MAGNESIUM

OSR6189 **4 x 40 mL** **R1**

Intended Use
System reagent for the quantitative determination of Magnesium in human serum, plasma and urine on Beckman Coulter AU analyzers.

Summary
Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low) and hypermagnesemia (abnormally high).

Magnesium is a major intracellular cation, second only to potassium in concentration. Little is known about the factors regulating magnesium levels in plasma. It is believed that the parathyroid gland may be involved.[1] Magnesium ions serve as activators for a number of important enzyme systems engaged in the transfer and hydrolysis of phosphate groups, such as hexokinase, alkaline phosphatase, prostatic acid phosphatase, and creatinine kinase.

Decreased serum magnesium levels have been observed in cases of diabetes, alcoholism, diuresis, hyperthyroidism, hypoparathyroidism, malabsorption, hyperalimentation, myocardial infarction, congestive heart failure and liver cirrhosis. Increased serum magnesium levels have been found in cases of renal failure, dehydration, severe diabetic acidosis and Addison's Disease.[1,2]

Methodology
This Magnesium procedure utilizes a direct method in which magnesium forms a colored complex with xylidyl blue in a strongly basic solution, where calcium interference is eliminated by glycoletherdiamine-N,N,N',N'-tetraacetic acid (GEDTA).[3,4,5] The color produced is measured bichromatically at 520/800 nm and is proportional to the magnesium concentration.

Mg^{2+} + Xylidyl blue $\xrightarrow{\text{pH 11.4}}$ Purple complex

System Information
For AU400/400^{e}/480, AU600/640/640^{e}/680 and AU2700/5400 Beckman Coulter Analyzers.

Reagents
Final concentration of reactive ingredients:

∈-Amino-n-Caproic Acid	450 mmol/L
Tris	100 mmol/L
Glycoletherdiamine-N,N,N',N' tetraacetic acid	0.12 mmol/L
Xylidyl blue	0.18 mmol/L

Also contains preservatives.

Precautions
1. For *in vitro* diagnostic use.
2. Do not ingest.
3. WARNING! POISON! Do not pipet by mouth. In case of external contact, immediately rinse affected area with plenty of water for 15 minutes. Obtain medical attention immediately for eye contact or ingestion.
4. Contains sodium azide as a preservative which may react with lead joints in copper plumbing to form explosive compounds. Even though the reagent contains minute quantities of sodium azide, drains should be well flushed with water when discarding the reagent.

Preparation Of Reagents
The Magnesium Reagent is ready for use. No preparation is required.

Storage And Stability
1. The unopened reagent is stable until the expiration date printed on the label when stored at 2 - 8°C.
2. Opened reagent is stable for 7 days when stored in the refrigerated compartment of the analyzer.

Indications of Deterioration
Visible signs of microbial growth, turbidity or precipitation or any change in the color of the reagent may indicate deterioration and may warrant discontinuance of use.

Specimen Collection and Preparation
Serum or heparinized plasma samples, free from hemolysis, are the recommended specimens. The use of anticoagulants which bind magnesium, such as EDTA, oxalate and citrate, must be avoided. Fresh, random collection is recommended for urine specimens.

Sample Storage and Stability
Magnesium in serum is stable for up to one week at 2 to 8°C.[2] Urine should be acidified to pH 1 with concentrated HCl. If a precipitate forms, shake, mix, acidify, and warm to 60°C to redissolve.

Interfering Substances
Erythrocytes contain about three times, and tissue fluid about 10 times, the magnesium concentration of serum. Results of studies[6] show that the following substances interfere with this magnesium procedure.

Magnesium

The criteria for no significant interference is recovery within 10% of the initial value.

Bilirubin: No significant interference up to 36 mg/dL Bilirubin
Calcium: No significant interference up to 30 mg/dL Calcium
Hemolysis: No significant interference up to 150 mg/dL Hemolysate
Lipemia: No significant interference up to 500 mg/dL Intralipid*
* Intralipid, manufactured by KabiVitrium Inc., is a 20% IV fat emulsion used to emulate extremely turbid samples.
The information presented is based on results from Beckman Coulter studies and is current at the date of publication. Beckman Coulter Inc., makes no representation about the completeness or accuracy of results generated by future studies. For further information on interfering substances, refer to Young[7] for a compilation of reported interferences with this test.

Procedure

A complete list of test parameters and operational procedure can be found in the User's Guide appropriate to the analyzer.

Materials Provided
Magnesium Reagent

Materials Required But Not Provided
Chemistry Calibrator (Cat # DR0070)
Urine Calibrator (Cat # DR0090)

Stability of Final Reaction Mixture
The Beckman Coulter AU analyzer automatically computes every determination at the same time interval.

Calibration
The calibration is stable for 7 days provided reagent is blanked daily. Calibration of this magnesium procedure is accomplished by use of the Chemistry Calibrator (Cat # DR0070), which is traceable to the National Institutes of Standards and Technology (NIST) Standard Reference Material (SRM) 909b for serum and plasma determinations. Calibration for urine determinations is determined by use of the Urine Calibrator (Cat. # DR0090). Recalibration of this test is required when any of these conditions exist:
1. A reagent lot number has changed or there is an observed shift in control values.
2. A fresh bottle of reagent is used for testing.
3. Major preventative maintenance was performed on the analyzer or a critical part was replaced.

Quality Control
During operation of the Beckman Coulter AU analyzer at least two levels of an appropriate quality control material should be tested a minimum of once a day. In addition, controls should be performed after calibration, with each new lot of reagent, and after specific maintenance or troubleshooting steps described in the appropriate User's Guide. Quality control testing should be performed in accordance with regulatory requirements and each laboratory's standard procedure.
Appropriate qualified urine controls should be established and utilized during urine analysis.

Results
Automatically printed out for each sample in mg/dL at 37°C. For SI units (mmol/L) the result must be multiplied by 0.4114.

Dynamic Range

The Magnesium procedure is linear from 0.5 to 8.0 mg/dL for serum determinations and to 10 mg/dL for urine determinations. Samples exceeding the upper limit of linearity should be diluted and repeated. The sample may be diluted, repeated and multiplied by the dilution factor automatically utilizing the AUTO REPEAT RUN.

Expected Values

Serum:[8] 1.9 - 2.7 mg/dL
Urine:[10] 24 - 255 mg/24 hours

Urinary excretion of magnesium is diet dependent but normally equals about one third of daily intake.

Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

Specific Performance Characteristics

The following data was obtained using the Magnesium Reagent on Beckman Coulter AU analyzers according to established procedures. Results obtained in individual laboratories may differ.

Precision[11]
Estimates of precision, based on CLSI recommendations,[9] are consistent with typical performance. The within run precision for serum samples is less than 3% CV and total precision is less than 5% CV. Assays of control materials were performed and this data reduced following CLSI guidelines above.

Serum

N = 60	Within run		Total	
Mean, mg/dL	SD	CV%	SD	CV%
1.87	0.02	0.90	0.02	1.08
2.55	0.03	1.26	0.04	1.53
7.01	0.08	1.09	0.09	1.25

Urine

N = 60	Within run		Total	
Mean, mg/dL	**SD**	**CV%**	**SD**	**CV%**
3.77	0.03	0.70	0.05	1.38
6.84	0.05	0.74	0.05	0.79
9.27	0.10	1.09	0.22	2.33

Method Comparison[11]

Serum

Patient samples were used to compare this Magnesium reagent. The table below demonstrates representative performance on AU analyzers.

Y Method	AU600/640/640[e]
X Method	OSR6131
Slope	1.003
Intercept	0.009
Correlation Coeff. (r)	1.000
No. of Samples (n)	102
Range (mg/dL)	0.66-4.46

Urine

Patient samples were used to compare this Magnesium reagent. The table below demonstrates representative performance on AU analyzers.

Y Method	AU640
X Method	OSR6131
Slope	0.996
Intercept	0.04
Correlation Coeff. (r)	1.000
No. of Samples (n)	52
Range (mg/dL)	0.56-8.94

Sensitivity

Typical change in absorbance for 1 mg/dL of Magnesium is 100 mAbsorbance.

References

1. Faulkner, W.R., Selected Methods for the Small Clinical Laboratory, AACC Press, 1982.
2. Tietz, N.W. (ed), Fundamentals of Clinical Chemistry, 3rd Edition, WB Saunders, 1987.
3. Mann, C.K. and Yoe, J.H., Anal Chem, 28: 202-205, 1956.
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5. Bohuon, C., Clin Chem Acta, 7: 811-817, 1962.
6. CLSI/NCCLS, Interference Testing in Clinical Chemistry EP7-A, 2002.
7. Young, D. S., Effects of Drugs on Clinical Laboratory Tests, 5th Edition, 2000.
8. Beckman Coulter Inc. data on samples collected from 200 blood donors in North Texas.
9. CLSI/NCCLS Evaluation Protocol EP5-A, 1999.
10. Pesce, A.J. and Kaplan, L.A., Methods in Clinical Chemistry, C.V. Mosby Co., St. Louis, 1987.
11. Data is on file for specific AU analyzers.

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