

Intended Use

For the quantitative determination of magnesium in serum using the Mindray BS-480 analyzer. For *in vitro* diagnostic use only.

Clinical Significance

Magnesium in the body is found primarily in bone with some in soft tissue, blood cells, and serum. Decreased levels have been observed in cases of diabetes, alcoholism, diuretics, hyperthyroidism, hypothyroidism, malabsorption, hyperalimination, myocardial infarction, congestive heart failure and liver cirrhosis. Increased serum magnesium levels have been found in renal failure, diabetic acidosis, Addison's disease, and vitamin D intoxication.

Method History

Serum magnesium measurement was first introduced in the 1920's with the laborious precipitation procedures of Kramer and Tisdall,¹ Briggs,² and Denis.³ These were followed by a variety of methods including: complexometric EDTA titration procedures,⁴ fluorometric procedures involving chelates of magnesium,^{5,6} and a dye absorption method based on the reaction of Titan Yellow with magnesium hydroxide to form a red-colored lake.⁷ Each of these procedures suffered from numerous technical difficulties which greatly affected the accuracy and precision of their results. Atomic absorption remains the most accurate method for magnesium determinations. However, this method requires expensive instrumentation and uses large sample volumes which limit its usefulness for pediatric testing.⁸

Most recently, colorimetric dye-complexing methods have been developed and are in popular use. These procedures use such dyes as Calmagite, Eriochrome Black T, Xylidyl Blue (Magon), and methylthymol blue.⁹ The present procedure uses the metallochromic dye Xylidyl Blue for a rapid, easy and accurate determination of magnesium in serum.

Principle

Serum magnesium ions react with Xylidyl Blue in alkaline medium to produce a red complex that is measured spectrophotometrically. The intensity of color produced is directly proportional to magnesium concentration. Calcium interference is virtually eliminated by use of EGTA and a surfactant system is included to remove protein interference.

Reagent Composition

When combined the reagent contains: xylidyl blue 0.1mM, EGTA 0.13mM, DMSO 1.4M, Buffer, surfactant, non-reactive stabilizers including potassium cyanide at 0.02% w/v. Caution: Poison/Caustic, Avoid All Contact.

Reagent Preparation

The reagents are ready to use.

Reagent Storage and Stability

The magnesium reagent kit should be stored at room temperature, (15-30°C) until the posted expiration date. Manufacturer studies have shown reagent is stable for 14 days once placed in the refrigerated reagent carousel (2-10°C), however reagent stability may vary based on individual laboratory conditions. Do not use if the reagent fails to achieve established values of fresh control sera or the reagent becomes visibly turbid.

Precautions and Hazards

This reagent is for *in vitro* diagnostic use only. Reagents are Poison/Caustic, Avoid All Contact.

All specimens and controls should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiological and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

Hazards:

R1: Hazard Classifications: Skin corrosion/irritation (Category 2), Serious eye damage/eye irritation (Category 2), Specific target organ toxicity, single exposure; Respiratory tract irritation (Category 3),

Hazard Statements: H315: Causes skin irritation, H319: Causes serious eye irritation, H335: May cause respiratory irritation

Precautionary Statements: Prevention: P261 Avoid breathing dust/fume/gas/mist/vapors/spray. P264 Wash skin thoroughly after handling. P271 Use only in a well-ventilated area. P280 Wear protective gloves/protective clothing/eye protection/face protection. **Response:** P312 Call a POISON CENTER or doctor/physician if you feel unwell. P362 Take off contaminated clothing and wash before reuse. P302 + P352 IF ON SKIN: wash with plenty of soap and water. P304 + P340 IF INHALED: Remove victim to fresh air and Keep at rest in a position comfortable for breathing.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332 + P313 IF SKIN irritation occurs: Get medical advice/attention. P337 + P313 IF eye irritation persists: Get medical advice/attention. **Storage:** P403 + P233 Store in a well-ventilated place. Keep container tightly closed. **Disposal:** P501: Dispose of contents.

R2: Hazard Classifications: Skin corrosion/irritation (Category 2), Serious eye damage/eye irritation (Category 2)

Hazard Statements: H315: Causes skin irritation, H319: Causes serious eye irritation

Precautionary Statements: Prevention: P264 Wash skin thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection. **Response:** P362 Take off contaminated clothing and wash before reuse. P302 + P352 IF ON SKIN: wash with plenty of soap and water.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332 + P313 IF SKIN irritation occurs: Get medical advice/attention. P337 + P313 IF eye irritation persists: Get medical advice/attention.

Storage: None **Disposal:** None. **Refer to the Safety Data Sheet for this product (SDS-MAG600) available at www.medtestdx.com.**



Signal Word: Warning



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Specimen Collection and Storage

1. Use fresh, unhemolyzed serum or heparinized plasma.
2. Red cells contain twice the magnesium concentration as serum. A hemolyzed sample would falsely elevate results.¹⁰
3. Grossly icteric or lipemic specimens should not be used in this method.
4. Specimen collection should be carried out in accordance with NCCLS M29-T2.¹¹ No method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood samples should be considered potentially infectious.

Magnesium – XB Reagent Set

Interferences

1. Hemolyzed, grossly icteric or lipemic specimens are unsuitable for this method.
2. A number of drugs and substances affect the concentration of magnesium. See Young, et al.¹²

Materials Provided

Magnesium (xylidyl blue) reagent R1 and R2

Materials required but not Provided

1. Mindray BS-480 Analyzer and BS-480 Operation manual
2. Chemistry Calibrator, catalog number CHEC480
3. Chemistry control, catalog number CHEQ480

Calibration

Use an NIST-traceable serum based calibrator. The procedure should be calibrated according to the instrument manufacturer's calibration instructions. If control results are found to be out of range, the test may need to be re-calibrated. Under typical operating conditions manufacturer calibration stability studies have shown the calibration curve will be stable for at least 3 days.

Quality Control

The validity of the reaction should be monitored by use of control sera with known normal and abnormal magnesium values. These controls should be run at least with every working shift in which magnesium assays are performed. It is recommended that each laboratory establish its own frequency of control determination. Quality control requirements should be performed in conformance with local, state, and/or Federal regulations or accreditation requirements.

Expected Values

Newborns	1.8 - 2.8 mg/dl
Children	1.7 – 2.3 mg/dl
Adults	1.6 – 3.0 mg/dl

The expected values were taken from literature.¹³ Each laboratory should establish its own normal range.

Performance

1. Assay Range: 0.0-4.86 mg/dL (4.0 mEq/L).
2. Correlation: A study was performed between the Mindray BS-480 and a similar analyzer using this method, resulting in the following:

Method	Magnesium
N	106
Mean Magnesium (mg/dL)	2.52
Range (mg/dL)	0.6-4.9
Standard Deviation	0.82
Regression Analysis	$y = 0.917 + 0.30$
Correlation Coefficient	0.9814

3. Precision: Precision studies were performed following a modification of the guidelines contained in the NCCLS document EP5-T2.¹⁴

Sample	Within Day			Total		
	LOW	MID	HIGH	LOW	MID	HIGH
N	20	20	20	40	40	40
Mean	1.32	3.34	4.81	1.52	3.30	4.84
Standard Deviation	0.04	0.05	0.04	0.07	0.20	0.17
Coefficient of Variation (%)	3.1%	1.5%	0.8%	4.5%	5.9%	3.6%

4. Sensitivity: 2SD limit of detection (95% Conf) = 0.0 mg/dL

References

1. Kramer, B. Tisdall, F.F., J. Biol. Chem. 47:475 (1921).
2. Briggs, A.P., J. Biol. Chem. 52:349 (1922).
3. Denis, W., J. Biol. Chem. 52:411 (1922).
4. Schwartzbach, G., et al, Helvet Chim. Acta 29:811 (1946).
5. Schachter, D., J. Lab. and Clin. Med. 54:763 (1959).
6. Brien, M., Marshall, R.T., J. Lab. and Clin. Med. 68:701 (1966).
7. Basinski, D.H., Standard Methods of Clinical Chemistry, 5, New York, Academic Press, pp. 137-142 (1965).
8. Natelson, S., Techniques of Clinical Chemistry, 3rd Ed., Springfield (Ill.), C.C., Thomas, pp. 190-197(1971).
9. Korbl, J., Pribl, R., Chem. Listy 51:1061 (1957) and Anal. Abst. 5:10 (1958).
10. Tietz, N.W., Fundamentals of Clinical Chemistry, Philadelphia, W.B. Saunders, p. 918 (1976).
11. NCCLS document "Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids and Tissue", 2nd Ed. (1991).
12. Young, D.S., et al, Clin. Chem. 21:1D (1975).
13. Bagniski, E.S., et al, Selected Methods of Clinical Chemistry, Vol. 9, Washington (DC), AACC, pp. 227-281 (1982).
14. NCCLS document "Evaluation of Precision Performance of Clinical Chemistry Devices", 2nd Ed. (1992).



CHEMISTRY PARAMETERS

Chem:	MG	No.:	226	Sample Type:	Serum
Chemistry:	Magnesium			Print Name:	MG
Reaction Type:	End Point			Reaction Direction:	Positive
Pri Wave:	546			Sec Wave:	660
Unit:	mg/dL			Decimal:	0.1
Blank Time:	47 49			Reaction Time:	68 70
	Sample Vol.	Aspirated	Diluent	Reagent Vol.	Diluent
Standard:	2.7 ul	-- ul	-- ul	R1: 120 ul	-- ul
Decreased:	-- ul	-- ul	-- ul	R2: 120 ul	-- ul
Increased:	-- ul	-- ul	-- ul	R3: -- ul	-- ul
	<input type="checkbox"/> Sample Blank	<input checked="" type="checkbox"/> Auto Rerun		R4: -- ul	-- ul
<u>Slope/Offset Adjustment</u>					
Slope: 1		Offset: 0			

Linearity Range (Standard)	0	4.86	Linearity Limit:
Linearity Range (Decreased)	___	___	Substrate Depletion:
Linearity Range (Increased)	___	___	Mixed Blank Abs:
R1 Blank Abs:	___	___	Uncapping Time
Blank Response:	___	___	Reagent Alarm Limit:
Twin Chemistry:			<input type="checkbox"/> Enzyme Linear Extension
<input type="checkbox"/> Prozone Check		<input type="radio"/> Rate Check	<input type="radio"/> Antigen Addition
Q1:	Q2:	Q3:	Q4:
PC:	ABS:		

