being used, and following any system maintenance.

A satisfactory level of performance is achieved when the analyte values obtained are within the "acceptable range" established by the laboratory.

8.0 CALIBRATION PROCEDURES

The magnesium assay is calibrated by referencing the absorbance of the unknown sample to the absorbance of the calibrator. Refer to your instrument manual for more details.

Calibration is required with the use of a new lot of reagent, any system maintenance or whenever indicated by quality control data.

9.0 PERFORMANCE CHARACTERISTICS

9.1 PRECISION

The estimates of precision shown below were obtained from assays of human control serum.

Within-Run: In this study, 15 replicates of 2 control sera were run.

Mean (mEq/L)	SD (mEq/L)	CV (%)
2.01	± 0.03	1.69
3.32	± 0.04	1.20

Between-Run: In this study, 5 runs were made, each run consisting of 5 replicates of 2 control sera.

Mean (mEq/L)	SD (mEq/L)	CV (%)
2.10	± 0.08	4.04
3.44	± 0.11	3.29

9.2 CORRELATION

A correlation study was done on the Technicon RA-500 operating at 37° C comparing this method (y) with a similar comparative method (x) using Xylidyl-blue. The samples range between 0.2 mEq/L and 5.5 mEq/L.

Number of Samples	Regression Equation y=Biotron, x=Comparative	Correlation Coefficient
48	y = .966 x + .084	0.997

9.3 LINEARITY

This method linear to 8.0 mEq/L. A sample with magnesium beyond the linearity limit should be diluted 1 to 1 with deionized water. Reassay the specimen and multiply the results by 2.

10.0 REFERENCES

- 10.1 Mann C.K., Yoe J.H., Anal Chem, 28, 202-205 (1956)
- 10.2 Mann C.K., Yoe J.H., Anal Chem, 16, 155-160 (1957)
- 10.3 Klotzsch, S.G., Jacobson, R. and Carabuena, G., Clinichem-87, albany NY Abstr. 18
- 10.4 Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 3rd ed., Washington DC, AACC Press (1990).