Magnesium

FOR USE WITH

ARCHITECT

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MAG

03P68

H06729R04

B3P6R0

Revised May 2023.

REF 03P6824

REF 03P6834

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

For laboratory professional use only.

NAME

Magnesium (also referred to as MAG)

INTENDED USE

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

Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

SUMMARY AND EXPLANATION OF THE TEST

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

The normal body contains 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. 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 impairment of neuromuscular function, carbohydrate intolerance, and cardiac arrhythmias. Hypermagnesemia results in hypotension, bradycardia, and respiratory depression, among other conditions.

PRINCIPLES OF THE PROCEDURE

The Magnesium assay is an automated clinical chemistry assay.

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.

$$\text{D-isocitric acid} + \text{NADP} \xrightarrow[Mg^{2+}]{\text{Isocitrate dehydrogenase}} \text{2-oxoglutarate} + CO_2 + \text{NADPH}$$

Methodology: Enzymatic

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

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REAGENTS

Kit Contents

Magnesium Reagent Kit 03P68

NOTE: Some kit sizes may not be available. Please contact your local distributor.

Volumes (mL) listed in the following table indicate the volume per cartridge.

REF	03P6824	03P6834
Tests per cartridge set	200 (Serum/Plasma) 134 (Urine)	375 (Serum/Plasma) 254 (Urine)
Number of cartridge sets per kit	5	10
Tests per kit	1000 (Serum/Plasma) 670 (Urine)	3750 (Serum/Plasma) 2540 (Urine)
R1	39 mL	71 mL
R2	11 mL	18 mL

R1 Active ingredients: Isocitrate dehydrogenase (0.75 U/mL), D-Isocitrate potassium salt (1.47 mg/mL). Preservative: sodium azide (0.1%).

R2 Active ingredient: NADP (8.37 mg/mL). Preservative: sodium azide (0.1%).

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[1-4]

The following warnings and precautions apply to: R1	
	
WARNING	Contains ethylene glycol, sodium azide and polyethylene glycol octylphenyl ether.
H373	May cause damage to organs through prolonged or repeated exposure.
H402*	Harmful to aquatic life.
H412	Harmful to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P260	Do not breathe mist / vapors / spray.
P273	Avoid release to the environment.
P280	Wear protective gloves / protective clothing / eye protection.

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Response	
P314	Get medical advice / attention if you feel unwell.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EC 1272/2008 (CLP) has been implemented.

The following warnings and precautions apply to: R2	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Reagent Handling

- Do not pool reagents within a kit or between kits.
- Do not use components from one lot with components from another lot.
- Do not reuse containers, caps or plugs due to the risk of contamination and the potential to compromise reagent performance.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position.

Reagents may be stored on or off the ARCHITECT c System. If reagents are removed from the system, store at 2 to 8°C (with replacement caps) in their original boxes.

For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Magnesium assay files must be installed on the ARCHITECT c System prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

Alternate Result Units

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
mg/dL	0.411	mmol/L
	0.823	mEq/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types, collection tube types, and anticoagulants have not been verified with this assay.

Specimen Type	Collection Vessel	Special Conditions
Serum	Serum tubes (with or without gel barrier)	Use nonhemolyzed specimens.
Plasma	Collection tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) Sodium heparin	
Urine (24 hour)	Urine specimens should be collected in acid to prevent precipitation of magnesium complexes.[5]	Do not use more than 2.5 mL 6N HCl per 100 mL of urine. Excess hydrochloric acid may cause elevated results with this methodology. Do not exceed 10 g/L boric acid.

- For tube type limitations, refer to the LIMITATIONS OF THE PROCEDURE section of this package insert.

The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- For accurate results, serum specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.

  For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.
- For additional information on specimen conditions, refer to the Interference section of this package insert.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low speed vortex.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.

Recentrifugation of Specimens

- Transfer specimens to a centrifuge tube and centrifuge.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time	Special Instructions
Serum/ Plasma	Room temperature (20 to 25°C)	8 hours	
	2 to 8°C	3 days	
	-20°C	3 months[6]	
Urine	Room Temperature (20 to 25°C)	2 days[7]	Acidify to pH < 2
	2 to 8°C	2 days[7]	Acidify to pH < 2
	-22°C	1 year[8]	Acidify to pH < 2

Serum/Plasma: If testing will be delayed longer than the maximum room temperature or 2 to 8°C storage time, remove serum or plasma from the clot, red blood cells, or separator gel and store frozen.

Urine: If testing will be delayed longer than the maximum room temperature or 2 to 8°C storage time, store frozen.

It is the responsibility of the individual laboratory to determine specific specimen stability criteria for their laboratory per their laboratory workflow.

For additional information on sample handling and processing, refer to CLSI GP44-A4.[9] The storage information provided here is based on references or data maintained by the manufacturer.

Each laboratory may establish a range around -20°C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

03P68 Magnesium Reagent Kit

Materials Required but not Provided

- Magnesium assay file found on www.corelaboratory.abbott
- 1E65-05 Multiconstituent Calibrator
- Controls containing magnesium
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the ARCHITECT System Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

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

- If using primary or aliquot tubes, refer to the ARCHITECT System Operations Manual, Section 5 to ensure sufficient specimen is present.
- Minimum sample cup volume is calculated by the system and printed on the Order List report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
  - Sample volume for single test: 3.2 µL (serum/plasma) 1.6 µL (urine).

    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the ARCHITECT System Operations Manual, Section 5.
- Refer to the Multiconstituent calibrator package insert REF 1E65-05 and/or commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

The ARCHITECT c Systems have an automatic dilution feature; for additional information, refer to the ARCHITECT System Operations Manual, Section 2.

Serum/Plasma: Specimens with magnesium values exceeding 9.50 mg/dL (3.90 mmol/L) are flagged and may be diluted using the Manual Dilution Procedure. The system automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

Urine: Urine samples are diluted 1:2.97 by the system using the Standard dilution option, then the system corrects the concentration by multiplying the result by the dilution factor. All samples should be initially tested using the STANDARD (1:3) Dilution Protocol. If a sample result is greater than the upper value of the measuring interval of 26.35 mg/dL (10.83 mmol/L), this sample should be retested using the 1:9 Automated Dilution Protocol. If the result obtained is within the analytical measuring interval of 1.81 to 26.35 mg/dL (0.74 to 10.83 mmol/L), the sample should not be diluted.

Automated Dilution Protocol

Urine: 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 the ARCHITECT System Operations Manual, Section 2.

Manual Dilution Procedure

1. Dilute the specimen with saline (0.85% to 0.90% NaCl) using a recommended dilution of 1:2.
2. 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 manually multiplied by the appropriate dilution factor before reporting the result.

$$\text{Manual Dilution Factor} = \frac{(\text{Volume of Specimen} + \text{Volume of Dilution Reagent})}{\text{Volume of Specimen}}$$

If a diluted specimen result is flagged indicating it is less than the linear low limit of 0.60 mg/dL (0.25 mmol/L) for the serum/plasma application and 1.81 mg/dL (0.74 mmol/L) for the urine application, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

For instructions on performing a calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Calibration is stable for approximately 30 days (720 hours), but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

For information on calibrator standardization, refer to the Multiconstituent Calibrator package insert REF 1E65-05.

Quality Control Procedures

As appropriate, 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.
- 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, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to "Basic QC Practices" by James O. Westgard, Ph.D. for guidance on laboratory quality control practices.[10]

RESULTS

Elevated Magnesium patient results may occur due to contamination from other sources of magnesium. You may wish to consider the troubleshooting recommendations below for magnesium issues that could be due to system-specific conditions. Refer to the ARCHITECT System Operations Manual, Section 9 and Section 10.

To minimize the potential for magnesium contamination:

1. Keep the system optimized by ensuring that appropriate and timely preventive maintenance activities are performed.
2. Verify that all SmartWash parameters are configured correctly.
3. Verify that recommended troubleshooting as outlined in the Operations Manual has been performed.
4. Verify that reagent carryover testing for non-Abbott assays has been performed prior to implementation in the laboratory. Refer to Reagent carryover evaluation in the ARCHITECT c Systems Assay Applications Guide.
5. Perform the following sequentially:
   a. Manually clean the cuvettes. Refer to As-needed maintenance procedure *6310 Clean cuvettes*.
   b. Remove any visible buildup around the carousel. Refer to As-needed maintenance procedure *6064 Clean Reaction Carousel*.
   c. Replace the cuvette dry tip(s) and any damaged cuvettes. Verify cuvettes are properly seated in segment.
6. Ensure the cuvette wash cycle completes in its entirety. If necessary, Pause **(do not STOP)** the system. If the system stops due to a hardware error or is stopped before cuvette washing is completed, promptly perform As-needed maintenance procedure *6052 Wash cuvettes*, as indicated by Error code 0550.
7. Replace the R1 probe(s).

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

Measuring Interval

The measuring interval of the Magnesium assay is 0.60 to 9.50 mg/dL (0.25 to 3.90 mmol/L) for the serum/plasma application and 1.81 mg/dL to 26.35 mg/dL (0.74 mmol/L to 10.83 mmol/L) for the urine application.

LIMITATIONS OF THE PROCEDURE

- The Magnesium assay is susceptible to interference from hemoglobin. Refer to the Interference section of this 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 100 mL 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 this package insert for additional information.

Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

EXPECTED VALUES

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

Reference Range

Serum/Plasma[11]

	Range (mg/dL)*	Range (mmol/L)*
Newborn, 2 to 4 days	1.5 - 2.2	0.62 - 0.91
5 months to 6 years	1.7 - 2.3	0.70 - 0.95
6 to 12 years	1.7 - 2.1	0.70 - 0.86
12 to 20 years	1.7 - 2.2	0.70 - 0.91
Adult	1.6 - 2.6	0.66 - 1.07

* Abbott has not evaluated reference ranges in the pediatric population.

NOTE: Higher values can be expected in females during menses. Refer to the Alternate Result Units section of this insert for the appropriate conversion factors.

Urine[11]

	Range (mg/day)	Range (mmol/day)
24 hour	72.9 - 121.5	3.00 - 5.00

24-Hour Urinary Excretion

To convert results from mg/dL to mg/day (24-hour urinary excretion):

24-hour excretion = [(V × c) ÷ 100] mg/day

Where:

V = 24-hour urine volume (mL)

c = analyte concentration (mg/dL)

To convert results from mmol/L to mmol/day (24-hour urinary excretion):

24-hour excretion = [(V × c) ÷ 1000] mmol/day

Where:

V = 24-hour urine volume (mL)

c = analyte concentration (mmol/L)

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

Precision

Within-Laboratory Precision

Serum/Plasma

A study was performed based on guidance from CLSI EP05-A2.[12] Testing was conducted using 1 lot of the Magnesium Reagent Kit, 1 lot of the Multiconstituent Calibrator, 1 lot of commercially available controls, and 1 instrument. Two controls and 4 human serum pools were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.

		Mean	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	n	(mg/dL)	SD	%CV	SD	%CV
Control 1	80	1.77	0.024	1.3	0.026	1.5
Control 2	80	4.18	0.023	0.6	0.034	0.8
Pool A	80	0.63	0.022	3.6	0.027	4.2
Pool B	80	1.92	0.032	1.7	0.038	2.0
Pool C	80	5.09	0.032	0.6	0.043	0.8
Pool D	80	9.34	0.041	0.4	0.059	0.6

[a] Includes within-run, between-run, and between-day variability.

Urine

A study was performed based on guidance from CLSI EP05-A2.[12] Testing was conducted using 1 lot of the Magnesium Reagent Kit, 1 lot of the Multiconstituent Calibrator, 1 lot of commercially available controls, and 1 instrument. Two controls and 3 human urine pools were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.

		Mean	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	n	(mg/dL)	SD	%CV	SD	%CV
Control 1	80	4.62	0.080	1.7	0.083	1.8
Control 2	80	11.56	0.138	1.2	0.143	1.2
Pool A	80	1.94	0.071	3.6	0.074	3.8
Pool B	80	6.07	0.084	1.4	0.110	1.8
Pool C	80	24.38	0.382	1.6	0.404	1.7

[a] Includes within-run, between-run, and between-day variability.

Accuracy

The bias for Magnesium serum or plasma is ≤ 7.5% or ± 0.1 mg/dL, whichever is greater. Representative data from serum studies using NIST SRM 956 standards are summarized below.

	Level 1	Level 2	Level 3
Target (mg/dL)	3.031	2.084	1.143
N	7	7	7
Concentration (mg/dL)	3.013	2.067	1.119
%Bias	-0.6	-0.8	-2.1

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[13] Testing was conducted using 2 lots of the Magnesium reagent kit on one instrument over a minimum of 3 days. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below.

Serum/Plasma

	mg/dL	mmol/L
LoB[a]	0.07	0.03
LoD[b]	0.10	0.04
LoQ[c]	0.16	0.07

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ was determined from n ≥ 60 replicates of low-analyte level samples and is defined as the lowest concentration at which a total allowable error of 15% or 0.3 mg/dL was met.

Urine

	mg/dL	mmol/L
LoB[a]	0.13	0.05
LoD[b]	0.24	0.10
LoQ[c]	0.79	0.33

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ was determined from n ≥ 60 replicates of low-analyte level samples and is defined as the lowest concentration at which a total allowable error of 22% was met.

Linearity

A study was performed based on guidance from CLSI EP06-A.[14]

The Magnesium assay is linear across the measuring interval of 0.60 to 9.50 mg/dL (0.25 to 3.90 mmol/L) for the serum/plasma application and 1.81 mg/dL to 26.35 mg/dL (0.74 mmol/L to 10.83 mmol/L) for the urine application.

Analytical Specificity

Interference

Serum

Studies were performed based on guidance from CLSI EP07-A2.[15] Interference effects were assessed by Dose Response and Paired Difference methods. The following interfering substances were tested at the concentrations indicated using an acceptance criteria of ± 7.5% from the target value. Values in the table represent the highest levels of interferents that met the acceptance criteria at various magnesium concentrations.

			Magnesium	
Interfering Substance	Interferent Concentration	N	Target (mg/dL)	% Difference
Ascorbic acid	3.0 mg/dL (0.170 mmol/L)	7	2.1	1.37
	3.0 mg/dL (0.170 mmol/L)	6	4.0	0.36
	3.0 mg/dL (0.170 mmol/L)	7	6.4	0.18
Bilirubin, Conjugated	55.3 mg/dL (945.6 µmol/L)	7	1.9	1.68
	55.9 mg/dL (955.9 µmol/L)	7	3.6	-2.33
	56.5 mg/dL (966.2 µmol/L)	7	5.7	1.40
Bilirubin, Unconjugated	60.3 mg/dL (1031.1 µmol/L)	7	2.0	1.52
	60.5 mg/dL (1034.6 µmol/L)	6	3.7	0.65
	60.9 mg/dL (1041.4 µmol/L)	7	6.0	1.65
Calcium	28.0 mg/dL (7 mmol/L)	6	2.0	2.70
	28.0 mg/dL (7 mmol/L)	7	3.8	3.86
	28.0 mg/dL (7 mmol/L)	7	6.1	3.94

Interfering Substance	Interferent Concentration	N	Magnesium Target (mg/dL)	Magnesium % Difference
Copper	6.5 µg/mL (102.29 µmol/L)	10	2.0	0.40
	6.5 µg/mL (102.29 µmol/L)	10	4.0	-0.30
	6.5 µg/mL (102.29 µmol/L)	10	6.3	0.63
Glucose	1240 mg/dL (68.82 mmol/L)	7	2.1	-0.46
	1311 mg/dL (72.76 mmol/L)	7	4.0	-0.44
	1199 mg/dL (66.54 mmol/L)	6	6.4	-0.54
Hemoglobin	250 mg/dL (2.5 g/L)	7	2.1	5.24
	1000 mg/dL (10.0 g/L)	6	3.9	6.50
	1200 mg/dL (12.0 g/L)	7	6.4	6.66
Intralipid	2476 mg/dL (24.76 g/L)	7	2.0	1.36
	2471 mg/dL (24.71 g/L)	7	3.7	0.38
	2482 mg/dL (24.82 g/L)	7	6.1	-2.69
Iron	641 µg/dL (114.78 µmol/L)	10	2.0	0.80
	641 µg/dL (114.78 µmol/L)	10	4.0	-0.22
	641 µg/dL (114.78 µmol/L)	10	6.4	-0.92
L-Dopamine	5.0 mg/dL (0.255 mmol/L)	7	2.1	1.83
	5.0 mg/dL (0.255 mmol/L)	6	4.0	1.10
	5.0 mg/dL (0.255 mmol/L)	7	6.4	1.85
Triglyceride	3647 mg/dL (41.21 mmol/L)	10	2.0	-2.04
	3598 mg/dL (40.66 mmol/L)	10	4.0	-1.60
	3580 mg/dL (40.45 mmol/L)	10	5.8	-0.47
Zinc	4.3 µg/mL (65.77 µmol/L)	10	2.0	-0.54
	4.3 µg/mL (65.77 µmol/L)	10	4.1	0.52
	4.3 µg/mL (65.77 µmol/L)	10	6.4	0.67

Drug Interference

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

Interfering Substance	Interferent Concentration	N	Magnesium Target (mg/dL)	Magnesium % Difference
Acetaminophen	241 µg/mL (1592 µmol/L)	10	1.9	0.75
	241 µg/mL (1592 µmol/L)	10	3.6	0.05
	241 µg/mL (1592 µmol/L)	10	5.8	0.54
Ibuprofen	601 µg/mL (2915 µmol/L)	10	1.8	1.03
	601 µg/mL (2915 µmol/L)	10	3.6	1.05
	601 µg/mL (2915 µmol/L)	10	5.8	0.74
Salicylic Acid	71.96 mg/dL (5.21 mmol/L)	10	1.8	1.63
	71.96 mg/dL (5.21 mmol/L)	10	3.7	0.68
	71.96 mg/dL (5.21 mmol/L)	9	5.8	0.67
Sulfapyridine	300 mg/L (1.20 mmol/L)	3	1.5	-0.40
Sulfasalazine	300 mg/L (0.754 mmol/L)	3	1.5	1.50
Temozolomide	20 mg/L (0.10 mmol/L)	3	3.5	0.26
	20 mg/L (0.10 mmol/L)	3	7.5	-1.11

Sulfapyridine and sulfasalazine solutions were prepared by addition of the interfering substances to human serum pool. Temozolomide was evaluated in human plasma.

Urine

Studies were performed based on guidance from CLSI EP07-A2.[15] Interference effects were assessed by Dose Response and Paired Difference methods. The following interfering substances were tested at the concentrations indicated using an acceptance criteria of ± 10% from the target value. Values in the table represent the highest levels of interferents that met the acceptance criteria at various magnesium concentrations.

Interfering Substance	Interferent Concentration	N	Magnesium Target (mg/dL)	Magnesium % Difference
Albumin	64.0 mg/dL (640 mg/L)	9	4.6	1.09
	64.0 mg/dL (640 mg/L)	10	13.8	1.24
Ascorbic Acid	200 mg/dL (2000 mg/L)	9	4.9	0.76
	200 mg/dL (2000 mg/L)	10	15.2	1.84
Bilirubin, Conjugated	59.9 mg/dL (1024.3 µmol/L)	10	4.3	-0.68
	59.5 mg/dL (1017.5 µmol/L)	10	13.4	-2.41
Calcium	26.0 mg/dL (6.5 mmol/L)	9	4.9	2.39
	27.0 mg/dL (6.8 mmol/L)	10	15.0	3.63
Copper	21.6 µg/dL (3.4 µmol/L)	12	5.1	-0.08
	21.6 µg/dL (3.4 µmol/L)	12	14.5	0.20
Glucose	1220 mg/dL (67.71 mmol/L)	10	5.1	-0.92
	1237 mg/dL (68.65 mmol/L)	10	15.6	3.04
Hemoglobin	1200 mg/dL (12.00 g/L)	10	5.2	4.36
	1200 mg/dL (12.00 g/L)	9	15.9	2.10
Phosphorous	307 mg/dL (99 mmol/L)	10	4.5	-0.65
	313 mg/dL (101 mmol/L)	9	14.1	-0.26
Zinc	3504 µg/L (54 µmol/L)	12	5.1	0.33
	3504 µg/L (54 µmol/L)	12	14.6	0.03

Preservatives	Interferent Concentration	N	Magnesium Target (mg/dL)	Magnesium % Difference
Boric Acid	1000 mg/dL (10 g/L)	10	4.8	0.07
	1000 mg/dL (10 g/L)	9	10.3	-0.63
6N HCl	3.0 mL/dL (180 mmol/L)	10	3.1	8.70
	3.0 mL/dL (180 mmol/L)	10	9.4	8.76

NOTE: Acetic acid, nitric acid, and sodium fluoride interfere with magnesium results and should not be used as urine preservatives. Interferences from medication or endogenous substances may affect results.[16]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3[17] using the Passing-Bablok regression method.

Magnesium on the ARCHITECT c System vs Commercially Available Comparative Magnesium Assay

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	122[a]	mg/dL	0.9979	-0.02	0.95	0.65-9.00
Urine[b]	118[a]	mg/dL	1.00	-0.14	1.08	1.82-23.25
Urine[c]	118[a]	mg/dL	1.00	-0.10	1.04	1.82-23.25

[a] < 10% of the Method Comparison samples were spiked or diluted to obtain necessary concentrations.

[b] Urine (pH < 2)

[c] Urine (no acidification)

Between ARCHITECT c Systems

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	134	mg/dL	0.9997	-0.05	1.00	0.68-9.35
Urine	174	mg/dL	0.9988	-0.06	1.04	1.91-23.72

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Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols	
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
DISTRIBUTED IN THE USA BY	Distributed in the USA by
FOR USE WITH	Identifies products to be used together
INFORMATION FOR USA ONLY	Information needed for United States of America only
MANUFACTURED FOR	Manufactured for
PRODUCT OF JAPAN	Product of Japan
R1	Reagent 1
R2	Reagent 2
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

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