# DXC (MG) MAGNESIUM

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## PURPOSE

To provide instructions for the quantitative determination of magnesium on the DXC 600/800.

## PRINCIPLE

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.

## BACKGROUND

### 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. 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.


## RELATED DOCUMENTS

| | |
|---|---|
| R-PO-CH-0810 | Quality Control Program General Laboratory |
| R-PO-CH-0809 | Quality Control Westgard Rules Statistics |
| R-PR-AD-0540 | Specimen Rejection/Cancellation Protocol |
| J-F-CH-0820 | DXC 800 Controls |
| M-F-CH-0820 | Chemistry Controls |
| J-F-CH-0826 | DXC 800 Calibrators |
| M-F-CH-0826 | Chemistry Calibrators |
| M-F-CH-1940 | DXC 600 (AMR) Analytical Measurement Range |

## SPECIMEN

### Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma is the preferred specimen. 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.

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.

| Sample Type | Volume | Sample Stability |
|---|---|---|
| Plasma/Serum | 0.5mL | • Separate serum from cells within 2 hours<br>• Room Temp 8 hours<br>• Refrigerated 48 hours<br>• Frozen 3 months |

### Critieria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

### Sample volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

## REAGENTS

### Contents

Each kit contains the following items:
Two MG Reagent Cartridges (2 x 100 tests)

| Volume per Test | |
|---|---|
| Sample Volume | 3 µL |
| Total Reagent Volume | 308 µL |
| Cartridge Volumes | A 280 µL<br>B 28 µL<br>C – – |

| Reactive Ingredients | |
|---|---|
| Calmagite (Dye Reagent) | 0.15 mmol/L |
| Alkaline Solution | pH > 13 |

Also non-reactive chemicals necessary for optimal system performance.

### 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. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE.

## 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. Do not use beyond the manufacturer's expiration date.

### Calibrator 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

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

## STEPS

1. If necessary, load the reagent onto the system.

2. After reagent load is completed, calibration is required.

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System Instructions For Use (IFU) manual.

## CALCULATIONS

SYNCHRON® System(s) perform 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.

## 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:

| Anticoagulant | Level Tested for In Vitro Interference |
|---|---|
| Ammonium Heparin | 14 Units/mL |
| Lithium Heparin | 14 Units/mL |
| Sodium Heparin | 14 Units/mL |

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

| Anticoagulant | Level Tested for In Vitro Interference | Plasma-Serum Bias (mg/dL)[d] |
|---|---|---|
| EDTA | 1.5 mg/mL | -2.4 |
| Potassium Oxalate/Sodium Fluoride | 2.0 / 2.5 mg/mL | -1.0 |

## PERFORMANCE CHARACTERISTICS

### Reference Range

| | Range | Critical Low | Critical High |
|---|---|---|---|
| Male/Female | 1.7 – 2.4 mg/dL | <1.0 mg/dL | >4.7 mg/dL |
| Female (Mg Therapy) | 4.0 – 7.0 mg/dL | <1.0 mg/dL | >7.9 mg/dL |

For Critical Value reporting protocol, refer to FHS Critical Policy

### Analytic Range

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

| Sample Type | Conventional Units |
|---|---|
| Serum or Plasma | 0.1 – 7.0 mg/dL |

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

### Reporting results outside of analytical range

| | | |
|---|---|---|
| Lower limit of range: serum / plasma | 0.1 mg/dL | Results below 0.1, report as <0.1 |
| Upper limit of range: serum / plasma | 7.0 mg/dL | Results >7.0 should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >14.0 are reported as >14.0 mg/dL. |

### 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 for serum or plasma.

## 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.

### Interferences

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

| Substance | Source | Level Tested | Observed Effect |
|---|---|---|---|
| Bilirubin (unconjugated) | Bovine | 30 mg/dL<br>INDEX OF 20 | NSI |
| Hemoglobin | RBC hemolysate | 200 mg/dL<br>INDEX OF 5 | ≤+0.2 mg/dL |
| Lipemia | Intralipid[g] | 320 mg/dL<br>INDEX OF 8<br>Airfuge recommended | ≤+0.16 mg/dL |
| Calcium | NA | 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 |

2. Refer to References (13,14,15) for other interferences caused by drugs, disease and preanalytical variables.

## ADDITIONAL INFORMATION

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

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