Pointe Magnesium – XB Reagent Set

HORIBA Instruments Incorporated
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Intended Use
For the quantitative determination of magnesium in serum using the Yumizen C560 analyzer. **Rx 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 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:

Signal Word: Warning

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.


Signal Word: Warning

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-HM929) available by calling 1-737-487-8300**

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 CLSI M29-A4.[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. Yumizen C560 Analyzer and Operation manual
2. Chemistry Calibrator, catalog number C7506-50
3. Chemistry control, catalog number C7592-100

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: 0.0-4.5 mg/dL (3.7 mEq/L).
2. Correlation: A study was performed between the Yumizen C560 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]

Within Day

Sample	LOW	MID	HIGH
N	20	20	20
Mean	1.32	3.34	4.81
Standard Deviation	0.04	0.05	0.04
Coefficient of Variation (%)	3.1%	1.5%	0.8%

Total

Sample	LOW	MID	HIGH
N	40	40	40
Mean	1.52	3.30	4.84
Standard Deviation	0.07	0.20	0.17
Coefficient of Variation (%)	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. Schwartzenbach, 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. CLSI M29-A4 "Protection of Laboratory Workers From Occupationally Acquired Infections", 4th Ed. (2014).
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).

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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
	☐ Sample Blank	☑ Auto Rerun		R4:	--- ul	--- ul

Slope/Offset Adjustment

Slope: 1 Offset: 0

Linearity Range (Standard)	0	4.5	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:			☐ Enzyme Linear Extension	

☐ Prozone Check ○ Rate Check ○ Antigen Addition

Q1: Q2: Q3: Q4:

PC: ABS:

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CALIBRATION PARAMETERS

Calibrator Definition

Calibrator: * Lot No.: *

Exp Date: *

Carousel	**Pos**
Sample Carousel 1	*
Sample Carousel 2	
Sample Carousel 3	

Reagent/Calibration

Calibrator	Pos	Lot No	Exp Date	Chem	Conc	Unit
Water	W	*	*	MG	0	mg/dL
Chemistry Calibrator	*	*	*	MG	*	mg/dL

Calibration Setup

Chem: MG

Calibration Settings

Math Model: Two-Point Linear

Factor: Replicates: 2

Acceptance Limits

Cal Time: 72 Hour

Slope Diff: --- SD: ---

Sensitivity : --- Repeatability: ---

Deter Coeff: ---

Auto Calib.

☐ Bottle Changed ☐ Lot Changed ☐ Cal Time

It is recommended that two levels of control material be assayed daily.
* Indicates user defined parameter.

REF 14-HM929-240

Manufactured by
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2°C 8°C IVD

Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

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Symbol Key

Use by (YYYY-MM-DD) LOT Lot and batch code REF Catalog number
Manufacturer Temperature limitation Consult instructions for use
IVD *In vitro* diagnostic medical device **Rx Only:** Prescription Use Only

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