



**SYNCHRON System(s)**  
**Chemistry Information Sheet**

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**MG**  
**Magnesium**  
**REF** 445360

**For *In Vitro* Diagnostic Use**

**Rx Only**

**ANNUAL REVIEW**

Reviewed by	Date	Reviewed by	Date

**PRINCIPLE**

**INTENDED USE**

MG reagent, when used in conjunction with UniCel DxC 600/800 System(s) and Synchron Systems Multi Calibrator, is intended for the quantitative determination of magnesium concentration in human serum, plasma or urine.

**CLINICAL SIGNIFICANCE**

Determination of magnesium is useful in assessing several diseases and conditions. High magnesium is associated with uremia, dehydration, diabetic acidosis, Addison's disease, and increased medicinal intake of magnesium, such as in the treatment of preeclampsia (hypertension induced by pregnancy). Low magnesium is associated with malabsorption syndrome, acute pancreatitis, hypoparathyroidism, chronic alcoholism and delirium tremens, chronic glomerulonephritis, aldosteronism, digitalis intoxication, and protracted I. V. feeding.

**METHODOLOGY**

MG reagent is used to measure the MG concentration by a timed endpoint method.<sup>1,2</sup> In the reaction, MG combines with calmagite to form a stable chromogen. The product is formed rapidly giving reproducible results with a minimum of interferences.

The SYNCHRON System(s) automatically dilutes urine samples and proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 103 parts reagent for serum or plasma and one part diluted sample to 103 parts reagent for urine. The system monitors the change in absorbance at 520 nanometers. This change in absorbance is directly proportional to the concentration of magnesium in the sample and is used by the System to calculate and express the magnesium concentration.

## CHEMICAL REACTION SCHEME



E015245L.EPS

## SPECIMEN

### TYPE OF SPECIMEN

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.<sup>3</sup> Freshly drawn serum or plasma are the preferred specimens. Freshly collected urine may also be used for testing. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood is not recommended for use as a sample.

### SPECIMEN STORAGE AND STABILITY

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.<sup>4</sup>
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.<sup>4</sup>
3. It is recommended that urine specimens be collected in a metal-free container. Specimens should be acidified to pH 1.0.<sup>5</sup> Assays should be performed within 2 hours of collection.<sup>6</sup>

### Additional specimen storage and stability conditions as designated by this laboratory:

### SAMPLE PREPARATION

Sample preparation is not required. Urine samples are diluted (1:10) automatically by the system using the DIL1 cartridge.

### SAMPLE VOLUME

The optimum volume, when using a 0.5 mL sample cup, is 0.3 mL of sample. For optimum primary sample tube volumes and minimum volumes, refer to the Primary Tube Sample Template for your system.

### CRITERIA FOR UNACCEPTABLE SPECIMENS

Refer to the PROCEDURAL NOTES section of this chemistry information sheet for information on unacceptable specimens.

**Criteria for sample rejection as designated by this laboratory:**

**PATIENT PREPARATION**

**Special instructions for patient preparation as designated by this laboratory:**

**SPECIMEN HANDLING**

**Special instructions for specimen handling as designated by this laboratory:**

**REAGENTS**

**CONTENTS**

Each kit contains the following items:

Two MG Reagent Cartridges (2 x 100 tests)

**VOLUMES PER TEST**

**Serum or Plasma**

Sample Volume	3 $\mu$ L
Total Reagent Volume	308 $\mu$ L
Cartridge Volumes	
A	280 $\mu$ L
B	28 $\mu$ L
C	--

## Urine

### Sample Dilution Volumes

Sample Volume	20 µL
Diluent Volume	180 µL
Diluted Sample Volume	3 µL
Total Reagent Volume	308 µL
Cartridge Volumes	
A	280 µL
B	28 µL
C	--

## REACTIVE INGREDIENTS

### REAGENT CONSTITUENTS

Calmagite (Dye Reagent)	0.15 mmol/L
Alkaline Solution	(pH > 13.0)

Also non-reactive chemicals necessary for optimal system performance.

## GHS HAZARD CLASSIFICATION

Magnesium Reagent  
(Compartment B)

DANGER



H314

Causes severe skin burns and eye damage.

P280

Wear protective gloves, protective clothing and eye/face protection.

P303+P361+P353

IF ON SKIN (or hair): Rinse skin with 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.

P310

Immediately call a POISON CENTER or doctor/physician.

Potassium Hydroxide 1 - 10%

Trisodium Phosphate, Dodecahydrate 1 - 10%

SDS

Safety Data Sheet is available at [techdocs.beckmancoulter.com](http://techdocs.beckmancoulter.com)

## **MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT**

Synchron Systems Multi Calibrator  
At least two levels of control material  
Saline  
DIL 1 for urine samples

## **REAGENT PREPARATION**

No preparation is required.

## **ACCEPTABLE REAGENT PERFORMANCE**

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility's acceptance criteria.

## **REAGENT STORAGE AND STABILITY**

MG reagent when stored unopened at room temperature is stable until the expiration date on the cartridge label. Once opened, the reagent is stable for 7 days at +2°C to +8°C unless the expiration date is exceeded. **DO NOT FREEZE.**

DIL 1 stored unopened at room temperature is stable until the expiration date indicated on each cartridge. Once opened, DIL 1 is stable for 60 days on instrument or until the expiration date, if sooner.

### **Reagent storage location:**

## **CALIBRATION**

### **CALIBRATOR REQUIRED**

Synchron Systems Multi Calibrator

### **CALIBRATOR PREPARATION**

No preparation is required.

### **CALIBRATOR STORAGE AND STABILITY**

If unopened, the Synchron Systems Multi Calibrator may be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Opened calibrators that are resealed and stored at +2°C to +8°C are stable for 20 days unless the expiration date is exceeded.

 **CAUTION**

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum or plasma donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HbsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples to be handled as specified in Centers for Disease Control's Biosafety Level 2 guidelines.<sup>7</sup>

**Calibrator storage location:**

## **CALIBRATION INFORMATION**

1. The system must have a valid calibration curve in memory before control or patient samples can be run.
2. Under typical operating conditions the MG reagent cartridge must be calibrated every 7 days and also with certain parts replacement or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.
3. This assay has within-lot calibration available. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions for Use* (IFU) manual.
4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

## **TRACEABILITY**

For Traceability information refer to the Calibrator instructions for use.

## **QUALITY CONTROL**

At least two levels of control material should be analyzed daily. In addition, these controls should be run with each new calibration, with each new reagent cartridge, and after specific maintenance or troubleshooting procedures as detailed in the appropriate system manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws.

The following controls should be prepared and used in accordance with the package inserts. Discrepant quality control results should be evaluated by your facility.

**Table 1.0 Quality Control Material**

CONTROL NAME	SAMPLE TYPE	STORAGE

## TESTING PROCEDURE(S)

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration is required.
3. Program samples and controls for analysis.
4. After loading samples and controls onto the system, follow the protocols for system operations.

For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

## CALCULATIONS

The SYNCHRON System(s) performs all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

## REPORTING RESULTS

Equivalency between the SYNCHRON CX, SYNCHRON LX, and UniCel DxC 600/800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

## REFERENCE INTERVALS

Each laboratory should establish its own reference intervals based upon its patient population. The following reference intervals were taken from literature and a study performed on SYNCHRON Systems.<sup>8</sup>

**Table 2.0 Reference intervals**

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Literature	Serum or Plasma	1.6 – 2.6 mg/dL	0.66 – 1.07 mmol/L
	Urine (timed)	72.9 – 121.5 mg/24 hrs	3.00 – 5.00 mmol/24 hrs
SYNCHRON	Serum or Plasma	1.8 – 2.5 mg/dL	0.74 – 1.03

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Laboratory			

Refer to References (9, 10, 11) for guidelines on establishing laboratory-specific reference intervals.

**Additional reporting information as designated by this laboratory:**

## PROCEDURAL NOTES

### ANTICOAGULANT TEST RESULTS

1. If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

**Table 3.0 Compatible Anticoagulants<sup>a</sup>**

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	AVERAGE PLASMA-SERUM BIAS (mg/dL)
Ammonium Heparin	14 Units/mL	NSI <sup>b</sup>
Lithium Heparin	14 Units/mL	NSI
Sodium Heparin	14 Units/mL	NSI

a Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.

b NSI = No Significant Interference (within  $\pm 0.16$  mg/dL or 4%).

2. The following anticoagulants were found to be incompatible with this method:

**Table 4.0 Incompatible Anticoagulants<sup>a</sup>**

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	PLASMA-SERUM BIAS (mg/dL) <sup>b</sup>
EDTA	1.5 mg/mL	-2.4
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	-1.0

a Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.

b Bias is based on worst case instead of average. Plus (+) or minus (-) signs in this column signify positive or negative bias.

### LIMITATIONS

1. Erythrocytes contain magnesium; therefore, hemolyzed samples should not be used for magnesium analysis.
2. EDTA, sodium citrate, and potassium oxalate are known to interfere with this method.
3. Some gadolinium magnetic resonance contrast agents such as Omniscan, Optimark, and Magnevist may interfere with this method<sup>12</sup>.

### INTERFERENCES

1. The following substances were tested for interference with this methodology:

**Table 5.0 Interferences**

SUBSTANCE	SOURCE	LEVEL	OBSERVED EFFECT <sup>a</sup>
Bilirubin (unconjugated)	Bovine	30 mg/dL	NSI <sup>b</sup>
Hemoglobin	RBC hemolysate	200 mg/dL	≤+0.2 mg/dL
Lipemia	Intralipid <sup>c</sup>	150 mg/dL	≤+0.16 mg/dL
Calcium	NA <sup>d</sup>	22 mg/dL	NSI
Copper	NA	500 µg/dL	NSI
Iron	NA	500 µg/dL	NSI
Methyl dopa	Methyl dopa HCl	0.3 mg/mL	NSI
Zinc	NA	280 µg/dL	NSI

a Plus (+) or minus (-) signs in this column signify positive or negative interference.

b NSI = No Significant Interference (within ±0.16 mg/dL or 4%).

c Intralipid is a registered trademark of KabiVitrum, Inc., Clayton, NC 27250.

d NA = Not applicable.

- Lipemic samples >2+ should be ultra-centrifuged and the analysis performed on the infranate.
- Refer to References (13,14,15) for other interferences caused by drugs, disease and preanalytical variables.

## PERFORMANCE CHARACTERISTICS

### ANALYTIC RANGE

The SYNCHRON System(s) method for the determination of this analyte provides the following analytical range:

**Table 6.0 Analytical Range**

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum or Plasma	0.1 – 7.0 mg/dL	0.04 – 2.88 mmol/L
Urine	1.0 – 70.0 mg/dL	0.4 – 28.8 mmol/L

Samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed.

### REPORTABLE RANGE (AS DETERMINED ON SITE):

**Table 7.0 Reportable Range**

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS

### SENSITIVITY

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for MG determination is 0.1 mg/dL (0.04 mmol/L) for serum or plasma, and 1.0 mg/dL (0.40 mmol/L) for urine.

## EQUIVALENCY

Equivalency was assessed by Deming regression analysis of patient samples to accepted clinical methods.

### Serum or plasma (in the range of 0.2 to 6.7 mg/dL):

Y (SYNCHRON LX Systems)	= 0.949X + 0.13
N	= 73
MEAN (SYNCHRON LX Systems)	= 2.29
MEAN (SYNCHRON CX7 DELTA)	= 2.28
CORRELATION COEFFICIENT (r)	= 0.998

### Urine (in the range of 1.4 to 63.6 mg/dL):

Y (SYNCHRON LX Systems)	= 0.979X + 0.45
N	= 78
MEAN (SYNCHRON LX Systems)	= 22.28
MEAN (SYNCHRON CX7 DELTA)	= 22.29
CORRELATION COEFFICIENT (r)	= 0.998

Refer to References (16) for guidelines on performing equivalency testing.

## PRECISION

A properly operating SYNCHRON System(s) should exhibit precision values less than or equal to the following:

**Table 8.0 Precision Values**

TYPE OF PRECISION	SAMPLE TYPE	1 SD		CHANGEOVER VALUE <sup>a</sup>		% CV
		mg/dL	mmol/L	mg/dL	mmol/L	
Within-run	Serum or Plasma	0.11	0.04	4.4	1.6	2.5
	Urine	0.8	0.3	26.7	10.0	3.0
Total	Serum or Plasma	0.17	0.06	4.4	1.6	3.8
	Urine	1.2	0.5	26.7	10.0	4.5

<sup>a</sup> When the mean of the test precision data is less than or equal to the changeover value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the changeover value, compare the test % CV to the guideline given above to determine acceptability. Changeover value = (SD guideline/CV guideline) x 100.

Comparative performance data for the SYNCHRON System(s) evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below.<sup>17</sup> Each laboratory should characterize their own instrument performance for comparison purposes.

**Table 9.0 NCCLS EP5-T2 Precision Estimate Method**

TYPE OF IMPRECISION	SAMPLE TYPE		No. Systems	No. Data Points <sup>a</sup>	Test Mean Value (mg/dL)	EP5-T2 Calculated Point Estimates	
						SD	%CV
Within-run	Serum	Control 1	1	80	1.12	0.03	3.0
	Serum	Control 2	1	80	3.63	0.06	1.5
	Urine	Control 1	1	80	7.98	0.17	2.1
	Urine	Control 2	1	80	33.72	0.61	1.8
Total	Serum	Control 1	1	80	1.12	0.04	4.0
	Serum	Control 2	1	80	3.63	0.07	2.0
	Urine	Control 1	1	80	7.98	0.23	2.9
	Urine	Control 2	1	80	33.72	0.93	2.8

<sup>a</sup> The point estimate is based on the pooled data from one system, run for twenty days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer's instructions.

**NOTICE**

These degrees of precision and equivalency were obtained in typical testing procedures on a SYNCHRON LX System and are not intended to represent the performance specifications for this reagent.

## ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

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May be covered by one or more pat. -see [www.beckmancoulter.com/patents](http://www.beckmancoulter.com/patents).

### SHIPPING DAMAGE

If damaged product is received, notify your Beckman Coulter Clinical Support Center.

### REVISION HISTORY

#### Revision AE

Revised Quality Control section

#### Revision AF

Updated corporate address; updated European Hazard Classification.

#### Revision AG

Added Revision History

#### Revision AH

Added new language requirement: Czech, and Korean.

**Revision AJ**

Removed references to CX and LX systems as they are discontinued effective 12/2013.

Added Beckman Coulter trademark statement and disclaimer.

**Revision AK**

Added GHS Classification information

**Revision AL**

Added new language requirement: Romanian

**Revision AM**

Updates to comply with requirements per Beckman Coulter Global Labeling Policy.

**Revision AN**

Additional changes to comply with requirements per Beckman Coulter Global Labeling Policy.

**Revision AP**

Added new language requirement: Bulgarian, Serbian, and Vietnamese. Additional changes to comply with requirements per Beckman Coulter Global Labeling Policy.

## SYMBOLS KEY

Table 10.0

	Catalogue Number		In Vitro Diagnostic
	Contents		Temperature limit
	Manufacturer		Expiration Date
	Batch code		Safety Data Sheet
	CE Mark		Consult Instructions for Use
	Authorized Representative in the European Community		Date of Manufacture
	Do Not Freeze		DANGER
	Do not reuse		
			Made in USA of US and Foreign Components

## FOOTNOTES

Registered trademarks are the property of their respective owners.

## REFERENCES

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