

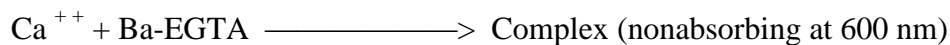
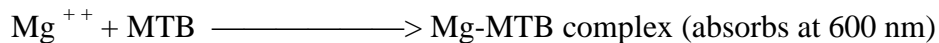
**BROWN CLINIC
LABORATORY PROCEDURE MANUAL****PROCEDURE:** Magnesium**PURPOSE:**

The MG method used on the Dimension EXL200 Integrated chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of magnesium in **serum** and **heparinized plasma**.

PRINCIPLE:

The magnesium method is a modification of the methylthymol blue (MTB) complexometric procedure described by Connerty, Lau, and Briggs.¹ The barium salt of ethylenedis(oxyethylenenitrilo) tetraacetic acid (Ba-EGTA) is used to reduce interference due to calcium which also reacts with MTB.²

MTB forms a blue complex with magnesium. Calcium interference is minimized by forming a complex between calcium and Ba-EGTA (chelating agent). The amount of MG-MTB complex formed is proportional to the magnesium concentration and is measured using a bichromatic (600 and 510 nm) endpoint technique. For Dimension® AR (software version 4.4 and above), ES (software 2.7 or 4.3 and above) and XL/RxL (software version 5.0 and above), a sample blank is used to minimize bilirubin interference.

**INSTRUMENT, REAGENTS & SUPPLIES:****Reagents**

Wells ^a	Form	Ingredient	Concentration ^b
1-3	Liquid	MTB	0.0528 g/L
		Acetic acid	
		Potassium sorbate	
4-6	Liquid	Ba-EGTA	0.5 mM
		Sodium metaborate	

Buffer

Microbial inhibitors

- a. Wells are numbered consecutively from the wide end of the cartridge.
- b. Nominal value per test at manufacture.

Precautions: Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact and ingestion.³

For *in vitro* diagnostic use

Safety Data Sheets (SDS/MSDS) can be found at www.siemens.com/healthcare

Reagent Preparation: All reagents are liquid and ready-to-use.

REAGENT STORAGE & STABILITY:

Store at 2 – 8° C.

Expiration: Refer to shelf carton for expiration date of individual unopened reagent cartridges. Sealed cartridge wells on the instrument are stable for 30 days. Once wells have been entered by the instrument, they are stable for 48 hours.

SPECIMEN REQUIREMENTS:

Normal procedures for collecting and storing serum, plasma may be used for samples to be analyzed by this method.

Follow the instruction provided with your specimen collection device for use and processing
Complete clot formation should take place before centrifugation.

Specimen:

Patient preparation: no patient preparation required

Specimen type: serum or heparinized plasma

Stability:

Room Temperature: 7 days

Refrigerated at 2-8°C: 7 days

Frozen at -20°C: up to 1 year

Blood collection tubes containing lithium heparin, potassium oxalate or sodium fluoride do not interfere with the MG method.

EDTA of 200 mg/dL [2g/dL] decreases the MG result by 0.4 mg/dL [0.16 mmol/L] at a magnesium concentration of 1.8 mg/dL [0.74 mmol/L].

CONTROLS:

At least once daily run solutions at two levels of a quality control material with known concentrations.

For further details, refer to your Dimension® system manual. The result obtained should fall within limits defined by the day-to-day variability of the system as measured in the user's

laboratory. If the results fall outside the laboratory's acceptable limits, follow the procedure in the quality control policy.

PROCEDURE:

The MG Flex® reagent cartridge, Cat. No. DF57, is required to perform the MG test. This test is performed on the Dimension® clinical chemistry system after the method is calibrated.

Test Steps Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® system. For details of this processing, refer to your Dimension® system manual.

The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus dead volume. Precise container filling is not required.

Test Conditions

Test Conditionsd

- Sample Size: 4 µL
- Reagent 1 Volume: 100 µL
- Reagent 2 Volume: 200 µL
- Diluent Volume: 696 µL
- Test Temperature: 37°C
- Wavelength: 600 and 510 nm
- Type of Measurement: bichromatic endpoint

Calibration The general calibration procedure is described in the Dimension® system manual (also see Appendix B).

The following information should be considered when calibrating the magnesium method:

- Assay Range: 0.0–20.0 mg/dL [0.0–8.22 mmol/L]
- Reference Material: Primary standards such as CHEM II Calibrator (Cat. No. DC20) or secondary calibrators.
- Suggested Calibration Levels: 0.0, 9.0, 18.0 mg/dL [0.0, 3.70, 7.41 mmol/L]
- Calibration Scheme: Three levels in triplicate
- Calibration Frequency: Every new reagent cartridge lot
Every 3 months for any one lot
For each new lot of Flex reagent cartridges
After major maintenance or service, if indicated by quality control results
As indicated in laboratory quality control procedures
When required by government regulations
- Assigned Coefficients: C₀ -0.200

C₁ 0.100

Backup Process:

Refer to Brown Clinic Back-up Policy

INTERPRETATION:

The instrument automatically calculates and prints the concentration of magnesium in mg/dL [mmol/L] using the calculation scheme illustrated in the Principles of Operation section of the Dimension® system manual.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

EXPECTED RESULTS:

Serum: 1.8–2.4 mg/dL [0.74–0.99 mmol/L]

Each laboratory should establish its own reference interval for magnesium as performed on the Dimension® system.

REPORTING:

report format: mg/dl

LIMITATIONS:

Results in excess of 20.0 mg/dL [8.23 mmol/L] should be repeated after diluting the sample with Purified Water or equivalent (see Dimension® system manual) to produce a sample concentration within the assay range. The resulting readout will then be multiplied by the dilution factor to give the concentration of the undiluted sample.

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to the Dimension® system manual for troubleshooting.

Analytical Specificity

For Known Interfering Substances section refer to package insert.

For Known Non-Interfering Substance refer to package insert.

For Additional Technical Information refer to package insert.

Reference: MG Flex® reagent cartridge insert sheet PN 717057.001 Issue Date 2-26-2016

Origination Date: 9-10-07

Date of Implementation: 11-10-10

Written By: ___Lori Murray MT(ASCP)_____ Date: _8-8-12

Approved By: __Aaron Shives, MD___ Date: __10/23/2017__

Laboratory Director

REVIEW - REVISION SUMMARY DOCUMENTATION

<u>Date</u>	<u>By</u>	<u>Revision Summary</u>
07/10	Lori Murray	New format
8-8-12	Lori Murray	Changed instrumentation to EXL200
6/16/15	Heather Hall	Updated information to package insert dated 2-4-10
10/18/17	Heather Hall	Updated information to package insert dated 2-26-2016, modified backup process