MAGNESIUM (Xylidyl Blue)

INTENDED USE
Bioline Magnesium is used for In vitro test for the quantitative determination of Mg concentration in serum and plasma on photometric systems.

CLINICAL SIGNIFICANCE
Magnesium is one of the most abundant cations in the body involved in many biochemical reactions. Many enzymes such as alkaline phosphatase, ALP require magnesium as activator. Magnesium is also necessary for the stability of conformational structure for many macro molecules such as DNA, RNA, etc.

Although little is know about the regulation of magnesium levels in blood ,it has been reported that para-thyroid gland is involved. Increased level of magnesium has been observed in Addison's disease, diabetic acidosis, renal failure and vitamin D in toxication, and decreased level of magnesium are observed in diabetes, diuretics ,hyperthyroidism, hyperalimentation, alcoholism ,myocardial infarction, congestive heart failure and liver cirrhosis.

METHOD AND PRINCIPLE
Magnesium forms a colored complex with dyes such as Calmagite, Eriochrome Black T, Xylidyl Blue (Magon), and Methylthymol blue.Serum Magnesium ions react with Xylidyl Blue in an alkaline solution to produce complex that is measured spectrophotometrically. The intensity of color produce is directly proportional to magnesium concentration. Calcium interference is virtually eliminated by the use of EGTA and a surfactant system is included to remove protein interference.
The change in absorbance at 505 nm.This change in absorbance is directly proportional to the concentration of magnesium in the sample

Xylidyl Blue + Mg $\xrightarrow{\text{Alkaline pH}}$ Mg-Xylidyl blue complex

REAGENT COMPOSITION
Magnesium Reagent contains :

Buffer	(pH 11.2 at 25^{O}C),
Xylidyl blue	0.09mmol/L,
EGTA	0.13mmol/L,
Surfactant	<2%(w/v).
Standard	2mg/dL.

WARNING AND PRECAUTIONS:
1. For invitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests

REAGENT PREPARATION
The reagents are as ready to use liquids.

REAGENT STORAGE AND STABILITY
Magnesium Reagent stored unopened at RT stable until the expiration date showed on the bottle label.
DO NOT FREEZE.

REAGENT DETERIORATION
Discard the reagent if the colour changes to Red it is an indication of contamination

SPECIMEN COLLECTION AND STABILITY
1. Serum, heparin plasma and urine are suitable for samples. Wholeblood, hemolysis not recommended for use as a sample. Freshly drawn serum is the preferred specimen.
2. Collect urine sample in a metal-free container with no preservatives; bring the urine to pH 1 prior to assay.
3. Use the suitable tubes or collection containers and follow the instruction of the manufacturer; avoid effect of the materials of the tubes or other collection containers.
4. Centrifuge samples containing precipitate before performing the assay.

Stability :Plasma must be assayed fresh.
Serum :7 days at4-8ºC
1 yearat-20 ºC

INTERFERENCE
1. Hemoglobin levels up to 500 mg/dl, Lipemia levels up to 500mg/dl, Ascorbic acid levels up to 50 mg/dl and Bilirubin levels upto 20 mg/dl were found to exhibit negligible interference.
2. On this method, refer to the work of Young for a review of drug and comprehensive list of substances effect on magnesium level.

ASSAY PROCEDURE FOR SEMIAUTO ANALYZER.
Wavelength : 505(500-520)nm
Temperature : 37 °C

	Blank	Standard	Sample
Reagent	1000 µL	1000 µL	1000 µL
Standard	-	10 µL	-
Sample	-	-	10 µL

Mix and read the Absorbance (A) of standard and sample after 5 minutes of incubation at 37 ºC. Final color is stable for at least thirty-minutes at room temperature.

CALCULATIONS
Abs.=Absorbance

$$\frac{\text{Abs.ofUnknown}}{\text{Abs. of Standard}} \times \text{Std Conc} = \text{Mg Concn (mg/dl)}$$

Example:	Abs.ofunknown	=	0.098
	Abs .of standard	=	0.113
	Concentration of standard	=	2.0 mg/dL

Then $\frac{0.098}{0.113} \times 2$ mg/dl=1.73 mg/dl

CALIBRATION
The procedures are calibrated with the standard solution, which is included with each series of tests. Its absorbance is used to calculate the results. It is recommended to establish a linearity curve up to 5.0 mg/dl with other available commercial standard solutions to verify the performance of instruments and reagents.

LIMITATIONS
1. The anticoagulants EDTA Potassium Oxalate, Sodium Fluoride and SodiumCitrate were found to be incompatible with this method.
2. The anticoagulants Ammonium heparin, Lithium Heparin and Sodium Heparin were found to be compatible with this method.

QUALITY CONTROL

It is recommended that controls be included in each set of assays. Commercially available control material with established triglyceride values may be used for quality control. The assigned value of the control material must be confirmed by the chosen application. Failure to obtain the proper range of values in the assay of control material may indicate either reagent deterioration, instrument malfunction, or procedural errors.

EXPECTED VALUE

Newborns 1.8 - 2.8 mg/dl
Children 1.7 - 2.3 mg/dl
Adults 1.6 - 3.0 mg/dl
Each laboratory should establish its own normal range.

PERFORMANCE CHARACTERISTICS

Linearity: 5.0 mg/dL. For samples above 5mg/dl dilute the sample with Distilled water, rerun the sample and multiply the obtained result with the dilution factor to get correct magnesium value.

Comparison: Studies performed using the present method with a similar method yielded a coefficient of correlation of 0.0.825 with aregression equation of y=0.984x-0.031. Sample values ranged from 1.8-2.6(N=20).

Precision: Precision for Magnesium Reagent Set was determined following a modification of NCCLS EP5-A2.

Within Day (N=22)			Day to Day (N=22)		
Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
3.0	0.07	2.33	2.9	0.24	8.28
5.5	0.07	1.27	5.2	0.30	5.77

General Technical Parameters

Mode	**End Point**
Wavelength (Filter)	**505(500-520)nm**
Reaction Direction	**Increasing**
Reagent Blank	**Yes**
Sample Vol.	**10 µL**
Reagent Vol.	**1000 µL**
Measuring Time	**5 min**
Reagent Blank Abs.(Max)	**NMT 1.000 Abs**
Calibration Method	**1- Point**
Standard (Conc.)	**2.0 mg/dL**
Linearity	**5.0 mg/dL**
Decimal Places	**2**
Temp.	**37 °C**
Unit	**mg/dL**
Ref. Low	**1.6 mg/dL**
Ref. High	**3.0 mg/dL**

REFERENCE

1. ThomasL.ClinicalLaboratoryDiagnostics.1sted.Frankfurt: TH-BooksVerlagsgesellschaft; 1998.
2. Guder WG, Narayanan S, Wisser H, Zawta B. List of Analytes;PreanalyticalVariables.Brochurein:Samples:FromthePatienttotheLaboratory. Darmstadt: GITVerlag, 1996.
3. CLSI. Evaluation of Precision Performance of Clinical ChemistryDevices;ApprovedGuideline.CLSIdocumentEP5-A[ISBN1-56238-368-].CLSI, 940 WestValley Road, Suite1400, Wayne, PA.