

Instructions For Use

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**MG
Magnesium**

OSR6189 4 x 40 mL R1

For *in vitro* diagnostic use only.**ANNUAL REVIEW**

Reviewed by	Date	Reviewed by	Date

PRINCIPLE**INTENDED USE**

Photometric colour test for the quantitative determination of magnesium in human serum, plasma and urine on Beckman Coulter analysers.

SUMMARY AND EXPLANATIONReference^{1,2}

Magnesium is an essential factor in many important enzymatic reactions, either as an integral part of a metalloenzyme or as an activator, and plays an important role in glycolysis, cellular respiration and transmembranous calcium transport. Magnesium is mainly regulated by the rate of renal magnesium excretion, which along with calcium is subject to the effects of parathyroid hormone. Increasing calcium reabsorption thus leads to competitive inhibition of magnesium absorption.

Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low) and hypermagnesemia (abnormally high). The best-defined manifestation of magnesium deficiency is impairment of neuromuscular function e.g. hyperirritability, tetany, convulsions, and electrocardiographic changes. Hypomagnesemia is observed in cases of diabetes, chronic alcoholism, forced diuresis, hyperthyroidism, hypoparathyroidism, hypocalcemia, malabsorption and acute pancreatitis. Increased serum magnesium levels have been found in cases of renal failure, dehydration, severe diabetic acidosis and Addison's Disease.

METHODOLOGYReference^{3,4,5}

The Magnesium reagent utilises a direct method in which magnesium ions form a coloured complex with xylidyl blue in a strongly basic solution. The colour produced is measured bichromatically at 520/800 nm and is proportional to the magnesium concentration in the sample. Calcium interference is eliminated by glycoetherdiamine-N,N,N',N'-tetraacetic acid (GEDTA).

CHEMICAL REACTION SCHEME



SPECIMEN

TYPE OF SPECIMEN

Serum or heparinised plasma.⁶ Do not use EDTA, oxalate or citrate plasma.

Separate serum from red blood cells immediately.

Haemolysed samples should be avoided due to the higher magnesium concentration in erythrocytes.

Magnesium in serum is stable for 7 days when stored at 15...25°C.¹

Urine:⁷ Acidified with 6M HCl. Collect timed 24 hour specimen using standard laboratory procedures.

Store at 2...8°C.

REAGENTS

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

REACTIVE INGREDIENTS

Final concentration of reactive ingredients:

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

The concentrations of the reactive components of the reagents shown on the kit label are the actual concentrations in the individual R1/R2 vials. The reagent composition which is shown in the Instructions For Use is the final concentration of these components in the reaction cuvette after addition of R1, Sample, and R2.

 **CAUTION**

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

Magnesium

DANGER



H316	Causes mild skin irritation.
H360	May damage fertility or the unborn child.
P201	Obtain special instructions before use.
P280	Wear protective gloves, protective clothing and eye/face protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P332+P313	If skin irritation occurs: Get medical advice/attention.
	N,N-Dimethylformamide 0.1 - 0.2%
	Tris(hydroxymethyl)- aminomethane 1 - 5%
	Aminocaproic Acid 5 - 8%

SDS

Safety Data Sheet is available at techdocs.beckmancoulter.com

REAGENT PREPARATION

The reagent is ready for use and can be placed directly on board the instrument.

STORAGE AND STABILITY

The reagent is stable, unopened, up to the stated expiry date when stored at 2...8°C. Once open, reagent stored on board the instrument is stable for 14 days.

CALIBRATION

CALIBRATOR REQUIRED

Use System Calibrator Cat. No. 66300 for serum and plasma application and Urine Calibrator Cat. No. B64606 for urine application.

The magnesium values of System Calibrator Cat. No. 66300 are traceable to the National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 909b Level 2. The magnesium values of the calibrator Urine Calibrator Cat. No. B64606 are traceable to the National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 929a.

Change in reagent lot or significant shift in control values;

Major preventative maintenance was performed on the analyser or a critical part was replaced.

QUALITY CONTROL

Controls Cat. No. ODC0003 and ODC0004 or other control materials with values determined by this Beckman Coulter system may be used for the serum/plasma application.

Biorad Liquichek Urine Chemistry Controls Cat. No. 397 and 398 or other control materials with values determined by this Beckman Coulter system may be used for the urine application.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration/blanking is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the relevant product literature.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

TESTING PROCEDURE(S)

Refer to the appropriate Beckman Coulter AU analyser User Guide/Instructions For Use (IFU) for analyser-specific assay instructions for the sample type as listed in the Intended Use statement.

CALCULATIONS

The Beckman Coulter analysers automatically compute the magnesium concentration of each sample.

REPORTING RESULTS

REFERENCE INTERVALS

Reference¹

Serum	Men	0.73 – 1.06 mmol/L (1.8 – 2.6 mg/dL)
	Women	0.77 – 1.03 mmol/L (1.9 – 2.5 mg/dL)
Urine	Adults	3 – 5 mmol/24 h (73 – 122 mg/24 h)

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

PROCEDURAL NOTES

INTERFERENCES

Results of serum studies conducted to evaluate the susceptibility of the method to interference were as follows:

Icterus:	Interference less than 10% up to 28 mg/dL or 479 µmol/L bilirubin
Calcium:	Interference less than 3% up to 30 mg/dL or 7.5 mmol/L calcium

Haemolysis: Interference less than 10% up to 1.5 g/L haemoglobin

Lipemia: Interference less than 10% up to 500 mg/dL Intralipid

Results of urine studies conducted to evaluate the susceptibility of the method to interference were as follows:

Calcium: Interference less than 10% up to 40 mg/dL or 10 mmol/L calcium

Eltrombopag and its metabolites may interfere with this assay causing erroneously high patient results.

Refer to Young⁸ for further information on interfering substances.

PERFORMANCE CHARACTERISTICS

PERFORMANCE CHARACTERISTICS

Data contained within this section is representative of performance on Beckman Coulter systems. Data obtained in your laboratory may differ from these values.

LINEARITY

The test is linear within a concentration range of 0.2 – 3.3 mmol/L (0.5 – 8.0 mg/dL) for serum and plasma.

The test is linear within a concentration range of 0.2 – 9.25 mmol/L (0.5 – 22.5 mg/dL) for urine.

AU5800/DxC 700 AU: The test is linear within a concentration range of 0.2 – 7.8 mmol/L (0.5 – 18.9 mg/dL) for urine.

SENSITIVITY

The lowest detectable level in serum on an AU640 analyser was estimated at 0.01 mmol/L.

The lowest detectable level in urine on the AU2700 was estimated at 0.02 mmol/L.

The lowest detectable level represents the lowest measurable level of magnesium that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample.

METHODS COMPARISON

Patient serum samples were used to compare this Magnesium OSR6189 assay on the AU640 against another commercially available magnesium assay. Results of linear regression analysis were as follows:

$y = 0.990x + 0.073$	$r = 1.000$	$n = 79$	Sample range = 0.23 – 1.97 mmol/L
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Patient urine samples were used to compare this Magnesium OSR6189 assay on the AU2700 against another commercially available magnesium assay. Results of linear regression analysis were as follows:

$y = 0.994x - 0.003$	$r = 0.999$	$n = 120$	Sample range = 0.36 – 6.53 mmol/L
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PRECISION

The following data was obtained on an AU640 using 3 serum pools analysed over 10 days.

n = 60	Within-run		Total	
Mean mmol/L	SD	CV%	SD	CV%
0.80	0.01	1.02	0.01	1.15
1.09	0.01	0.75	0.01	1.29
3.02	0.03	0.90	0.04	1.24

The following data was obtained on an AU640 using 3 urine pools analysed over 20 days.

n = 80	Within-run		Total	
Mean mmol/L	SD	CV%	SD	CV%
0.78	0.01	1.15	0.04	4.96
3.76	0.03	0.71	0.10	2.73
7.81	0.06	0.71	0.27	3.40

ADDITIONAL INFORMATION

DxC 700 AU requires that each reagent application has a standard format of abbreviated Closed Test Name. This Closed Test Name is required to allow automated loading of the calibrator information for each application as part of the DxC 700 AU Closed System. Refer to the table below for the Closed Test Name assigned to each application for this assay.

Test Name	Description
MG-1N	Magnesium (Serum)
MG-1N	Magnesium (Urine)

Setting Sheet Footnotes

User defined

Serum: † System Calibrator Cat. No.: 66300.

Urine: † Urine Calibrator Cat. No: B64606. Ensure relevant value sheet is used.

* Values set for working in SI units (mmol/L). To work in mg/dL multiply by 2.43.

REVISION HISTORY

Revised Interferences section.

Preceding version revision history

Removed reference to obsolete calibrator.

REFERENCES

1. Dörner K. Magnesium (Mg). In: Thomas L, ed. Clinical laboratory diagnostics. Use and assessment of clinical laboratory results. Frankfurt/Main: TH-Books Verlagsgesellschaft mbH, 1998:339-340.
2. Jacob RA. Trace Elements. In: Tietz NW, ed. Fundamentals of clinical chemistry. Philadelphia:WB Saunders Company, 1987:521-524.
3. Mann CK, Yoe JH. Spectrophotometric determination of magnesium with sodium 1-Azo-2-hydroxy-3-(2,4-dimethylcarboxanilido) naphthalene-1'-(2-hydroxybenzene-5-sulfonate). Anal Chem 1956;28:202-205.
4. Mann CK, Yoe JH. Spectrophotometric determination of magnesium with 1-Azo-2-hydroxy-3-(2,4-dimethylcarboxanilido) naphthalene-1'-(2-hydroxybenzene). Anal Chim Acta 1957;16:155-160.
5. Bohuon C. Microdosage du magnésium dans divers milieux biologiques. Clin Chim Acta 1962;7:811-817.
6. Kazmierczak SC. Magnesium. In: Kaplan LA, Pesce AJ, eds. Clinical chemistry theory, analysis, and correlation. St Louis: Mosby, 1996:551pp.
7. NCCLS. Urinalysis and collection, transportation, and preservation of urine specimens; approved guideline. NCCLS Document GP16-A2, 2nd ed. Pennsylvania: NCCLS, 2001.
8. Young DS. Effects of Drugs on Clinical Laboratory Tests, AACC, 5th ed. AACC Press, 2000.

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