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Magnesium - XB Reagent Set

Intended Use
For the quantitative determination of magnesium in serum using the Mindray BS-200 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, hyperalimenation, 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.

Do not use if:
1. The reagent fails to achieve established values of fresh control sera.
2. The reagent becomes visibly turbid.

Precautions
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.

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.

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-200 Analyzer and BS-200 Operation manual
2. Chemistry Calibrator, catalog number C7506-50
3. Chemistry control, catalog number C7592-100

Mindray BS-200 Test Parameters

Test :	MG	R1:	180
No.:	026	R2:	180
Full Name:	Magnesium	Sample Volume:	4
Standard No.:		R1 Blank:	
Reac.Type:	Endpoint	Mixed Rgt. Blank:	
Pri. Wave:	546nm	Linearity Range:	0.05 – 4.86
Sec. Wave:	670nm	Linearity Limit:	
Direction:	Increase	Substrate Limit:	
Reac. Time:	0 / 10	Factor:	
		Compensate: Slope 1.0	Intercept: 0
Incuba. Time:	3	□ Prozone check	
Unit:	mg/dl	q1: q2: q3: q4:	
Precision:	0.1	PC:	Abs:

Calibration Parameters

Rule:	Two-point linear	Calibrator 1:	Deionized Water
Sensitivity:		Calibrator 2:	Chem Cal
Replicates:	2	Calibrator 3:	
Interval (day):		Calibrator 4:	
Difference Limit:		Calibrator 5:	
SD:		Calibrator 6:	
Blank Response:			
Error Limit:			
Coefficient:	0		

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NOTE: When running the Magnesium assay set the Carryover Settings as listed below: Go to Parameters → Carryover

Select MG_R1 in upper column and then select the listed assays on lower column GLU_R1, ALP_R1, ALP_R2, CO2-R1, CK_R1, CK_R2 AND TRIG_R1 – Press OK

Select MG_R2 in upper column and then select the listed assays on lower column GLU_R1, ALP_R1, ALP_R2, CO2-R1, CK_R1, CK_R2 AND TRIG_R1 – Press OK

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 procedure should be recalibrated.

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.

Calculation (Ratiometric Calculation) (Example)
Abs. = Absorbance

$$\frac{\text{Abs. of Unknown}}{\text{Abs. of Standard}} \times \text{Conc. of Standard} = \text{Value mg/dl}$$

Example: Abs. of Unknown = .140
Abs. of Standard = .120
Conc. of Standard = 2.4 mg/dl

Then: $\frac{.140}{.120} \times 2.4 \text{ mg/dl} = 2.8 \text{ mg/dl}$

NOTE: "mg/dl" may be converted to "mEq/L" by dividing the result by 1.21525.

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
Linearity: 0-05 - 4.86 mg/dl

Comparison: A study was performed between the Mindray BS-200 and a similar analyzer using this method, resulting in a correlation coefficient of correlation of 0.983 with a regression equation of y=0.945x + 0.05. (N=36).

Precision: Precision studies were performed using the Mindray BS-200 analyzer following a modification of the guidelines which are contained in NCCLS document EP5-T2.[14]

Within Day (N=20)			**Day to Day (N=22)***		
Mean	**S.D.**	**C.V.%**	**Mean**	**S.D.**	**C.V.%**
1.91	0.03	1.6	2.9	0.24	8.28
4.37	0.06	1.3	5.2	0.30	5.77

*Note: Day to Day precision does not reflect Mindray BS-200 performance.

References
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