

**MAGNESIUM**

**SERUM, PLASMA OR URINE**

**ABBOTT ARCHITECT**

**Intended Use**

The Magnesium assay is used for the quantitation of magnesium in human serum, plasma, or urine.

**Clinical Significance**

Magnesium is an essential nutrient which is involved in many biochemical functions. It has a structural role in nucleic acids and ribosomal particles, required as an activator for many enzymes and has

a role in energy producing oxidative phosphorylation. The normal body contains between 21 to 28 g magnesium, more than 50% of which is complexed with calcium and phosphate in bone. Only approximately 1% of the total magnesium is found in the extracellular fluid; hence, it tends to enter and leave cells under the same conditions as potassium. Approximately 35% of plasma magnesium is protein-bound, mainly to albumin, and therefore changes in albumin concentration may affect magnesium. Hypomagnesemia results in the impairment of neuromuscular function and may develop in severe prolonged diarrhea, malabsorption syndromes, hyperaldosteronism, and diuretic therapy. Hypermagnesemia results in hypotension, bradycardia, and respiratory depression, among other conditions.

**Principle**

Magnesium present in the sample is a cofactor in an enzymatic reaction with isocitrate dehydrogenase. The rate of increase in absorbance at 340 nm, due to the formation of NADPH, is directly proportional to the magnesium concentration.

**Methodology:** Enzymatic

**Specimen Collection and Handling**

**Suitable Specimens**

Serum, plasma, and urine are acceptable specimens.

• **Serum:** Use nonhemolyzed serum collected by standard venipuncture techniques into glass or plastic tubes with or without gel barriers. Ensure complete clot formation has taken place prior to centrifugation. Centrifuge according to tube manufacturer’s instructions to ensure proper separation of serum from blood cells.

Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting processes. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results.

• **Plasma:** Use plasma collected by standard venipuncture techniques into glass or plastic tubes. Acceptable anticoagulants are lithium heparin (with or without gel barrier) and sodium heparin. Ensure centrifugation is adequate to remove platelets. Centrifuge according to tube manufacturer’s instructions to ensure proper separation of plasma from blood cells.

• **Urine:** Urine specimens should be collected in HCl, 20 to 30 mL of 6 mol/L for a 24 hour specimen, to prevent precipitation of magnesium complexes

**Specimen Storage**



**NOTE:** Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

**Materials and Equipment Required**

**TEST INSTRUMENT**: Abbott ARCHITECT System

**MATERIALS PROVIDED**

3P68 Magnesium Reagent Kit

**MATERIALS REQUIRED BUT NOT PROVIDED**

• 1E65 Multiconstituent Calibrator

• Control Material

• Saline (0.85% to 0.90% NaCl) for specimens that require dilution

**Reagent Handling and Storage:**

***CAUTION*:**

1. For in vitro diagnostic use.

2. Do not use components beyond the expiration date.

3. Do not mix reagents prepared at different times.

 **CAUTION:** This product requires the handling of human specimens.

It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

• The following warning and precaution apply to R1 .

Contains sodium azide and polyethylene glycol octylphenyl ether.

EUH032 Contact with acids liberates very toxic gas.

H402 Harmful to aquatic life.

H412 Harmful to aquatic life with long lasting effects.

**Prevention**

P273 Avoid release to the environment.

**Disposal**

P501 Dispose of contents / container in accordance with local regulations.

**Reagent Handling**

Do not use reagents beyond the expiration date.

Do not use components from one lot with components from another lot.

Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate. To minimize volume depletion, do not use a transfer pipette to remove the bubbles.

**CAUTION:** Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

**Reagent Storage**

Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagent stability is 30 days if the reagent is uncapped and onboard.

Reagent Preparation:

Magnesium is supplied as a liquid, ready-to-use, two-reagent kit.



**Calibrator:** 1E65 Multiconstituent Calibrator

**Quality Control:** Minimum 2 levels of ChemistryControl (Normal and Abnormal), Urine Controls

**Calibration**

**Frequency:**

Calibration is stable for approximately 30 days (720 hours) for any one lot.

**A new calibration is required:**

1. If quality control results do not meet acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
2. Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

**Calibration Procedure:**

Calibration is performed by running a water blank and the Multiconstituent Calibrator set. Water for the blank is provided by the instrument.

1. Verify that the correct calibrator values have been entered into the calibration file.

2. Allow calibrator to come to room temperature.

3. Mix bottle five times by gentle inversion.

4. Open bottle, place an appropriate amount of each calibrator in a separate sample cup, and place in the assigned positions.

5. Cap bottle tightly and return to refrigerated storage immediately after use.

6. Perform calibration as indicated in the **ARCHITECT System Operations Manual**.

**Troubleshooting and Overall Acceptance Criteria Failure**

See ARCHITECT Operations Manual for further calibration troubleshooting.

**Quality Control:**

Abbott recommends, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions:

• Two levels of controls (normal and abnormal) are to be run every 24 hours.

Some controls may require addition of Liquid Stabilizer.

• If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.

• If quality control results do not meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory.

Recalibration may be necessary.

• Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

**Procedure**

For a detailed description of how to run an assay, refer to *Section 5* of the **ARCHITECT System Operations Manual**.

**Calculations**

Refer to *Appendix C* of the **ARCHITECT System Operations Manual** for information on results calculations.

**Reporting Results**

The ARCHITECT Magnesium assay unit is mg/dL

**Specific Performance Characteristics**

**Reference Ranges**

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

**Serum/Plasma:**

<6 years: 1.7 – 2.3 mg/dL

6-12 years: 1.7 – 2.1 mg/dL

12-20 years: 1.7 – 2.2 mg/dL

Adult: 1.6 – 2.6 mg/dL

**Urine:** 72.9 – 121.5 mg/24 hours

**Critical Values**

**Serum/Plasma: < 1 and > 5 mg/dL**

**Urine: N/A**

**Performance Characteristics**

**Linearity**

Magnesium serum is linear across the measuring interval of 0.60 to 9.5 mg/dL

Magnesium urine is linear across the measuring interval of 1.81 mg/dL to 26.35 mg/dL

**Dilution:**

**Serum and Plasma:** Specimens with magnesium values exceeding 9.5 mg/dL are flagged and may be diluted by following either the Automated Dilution Protocol or the Manual Dilution Procedure.

**Urine:** Urine samples are automatically diluted 1:2 by the system using the Standard dilution option, then the system automatically corrects the concentration by multiplying the result by the appropriate dilution factor. This dilution extends urine Magnesium linearity to 26.35 mg/dL. Samples exceeding this concentration are flagged and may be diluted by following either the Automated Dilution Protocol or the Manual Dilution Procedure.

**Serum/Plasma Automated Dilution Protocol**

If using the Automated Dilution Protocol, the system performs a dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor. To set up the automatic dilution feature, refer to *Section 2* of the **ARCHITECT System**

**Operations Manual** for additional information.

**Urine Automated Dilution Protocol**

If using the Automated Dilution Protocol, the system performs a 1:10 dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

**Manual Dilution Procedure**

Manual dilutions should be performed as follows:

• Use saline (0.85% to 0.90% NaCl) to dilute the sample.

• The operator must enter the dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor.

• If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.

**NOTE:** If a diluted sample result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution.

**Limit of Detection (LOD):** The LOD for Magnesium serum is 0.10 mg/dL

(0.04 mmol/L). The LOD for Magnesium urine is 0.24 mg/dL (0.10 mmol/L).

**Limit of Quantitation (LOQ):** The LOQ for Magnesium serum is 0.16 mg/dL

(0.07 mmol/L). The LOQ for Magnesium urine is 0.79 mg/dL (0.33 mmol/L).

**Limitation of Procedure:**

* The Magnesium assay is susceptible to interference from hemoglobin. Refer to the Interference section of the package insert for additional details.
* Do not use acetic acid, nitric acid, and sodium fluoride as urine preservatives.
* Do not use more than 2.5 mL 6N HCL per 100mL of urine. Excess hydrochloric acid may cause elevated results with this methodology.
* Do not exceed 10 g/L boric acid.
* Elevated Magnesium patient results may occur due to contamination from other sources of magnesium. Refer to Results section of the package insert for additional information.

**Precision:**

**Serum**



**Urine**

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#### Interfering Substances:

**Interfering Substances**





The above solutions were prepared by addition of the interfering substances to human serum pool.

**Drug Interference**

The following drugs were tested for interference at the concentrations indicated using an acceptance criteria of +/- 7.5% from the target value.



**References:**

1. ABBOTT ARCHITECT Magnesium package insert

Abbott Laboratories

Diagnostics Division

Abbott Park, IL 60064

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1. ABBOTT Multiconstituent Calibrator

Abbott Laboratories

Diagnostics Division

Abbott Park, IL 60064

June 2013 306297/R04

1. Abbott ARCHITECT Operator’s Guide