

High-Q Magnesium-ML (Xylidyl Blue Method)

Intended Use

Kit for the quantitative determination of Magnesium in human serum.

Summary and Clinical Significance:

Magnesium is a major intracellular cation. Approximately one-half of the body's magnesium is present in the bone. Most of the remainder is found in soft tissue. Little is known about the factors regulating magnesium levels in plasma. It is believed that the parathyroid gland may be involved. Magnesium ions serve as activators for a number of important enzyme systems engaged in the transfer and hydrolysis of phosphate groups, such as hexokinase, creatinine kinase, alkaline phosphatase and prostatic acid phosphatase. 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. The determination of magnesium in serum has been impeded by technical difficulties. A simple, rapid, and reliable method is needed to serve as an alternative to atomic absorption which requires expensive instrumentation and a large sample. In this reagent, a direct method in which magnesium forms a colored complex with Xylidyl Blue in a strongly basic solution, where calcium and protein interference is eliminated.

Principle:

$Mg^{2+} + \text{Xylidyl Blue} \xrightarrow{OH^-}$ Colored complex

Magnesium forms a colored complex with Xylidyl Blue in a strongly alkaline solution. Ethylene bis (oxyethylenetriole) tetraacetic acid (EGTA) serves to complex and prevent calcium interference while dimethyl sulfoxide (DMSO) eliminates the effect of protein. The color produced is measured bichromatically at 520/800 nm and is proportional to the amount of magnesium present.

Reactive Ingredients	Initial Conc.	Final Conc.
Magnesium Reagent		
magon sulfonate	0.625 mmol/L	0.063 mmol/L
DMSO	7.0 Mol/L	0.7 Mol/L
EGTA	1.3mmol/L	0.13 mmol/L
buffer		
surfactant		
potassium hydroxide	930 mmol/L	93 mmol/L

Reagent Storage and Stability:

The Reagent and Standard are stable at 2-8°C till the expiry date mentioned on the labels if external contamination of Magnesium is avoided.

Specimen Collection:

Non-hemolyzed serum is the recommended sample. Separate from clot as soon as possible.

Sample Storage:

Magnesium in serum is stable for several days, if serum is stored at 2° - 8°C and separated from the red cells.

Expected Values:

Newborns	1.5-2.3 mg/dL
Children	1.7-2.2 mg/dL
Adults	1.6-2.8 mg/dL

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

Procedure:

High-Q Magnesium - ML is available as Mono Reagent. Directly pipette the Magnesium Reagent in to the tubes labelled as Blank (B) Standard (S) and Test (T) as follows :

Reagent	B	S	T
Magnesium Reagent	1.0 ml	1.0 ml	1.0 ml
Magnesium Standard (Conc. 2 mg/dl)	----	20 µl	----
Specimen	----	----	20 µl

Incubate for 5 minutes at 37°C and Read absorbance of Standard (S) and Test (T) against Reagent Blank (B) at 505 nm (500-520).

Calculations:

$$\text{Serum Magnesium in mg/dl} = \frac{\text{Abs. of Test}}{\text{Abs. of Standard}} \times 2$$

System Parameters:

Reaction type (mode)	:	End Point
Wavelength	:	505 nm (500-520).
Flow cell temperature	:	37°C
Sample volume	:	20 µl
Reagent volume	:	1000 µl
Standard concentration	:	2.0
Units	:	mg / dl
Blank	:	Reagent
Low normal	:	1.6
High normal	:	2.8
Linearity	:	5

Interfering Substances:

- At a Magnesium level of 2.0 mg/dL, a positive interference was observed at a Triglyceride concentration of 330 mg/dL.
- No interference was observed at a Bilirubin concentration of 14 mg/dL.
- No interference was observed at a Hemoglobin concentration of 400 mg/dL.
- Young has reviewed drug effects on serum magnesium levels.

Linearity:

Linearity extends to 5.0 mg/dL. Samples exceeding linearity should be diluted with normal saline and repeated. Multiply the concentration by the dilution factor when calculating the unknown.

Quality Control:

To ensure adequate quality control, the use of commercial control sera is recommended with each assay batch. Use of quality control material checks both, the instrument and reagent functions.

The detection limit represents the lowest measurable calcium concentration that can be distinguished from zero.

Performance Characteristics:

Precision

WITHIN-RUN	Level 1	Level 2
No. of Data Points	40	40
Mean mg/dL	2.0	2.5
SD	0.014	0.016
CV%	0.7	0.6

TOTAL	Level 1	Level 2
No. of Data Points	40	40
Mean mg/dL	2.0	2.5
SD	0.032	0.042
CV%	1.6	1.7

Method comparison:

A comparison of the High-Q Magnesium - ML (y) with a commercial obtainable assay (x) gave the following result : $y = 1.113x - 0.278$; $r = 0.990$

Notes:

- All glassware and cuvettes should be rinsed with 30% Hydrochloric acid and again rinse with high quality distilled water thoroughly and repeatedly before use.
- If a larger volume of working reagent is required for the absorbance reading, requisite volumes can be taken in multiples keeping the same ratio of reagent to specimen or standard.
- Dilute lipemic samples with normal saline (made in deionised water) and multiply with dilution factor.
- Protect the kit from direct sunlight.
- For accuracy of results, procedure has to be followed meticulously.
- As with all diagnostic procedures the physician should evaluate data obtained by way of this kit in light of other clinical information.

Bibliography

- Tietz, N.W., Fundamentals of Clinical Chemistry, W.B. Saunders Co., Philadelphia, 1976, p. 917-919.
- Faulkner, W.R., Selected Methods for a Small Clinical Chemistry Laboratory, AACC Press, Washington, D.C., 1982, p. 277-280.

















Ordering Information:

Ref./Cat. No.	Pack Size	Presentation
P-MAG - 25	25 ml	Mono Reagent
P-MAG - 50	2 x 25 ml	Mono Reagent

Product Features:

- Liquid Stable, Ready to use Mono Reagent
- Available as mono test packs.
- One step End Point assay.
- Addition of EGTA overcomes Calcium interference
- Aqueous Magnesium standard provided (Standard Conc: 2.0 mg/dL)
- Linearity: 5 mg/dL
- Measuring Wavelength 505 nm (500 – 520 nm)
- Serum is the only specimen
- Available as multipurpose reagents and dedicated system packs

Symbols used with IVD devices

	Date of manufacture		Manufactured by
	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)		Reagent
	Calibrator Material		Batch code
	Temperature limitation (store at)		Control
	Consult instructions for use		Keep dry
	Catalog Number		Keep away from rain

eIFU Indicator



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