Magnesium (MAG)-27

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BIENNIAL REVIEW:

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SUPERSEDES: Procedure titled _____

INTENDED USE

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

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 Alinity ci-series Operations Manual, Section 3.**

REAGENTS

Kit Contents

Magnesium Reagent Kit 08P19

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

REF	08P1925	08P1934
Tests per cartridge	360 (serum/plasma) 240 (urine)	360 (serum/plasma) 240 (urine)
Number of cartridges per kit	2	10
Tests per kit	720 (serum/plasma) 480 (urine)	3600 (serum/plasma) 2400 (urine)
R1	68.1 mL	68.1 mL
R2	17.9 mL	17.9 mL

REF	08P1925	08P1934
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, 2, 3, 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.
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/and SDS folder.

For a detailed discussion of safety precautions during system operation, **refer to the Alinity ci-series Operations Manual, Section 8.**

Reagent Handling

- Reagents are shipped refrigerated.
- Upon receipt, place reagent cartridges in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate.
- 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 Alinity ci-series 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	

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Opened	2 to 8°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, **refer to the Alinity ci-series Operations Manual, Section 5.**

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when:

- a calibration error occurs
- 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 Alinity ci-series Operations Manual, Section 10**.

INSTRUMENT PROCEDURE

The Magnesium assay file must be installed on the Alinity c system prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 2.**

For information on printing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 5.**

For a detailed description of system procedures, refer to the Alinity ci-series Operations Manual.

Alternate Result Units

Edit assay parameter "Result Units" to select an alternate unit.

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*

* NOTE: For information only. The mEq/L alternate result unit is not included in the assay parameter "Result Units".

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)	Collect specimens in a container with boric acid or 20 to 30 mL of 6N HCl 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.

Specimen Conditions

- For accurate results, serum and plasma 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.

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

08P19 Magnesium Reagent Kit

Materials Required but not Provided

- Magnesium assay file
- 08P6001 Alinity c Multiconstituent Calibrator Kit
- 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 Alinity ci-series Operations Manual, Section 1.**

For information on materials required for maintenance procedures**, refer to the Alinity ci-series Operations Manual, Section 9.**

Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 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 Alinity ci-series Operations Manual, Section 4.

- Refer to the Alinity c Multiconstituent Calibrator Kit package insert REF 08P6001 and/or commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Serum/Plasma

Samples with a magnesium value exceeding 9.50 mg/dL (3.90 mmol/L) are flagged with the code "> 9.50 mg/dL" (> 3.90 mmol/L) and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

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. Urine samples with values exceeding 26.35 mg/dL (10.83 mmol/L) are flagged with the code "> 26.35 mg/dL" (> 10.83 mmol/L) and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

Serum/Plasma

If using an automated dilution protocol, the system performs a dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor. For details on configuring automated dilutions, refer to the Alinity ci-series Operations Manual, Section 2.

Urine

The system performs a 1:8.90 dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor.

Manual Dilution Procedure

Dilute the sample with saline (0.85% to 0.90% NaCl) using a recommended dilution of 1:2.

The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result.

If the operator does not enter the dilution factor, the result must be manually multiplied by

the appropriate dilution factor before reporting the result. If a diluted sample result is less than the lower value of the measuring interval 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 Alinity ci-series Operations Manual, Section 5.

Calibration

For instructions on performing a calibration, **refer to the Alinity ci-series Operations Manual, Section 5.**

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 laboratory quality control procedure. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

- At least two levels of controls (normal and abnormal) are to be run every day testing performed.
- If quality control results do not meet the acceptance criteria defined by laboratory quality controls procedure, sample results may be suspect. Follow laboratory quality control procedures to troubleshoot. Recalibration may be necessary. For troubleshooting information, **refer to the Alinity ci-series 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*

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

Calculation

The Magnesium assay utilizes the Linear data reduction method to generate a calibration and results.

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 Alinity ci-series Operations Manual, Section 5.

Measuring Interval

Measuring interval is defined as the range of values in mg/dL (mmol/L) which meets the limits of acceptable performance for linearity, imprecision, and bias.

The measuring interval of the Magnesium assay is **0.60 mg/dL to 9.50 mg/dL** (0.25 mmol/L 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 Analytical Specificity section of this package insert for additional details.
- Acetic acid, nitric acid, and sodium fluoride interfere with magnesium results and should not be used 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.

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

EXPECTED VALUES

The laboratory adopt manufacturer provided reference ranges. Effort will be made to verify in house.

Serum/Plasma*11*

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

	Range (mg/dL)	Range (mmol/L)
Adult	1.6 to 2.6	0.66 to 1.07

Abbott has not evaluated reference ranges in the pediatric population.

Will use CALIPER published; https://caliperdatabase.org

Reference Intervals (Female and Male)

Age	Lower Limit	Upper Limit	Sample Size	Lower Confidence Intervals	Higher Confidence Intervals
0 to < 15 Days	1.99	3.94	183	(1.80, 2.19)	(3.77, 4.11)
15 Days to < 1 Year	1.97	3.09	145	(1.85, 2.11)	(3.01, 3.21)
1 to < 19 Years	2.09	2.84	897	(2.09, 2.11)	(2.82, 2.87)

NOTE: Higher values can be expected in females during menses.

Urine*11*

	Range (mg/day)	Range (mmol/day)
24 hour	72.9 to 121.5	3.00 to 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.

The Alinity c system and the ARCHITECT c System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity c system.

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 Alinity c Multiconstituent Calibrator Kit, 1 lot of commercially available controls, and 1 instrument. Three control levels were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.

			Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	**n**	**Mean (mg/dL)**	**SD**	**%CV**	**SD**	**%CV**
Control Level 1	120	1.37	0.019	1.4	0.029	2.1
Control Level 2	120	2.22	0.019	0.8	0.032	1.4
Control Level 3	120	3.88	0.026	0.7	0.050	1.3

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

			Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	**n**	**Mean (mmol/L)**	**SD**	**%CV**	**SD**	**%CV**
Control Level 1	120	0.56	0.009	1.6	0.013	2.3
Control Level 2	120	0.91	0.008	0.9	0.013	1.4
Control Level 3	120	1.59	0.011	0.7	0.021	1.3

[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 Alinity c Multiconstituent Calibrator Kit, 1 lot of commercially available controls, and 1 instrument. Two control levels were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.

			Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	**n**	**Mean (mg/dL)**	**SD**	**%CV**	**SD**	**%CV**
Control Level 1	120	6.35	0.062	1.0	0.107	1.7
Control Level 2	120	10.75	0.077	0.7	0.168	1.6

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

Sample	n	Mean (mmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
			SD	%CV	SD	%CV
Control Level 1	120	2.61	0.026	1.0	0.044	1.7
Control Level 2	120	4.42	0.032	0.7	0.069	1.6

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

Accuracy

This study was performed on the ARCHITECT c System.

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 3 lots of the Magnesium Reagent Kit on each of 2 instruments over a minimum of 3 days. The maximum observed Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) values are reported in the table.

Serum/Plasma

	mg/dL	mmol/L
LoB[a]	0.08	0.03
LoD[b]	0.11	0.05
LoQ[c]	**0.17**	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%.

Urine

	mg/dL	mmol/L
LoB[a]	0.10	0.04
LoD[b]	0.25	0.10
LoQ[c]	1.68	0.69

[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*

This assay is linear across the measuring interval of **0.60 mg/dL to 9.50** mg/dL (0.25 mmol/L 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

This study was performed on the ARCHITECT c System.

Potentially Interfering Substances

A study was 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.

Serum

Potentially Interfering Substance	Interferent Level		Magnesium Level	
	Default Units	Alternate Units	Target (mg/dL)	% Difference
Ascorbic Acid	3.0 mg/dL	0.170 mmol/L	2.1	1.37
	3.0 mg/dL	0.170 mmol/L	4.0	0.36
	3.0 mg/dL	0.170 mmol/L	6.4	0.18
Bilirubin, Conjugated	55.3 mg/dL	945.6 µmol/L	1.9	1.68
	55.9 mg/dL	955.9 µmol/L	3.6	-2.33

Potentially Interfering Substance	Interferent Level		Magnesium Level	
	Default Units	Alternate Units	Target (mg/dL)	% Difference
	56.5 mg/dL	966.2 µmol/L	5.7	1.40
Bilirubin, Unconjugated	60.3 mg/dL	1031.1 µmol/L	2.0	1.52
	60.5 mg/dL	1034.6 µmol/L	3.7	0.65
	60.9 mg/dL	1041.4 µmol/L	6.0	1.65
Calcium	28.0 mg/dL	7 mmol/L	2.0	2.70
	28.0 mg/dL	7 mmol/L	3.8	3.86
	28.0 mg/dL	7 mmol/L	6.1	3.94
Copper	6.5 µg/mL	102.29 µmol/L	2.0	0.40
	6.5 µg/mL	102.29 µmol/L	4.0	-0.30
	6.5 µg/mL	102.29 µmol/L	6.3	0.63
Glucose	1240 mg/dL	68.82 mmol/L	2.1	-0.46
	1311 mg/dL	72.76 mmol/L	4.0	-0.44
	1199 mg/dL	66.54 mmol/L	6.4	-0.54
Hemoglobin	250 mg/dL	2.5 g/L	2.1	5.24
	1000 mg/dL	10.0 g/L	3.9	6.50
	1200 mg/dL	12.0 g/L	6.4	6.66
Intralipid	2476 mg/dL	24.76 g/L	2.0	1.36
	2471 mg/dL	24.71 g/L	3.7	0.38
	2482 mg/dL	24.82 g/L	6.1	-2.69
Iron	641 µg/dL	114.78 µmol/L	2.0	0.80
	641 µg/dL	114.78 µmol/L	4.0	-0.22
	641 µg/dL	114.78 µmol/L	6.4	-0.92
L-Dopamine	5.0 mg/dL	0.255 mmol/L	2.1	1.83
	5.0 mg/dL	0.255 mmol/L	4.0	1.10
	5.0 mg/dL	0.255 mmol/L	6.4	1.85
Triglyceride	3647 mg/dL	41.21 mmol/L	2.0	-2.04
	3598 mg/dL	40.66 mmol/L	4.0	-1.60
	3580 mg/dL	40.45 mmol/L	5.8	-0.47

Potentially Interfering Substance	Interferent Level		Magnesium Level	
	Default Units	Alternate Units	Target (mg/dL)	% Difference
Zinc	4.3 µg/mL	65.77 µmol/L	2.0	-0.54
	4.3 µg/mL	65.77 µmol/L	4.1	0.52
	4.3 µg/mL	65.77 µmol/L	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.

Potentially Interfering Substance	Interferent Level		Magnesium Level	
	Default Units	Alternate Units	Target (mg/dL)	% Difference
Acetaminophen	241 µg/mL	1592 µmol/L	1.9	0.75
	241 µg/mL	1592 µmol/L	3.6	0.05
	241 µg/mL	1592 µmol/L	5.8	0.54
Ibuprofen	601 µg/mL	2915 µmol/L	1.8	1.03
	601 µg/mL	2915 µmol/L	3.6	1.05
	601 µg/mL	2915 µmol/L	5.8	0.74
Salicylic Acid	71.96 mg/dL	5.21 mmol/L	1.8	1.63
	71.96 mg/dL	5.21 mmol/L	3.7	0.68
	71.96 mg/dL	5.21 mmol/L	5.8	0.67
Sulfapyridine	300 mg/L	1.20 mmol/L	1.5	-0.40
Sulfasalazine	300 mg/L	0.754 mmol/L	1.5	1.50
Temozolomide	20 mg/L	0.10 mmol/L	3.5	0.26
	20 mg/L	0.10 mmol/L	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 conducted on the ARCHITECT c System 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.

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

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

Urine samples at the above concentrations were prepared by addition of the interfering substances to human urine pools.

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 using the Passing-Bablok regression method.[17]

In addition, serum/plasma results from Magnesium on ARCHITECT were compared with Atomic Absorption Spectroscopy (AAS).

Magnesium on Alinity c vs Magnesium on ARCHITECT

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	122	mg/dL	1.00	-0.03	1.01	0.77-9.32
	122	mmol/L	1.00	-0.01	1.01	0.32-3.83
Urine	43	mg/dL	1.00	-0.03	0.99	2.08-24.10
	43	mmol/L	1.00	-0.01	0.99	0.86-9.90

Magnesium on ARCHITECT vs. AAS

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum/Plasma	47	mg/dL	0.996	-0.19	1.0	1.00-5.00

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